

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 403, 405, 410, 411, 414, 418, 424, 484, and  
486**

**[CMS-1429-FC]**

**RIN 0938-AM90**

**Medicare Program; Revisions to Payment Policies Under the  
Physician Fee Schedule for Calendar Year 2005**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS),  
HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule refines the resource-based practice expense relative value units (RVUs) and makes other changes to Medicare Part B payment policy. These policy changes concern: supplemental survey data for practice expense; updated geographic practice cost indices for physician work and practice expense; updated malpractice RVUs; revised requirements for supervision of therapy assistants; revised payment rules for low osmolar contrast media; changes to payment policies for physicians and practitioners managing dialysis patients; clarification of care plan oversight requirements; revised requirements for supervision of diagnostic psychological testing services; clarifications to the policies affecting therapy

services; revised requirements for assignment of Medicare claims; addition to the list of telehealth services; and, several coding issues. We are making these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

This final rule also addresses the following provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-17) (MMA): coverage of an initial preventive physical examination; coverage of cardiovascular (CV) screening blood tests; coverage of diabetes screening tests; incentive payment improvements for physicians in shortage areas; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; coverage of routine costs associated with certain clinical trials of category A devices as defined by the Food and Drug Administration; hospice consultation service; indexing the Part B deductible to inflation; extension of coverage of intravenous immune globulin (IVIG) for the treatment in the home of primary immune deficiency diseases; revisions to reassignment provisions; and, payment for diagnostic mammograms, physicians' services associated with drug administration

services and coverage of religious nonmedical health care institution items and services to the beneficiary's home.

In addition, this rule updates the codes subject to the physician self-referral prohibition, discusses payment for set-up of portable x-ray equipment, discusses the third five-year refinement of work RVUs, and solicits comments on potentially misvalued work RVUs.

We are also finalizing the calendar year (CY) 2004 interim RVUs and are issuing interim RVUs for new and revised procedure codes for CY 2005.

As required by the statute, we are announcing that the physician fee schedule update for CY 2005 is 1.5 percent, the initial estimate for the sustainable growth rate for CY 2005 is 4.3, and the conversion factor for CY 2005 is \$37.8975.

**DATES:** Effective Date: These regulations are effective on January 1, 2005.

Applicability Date: Section 623 of the MMA, that is, case-mix portion of the revised composite payment methodology and the budget neutrality adjustment required by the MMA is applicable on April 1, 2005.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no

later than 5 p.m. on [OFR—insert date 60 days after the date of filing for public inspection at OFR.]

**ADDRESSES:** In commenting, please refer to file code CMS-1429-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>.  
  
(Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)
2. By mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
  
Department of Health and Human Services,  
  
Attention: CMS-1429-FC,  
  
P.O. Box 8012,  
  
Baltimore, MD 21244-8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original

and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number 800-743-3951 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201; or  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

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Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses

provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Pam West (410) 786-2302 (for issues related to Practice Expense, Respiratory Therapy Coding, and Therapy Supervision).

Rick Ensor (410) 786-5617 (for issues related to Geographic Practice Cost Index (GPCI) and malpractice RVUs).

Craig Dobyski (410) 786-4584 (for issues related to list of telehealth services or payments for physicians and practitioners managing dialysis patients).

Bill Larson or Tiffany Sanders (410) 786-7176 (for issues related to coverage of an initial preventive physical examination).

Cathleen Scally (410) 786-5714 (for issues related to payment of an initial preventive physical examination).

Joyce Eng (410) 786-7176 (for issues related to coverage of cardiovascular screening tests).

Betty Shaw (410) 786-7176 (for issues related to coverage of diabetes screening tests).

Anita Greenberg (410) 786-0548 (for issues related to payment of cardiovascular and diabetes screening tests).

David Worgo (410) 786-5919, (for issues related to incentive payment improvements for physicians practicing in shortage areas).

Angela Mason or Jennifer Fan (410) 786-0548 (for issues related to payment for covered outpatient drugs and biologicals).

David Walczak (410) 786-4475 (for issues related to reassignment provisions).

Henry Richter (410) 786-4562 (for issues related to payments for ESRD facilities).

Steve Berkowitz (410) 786-7176 (for issues related to coverage of routine costs associated with certain clinical trials of category A devices).

Terri Deutsch (410) 786-9462 (for issues related to hospice consultation services).

Karen Daily (410) 786-7176 (for issues related to clinical conditions for payment of covered items of durable medical equipment).

Dorothy Shannon (410) 786-3396 (for issues related to outpatient therapy services performed "incident to" physicians' services).

Robertta Epps (410) 786-5919 (for issues related to low osmolar contrast media or supervision of diagnostic psychological testing services).

Gail Addis (410) 786-4522 (for issues related to care plan oversight).

Jean-Marie Moore (410) 786-3508 (for issues related to religious nonmedical health care institution services).

Diane Milstead (410) 786-3355 or Gaysha Brooks (410) 786-9649 (for all other issues).

**SUPPLEMENTARY INFORMATION:**

Submitting Comments: We welcome comments from the public on the following issues: interim RVUs for selected procedure codes identified in Addendum C; zip code areas for Health Professional Shortage Areas (HPSAs); the coverage of religious nonmedical health care institution items and services to the beneficiary's home; the physician self referral designated health services listed in tables 20 and 21; the third five-year refinement of work RVUs for services furnished beginning January 1, 2007; and, potentially misvalued work RVUs for all services in the CY 2005 physician fee schedule. You can assist us by referencing the file code CMS-1429-FC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are processed, generally beginning approximately 3 weeks after



publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 800-743-3951.

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site address is:

<http://www.access.gpo.gov/nara/index.html>.

Information on the physician fee schedule can be found on the CMS homepage. You can access this data by using the following directions:

1. Go to the CMS homepage (<http://www.cms.hhs.gov>).
2. Place your cursor over the word "Professionals" in the blue area near the top of the page. Select "physicians" from the drop-down menu.
3. Under "Policies/Regulations" select "Physician Fee Schedule."

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents. Some of the issues discussed in this preamble affect the payment policies but do not require changes to the regulations in the Code of Federal Regulations. Information on the regulation's impact appears throughout the preamble and is not exclusively in section VII.

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In addition, because of the many organizations and  
terms to which we refer by acronym in this final rule, we  
are listing these acronyms and their corresponding terms in  
alphabetical order below:

AAA	Abdominal aortic aneurysm
AAFP	American Academy of Family Physicians
AAKP	American Association of Kidney Patients
AANA	American Association of Nurse Anesthetists

ABI	Ankle brachial index
ABN	Advanced beneficiary notice
ACC	American College of Cardiology
ACLA	American Clinical Laboratory Association
ACP	American College of Physicians
ACPM	American College of Preventative Medicine
ACR	American College of Radiology
ADLs	Activities of daily living
AFROC	Association of Freestanding Radiation Oncology Centers
AGS	American Geriatric Society
AHA	American Heart Association
AMA	American Medical Association
AOA	American Osteopathic Association
APA	Administrative Procedures Act
APTA	American Physical Therapy Association
ASA	American Society of Anesthesiologists
ASCP	American Society for Clinical Pathology
ASN	American Society of Nephrology
ASP	Average sales price
ASTRO	American Society for Therapeutic Radiation Oncology
ATA	American Telemedicine Association
AWP	Average wholesale price

BBA	Balanced Budget Act of 1997
BBRA	Balanced Budget Refinement Act of 1999
BIPA	Benefits Improvement and Protection Act of 2000
BLS	Bureau of Labor Statistics
BMI	Body mass index
BSA	Body surface area
CAH	Critical access hospital
CAP	College of American Pathologists
CAPD	Continuous ambulatory peritoneal dialysis
CCPD	Continuous cycling peritoneal dialysis
CDC	Centers for Disease Control and Prevention
CF	Conversion factor
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendment
CMA	California Medical Association
CMS	Centers for Medicare & Medicaid Services
CNMs	Certified nurse midwives
CNS	Clinical nurse specialist
COPD	Chronic obstructive pulmonary disease
CORF	Comprehensive outpatient rehabilitation facilities
CPEP	Clinical Practice Expert Panel
CPI	Consumer Price Index
CPO	Care Plan Oversight



CPT	[Physicians'] Current Procedural Terminology [4th Edition, 2002, copyrighted by the American Medical Association]
CRNAs	Certified Registered Nurse Anesthetists
CT	Computed tomography
CV	Cardiovascular
CY	Calendar year
DEXA	Dual energy x-ray absorptiometry
DHS	Designated health services
DME	Durable medical equipment
DMEPOS	Durable medical equipment, prosthetics, orthotics, and supplies
DMERC	Durable medical equipment regional carrier
DOI	Departments of Insurance
DRE	Digital rectal exam
DRG	Diagnosis-related groups
DVT	Deep venous thrombosis
EKG	Electrocardiogram
E/M	Evaluation and management
EPO	Erythropoeitin
ESRD	End-stage renal disease
FAX	Facsimile
FMR	Fair market rental
FQHC	Federally qualified healthcare center

FR	Federal Register
FY	Fiscal year
GAF	Geographic adjustment factor
GPCI	Geographic practice cost index
GTT	Glucose tolerance test
HBO	Hyperbaric oxygen
HCPAC	Health Care Professional Advisory Committee
HCPCS	Healthcare Common Procedure Coding System
HHA	Home health agency
HHS	[Department of] Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HOCM	High osmolar contrast media
HPSA	Health professional shortage area
HRSA	Health Resources and Services Administration
HsCRP	high sensitivity C-reactive protein
HUD	Housing and Urban Development
IDTFs	Independent diagnostic testing facilities
IMRT	Intensity modulated radiation therapy
IOM	Internet Only Manual
IPD	Intermittent peritoneal dialysis
IPPE	Initial preventive physical examination
IPPS	Inpatient prospective payment system
ISO	Insurance Services Office

IVIG	Intravenous immune globulin
JUAs	Joint underwriting associations
KCP	Kidney Care Partners
KECC	Kidney Epidemiology and Cost Center
LCD	Local coverage determination
LMRP	Local medical review policies
LOCM	Low osmolar contrast media
LUPA	Low utilization payment adjustment
MCM	Medicare Carrier Manual
MCP	Monthly capitation payment
MedPAC	Medicare Payment Advisory Commission
MEI	Medicare Economic Index
MGMA	Medical Group Management Association
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MPFS	Medicare physician fee schedule
MSA	Metropolitan statistical area
NAMCS	National Ambulatory Medical Care Survey
NCD	National coverage determination
NCIPC	National Center for Injury Prevention and Control
NDC	National drug code
NIH	National Institutes of Health
NP	Nurse practitioner
NPP	Nonphysician practitioners

OASIS	Outcome and Assessment Information Set
OBRA	Omnibus Budget Reconciliation Act
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPPS	Outpatient prospective payment system
OT	Occupational therapy
OTA	Occupational therapist assistant
OTPP	Occupational therapists in private practice
PA	Physician assistant
PAD	Peripheral arterial disease
PC	Professional component
PCF	Patient compensation fund
PD	Peritoneal dialysis
PEAC	Practice Expense Advisory Committee
PET	Positron emission tomography
PFS	Physician Fee Schedule
PHSA	Public Health Services Act
PIAA	Physician Insurers Association of America
PIN	Provider identification number
PLI	Professional liability insurance
POS	Prosthetics, orthotics and supplies
PPI	Producer price index
PPS	Prospective payment system
PRA	Paperwork Reduction Act

PSA	Physician scarcity area
PT	Physical therapy
PTA	Physical therapist assistant
PTPP	Physical therapists in private practice
PVD	Peripheral vascular disease
RFA	Regulatory Flexibility Act
RHC	Rural health clinic
RHHI	Regional home health intermediary
RIA	Regulatory impact analysis
RN	Registered nurse
RNHCI	Religious nonmedical health care institution
RPA	Renal Physicians Association
RT	Respiratory therapy
RTs	Respiratory therapists
RUC	[AMA's Specialty Society] Relative [Value] Update Committee
RUCA	Rural-Urban commuting area
RVU	Relative value unit
SAF	Standard analytic file
SCHIP	State Child Health Insurance Program
SGR	Sustainable growth rate
SHIPs	State Health Insurance Assistance Programs
SIR	Society for Interventional Radiology
SLP	Speech language pathology

SMR	Standardized mortality ratio
SMS	[AMA's] Socioeconomic Monitoring System
SNF	Skilled nursing facility
TC	Technical component
UAF	Update adjustment factor
URR	Urea reduction ratios
USPSTF	U.S. Preventive Services Task Force

## **I. Background**

### **A. Legislative History**

Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), "Payment for Physicians' Services" since January 1, 1992. The Act requires that payments under the fee schedule be based on national uniform relative value units (RVUs) reflecting the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense. Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs may not cause total physician fee schedule payments to differ by more than \$20 million from what they would have been had the adjustments not been made. If adjustments to RVUs cause expenditures to change by more than \$20 million, we must make adjustments to

ensure that they do not increase or decrease by more than \$20 million.

B. Published Changes to the Fee Schedule

The July 2000 and August 2003 proposed rules ((65 FR 44177) and (68 FR 49030), respectively), include a summary of the final physician fee schedule rules published through February 2003.

In the November 7, 2003 final rule, we refined the resource-based practice expense RVUs and made other changes to Medicare Part B payment policy. The specific policy changes concerned: the Medicare Economic Index; practice expense for professional component services; definition of diabetes for diabetes self-management training; supplemental survey data for practice expense; geographic practice cost indices; and several coding issues. In addition, this rule updated the codes subject to the physician self-referral prohibition. We also made revisions to the sustainable growth rate and the anesthesia conversion factor. Additionally, we finalized the CY 2003 interim RVUs and issued interim RVUs for new and revised procedure codes for CY 2004.

As required by the statute, we announced that the physician fee schedule update for CY 2004 was -4.5 percent; that the initial estimate of the sustainable growth rate

for CY 2004 was 7.4 percent; and that the conversion factor for CY 2004 was \$35.1339.

Subsequent to the November 7, 2003 final rule, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-17) (MMA). On January 7, 2004, an interim final rule was published to implement provisions of the MMA applicable in 2004 to Medicare payment for covered drugs and physician fee schedule services. These provisions included--

- Revising the current payment methodology for Medicare Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis;
- Making changes to Medicare payment for furnishing or administering drugs and biologicals;
- Revising the geographic practice cost indices;
- Changing the physician fee schedule conversion factor.  
(Note: The 2004 physician fee schedule conversion factor is \$37.3374); and
- Extending the "opt-out" provisions of section 1802(b)(5)(3) of the Act to dentists, podiatrists, and optometrists.

The information contained in the January 7, 2004 interim final rule concerning payment under the physician



fee schedule superceded information contained in the November 7, 2003 final rule to the extent that the two are inconsistent.

### C. Components of the Fee Schedule Payment Amounts

Under the formula set forth in section 1848(b)(1) of the Act, the payment amount for each service paid under the physician fee schedule is the product of three factors: (1) a nationally uniform relative value unit (RVU) for the service; (2) a geographic adjustment factor (GAF) for each physician fee schedule area; and (3) a nationally uniform conversion factor (CF) for the service. The CF converts the relative values into payment amounts.

For each physician fee schedule service, there are three relative values: (1) an RVU for physician work; (2) an RVU for practice expense; and (3) an RVU for malpractice expense. For each of these components of the fee schedule, there is a geographic practice cost index (GPCI) for each fee schedule area. The GPCIs reflect the relative costs of practice expenses, malpractice insurance, and physician work in an area compared to the national average for each component.

The general formula for calculating the Medicare fee schedule amount for a given service in a given fee schedule area can be expressed as:

Payment = [(RVU work x GPCI work) + (RVU practice expense x GPCI practice expense) + (RVU malpractice x GPCI malpractice)] x CF

The CF for calendar year (CY) 2005 appears in section X. The RVUs for CY 2005 are in Addendum B. The GPCIs for CY 2005 can be found in Addendum D.

Section 1848(e) of the Act requires us to develop GAFs for all physician fee schedule areas. The total GAF for a fee schedule area is equal to a weighted average of the individual GPCIs for each of the three components of the service. In accordance with the statute, however, the GAF for the physician's work reflects one-quarter of the relative cost of physician's work compared to the national average.

#### D. Development of the Relative Value System

##### 1. Work Relative Value Units

Approximately 7,500 codes represent services included in the physician fee schedule. The work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes in a cooperative agreement with us. In constructing the vignettes for the original RVUs, Harvard worked with expert

panels of physicians and obtained input from physicians from numerous specialties.

The RVUs for radiology services were based on the American College of Radiology (ACR) relative value scale, which we integrated into the overall physician fee schedule. The RVUs for anesthesia services were based on RVUs from a uniform relative value guide. We established a separate CF for anesthesia services, and we continue to recognize time as a factor in determining payment for these services. As a result, there is a separate payment system for anesthesia services.

## 2. Practice Expense and Malpractice Expense Relative Value Units

Section 1848(c)(2)(C) of the Act requires that the practice expense and malpractice expense RVUs equal the product of the base allowed charges and the practice expense and malpractice percentages for the service. Base allowed charges are defined as the national average allowed charges for the service furnished during 1991, as estimated using the most recent data available. For most services, we used 1989 charge data aged to reflect the 1991 payment rules, because those were the most recent data available for the 1992 fee schedule.

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103-432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician's service. As amended by the Balanced Budget Act of 1997 (BBA) (Pub.L. 105-33), enacted on August 5, 1997, section 1848(c) required the new payment methodology to be phased in over 4 years, effective for services furnished in 1999, with resource-based practice expense RVUs becoming fully effective in 2002. The BBA also required us to implement resource-based malpractice RVUs for services furnished beginning in 2000.

## **II. Provisions of the Proposed Rule Related to the Physician Fee Schedule**

In response to the publication of the August 5, 2004 proposed rule (69 FR 47488), we received approximately 9,302 comments. We received comments from individual physicians, health care workers, professional associations and societies, and beneficiaries. The majority of the comments addressed the proposals related to "incident to" therapy services, GPCI, diagnostic psychological testing, and drug issues including average sales price (ASP).

The proposed rule discussed policies that affected the number of RVUs on which payment for certain services would

be based. The proposed rule also discussed policies related to implementation of the MMA. RVU changes implemented through this final rule are subject to the \$20 million limitation on annual adjustments contained in section 1848(c)(2)(B)(ii)(II) of the Act.

After reviewing the comments and determining the policies we would implement, we have estimated the costs and savings of these policies and discuss in detail the effects of these changes in the Regulatory Impact Analysis in section XIV.

For the convenience of the reader, the headings for the policy issues correspond to the headings used in the August 5, 2004 proposed rule. More detailed background information for each issue can be found in the August 5, 2004 proposed rule.

A. Resource-Based Practice Expense Relative Value Units

1. Resource-Based Practice Expense Legislation

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103-432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Social Security Act (the Act) and required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician's service beginning in 1998. Until

that time, physicians' practice expenses were established based on historical allowed charges.

In developing the methodology, we were to consider the staff, equipment, and supplies used in providing medical and surgical services in various settings. The legislation specifically required that, in implementing the new system of practice expense RVUs, we apply the same budget-neutrality provisions that we apply to other adjustments under the physician fee schedule.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, amended section 1848(c)(2)(C)(ii) of the Act and delayed the effective date of the resource-based practice expense RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based practice expense RVUs to resource-based RVUs.

Further legislation affecting resource-based practice expense RVUs was included in the Medicare, Medicaid and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) enacted on November 29, 1999. Section 212 of the BBRA amended section 1848(c)(2)(C)(ii) of the Act by directing us to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound

data practices, data collected or developed by entities and organizations. These data would supplement the data we normally collect in determining the practice expense component of the physician fee schedule for payments in CY 2001 and CY 2002. (The 1999 and 2003 final rules (64 FR 59380 and 68 FR 63196, respectively, extended the period during which we would accept supplemental data.)

## 2. Current Methodology for Computing the Practice Expense Relative Value Unit System

In the November 2, 1998 final rule (63 FR 58910), effective with services furnished on or after January 1, 1999, we established at 42 CFR 414.22(b)(5) a new methodology for computing resource-based practice expense RVUs that used the two significant sources of actual practice expense data we have available--the Clinical Practice Expert Panel (CPEP) data and the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysicians (for example registered nurses) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physicians service in both the office setting and out-of-office setting. The AMA's SMS data provided aggregate specialty-specific information

on hours worked and practice expenses. The methodology was based on an assumption that current aggregate specialty practice costs are a reasonable way to establish initial estimates of relative resource costs for physicians' services across specialties. The methodology allocated these aggregate specialty practice costs to specific procedures and, thus, can be seen as a "top-down" approach.

Also in the November 2, 1998 final rule, in response to comments, we discussed the establishment of the Practice Expense Advisory Committee (PEAC) of the AMA's Specialty Society Relative Value Update Committee (RUC), which would review code-specific CPEP data during the refinement period. This committee would include representatives from all major specialty societies and would make recommendations to us on suggested changes to the CPEP data.

As directed by the BBRA, we also established a process (see 65 FR 65380) under which we would accept and use, to the maximum extent practicable and consistent with sound data practices, data collected by entities and organizations to supplement the data we normally collect in determining the practice expense component of the physician fee schedule.

a. Major Steps



A brief discussion of the major steps involved in the determination of the practice expense RVUs follows.

(Please see the November 1, 2001 final rule (66 FR 55249) for a more detailed explanation of the top-down methodology.)

- Step 1--Determine the specialty specific practice expense per hour of physician direct patient care. We used the AMA's SMS survey of actual aggregate cost data by specialty to determine the practice expenses per hour for each specialty. We calculated the practice expenses per hour for the specialty by dividing the aggregate practice expenses for the specialty by the total number of hours spent in patient care activities.
- Step 2--Create a specialty-specific practice expense pool of practice expense costs for treating Medicare patients. To calculate the total number of hours spent treating Medicare patients for each specialty, we used the physician time assigned to each procedure code and the Medicare utilization data. The primary sources for the physician time data were surveys submitted to the AMA's RUC and surveys done by Harvard for the establishment of the work RVUs. We then multiplied the physician time assigned per procedure code by the number of times that code was billed by each specialty, and summed the

products for each code, by specialty, to get the total physician hours spent treating Medicare patients for that specialty. We then calculated the specialty specific practice expense pools by multiplying the specialty practice expenses per hour (from step 1) by the total Medicare physician hours for the specialty.

- Step 3--Allocate the specialty specific practice expense pool to the specific services (procedure codes) performed by each specialty. For each specialty, we divided the practice expense pool into two groups based on whether direct or indirect costs were involved and used a different allocation basis for each group.

(i) Direct costs--For direct costs (which include clinical labor, medical supplies, and medical equipment), we used the procedure-specific CPEP data on the staff time, supplies, and equipment as the allocation basis. For the separate practice expense pool for services without physician work RVUs, we have used, on an interim basis, 1998 practice expense RVUs to allocate the direct cost pools.

(ii) Indirect costs--To allocate the cost pools for indirect costs, including administrative labor, office expenses, and all other expenses, we used the total direct costs, or the 1998 practice expense RVUs, in

combination with the physician fee schedule work RVUs.

We converted the work RVUs to dollars using the Medicare CF (expressed in 1995 dollars for consistency with the SMS survey years).

- Step 4---The direct and indirect costs are then added together to attain the practice expense for each procedure, by specialty. For procedures performed by more than one specialty, the final practice expense allocation was a weighted average of practice expense allocations for the specialties that perform the procedure, based on the frequency with which each specialty performs the procedure on Medicare patients.

b. Other Methodological Issues

i. Nonphysician Work Pool

As an interim measure, until we could further analyze the effect of the top-down methodology on the Medicare payment for services with physician work RVUs equal to zero (including the technical components of radiology services and other diagnostic tests), we created a separate practice expense pool. We first used the average clinical staff time from the CPEP data and the "all physicians" practice expense per hour to create the pool. In the December 2002 final rule, we changed this policy and now use the total clinical staff time and the weighted average specialty-

specific practice expense per hour for specialties with services in this pool. In the next step, we used the adjusted 1998 practice expense RVUs to allocate this pool to each service. Also, for all radiology services that are assigned physician work RVUs, we used the adjusted 1998 practice expense RVUs for radiology services as an interim measure to allocate the direct practice expense cost pool for radiology.

A specialty society may request that its services be removed from the nonphysician work pool. We have removed services from the nonphysician work pool if the requesting specialty predominates utilization of the service.

ii. Crosswalks for Specialties Without Practice Expense Survey Data

Since many specialties identified in our claims data did not correspond exactly to the specialties included in the SMS survey data, it was necessary to crosswalk these specialties to the most appropriate SMS specialty.

iii. Physical Therapy Services

Because we believe that most physical therapy services furnished in physicians' offices are performed by physical therapists, we crosswalked all utilization for therapy services in the CPT 97000 series to the physical and occupational therapy practice expense pool.

### 3. Practice Expense Proposals for Calendar Year 2005

#### a. Supplemental Practice Expense Surveys

##### i. Survey Criteria and Submission Dates

As required by the BBRA, we established criteria to evaluate survey data collected by organizations to supplement the SMS survey data used in the calculation of the practice expense component of the physician fee schedule. The deadline for submission of supplemental data to be considered in CY 2006 is March 1, 2005.

##### ii. Survey by the College of American Pathologists (CAP)

In the August 5, 2004 rule, we proposed to incorporate the CAP survey data into the practice expense methodology and to implement a change to the practice expense methodology to calculate the technical component RVUs for pathology services as the difference between the global and professional component RVUs. (This technical change was proposed in the June 28, 2002 **Federal Register** (67 FR 43849), but, at the specialty's request, we delayed implementation of this change for pathology services to permit evaluation of the combined effects of the use of the new survey data along with this technical change to the methodology.) We proposed to use the following practice expense per hour figures for specialty 69--Independent Laboratory.

**TABLE 1:** Practice Expense Per Hour Figures for  
Specialty 69--Independent Laboratory

Specialty	Clinical Staff	Admin. Staff	Office Expense	Medical Supplies	Medical Equipment	Other	Total
Independent Laboratory	\$66.5	\$20.2	\$15.0	\$15.8	\$6.9	\$16.9	\$141.1

Comment: Specialty organizations representing clinical laboratories and pathologists expressed support for the use of the CAP supplemental survey data and urged us to finalize this proposal.

Response: We will incorporate the CAP survey data into the practice expense methodology and implement the proposed change to the practice expense methodology to calculate the technical component RVUs for pathology services as the difference between the global and professional component RVUs.

### iii. Submission of Supplemental Surveys

We received surveys from the American College of Cardiology (ACC), the American College of Radiology (ACR), and the American Society for Therapeutic Radiation Oncology (ASTRO). Our contractor, The Lewin Group, evaluated the data and recommended that we accept the data from the ACC and the ACR, but indicated that the survey from ASTRO did not meet the precision criteria established for

supplemental surveys and, thus, did not recommend using the ASTRO survey results at this time. We agreed with these recommendations. However, as explained in the August 5, 2004 proposed rule, the ACR and the ACC requested that we not use the data until we have a stable and global solution that is workable for all specialties that are currently paid using the nonphysician work pool. We agreed with these requests and proposed delaying use of these supplemental surveys until issues related to the nonphysician work pool can be addressed.

Comment: The ACR expressed appreciation for our acceptance of the supplemental data and for our proposal to delay implementation until next year, as they had requested, to allow further time to examine the issue of the nonphysician work pool. The Society for Interventional Radiology (SIR) also expressed support for the use of the ACR data and the delay in implementation.

Response: We look forward to working with these and other specialties as we seek a permanent solution to practice expense issues associated with the nonphysician work pool.

Comment: ASTRO stated that they appreciate the opportunity to submit data and, that they understand we will not be using the data in 2005. ASTRO further

commented that, due to the specific practice patterns and practice environment of radiation oncology, new data, regardless of the response rate, may not meet the criteria. ASTRO further stated that they will continue to work with CMS and with the Lewin Group as this issue is analyzed. The Association of Freestanding Radiation Oncology Centers (AFROC) expressed concern that freestanding centers that have higher costs than hospital-based centers were underrepresented by the ASTRO survey. They also expressed concern about the reference in the Lewin Group report to crosswalking radiation oncology costs from another specialty. In addition, AFROC argued that we should not average costs associated with freestanding centers with those that are hospital-based, because the costs would be understated. They urged us to ensure that any assumption regarding representativeness of any survey data is justified.

Response: We will take these comments into consideration as we continue to work with these groups concerning the supplemental survey data. We currently have no plans to propose a practice expense crosswalk for radiation oncology.

Comment: The ACC expressed appreciation that we are not eliminating the nonphysician workpool until



methodologic issues are addressed. While they support the delay in implementing their supplemental survey data, they believe that the contractor's suggestion that the ACC survey data could be blended with the existing SMS survey data is invalid for two reasons: (1) the suggestion that similar changes to physician practice (for example, increased use of technology) may have occurred throughout all physician services is an unfounded speculation because few other specialties are as technologically driven as cardiology; and (2) other supplemental data has not been blended and all specialties must be treated consistently.

Response: We will take these comments into consideration as part of the evaluation and discussion of the cardiology survey data in next year's proposed rule.

Comment: The American Urological Association requested that, as we explore alternate sources of data and consider how to incorporate new practice expense data into the methodology, we find a way to incorporate recently collected specialty supplemental data into the new efforts. They also requested that we clarify whether we would apply the budget neutrality exemption to any increases in drug administration PE RVUs that result from the use of urology survey data that will be submitted under the supplemental survey process.

Response: We anticipate that we would incorporate all accepted supplemental survey data into any comprehensive changes to the nonphysician work pool.

As we explained in the January 7, 2004 **Federal Register** (69 FR 1093 through 1094), section 303(a)(1) of the MMA modifies section 1848(c)(2)(B) of the Act to provide an exemption from the budget neutrality requirements in 2006 for further increases in the practice expense RVUs for drug administration that may result from using survey data from specialties meeting certain criteria. The survey must include expenses for the administration of drugs and biologicals and be submitted by a specialty that receives more than 40 percent of its 2002 Medicare revenues from drugs. Urology received more than

40 percent of its 2002 Medicare revenues from drugs.

Therefore, if we were to receive a practice expense survey of urologists by March 1, 2005 that included expenses for the administration of drugs and biologicals and the survey met the criteria we have established (and those of section 1848(c)(2)(I)(ii) of the Act), we would exempt the change in the practice expense RVUs for drug administration services from the budget neutrality requirements of section 1848(c)(2)(B) of the Act.

b. Practice Expense Advisory Committee (PEAC)

Recommendations on CPEP inputs for 2005

- CPEP Refinement Process

In the August 5, 2004 proposed rule, we included the PEAC recommendations from meetings held in March and August 2003 and January and March 2004, which accounted for over 2,200 codes from many specialties. We also stated that future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC.

Comment: We received comments from the AMA that future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC with the help of a new ad hoc committee, now termed the Practice Expense Review Committee (PERC),

comprised of former PEAC members. The RUC also noted that their Practice Expense Subcommittee remains committed to reviewing improvements to the practice expense methodology.

The AMA and the RUC, as well as the specialty society representing neurological surgeons, noted their appreciation of our continued efforts to improve the direct practice expense data and to establish a reasonable methodology for determining practice expense relative values.

Response: We look forward to our continuing work with the AMA, the RUC and all the specialty societies on the refinement of the remaining codes and with ongoing practice expense issues.

Comment: The National Association for the Support of Long Term Care expressed concern about the dissolution of the PEAC and requested that we require the RUC to expand its membership to include a broad array of providers who are reimbursed under the physician fee schedule.

Response: Because the RUC is an independent committee, we are not in a position to set the requirements for RUC membership. However, we are confident that the RUC and the Health Care Professional Advisory Committee, which also sends practice expense recommendations directly to us,

together represent two broad range of practitioners, both physician and nonphysician.

Comment: A specialty society suggested that there should be a process for fixing minor errors that are identified outside of the refinement process. The commenter also suggested that there should be a system to address individual exceptions to PEAC standard packages.

Response: If we have made errors, major or minor, in any part of our calculation of practice expense RVUs in this final rule, inform us as soon as possible so that we are able to correct them in the physician fee schedule correction notice. Any other revisions would have to be made in the next physician fee schedule rule. If a specialty society believes that a RUC decision is not appropriate, the society can always request that the decision be revisited or can discuss the issue with us at any time. For the concern with the standard packages adopted by the PEAC, it is our understanding that all presenters at the RUC have the opportunity to demonstrate that something other than the standard would be more appropriate.

- PEAC Recommendations

We proposed to adopt nearly all of the PEAC recommendations. However, we disagreed with the PEAC

recommendation for clinical labor time for CPT code 99183, Physician attendance and supervision of hyperbaric oxygen therapy, per session, and proposed a total clinical labor time of 112 minutes for this service.

Comment: Specialty societies representing interventional radiology and neurological surgeons, as well as the AMA, expressed appreciation for our acceptance of well over 2,000 PEAC refinements in this rule. However, the specialty society representing orthopaedic surgeons commented that some of our proposals appeared to be circumventing the PEAC process, in that we changed the PEAC recommendation for hyperbaric oxygen (HBO) therapy and proposed in-office inputs for two services rather than referring these to the RUC.

Response: We appreciate the hard work and perseverance on the part of the PEAC and the specialty societies that produced the recommended refinements for so many services. In addition, we do not believe that we circumvented the PEAC process in any way. We have the greatest respect for the PEAC and RUC recommendations that we received. However, we do have the final responsibility for all payments made under the physician fee schedule, and this can lead to disagreement with a specific recommendation. The RUC itself has always demonstrated its

understanding and respect for our responsibility in this regard. With regard to the two services that we priced in the office, we stated explicitly in the proposed rule that we were requesting that the RUC review the practice expense inputs.

Comment: The specialty society representing family physicians disagreed with our proposed changes to the PEAC recommendations for the clinical labor time for CPT code 99183, Physician attendance and supervision of hyperbaric oxygen therapy, per session. The commenter contended that a physician providing this service would probably have multiple hyperbaric oxygen chambers; therefore, staff would not be in constant attendance. However, the specialty society representing podiatrists supported this change in clinical staff time.

Response: Based on our concern that the PEAC recommendation of 20 minutes of clinical staff time during the intra-service period undervalued the clinical staff time, we proposed increasing this time to 90 minutes in the proposed rule. This was, of course, subject to comment. We believe there is some merit to the claim that the clinical staff may be monitoring more than one chamber at a time. Therefore, we are adjusting the time for the intra-service period from the proposed 90 minutes to 60 minutes

in recognition of this point. We will continue our examination of this issue and entertain ongoing dialog with all interested organizations and individuals familiar with this service to assure the accuracy of the intra-service time.

Comment: The Cardiac Event Monitoring Provider Group Coalition expressed concern about the PEAC recommendations that would substantially reduce the clinical staff time associated with cardiac monitoring services. Of particular concern to the Coalition was the 70 percent reduction in time for CPT code 93271, the code for cardiac event monitoring, receipt of transmissions, and analysis. Although all these services are currently priced in the nonphysician work pool and this decrease in the staff times has no immediate impact, the commenter was concerned that, when the nonphysician work pool is eliminated, these services will be undervalued. The commenter also believed that the PEAC recommendations may not have reflected all the supplies and equipment utilized in these services and included a complete list of necessary supplies and equipment. The American College of Cardiology (ACC) presented these services at the PEAC meeting and commented they had been unable to collect sufficient data so that the PEAC could make an appropriate recommendation.



Response: It is clear from the Coalition and ACC comments that more information is needed in order to ensure that the appropriate practice expense inputs are assigned to these services in the event that they are removed from the nonphysician work pool. We would be glad to work with the Coalition and the specialty society so that they can make a new presentation to the RUC this coming year.

- Adjustments to Conform With PEAC Standards

We also reviewed those codes that are currently unrefined or that were refined early in the PEAC process to apply some of the major PEAC-agreed standards. For the unrefined 10-day global services, we proposed to substitute for the original CPEP times the PEAC-agreed standard post-service office visit clinical staff times used for all 90-day and refined 10-day global services. We also proposed to eliminate the discharge day management clinical staff time from all but the 10 and 90-day global codes, substituting one post-service phone call if not already in the earlier data. Lastly, we proposed to delete any extra clinical staff time for post-visit phone calls for 10 and 90-day global service because that time is already included in the time allotted for the visits.

Comment: A specialty society representing family physicians supported the elimination of the discharge day

management time assigned in the facility setting for all 0-day global services, as well as all the other adjustments we made to apply PEAC standards. However, several specialty societies representing gastroenterology and orthopaedics, as well as the American College of Physicians, did not agree with the deletion of the discharge day management time. These groups requested restoration of the six minutes allocated to the discharge day management for 0-day global services and argued that most 0-day services require as much staff time as do many 10-day global services performed in the outpatient setting. One of these commenters did not believe a rationale was provided for this change. Another commenter, although recommending that any future refinements take into account all of the PEAC standards, expressed concern regarding all of the above changes, suggesting that this could lead to additional anomalies and recommending that the revisions should be reviewed by the RUC.

Response: The PEAC recommended that the discharge day management time apply only to 10-day and 90-day global services and we were complying with this recommendation. We also believe that this PEAC recommendation is reasonable; it is hard to imagine what tasks a physician's clinical staff back in the office is performing for a

patient during the period that the patient is undergoing a same-day procedure in the hospital outpatient department. However, the point made about 10-day global procedures is pertinent. We would suggest that the RUC reconsider whether the discharge day management clinical staff time should apply only to services that are typically performed in the inpatient setting. We also believe that it was appropriate to apply the PEAC standards to codes that were not refined or that were refined before the standards were developed. The application of these standards is not only fair, but can also help to avoid the possible rank order anomalies cited by the commenter.

#### Methacholine Chloride

The PEAC recommendations for CPT codes 91011 and 91052 included a supply input for methacholine chloride as the injected stimulant for these two services. In discussions with representatives from the gastroenterology specialty society subsequent to receipt of the PEAC recommendations, we learned this is incorrect. For the esophageal motility study, CPT code 91011, we proposed to include edrophonium as the drug typically used in this procedure. For the gastric analysis study, CPT code 91052, we were unable to identify the single drug that is most typically used with this procedure. We requested that commenters provide us

with information on the drug that is most typically used for CPT code 91052, including drug dosage and price, so that it could be included in the practice expense database.

Comment: Several specialty societies representing allergists, pulmonologists and chest physicians, as well as the AMA, requested that the additional cost of methacholine be reflected in the RVUS for the bronchial challenge test, CPT code 95070. As an alternative, the specialty society representing allergists suggested that a HCPCS code could be created so that methacholine could be billed separately.

In response to our request for information about the supply inputs for CPT codes 91011 and 91052, the American Gastroenterological Association (AGA) indicated that edrophonium may be an appropriate supply proxy for CPT code 91011, but, in practice, other agents are more commonly used. However, they provided no additional information regarding these other agents. AGA also stated that the most commonly used drug for CPT code 91052 is pentagastrin, but betazole or histamine may also be used. Again, they did not provide further specific information.

Response: Because CPT code 95070 is valued in the nonphysician work pool, the PEAC's addition of methacholine to this procedure could not be captured by the practice expense RVUs. However, a J-code was established, J7674,

Methacholine chloride administered as inhalation solution through nebulizer, per 1mg, so that this drug can be billed separately. Accordingly, we have deleted methacholine from the practice expense database.

For CPT code 91011, we have retained the drug edrophonium, and our proposed price of \$4.67 per ml, as a supply in the practice expense database. However, we were not able to include a price for pentagastrin in the supply practice expense database for CPT code 91052. We will be happy to work with the specialty societies involved with both of these procedures to obtain accurate drug pricing for the 2006 fee schedule.

- **Nursing Facility and Home Visits**

We proposed to adopt the direct practice expense input recommendations from the March 2003 PEAC meeting for CPT codes 99348 and 99350, two E/M codes for home visits, as well as the March 2004 PEAC recommendations for E/M codes for nursing home services (CPT codes 99301 through 99316).

Comment: A specialty group representing family physicians supported the acceptance of the PEAC recommendations for nursing facility visits, even though this resulted in a decrease for these services. The commenter stated that the decrease occurred because the original CPEP data was flawed and the clinical staff times

were too high. The commenter also stated that the payments in the facility setting will increase for these services and that setting has the higher volume of visits. Other commenters representing long term care physicians, geriatricians and podiatrists expressed disappointment in these PEAC recommendations and stated that, while the PEAC did consider the views of long term care physicians, the PEAC failed to accept these views even though they were supported by data. These commenters believe the PEAC did not recommend an appropriate increase based on a false assumption that the nursing home provides the staff. Another commenter contended that the new values do not adequately account for work performed by the physician's clinical staff. The commenter stated that the pre- and post-times for these codes are less than for the comparable office visit codes, even though it is clear that more clinical staff time is required for the nursing facility resident. One commenter suggested that these concerns would need to be addressed within the framework of the 5-year review. The specialty society representing homecare physicians also commented that, rather than challenging a flawed system, they will use the 5-year review process to have work and practice expense re-valuated for the home visit codes.

Response: While sympathetic to the concerns expressed by the long-term care physicians regarding the overall decrease in clinical staff time in the nursing facility E/M procedures, we believe the PEAC recommendations for these services to be reasonable. We also agree with commenters regarding the upcoming 5-year review process as a means to address the physician work component of these codes. To the extent that there is overlap between the physician time and the clinical labor practice expenses involved in a particular procedure, the 5-year review process can be utilized to address these issues. We encourage the home care physicians and the long-term care physicians to consider using the 5-year review process for these codes.

- Suggested Corrections to the CPEP Data

Comment: The RUC and American Podiatric Medical Association identified a number of PEAC refinements from the August 2003 meeting that were not reflected in the practice expense database and asked that these be implemented. The RUC also asked us to correct the equipment times for all of the 90-day global services to correspond with the PEAC-refined clinical staff times for these codes.

Response: We have made the recommended corrections to our practice expense database.

Comment: The specialty society representing hematology noted the supply items missing from the practice expense database for CPT codes 36514 through 36516 that had been included in the CMS-accepted PEAC refinements.

Response: We regret the error. These items are incorporated into the practice expense database.

Comment: The specialty society representing pediatrics as well as the RUC commented that the PEAC recommendations also included a recommendation for a change in the global period for CPT code 54150, Circumcision, using clamp or other device; newborn, from a 10-day global to an "xxx" designation, which would mean the global period does not apply. This issue was not discussed in the proposed rule and the commenters requested that this change be reflected in the final rule.

Response: As stated by the commenters, this request was included in the PEAC recommendations but was inadvertently omitted from the proposed rule. We agree that the 10-day global period currently assigned to this procedure may not be appropriate because the physician performing the procedure most likely does not see the infant for a post-procedure visit. However, we believe that a 0-day global period rather than "xxx" should be assigned to this procedure. We generally use the "xxx" designation



for diagnostic tests and no surgical procedure currently is designated as an "xxx" global service. We believe this will accomplish the same end because most any other service performed at the same time as the circumcision could be billed with the appropriate modifier. We are adjusting the practice expense database to delete any staff time, supplies and equipment associated with the post-procedure office visit.

Comment: Specialty societies representing dermatology stated that there was an error in the nonfacility practice expense RVUS for the Mohs micrographic surgery service, CPT code 17307, due to the omission of clinical staff time from the practice expense database.

Response: We have corrected the practice expense database to reflect the appropriate clinical staff time.

Comment: We received comments from the American College of Radiology (ACR) and Society of Nuclear Medicine noting that some of the codes used by their specialty were omitted from the listing of PEAC-refined codes that appeared in Addendum C in our proposed rule. They submitted a complete list of the codes that had gone through PEAC refinement, beginning at the first PEAC meeting in April 1999, and asked that we include these codes on the Addendum.

Response: We appreciate the specialty societies bringing to our attention that some of their codes were omitted from Addendum C and we have reviewed the codes on their submitted list. Addendum C was meant to list only those codes that were refined in this year's rule, and thus, only listed those refined by the PEAC from March and August 2003 and January and March 2004. However, it does appear that there is some confusion regarding what codes were refined during this period, particularly from the March 2004 meeting. We will work with all medical societies and the RUC to clarify the status of all the codes in question.

- Other Issues

Comment: The RUC requested that we publish practice expense RVUs for all Medicare noncovered services for which the RUC has recommended direct inputs. We also received a request from the American Academy of Pediatrics to publish work and practice expense RVUs for the noncovered nasal or oral immunization services (CPT codes 90473 and 90474) and the visual acuity test (CPT code 99173).

Response: In the past, we have published the practice expense RVUs for only a small number of noncovered codes which are listed in our national payment files that can be accessed via our physician web page under "Medicare Payment

Systems” as part of the public use files at [www.cms.hhs.gov/physicians/](http://www.cms.hhs.gov/physicians/). Because we have not yet established a consistent policy regarding the publication of RVUs for noncovered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for noncovered services.

Comment: The American Speech-Language Hearing Association (ASHA) and the American Academy of Audiology (AAA), expressed concern about the reduction of practice expense RVUs for CPT code 92547, Use of vertical electrodes (List separately in addition to code for primary procedure), which resulted after the PEAC refinement. The commenters asked for our assistance to clarify a CPT instruction regarding this procedure because they believe it prevents the multiple billings of CPT 92547 in a given patient encounter.

Response: While we are sympathetic to the concerns expressed by ASHA and AAA, we also want to note that CPT code descriptors and accompanying coding instructions are proprietary to CPT. We would encourage these organizations to discuss this issue directly with the CPT editorial committee.

Comment: A specialty society representing vascular surgery expressed concern about the wide variations in

practice expense RVUs that are sometimes derived under the current methodology. The commenter suggested that some outliers require additional focus to determine whether these are errors in the direct inputs or if they reflect problems inherent in the methodology. According to the commenter, it would appear that some of the extreme variation is due to the high costs of certain disposable supplies in the office setting as well as high scaling factors. A few examples of outlier codes were provided. The commenter suggested that we consider an alternative methodology for payment of high-priced single-use items in the nonfacility setting.

Response: We agree with the commenter that the issue raised is one worth study and analysis. Unfortunately, this is not a task that can be accomplished in time for discussion in this final rule. We will be very willing to work with the specialty society and with the Practice Expense Subcommittee of the RUC, as well as any other interested parties, to work further on this issue that will only be magnified as more complex procedures are moved into the office setting.

Comment: A provider of radiology services questioned the reductions in practice expense for CPT code 77370, Special medical radiation physics consultation.

Response: The practice expense RVUs for CPT code 77370 decreased by 0.02 RVUs between last year's final rule and this year's proposed rule. This small decrease is due to the normal fluctuations resulting from updating our practice expense data.

c. Repricing of Clinical Practice Expense Inputs--

Equipment

We use the practice expense inputs (the clinical staff, supplies, and equipment assigned to each procedure) to allocate the specialty-specific practice expense cost pools to the procedures performed by each specialty. The costs of the original equipment inputs assigned by the CPEP panels were determined in 1997 by our contractor, Abt Associates, based primarily on list prices from equipment suppliers. Subsequent to the CPEP panels, equipment has also been added to the CPEP data, with the costs of the inputs provided by the relevant specialty society. We only include equipment with costs equal to or exceeding \$500 in our practice expense database because the cost per use for equipment costing less than \$500 would be negligible. We also consider the useful life of the equipment in establishing an equipment cost per minute of use.

We contracted with a consultant to assist in obtaining the current price for each equipment item in our CPEP database. The consultant was able to determine the current prices for most of the equipment inputs and clarified the

specific composition of each of the various packaged and standardized rooms or ophthalmology "lanes" currently identified in the equipment practice expense database (for example, mammography room or exam lane). We proposed to delete the current "room" designation for the radiopharmaceutical receiving area and, in its place, list separately the equipment necessary for each procedure as individual line items.

Also, we proposed to replace all surgical packs and trays in the practice expense database with the appropriate standardized packs that were recommended by the PEAC, either the basic instrument pack or the medium pack.

The useful life for each equipment item was also updated as necessary, primarily based on the AHA's "Estimated Useful Lives of Depreciable Hospital Assets" (1998 edition). We noted in the August 5, 2004 proposed rule that AHA would be publishing updated guidelines this summer and that we would reflect any updates in our final rule.

In addition, we proposed the following database revisions:

#### Assignment of equipment categories

We proposed that equipment be assigned to one of the following six categories: documentation, laboratory, scopes, radiology, furniture, rooms-lanes, and other

equipment. These categories would also be used to establish a new numbering system for equipment that would more clearly identify them for practice expense purposes. Consolidation and standardization of item descriptions

We proposed combining items that appeared to be duplicative. For example, for two cervical endoscopy procedures, our contractor identified that the price of the LEEP system includes a smoke evacuation system but that system is also listed separately. We proposed to merge these two line items and reflect both prices in the price of the LEEP system.

These changes were reflected in Addendum D of the proposed rule.

Additionally, there were specific equipment items for which a source was not identified or for which pricing information was not found that were included in Table 2 of the August 5 proposed rule. Items that we proposed to delete from the database were also identified in this table. We requested that commenters, particularly the relevant specialty groups, provide us with the needed pricing information, including appropriate documentation. Also, we stated that if we were not able to obtain any verified pricing information for an item, we might eliminate it from the database.

Comment: The Society of Nuclear Medicine agreed with the deletion of the current room designation for radiopharmaceutical area and designation of categories for equipment. However, the society recommended that the category designation of "radiology" be changed to "imaging equipment" and "other equipment" be changed to "non-imaging equipment" to be inclusive of these modalities. The American College of Radiology also concurred with the elimination of the current room designation for radiopharmaceutical area.

Response: We agree that the term "imaging equipment" rather than the term "radiology" more accurately reflects current practice and have changed the practice expense database accordingly. However, it would be inappropriate to change the "other equipment" category to "non-imaging equipment" because there are items in other categories that would not be encompassed in the proposed title change.

Comment: The Society of Nuclear Medicine supplied information on the equipment item E51076 with the requested documentation.

Response: We have revised the practice expense database to reflect the information provided.

Comment: The American Society for Therapeutic Radiology and Oncology (ASTRO) submitted information and



the requested documentation for fifteen items, often supplying two or more pricing sources.

Response: We greatly appreciate the information and have revised the practice expense database to reflect the information provided.

Comment: Commenters representing manufacturers and providers expressed concern about the reduction in payment (9 percent) for external counterpulsation (ECP), G0166. The commenters questioned the proposed change made to the life of the ECP equipment, from seven to five years, used for this service. Commenters did not believe this was supported by the AHA information (which indicated that similar diagnostic cardiovascular equipment has an equipment life of five years) and requested that this timeframe be applied to the ECP equipment for this service. The American College of Cardiology also questioned the change to the ECP equipment life. The commenters also questioned the allocation for maintenance and indirect costs applied under the practice expense methodology as well as the time allocated for this service. As a final point, some of the commenters requested that we adjust the work RVUs assigned to this G-code to that of an echocardiogram (CPT code 93307) and include it in the nonphysician work pool.

Response: Based upon review of the information provided we have revised the equipment life to five years. The methodology used for the allocation for maintenance and indirect costs is consistent with our methodology. For the request to adjust the work RVUs for this service, we refer the commenters to section VI of this final rule where we are soliciting comments on services where the physician work may be misvalued.

Comment: The College of American Pathologists provided information on items listed in table 2: the DNA image analyzer (ACIS), and image analyzer (CAS system) code E13652. They noted that the CAS system is no longer marketed and that the ACIS system would be used in its place. Thus, they provided documentation on the price for the ACIS system.

Response: We appreciate the information and have made the necessary changes to the database.

Comment: The American College of Cardiology (ACC) agreed with the pricing for the ambulatory blood pressure monitor, provided prices for the ECG signal averaging system (E55035), but provided no documentation for these prices. They stated that the echocardiography digital acquisition ultrasound referenced in table 2 was no longer in the marketplace and that a digital workstation was now

typically used. They requested that an appropriate equipment code be available for this item and provided a price range for this item (although without the supporting documentation). ACC also recommended that the pacemaker programmer (E55013) be removed from the equipment list because it is provided at no cost to the physician. Removal of this item from the PE database was also supported by a manufacturer that commented on the rule.

Response: We have removed the pacemaker programmer from the practice expense database. We will temporarily retain other items and prices for the 2005 physician fee schedule and request that ACC forward the documentation as soon as possible.

Comment: The American College of Radiology (ACR) provided partial information for the CAD processor unit and software. ACR also submitted information regarding the computer workstation for MRA and the mammography reporting software, but with insufficient documentation. For the various equipment items ACR listed for the mammography room, updated information was provided for a few of the items. ACR noted that they would submit documentation for all outstanding pieces of equipment when it is available. ACR did not agree with the room price for MRI and CT that

was referenced in Addendum D and requested an extension so that they can work with us to accurately price these items.

Response: We will maintain current pricing for all equipment items and the mammography room on an interim basis, until sufficient documentation is provided.

Comment: The American Ophthalmology Association (AOA) and American Optometric Association both supplied pricing information along with the requested documentation for the computer, VDT, and software (E71013) listed in table 2. AOA also provided pricing information for the ophthalmology drill listed in this table, indicating a cost of \$57. They expressed their appreciation for the recategorization and standardization of descriptions for equipment and supplies.

Response: We appreciate the documentation forwarded by these two organizations and have incorporated into the practice expense database the pricing information provided for the computer, VDT, and software. Because the ophthalmology drill is less than \$500 (the standard established for equipment), we are removing it from the equipment list for the practice expense database.

Comment: The American Gastroenterological Association (AGA) expressed concern about the reduction in RVUs for CPT code 91065, a breath hydrogen test. They believe that the newer equipment listed in the practice expense database

does not reflect the analyzer that is typically used, which is more expensive, and noted that the costs for the reagents have also increased.

Response: We are sympathetic to the concerns of the AGA regarding the typical equipment used for CPT code 91065 and would like to work with them to ascertain updated pricing information about the equipment most physicians utilize for this service. However, the majority of the decrease (76 percent) in practice expense RVUs for this procedure is due to the PEAC refinement for the clinical labor time that was reduced by nearly 50 percent.

Comment: The American Academy of Sleep Medicine indicated that most typical CPAP/BiPAP remote unit is a bilevel positive airway pressure unit and provided documentation for the price of this item.

Response: This price is reflected in the practice expense database.

Comment: The Society for Vascular Surgery (SVS), Society for Vascular Ultrasound and Society of Diagnostic Medical Sonography all expressed appreciation for the refinement to the inputs that apply to vascular ultrasound services. However, the commenters requested that we incorporate the requested refinements for the other ancillary equipment present in a vascular ultrasound room

into other similar procedures. SVS specifically listed the following CPT codes: 93875-9 and 93990.

Response: In addition to the three new CPT codes for cerebrovascular arterial studies CPT 93890, 93892 and 93893, we have added the vascular ultrasound room to the codes indicated in the SVS comment noted above.

Comment: The American Psychiatric Association provided documentation for the cost of the ECT machine and the American Psychological Association provided information on the neurobehavioral status exam and testing, as well as the biofeedback equipment listed in table 2, along with the requested documentation.

Response: We appreciate this information. The practice expense database was revised to reflect this cost information.

Comment: The American Society of Clinical Oncology requested that the biohazard hood be substituted for the ventilator and hood blower as a practice expense input for the chemotherapy codes.

Response: We revised the database to reflect this change.

Comment: American Academy of Neurology supplied information and the necessary documentation on several

equipment items listed in table 2 associated with neurology services.

Response: We have made the revisions to the prices for the ambulatory EEG recorder (E54008), ambulatory review station (E54009), and portable digital EEG monitor based on the documentation provided. Based on the documentation provided, we note that the price for the ambulatory review station was substantially reduced (\$44,950 to \$7,950).

Comment: The American Clinical Neurophysiology Society (ACNS) stated that the payment for CPT code 95819, an EEG service, was substantially reduced. The Society believes it is due to a price reduction for the EEG equipment (E54006) used in this service that was listed in Addendum D of the proposed rule. The commenter indicated that the proposed price does not include the review station and software which is needed for this service and provided documentation for appropriately pricing this item.

Response: Based on the documentation provided, we have changed, on an interim basis for the 2005 fee schedule, the price for this item and note that this equipment price is associated only with CPT code 95819. We would be happy to work with ACNS in order to resolve any issues surrounding the RVUs for CPT code 95819. Reviewing the direct inputs for this code, we note that the largest

contributor to the reduction of practice expense RVUs is the PEAC's refinement of this code's supply items.

Comment: The National Association for Medical Direction of Respiratory Care and the American College of Chest Physicians were in agreement with the proposed prices for equipment except for the pulse oximeter (including printer), E55003. The commenters referenced a price that is \$83 more than that listed in the table, but provided no documentation.

Response: We appreciate the comments from these organizations regarding the repricing of the equipment items in the practice expense database. We have retained our price of \$1,207 for the pulse oximeter and note that it is an average from two different available sources.

Comment: We received a comment from a consumer regarding the price of the electromagnetic therapy machine for HCPCS code G0329 with concerns about the low payment for this modality. While no documentation was submitted, the commenter noted that the cost for this equipment ranged from \$25,000 to \$35,000.

Response: We appreciate the commenter's remarks about the price of the electromagnetic therapy equipment, Diapulse. We have retained our price of \$25,000 in the practice expense database because we do not have



documentation that any higher-priced equipment is typically used. Similar to other modalities used in rehabilitation, including those used in wound care, we note that this procedure reflects comparable practice expense values.

Comment: Several specialty organizations questioned our substitution of the two standardized packs for previously PEAC-approved packs and trays, as discussed in our proposed rule. One specialty society suggested we consult with the AMA before proceeding on this point.

Response: We uniformly applied the PEAC-approved values for the packs and trays to all packs and trays, regardless of whether the codes had previously been refined by the PEAC. To the extent that a specialty society feels that it was disadvantaged by this policy, we would encourage them to bring the specific codes that should be excluded from this policy to the newly formed PERC (formerly PEAC) at the next RUC meeting in February 2005.

Comment: Several specialty organizations indicated that they were in the process of obtaining pricing information on equipment items and would provide it as soon as possible. One commenter also asked that we retain the items proposed for deletion as they are necessary in providing their services, but provided no documentation.

Response: In the proposed rule, we noted that we might eliminate those items from the database for which documented pricing information was not received. Due to the number of outstanding equipment prices, and the number of societies that are underway in their search for this data, we have decided to extend the submission deadline. We would encourage specialty societies to submit price information soon to help ensure that it can be used to establish practice expense RVUs in next year's proposed rule.

Table 2**Equipment Items Needing Specialty Input for Pricing and Proposed Deletions**

<b>2005 Description</b>	<b>2004 Price</b>	<b>Primary specialties associated with item</b>	<b>*CPT code(s) associated with item</b>	<b>Prior status of equipment item</b>	<b>Commenter response</b>	<b>CMS action taken</b>
ambulatory blood pressure monitor	3,000.00	cardiology	93784, 93786, 93788	See Note A	No/Insufficient documentation received	See Note D.
biofeedback equipment		psychology	90875	See Note A	Submitted price of \$9,925	See Note F.
CAD processor unit (mammography)	210,000.00	radiology	76082, 76083, 76085	See Note A (Need system components)	No/Insufficient documentation received	See Note D.
camera system, cardiac, nuclear	675,000.00	anesthesia, IM, cardiology	78414	See Note A	Submitted price of \$406,817	See Note F.
collimator, cardiofocal set	29,990.00	radiology	78206, 78607, 78647, 78803, 78807	See Note A	No/Insufficient documentation received	See Note D.
computer and VDT and software	9,000.00	ophthalmology, optometry	92060, 92065	See Notes A and C	Submitted price of \$7,100	See Note F.
computer software, MR/PET/CT fusion	60,000.00	radiation oncology	77301	See Note A	Submitted price of \$60,000	See Note F.
computer system, record and verify	60,000.00	radiation oncology	77418	See Note A	Submitted prices from 2 sources, average of \$163,593	See Note F.
computer workstation, 3D teletherapy treatment planning	221,500.00	radiation oncology	77300, 77305, 77310, 77315, 77321, 77331	See Note A	Submitted prices from 4 sources, average of \$256,224	See Note F.
computer workstation, MRA post processing		radiology	71555, 72159, 72198, 73225, 73725, 74185	See Note A	No/Insufficient documentation received	See Note E.

<b>2005 Description</b>	<b>2004 Price</b>	<b>Primary specialties associated with item</b>	<b>*CPT code(s) associated with item</b>	<b>Prior status of equipment item</b>	<b>Commenter response</b>	<b>CMS action taken</b>
computer, server		radiation oncology	77301	See Note A (Need system components)	Submitted prices from 3 sources, average of \$22,567	See Note F.
cortical bipolar-biphasic stimulating equipment		neurosurgery, neurology	95961, 95962	See Note A	No/Insufficient documentation received	See Note E.
CPAP/BiPAP remote clinical unit		pulmonary disease, neurology	95811	See Note A	Submitted price of \$3,100	See Note F.
cryo-thermal unit		anesthesia	64620	See Notes A and C	No/Insufficient documentation received	See Note E.
densitometry unit, whole body, DPA	65,000.00	radiology	78351	See Notes A and C	No/Insufficient documentation received	See Note D.
densitometry unit, whole body, SPA	22,500.00	radiology	78350	See Notes A and C	No/Insufficient documentation received	See Note D.
Detector (Probe)	14,000.00	radiology, cardiology	78455	See Notes A and C	No/Insufficient documentation received	See Note D.
dialysis access flow monitor	10,000.00	nephrology	90940	See Note A	No/Insufficient documentation received	See Note D.
diathermy, microwave		anesthesia, GP, podiatry	97020	See Notes A and C	No/Insufficient documentation received	See Note D.
DNA image analyzer (ACIS)	200,000.00	lab, pathology	88358, 88361	See Note A	Submitted price of \$195,000	See Note F.
drill, ophthalmology		ophthalmology	65125	See Note A	Submitted price of \$57, less than \$500	See Note G.
ECG signal averaging system	8,250.00	cardiology, IM	93278	See Note A	No/Insufficient documentation received	See Note D.
EEG monitor, digital, portable		neurology	95953	See Note A	Submitted price of \$17,500	See Note F.
EEG recorder, ambulatory	6,940.00	neurology	95950	See Note A	Submitted price of \$12,500	See Note F.
EEG review station, ambulatory	44,950.00	neurology	95950	See Note A	Submitted price of \$7,950	See Note F.

<b>2005 Description</b>	<b>2004 Price</b>	<b>Primary specialties associated with item</b>	<b>*CPT code(s) associated with item</b>	<b>Prior status of equipment item</b>	<b>Commenter response</b>	<b>CMS action taken</b>
electroconvulsive therapy machine		psychiatry	90870	See Note A	Submitted price of \$13,995	See Note F.
Electromagnetic therapy machine	25,000.00	physical therapy	G0329	See Note A	No/Insufficient documentation received	See Note D.
EMG botox	1,500.00	critical care, pulmonary, ophthalmology	92265	See Note A	No/Insufficient documentation received	See Note D.
fetal monitor <u>software</u>	35,000.00	ob-gyn, radiology	76818, 76819	See Note A	No/Insufficient documentation received	See Note D.
film alternator (motorized film viewbox)	27,500.00	radiology	329 codes	See Note B	No/Insufficient documentation received	See Note D.
generator, constant current	950.00	neurology, NP	95923	See Note A	No/Insufficient documentation received	See Note D.
HDR Afterload System, Nucletron - Oldelft	375,000.00	radiation oncology	77781-84	See Note A	Submitted prices from 2 sources, average of \$375,9665	See Note F.
hyperbaric chamber	125,000.00	FP, IM, EM	99183	See Note A	No/Insufficient documentation received	See Note D.
hyperthermia system, ultrasound, external	360,000.00	radiation oncology	77600	See Note A	Submitted price of \$360,000	See Note F.
hyperthermia system, ultrasound, intracavitary	250,000.00	radiation oncology	77620	See Note A	No/Insufficient documentation received	See Note D.
hysteroscopy ablation system	19,500.00	ob-gyn	58563	See Note A	No/Insufficient documentation received	See Note D.
image analyzer (CAS system)	92,000.00	pathology, neurology	88355, 88356	See Note A	No longer available	See Note H.
IMRT physics tools	55,485.00	radiation oncology	77301, 77418	See Note A	Submitted prices from 3 sources, average of \$78,600	See Note F.
IVAC Injection Automatic Pump	2,500.00	radiology	78206, 78607, 78647, 78803, 78807	See Note A	No/Insufficient documentation received	See Note D.

<b>2005 Description</b>	<b>2004 Price</b>	<b>Primary specialties associated with item</b>	<b>*CPT code(s) associated with item</b>	<b>Prior status of equipment item</b>	<b>Commenter response</b>	<b>CMS action taken</b>
mammography reporting software		radiology	76090, 76091, 76092	See Note A	No/Insufficient documentation received	See Note E.
neurobehavioral status instrument-average	717.00	psychology, IM	96115, 96117	See Note A	Submitted price of \$1,136.25	See Note F.
orthovoltage radiotherapy system	140,000.00	radiation oncology	77401	See Note A	No/Insufficient documentation received	See Note D.
OSHA ventilated hood	5,000.00	radiation oncology	77334	See Note B	No/Insufficient documentation received	See Note D.
plasma pheresis machine w/UV light source	37,900.00	radiology, dermatology	36481, 36510, 36522	See Note A	No/Insufficient documentation received	See Note D.
programmer, pacemaker	10,000.00	cardiology, cardiothoracic surgery, general surgery	33200-01, 33206-08, 33212-18, 33220, 33222, 33240, 33245-46, 33249, 33282	See Note A	Supplied without cost to physician offices, IDTFs, etc	See Note G.
pulse oxymetry recording <u>software</u> (prolonged monitoring)	3,660.00	pulmonary disease, IM	94762	See Note A	No/Insufficient documentation received	See Note D.
radiation treatment vault	550,670.00	radiation oncology	774XX	See Note B	Submitted prices from 3 sources, average \$773,104	See Note F.
radiation virtual simulation system		radiation oncology	77280, 77285, 77290, 77402-16	See Note A	Submitted price of \$967,000	See Note F.
remote monitoring service (neurodiagnostics)	9,500.00	neurology	95955	See Note A	No/Insufficient documentation received	See Note D.

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
review master	23,500.00	pulmonary disease, neurology	95805, 95807-11, 95816, 95822, 95955-56	See Note A	No/Insufficient documentation received	See Note D.
room, basic radiology	150,000.00	radiology	103 codes	See Note A	No/Insufficient documentation received	See Note D.
room, mammography	130,000.00	radiology	19030, 19290-91, 19295, 76086-92, 76096	See Note A	No/Insufficient documentation received	See Note D.
room, radiographic-fluoroscopic	475,000.00		123 codes	See Note A	No/Insufficient documentation received	See Note D.
room, ultrasound, vascular		vascular		New-Added 10/04	Submitted price of \$466,492	See Note F.
source, 10 Ci Ir 192	22,000.00	radiation oncology	77781-84	See Note A	Submitted prices from 2 sources, average \$45,326	See Note F.
strontium-90 applicator	8,599.00	radiation oncology	77789	See Note A	Submitted prices from 3 sources, average \$6,705	See Note F.
table, cystoscopy		urology	52204-24, 52265-75, 52310-17, 52327-32	See Note A	No/Insufficient documentation received	See Note E.
ultrasound color doppler, transducers and vaginal probe	155,000.00	ob-gyn	59070, 59074, 76818-19	See Note A	No/Insufficient documentation received	See Note D.
ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)	29,900.00	ob-gyn, cardiology, pediatrics	76825-28, 93303-12, 93314, 93320, 93325, 93350	See Note A	No/Insufficient documentation received	See Note D.
vacuum cart		anesthesia	64620	See Notes A and C	No/Insufficient documentation received	See Note E.

<b>2005 Description</b>	<b>2004 Price</b>	<b>Primary specialties associated with item</b>	<b>*CPT code(s) associated with item</b>	<b>Prior status of equipment item</b>	<b>Commenter response</b>	<b>CMS action taken</b>
video camera	1,000.00	radiation oncology	77418	See Note A	Submitted price of \$1,000	See Note F.
water chiller (radiation treatment)	28,000.00	radiation oncology	77402-16	See Note B	Submitted prices from 2 sources, average \$25,565	See Note F.
well counter		radiology	78160-72, 78282	See Note A	Submitted price of \$3,450	See Note F.

**Notes:**

- A. Additional information required. Need detailed description, source, and current pricing information.
- B. Proposed deletion as indirect expense.
- C. Item may no longer be available.
- D. No/Insufficient documentation. Current price retained on an interim basis. Forward documentation promptly.
- E. No/Insufficient documentation. No price in database. Forward documentation promptly.
- F. Submitted price accepted.
- G. Equipment deleted, per comment.
- H. No longer available/marketed. Item deleted.



d. Miscellaneous Practice Expense Issues

- Pricing for Seldinger Needle

We proposed to average two prices of this supply item to reflect a cost of \$5.175. We requested that, if commenters disagreed with this change in price, the comment should provide documentation to support the recommended price, as well as the specific type of needle that is most commonly used.

Comment: Commenters were in agreement with the proposed pricing of the seldinger needle.

Response: We will use the proposed price of \$5.175 for this supply item in the practice expense database.

- Hysteroscopic Endometrial Ablation

We proposed to assign, on an interim basis, the following direct practice expense inputs in the nonfacility setting for CPT code 58563, Hysteroscopy, surgical; with endometrial ablation. (Note: In the August 5, 2004 proposed rule this code was erroneously identified as 56853, which does not exist.) We also stated we would request that the RUC review these inputs as part of the practice expense refinement process.

+ Clinical Staff: RN/LPN/MTA--72 minutes (18 pre-service and 54 service)

+ Supplies: PEAC multispecialty visit supply package, pelvic exam package, irrigation tubing, sterile impervious gown, surgical cap, shoe cover, surgical mask with face shield, 3x3 sterile gauze (20), cotton tip applicator, cotton balls (4), irrigation 0.9 percent sodium chloride 500-1000ml(3), maxi-pad, mini-pad, 3-pack betadine swab (4), Monsel's solution (10ml), lidocaine jelly (1000ml), disposable speculum, spinal needle, 18-24g needle, 20 ml syringe, bupivacaine 0.25 percent (10ml), 1 percent xylocaine (20ml), cidex (10ml), Polaroid film-type 667 (2), endosheath, and hysteroscopic ablation device kit.

+ Equipment: power table, fiberoptic exam light, endoscopic-rigid hysteroscope, endoscopy video system, and hysteroscopic ablation system.

Comment: Commenters, including many individual practitioners, were supportive of this proposed change. The specialty society also stated that they plan to present the inputs for this service at the RUC meeting in February 2005

Response: With the exception of the post incision care kit that we deleted because this procedure does not require an incision, we will finalize these inputs as proposed.

- Photopheresis

We proposed to assign, on an interim basis, the following nonfacility practice expense inputs for the photopheresis service, CPT code 36522:

+ Clinical Staff: RN--223 minutes (treatment is for approximately 4 hours)

+ Supplies: multispecialty visit supply package, photopheresis procedural kit, blood filter (filter iv set), IV blood administration set, 0.9 percent irrigation sodium chloride 500-1000 ml (2), heparin 1,000 units-ml (10), povidone solution-betadine, methoxsalen (UVADEX) sterile solution-10 ml vial, 1 percent-2 percent lidocaine-xylocaine, paper surgical tape (12), 2x3 underpad (chux), nonsterile drape sheet 40 inches x 60 inches, nonsterile Kling bandage, bandage strip, 3x3 sterile gauze, 4x4 sterile gauze, alcohol swab pad (3), impervious staff gown, 19-25 g butterfly needle, 14-24g angiocatheter, 18-27 g needle, 20 ml syringe, 10-12 ml syringe, 1 ml syringe, 22-26 g syringe needle-3 ml.

+ Equipment: plasma pheresis machine with ultraviolet light source, medical recliner.

We also stated we would request that the RUC review these inputs.

Comment: One commenter supplied information on practice expense inputs for this code and indicated that an oncology nurse should be used, instead of an RN, to perform the procedure. A specialty society also stated that they would be providing information on this service at the September RUC meeting.

Response: We appreciate the information submitted by the commenters. This code was discussed at the September RUC meeting and recommended practice expense inputs for this service were provided to us. We do not agree with the RUC recommended clinical staff procedure (intra) time of 90 minutes. We believe that this time, which is half of the proposed intra time, does not accurately reflect the total time involved in performing this procedure. Our understanding is that the filtration rate and the procedures performed by the nurse for photopheresis are similar to those that are reflected in the selective apheresis services, CPT code 36516, with a PEAC-approved intra time of 240 minutes. Based on this, and the absence of specialty representation at the RUC familiar with the process, we are assigning 180 minutes for the intra time, as proposed. We are also assigning the RN/LPN staff type to this procedure, because we believe it is similar to other apheresis procedures. We will continue our

examination of this issue and entertain ongoing dialog with all interested organizations and individuals, including the AMA and the RUC, the industry, and those physicians and individuals familiar with the photopheresis procedure in order to assure the accuracy of the intra time.

- Pricing of New Supply Items

As part of last year's rulemaking process, we reviewed and updated the prices for supply items in our practice expense database. During subsequent meetings of both the PEAC and the RUC, supply items were added that were not included in the supply pricing update. The August 5, 2004 proposed rule included Table 3 Proposed Practice Expense Supply Item Additions for 2005, which listed supply items added as a result of PEAC or RUC recommendations subsequent to last year's update of the supply items and the proposed associated prices that we will use in the practice expense calculation.

We also identified certain supply items for which we were unable to verify the pricing information (see Table 4, Supply Items Needing Specialty Input for Pricing, in the August 5, 2004 proposed rule). We requested that commenters provide pricing information on these items along with documentation to support the recommended price. In addition, we also requested information on the specific

contents of the listed kits, so that we do not duplicate any supply items.

Comment: Several commenters representing providers of these services stated that table 3 incorrectly associated “gold markers” with the brachtherapy intracavity codes. They were all in agreement that these markers are typically used in external beam treatments and payment is associated with unlisted procedure codes and should be paid for at cost.

Response: We have deleted the gold markers from CPT codes 77761-77763 and removed this supply from the practice expense database.

Comment: The American Urology Association noted that we should exclude the vasotomy kit from CPT codes 55200 and 55250.

Response: We have deleted the vasotomy kit from CPT codes 55200 and 55250.

Comment: The American College of Chest Physicians agreed with pricing of items used in their practices in table 3 and stated that the bronchogram tray does not need to be included in the practice expense database, as the procedure is seldom performed and, when it is, the procedure is performed in a facility.

Response: We have deleted the bronchogram tray from the practice expense database and corrected the direct inputs for CPT code 31708 accordingly.

Comment: We received comments from the American College of Cardiology (ACC) that included price quotes and names of sources for supply items listed on table 3.

Response: Unfortunately, ACC did not include the requested sufficient documentation, such as invoices or catalog web page links. We have asked ACC to forward this pricing documentation to us as soon as possible because it will be required for supplies to remain valued in the practice expense database. In the interim, for the 2005 fee schedule, we will maintain the prices currently in the practice expense database for the following supplies: blood pressure recording form at \$0.31, pressure bag (infuser) 500cc or 1000cc at \$8.925, sterile, non-vented, tubing at \$1.99.

Comment: Noting that a \$15 supply item, needle-wire for localization of lesions in the breast (used preoperatively in CPT codes 19290 and 19291) was no longer used, a manufacturer requested that we replace this supply with an anchor-guide device valued at \$245. The commenters also stated that this device is used in over 70 offices and imaging centers.

Response: We appreciate the comments from the manufacturer. However, during last year's rulemaking process we repriced all of our supplies, and the needle-wire price of \$15 was an average of prices from two different sources (\$17 and \$13). This price was proposed and accepted by the medical specialty societies that we depend on to verify typical items in our practice expense database. We have retained the \$15 needle-wire for localization because we believe it is typically used for this procedure.

The following table lists the items on which we requested input, the comments received, and the action taken.



**Table 3: Supplies Needing Specialty Input**

2005 Description	Unit	Unit Price	Primary specialties associated with item	Prior status of item	Commenter response	CMS action taken
antibodies - detection	slide	30.90	lab, pathology	See Note A.	Deleted, CPEP refinement	See Note D.
blood pressure recording form, average	item	0.31	cardiology	See Note A.	No/Insufficient documentaion received	See Note B.
catheter, hyperthermia, closed-end	item		radiation oncology	See Note A.	Submitted price of \$20	See Note C.
catheter, hyperthermia, open-end	item		radiation oncology	See Note A.	Submitted price of \$20	See Note C.
Edrophonium	ml	4.67	gastroenterology	See Note A	No/Insufficient documentaion received	See Note B.
hysteroscope, ablation device	item	1,146.00	ob-gyn	See Note A	No/Insufficient documentaion received	See Note B.
kit, BCR/ABL DNA probe	kit	42.65	pathology	See Note A.	Submitted price of \$42.65	See Note C.
kit, Her-2/Neu DNA probe	kit		pathology	New-Added 10/04	Submitted price of \$105	See Note C.
kit, detection	slide	8.50	pathology, neurology	See Note A.	Refinement scheduled 2/05	See Note B.
kit, photopheresis procedure	kit	809.00	dermatology, ob-gyn	See Note A.	Submitted price of \$858	See Note C.
kit, vasotomy	kit		urology	See Note A.	Delete, per comment	See Note D.
methoxsalen, sterile solution (UVADEX) 10 ml vial	ml	49.50	dermatology, radiation oncology	See Note A.	Submitted price of \$49.50	See Note C.
pressure bag	item		cardiology	See Note A.	No/Insufficient documentaion received	See Note E.

2005 Description	Unit	Unit Price	Primary specialties associated with item	Prior status of item	Commenter response	CMS action taken
primary antibodies	slide	3.52	pathology, neurology	See Note A.	Refinement scheduled 2/05	See Note B.
tray, bronchogram	tray		pulmonary disease	See Note A.	Delete, per comment	See Note D.
tubing, sterile, non-vented (fluid administration)	item		cardiology	See Note A.	No/Insufficient documentaion received	See Note E.

\*CPT codes and descriptions only are copyright 2004 American Medical Association. All rights reserved. Applicable FARS/DFARS apply.

Notes:

A. Additional information required. Need detailed description (including kit contents), source, and current pricing information.

B. No/Insufficient documentation. Retained price in database, on interim basis. Forward documentation promptly.

C. Submitted price accepted.

D. Deleted per comment.

E. 2004 price retained on an interim basis. Forward documentation promptly.

- Addition of Supply Item to CPT 88365, Tissue In Situ Hybridization

We proposed to add, on an interim basis, a DNA probe to the CPEP database for CPT 88365, tissue in situ hybridization, with the understanding that the inclusion of the item would be subject to forthcoming RUC review.

Comment: Commenters were supportive of this proposal. The College of American Pathologists also encouraged us to include updated information on practice expense inputs from the September RUC meeting, while another commenter suggested that we run the information by the specialty society.

Response: The direct practice expense inputs for this code and two other codes in the same family were discussed at the September RUC after a presentation made by the specialty society. We have reviewed and accepted the RUC recommendations, and these practice expense inputs will be included in the practice expense database.

- Ophthalmology Equipment

In cases where both the screening and exam lanes are included in the equipment list for the same ophthalmology service, we proposed to include only one lane because the patient could only be in one lane at a time. We proposed defaulting to the exam lane and, thus, we proposed deleting

the screening lane from the practice expense inputs for these procedures. For the services where a lane change was made, time values were assigned to the exam lane in accordance with our established standard procedure.

Comment: The American Academy of Ophthalmology requested that we specifically identify the codes for which we deleted the screening lane, so that they can ensure that the correct lane was deleted.

Response: This information can be obtained by comparing the direct inputs in the practice expense database files for the 2004 and 2005 fee schedules that are posted on our website (<http://www.cms.hhs.gov/physicians/pfs>). However, we would be happy to work with the specialty organization to verify the accuracy of the information.

- Parathyroid Imaging, CPT code 78070

Based on comments received from the RUC and the specialty society representing nuclear medicine, we proposed to crosswalk the charge-based RVUs from CPT 78306, Bone and/or joint imaging; whole body, to CPT 78070, Parathyroid imaging.

Comment: Several specialty societies expressed appreciation for this proposed change.

Response: We will finalize our proposal and crosswalk the charge-based RVUs from CPT code 78306 to CPT code 78070.

- Additional PE concerns

Comment: We received information from the American Academy of Ophthalmology that two biometry devices (a-scan ultrasonic biometry unit and an optical coherence biometer) were listed as equipment for the ophthalmic biometry service, CPT code 92136. Only the optical coherence biometer should be included for this code.

Response: As requested by the specialty society, we have deleted the a-scan biometry unit from the equipment list for CPT code 92136.

Comment: We received comments from manufacturers, specialty societies representing renal physicians and vascular surgeons, and individual providers questioning the decrease in nonfacility practice expense RVUS for CPT code 36870, Percutaneous thrombectomy, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis). Some commenters believe this reduction occurred because the supplies listed in the database for this service reflect only one method of providing this service. While commenters acknowledged that the database includes the

supplies used in approximately 50 percent of the instances this procedure is performed, the commenters claimed that other supplies may be used in the remaining occasions. Commenters requested that we add these other specific supplies to the database.

Response: Because there are a variety of supplies and equipment that can be used in performing a service, under the practice expense methodology, the supplies and equipment that are used in determining payment are those that are most typical for the procedure. Although there may be alternative supplies used, the inputs in the database reflect what is typically used (which is acknowledged by the commenters) and thus we are not adding the requested supplies to the practice expense database. However, we did note that the list of equipment did not reflect the cost of the angiography room that is used during the procedure, and this has been added to our database for this code.

Comment: Societies representing dermatologic specialties expressed concern about the reduction in practice expense RVUs for a photodynamic therapy service, CPT code 96567. The commenters believe that this reduction is due to the application of the dermatology scaling factor based on updated practice expense utilization and requested

that this be reconsidered. These commenters also expressed appreciation that there is now a separate HCPCS code to bill for levulan that is needed for this procedure, but stated that there are two medical supplies that need to be included in the practice expense database: bacitracin, and a topical anesthetic cream.

Response: The practice expense RVUs for photodynamic therapy decreased only slightly in this year's proposed rule due to the proposed repricing of equipment. The decrease referred to by the commenter occurred after the first year that the code was established. At that time we obtained the utilization data that demonstrated that dermatologists performed the service and we then applied the same scaling factors to the code that we do for all dermatology services. Therefore, the scaling factor we now apply is correct. We will add the requested amount of bacitracin to the supply list for the code. Unfortunately, the topical anesthetic requested is not in our database and the commenters did not include pricing information so we are not able to include the item in our practice expense calculation.

Comment: A society representing interventional pain physicians expressed concern that the practice expense RVUs for CPT code 95990, Refilling and maintenance of

implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), are understated when compared to the RVUs for CPT code 95991, the same service administered by a physician. According to the commenter, CPT code 95991 includes a total of 47 minutes of nonphysician labor and 37 minutes of physician labor or total professional time of 84 minutes. This is the total time spent with the patient before, during and after the refill. The commenter requested that the number of minutes of direct labor for CPT code 95990 should be a minimum of 84 minutes, since the nonphysician practitioner would be performing all the services associated with CPT code 95991 that are performed by both the physician and clinical staff. In addition, the commenter stated that CPT code 95990 should also be assigned physician work RVUs because there is physician oversight of the service even when performed by clinical staff. Two other commenters stated that both CPT codes 95990 and 95991 should be valued the same as the chemotherapy implanted pump refill service, CPT code 96530. The commenters state that this was the code originally used to report the above services, that CPT codes 95990 and 95991 originally were assigned higher RVUs than CPT code 96530 and that the MMA adjustments that



increased the payment for CPT code 96530 should be applied to CPT codes 95990 and 95991.

Response: The commenter is correct that the clinical staff times for CPT codes 95990 and 95991 are the same (50 minutes of clinical staff time), although the clinical staff is performing the procedure in one case and assisting the physician in the other. However, the assumption underlying these times is that, in the cases where it is necessary for the physician to personally perform the procedure, the nurse is assisting for the entire time. If this assumption is not correct, then the clinical staff time for CPT code 95991 is overstated. Because CPT codes 95990 and 95991 are not considered drug administration codes under section 303 of the MMA, we will not apply the adjustments made for CPT code 96530 to these services. Therefore, we will not be revising the staff time for either code at this time, but would suggest that the RUC look further at this issue. We would also suggest that the society bring CPT code 95990 to the 5-year review, if they wish to make the case that work RVUs should be assigned.

Comment: The society representing interventional pain physicians questioned the "professional component only" designation we assigned to the codes for the analysis of an implanted intrathecal pump, CPT codes 62367 and 62368, and

the subsequent low RVUs for these services. The commenter stated that if the payment is left as proposed, more physicians would stop offering intrathecal pumps to patients.

Response: This was an inadvertent error on our part that we have corrected for the final rule. These services are physicians' services that do not have separate professional and technical components. We thank the commenter for pointing out this error.

Comment: The Joint Council of Allergy, Asthma and Immunology expressed concern about the reduction in the proposed rule in practice expense RVUs for a number of allergy codes, in particular the venom therapy CPT codes, 95145 through 95149. The commenter stated that Medicare reimbursement for these services does not cover the physician's supply expense, due to the expensive venom antigens that are part of the service, and believes this is a result of the scaling factor being used.

Response: We are sympathetic to the commenter's concern about the high cost of the venom antigens and the specialty's low scaling factor. We would be happy to work with JCAAI further to see if a remedy can be identified regarding this subset of the allergy codes.

Comment: Two commenters stated that the practice expense RVUs for HCPCS code G0329, Electromagnetic Therapy for ulcers, were too low and supplied information on the supplies, equipment and clinical staff time for this service.

Response: Based on the information provided by the commenters, we added diapulse asetips and chux to the supplies in the practice expense database for this service. We also increased the equipment time to 30 minutes.

Comment: We received comments from the North American Spine Society (NASS) stating that the specific needle used for CPT codes 22520 and 22522, which was originally recommended by NASS, is the most expensive needle and may not be the most typical. The specialty noted that available needles range from \$26 to \$1,295, which represent the needle (termed vertebroplasty kit) in the practice expense database. NASS indicated that the specialties involved in performing these procedures are conducting a survey to determine the most commonly used needles and their costs.

Response: We appreciate the comments from NASS and look forward to receiving the survey results. In the interim, we have averaged the needle costs for the range indicated above by the specialty and have entered this

figure, \$660.50, as a placeholder for the 2005 fee schedule. Because of the large disparity between the lowest and highest needle costs, it is not reasonable to consider \$660.50 as a true average cost for this supply item. We will continue to work with the specialty organizations in order to ensure that the 2006 fee schedule practice expense database reflects the value for the most typical needle used in these procedures.

Comment: We received comments from two medical societies with concerns about a decrease in practice expense RVUs for CPT code 95819, which is part of the EEG sleep study series of codes. These two organizations noted their willingness to bring this code to the February 2005 RUC meeting in order to rectify the direct practice expense inputs for this procedure.

Response: We have reviewed the family of EEG sleep-study codes and believe that a rank order anomaly exists relating primarily to the 2004 PEAC recommendation to delete the 25 reusable electrodes from CPT code 95819. We support and encourage these organizations to bring the entire EEG family of codes to the February 2005 RUC to ensure that this rank order anomaly can be resolved and the correct direct inputs can be identified for these procedures.

Comment: The Coalition for Advancement of Prosthetic Urology expressed concern about the continuing decline in practice expense RVUs for prosthetic urology procedures. They believe that this is due in part to the number of post service visits assigned to these services. They stated that information from a survey they conducted shows there are typically four to five post service visits rather than three as reflected in the database. The commenter also provided a copy of the survey information.

Response: The number of post service visits for these services was established based on recommendations from the RUC or by using the Harvard data. If they believe that the information regarding the number of post service visits for specific procedures is incorrect, the Coalition must request that the codes be examined as part of the 5-year refinement of work RVUs. An explanation of this process and the information that must be provided is found in section VI. of this rule.

B. Geographic Practice Cost Indices (GPCIs)

We are required by section 1848(e)(1)(A) of the Act to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components. While requiring that the practice expense and malpractice GPCIs reflect the full

relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the physician work GPCIs reflect only one-quarter of the relative cost differences compared to the national average.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, to adjust the GPCIs at least every 3 years. This section of the Act also requires us to phase-in the adjustment over 2 years and to implement only one-half of any adjustment if more than 1 year has elapsed since the last GPCI revision. The GPCIs were first implemented in 1992. The first review and revision was implemented in 1995, the second review was implemented in 1998, and the third review was implemented in 2001. We reviewed and revised the malpractice GPCIs as part of the November 7, 2003 (68 FR 63196) physician fee schedule final rule. We were unable to revise the work and practice expense GPCIs at the time of the publication of the November 2003 final rule because the U.S. Census data, upon which the work and practice expense GPCIs are based, were not yet available.

In addition, section 412 of the MMA amended section 1848(e)(1) of the Act and established a floor of 1.0 for the work GPCI for any locality where the GPCI would otherwise fall below 1.0. This 1.0 work GPCI floor is used

for purposes of payment for services furnished on or after January 1, 2004 and before January 1, 2007. Section 602 of the MMA further amended section 1848(e)(1) of the Act for purposes of payment for services furnished in Alaska under the physician fee schedule on or after January 1, 2004 and before January 1, 2006, and sets the work, practice expense, and malpractice expense GPCIs at 1.67 if any GPCI would otherwise be less than 1.67.

In the August 5, 2004 proposed rule, we proposed to revise the work and practice expense GPCIs for 2005 through 2007 based on updated U.S. Census data and Department of Housing and Urban Development (HUD) fair market rental (FMR) data. The same data sources and methodology used for the development of the 2001 through 2003 GPCIs were used for the proposed 2005 through 2007 work and practice expense GPCIs.

The relative respective weights for the 2004 work, practice expense and malpractice GPCIs, as well as the proposed 2005 through 2007 GPCI revisions, were derived using the same weights that were used in the Medicare Economic Index (MEI) revision discussed in the November 2003 physician fee schedule final rule (68 FR 63245).

#### 1. Work Geographic Practice Cost Indices

As explained in the August 5, 2004 proposed rule, we used data from the 2000 decennial U.S. Census, by county,

of seven professional occupations (architecture and engineering; computer, mathematical, and natural sciences; social scientists, social workers, lawyers; education, library, training; registered nurses; pharmacists; writers, artists, editors) in the development of the proposed work GPCIs. Physicians' wages are not included because Medicare payments are determinant of the physicians' earnings.

Including physician wages in the physician work GPCI would, in effect, make the index dependent upon Medicare payments. Based on analysis performed by Health Economics Research, we believe that, in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals vary.

The U.S. Census Bureau has very specific criteria that tabulations must meet in order to be released to the public. To maximize the accuracy and availability of the data collection, the nonphysician professional wage data were aggregated by county and a median wage by county was calculated for each occupational category. These median wages were then weighted by the total RVUs associated with a given county to ultimately arrive at locality-specific work GPCIs. This geographic aggregation of Census data is the same methodology that was used in previous updates to the GPCIs.



The proposed work GPCIs reflected one-fourth of the relative cost differences, as required by statute, with the exception of those areas where MMA requires that the GPCI be set at no lower than 1.00 and that the Alaska GPCIs be set at 1.67.

## 2. Practice Expense GPCIs

As in the past, we proposed that the practice expense GPCI would be comprised of several factors that represent the major expenses incurred in operating a physician practice. The impact of each individual factor on the calculation of the practice expense GPCI is based on the relative weight for that factor consistent with the calculation of the MEI. The specific factors included:

- Employee Wage Indices--The employee wage index is based on special tabulations of 2000 Census data and is designed to capture the median wage by county of the professional labor force. The employee wage index uses the median wages of four labor categories that are most commonly present in a physician's private practice (administrative support, registered nurses, licensed practical nurses, and health technicians). Median wages for these occupations were aggregated by county in the same manner as the data for the work GPCI.

- Office Rent Indices-- The HUD FMR data for the residential rents were again used as the proxy for physician office rents as they are in the current practice expense GPCIs. The proposed 2005 through 2007 practice expense GPCIs reflect the final fiscal year 2004 HUD FMR data. We believe that the FMR data remain the best available source for constructing the office rent index. The FMR data are available for all areas, are updated annually, and retain consistency from area-to-area and from year-to-year. A reduction in an area's rent index does not necessarily mean that rents have gone down in that area since the last GPCI update. Since the GPCIs measure area costs compared to the national average, a decrease in an area's rent index means that that area's rental costs are lower relative to the national average rental costs. Addendum X illustrates the changes in the rental index based upon the new FMR data.
- Medical Equipment, Supplies, and other Miscellaneous Expenses--The GPCIs assume that items such as medical equipment and supplies have a national market and that input prices do not vary among geographic areas. We were again unable to find any data sources that demonstrated price differences by geographic areas.

As mentioned in previous updates, some price differences may exist, but these differences are more likely to be based on volume discounts rather than on geographic areas. The medical equipment, supplies, and miscellaneous expense portion of the practice expense geographic index will continue to be 1.000 for all areas in the proposed GPCIs, except for Alaska which will have an overall practice expense GPCI set at 1.67 for 2005 and 2006.

### 3. Fee Schedule Payments

All three of the indices for a specific fee schedule locality are based on the indices for the individual counties within the respective fee schedule localities. As in the past, fee schedule RVUs are again used to weight the county indices (to reflect volumes of services within counties) when mapping to fee schedule areas and in constructing the national average indices.

Fee schedule payments are the product of the RVUs, the GPCIs, and the conversion factor. Updating the GPCIs changes the relative position of fee schedule areas compared to the national average. Because the changes represented by the GPCIs could result in total payments either greater than or less than what would have been paid if the GPCIs were not updated, it is necessary to apply scaling factors to the proposed GPCIs to ensure budget neutrality (prior to applying the provisions of MMA that change the work GPCIs to

a minimum of 1.0 and increase the Alaska GPCIs to 1.67 because these provisions are exempted from budget neutrality). We determined that the proposed work and practice expense GPCIs would have resulted in slightly higher total national payments. Because the law requires that each individual component of the fee schedule--work, practice expense, and malpractice expense--be separately adjusted by its respective GPCI, we proposed to scale each of the GPCIs separately. To ensure budget neutrality prior to applying the MMA provisions, we have made the following adjustments:

- Decreased the proposed work GPCI by 0.9965;
- Decreased the proposed practice expense GPCI by 0.9930; and
- Increased the malpractice GPCIs that were published in the November 7, 2003 final rule by 1.0021.

Because all geographic payment areas will receive the same percentage adjustments, the adjustments do not change the new relative positions among areas indicated by the proposed GPCIs. After the appropriate scaling factors are applied, the MMA provision setting a 1.0 floor has been applied to all work GPCIs falling below 1.0. Additionally, the GPCIs for Alaska have been set to 1.67 in accordance with MMA.

Comment: A specialty society representing family physicians recommended that we work with the Congress to

eliminate the GPCIs or set them all at 1.00. The society stated that they understand the statutory requirement to apply the GPCIs, but that all geographic adjustment factors should be eliminated from the physician fee schedule, except for those designed to achieve a specific policy good, such as adjustment to encourage physicians to practice in underserved areas. The commenter contended that elimination of the GPCIs would have a positive effect on the availability of medical care to rural beneficiaries. Other commenters suggested that we should no longer apply the work GPCI to the work RVUs.

We also received numerous comments on the subject of the source of the data we use in the development of the GPCIs. Commenters suggested that we find data sources other than Census Bureau data. They believe the census data become obsolete very quickly and want us to use data that reflect up-to-date prices for inputs. This would, they argue, make the GPCI values more realistic.

A medical specialty group commented that the index is flawed because--

- It is based on the tenuous assumption that the relative differences in the prices of the input proxies accurately reflect relative changes in prices

of corresponding physician practice cost components;  
and,

- It applies uniform weights to practice cost components, despite evidence of geographic variation in component shares.

Several commenters had specific concerns about the proxies used for the work and practice expense GPCIs, for example—

- Using data for four employee classes to measure relative compensation differences for all physicians' office staff which does not reflect the changes in medical practice that have occurred since the index was developed;
- Using residential real estate prices to reflect relative differences in physicians' office costs; and
- Using nationally uniform prices for supplies, equipment, and other expenses.

Another particular concern among commenters is the use of HUD apartment rental data as the source of costs for physicians' rents. Instead, they argue, we should find, or carry out, a national study of retail and business rents.

Another commenter asserts that these indices have not been verified by peer-reviewed published research since they were instituted and that we should replace the indices

with data from nationwide studies that validate and update actual cost of practice data.

Response: As noted by a commenter, we are required by the Congress to adjust for geographic differences in the operational cost of physicians' practices by applying geographic price indices to each component of the Physician Fee Schedule. However, we also believe it appropriate in our resource based payment system to account for real differences in physicians' costs in different geographical areas. We share the concern about access to care for our rural beneficiaries and, in this rule, we are finalizing our proposals on payment adjustments to physicians in underserved areas through the HPSA Incentive Payment Program. For the commenters who object to the GPCI adjustment to the work RVUs, we would note that for 2005 and 2006 the floor for the work GPCI will be 1.00.

With reference to the issue of the GPCI data source, we are always open to suggestions about possible data sources; however, we believe the most reliable source of national, comparable data at the county level is the Census Bureau. Other data sources that we have examined either fail to produce the data at the county level, cannot be compared nationally, or offer no means of comparability over time.

We believe that the proxies, while not perfect, are the best tools available for the development of the GPCIs. For example, if we were to eliminate all proxies, we would have to collect actual physicians' office data from a sufficiently large sample in each locality to calculate the GPCIs. This would place a substantial burden on the office staff and would be prohibitively expensive. Also, the benefits from that approach would be uncertain.

The question of applying uniform weights to practice components is an area where more research could lead to better information about the variation attributable to case mix and the availability of other health resources, input prices, and practice styles. However, it is important to note that much of the variation associated with case and specialty mix is accounted for by the varying RVUs for different services. However, we are open to exploring this issue.

On the issue of which employee categories are included in the employee wage index component of the practice expense GPCI calculation, we included those that have been determined in the past to be most commonly present in a physician's private practice. We are considering the suggestion that we include a broader group of employment categories in the future.



While we recognize that apartment rents are not a perfect proxy for physician office rents, there are no existing national studies that present reliable retail and business rentals data. We would welcome any nationally consistent data that could be used for this purpose.

We noted in the proposed rule that we were unable to find any data sources that demonstrate price differences by geographic areas for medical equipment and supplies. Once again, however, we welcome any nationally consistent data for this purpose.

We appreciate the concern expressed by the commenter who suggested our GPCI methodology has not been subjected to peer-review validation since its inception, but we are not aware of any currently available data that could replace our methodology. Furthermore, we believe the process of updating the GPICs periodically through notice and comment rulemaking affords an opportunity for a thorough review of the GPCI calculation methodology.

Comment: A member of a medical society suggested that we make the floor of 1.00 permanent for the work GPCI and incrementally increase both the practice expense GPCI and the professional liability insurance GPCI to 1.00 over the next ten years.

Response: We have no authority to extend the floor of the work GPCI, or to create a 1.00 floor for the practice expense and professional liability insurance GPICs.

Section 1848(c)(1)(A) of the Act requires that the index reflect resource costs relative to the national average, indicating that, aside from the MMA provision establishing a floor on the work GPCI through 2006, localities with costs below the national average have GPICs below 1.00.

Comment: A specialty organization representing the long term care industry suggested that we phase in the new GPCI values over a three-year period to minimize the impact of the changes.

Response: We are required by section 1848(e)(1)(C) of the Act to review and adjust the GPICs every 3 years. This section of the Act also requires us to phase in the adjustment over 2 years and implement only one-half of any adjustment if more than 1 year has elapsed since the last GPCI revision. We believe this phase-in appropriately balances any negative impacts of the changes with the positive impacts on those localities where the GPICs increase.

#### 4. Payment Localities

As discussed in the August 5, 2004 proposed rule, we have considered, and are continuing to examine, alternatives

to the composition of the current 89 Medicare physician payment localities to which the GPCIs are applied.

While we have considered alternatives, we have been unable to establish a policy and criteria that would satisfactorily apply to all situations. Any policy that we would propose would have to apply to all States and payment localities. If, for example, we were to establish a policy that when adjacent county geographic indices exceeded a threshold amount the lower county could be moved to the higher county or that a separate locality could be created, redistributions would be caused within a State.

Because there will be both winners and losers in any locality reconfiguration, the State medical associations should be the impetus behind these changes. The support of State medical associations has been the basis for previous changes to statewide areas, and continues to be equally important in our consideration of other future locality changes.

Comment: We received numerous comments from physicians and individuals, including members of the Congress, living in and around Santa Cruz County, California. Their comments uniformly expressed the opinion that Santa Cruz be taken out of the "Rest of California" payment locality and placed in a separate payment locality.

Additionally, the California Medical Association (CMA) submitted a "placeholder" proposal to move any county with a county-specific geographic adjustment factor (GAF) that is 5 percent greater than its locality GAF to its own individual county payment locality. Under their proposal, any reductions in payments to maintain budget neutrality in light of the higher payments to physicians in the counties that are moved into the new independent county localities would be divided equally among all payment localities within the State of California. Additionally, for 2005 and 2006, the GAFs in localities from which the high-cost counties are removed would not be reduced as a result of removing the counties.

Response: We greatly appreciate the efforts of the CMA and many others toward addressing this difficult issue. We also recognize the concerns expressed by the residents of Santa Cruz County about the impact of the current payment disparities upon physicians in their community. Our consistent position has been that we will be responsive to requests for locality changes when there is a demonstrated consensus within the State medical association for the change. Due to the re-distributive impacts of these types of changes, we believe this approach helps ensure the appropriateness of any such change.

We are required, however, to publish the final 2005 GPCIs and GAFs in this rule, and we have applied the current definitions for all California localities.

On October 21, 2004, the CMA Board of Trustees voted without objection to support the placeholder proposal submitted in the CMA's comment with the amendment to limit the time period to the years 2005 through 2006. However, we have determined that we do not have the authority under section 1848(e) of the Act to reduce the GPCIs of some localities in a State to offset higher payments to other localities. Nonetheless, we are eager to work with CMA and its Congressional Representatives to resolve this difficult problem as quickly and fairly as possible.

Comment: We received comments from physicians, individuals and the Texas Medical Association regarding locality payments. These commenters request that we regard all counties in a metropolitan statistical area (MSA) as being in a single payment locality. This would, they argue, equalize payments in those areas where growth has expanded city boundaries across county lines.

Response: As noted above, we will be responsive to requests for locality changes when there is a demonstrated consensus within the State medical association for the change.

Result of Evaluation of Comments

We will finalize the GPCIs as proposed.

C. Malpractice Relative Value Units (RVUs)

1. Proposed Methodology for the Revision of Resource-based Malpractice RVUs

The methodology used in calculating the proposed resource-based malpractice RVUs is the same methodology that was used in the initial development of resource-based RVUs, the only difference being the use of more current data. The proposed resource-based malpractice expense RVUs are based upon:

- Actual 2001 and 2002 malpractice premium data;
- Projected 2003 premium data; and
- 2003 Medicare payment data on allowed services and charges.

As in the initial development of resource-based malpractice expense RVUs in the November 2, 1999 final rule, we proposed to revise resource-based malpractice expense RVUs using specialty-specific malpractice premium data because they represent the actual malpractice expense to the physician. In addition, malpractice premium data are widely available. We proposed using actual 2001 and 2002 malpractice premium data and projected 2003 malpractice premium data for three reasons:

- These are the most current national claims-made premium data available.
- These data capture the highly publicized and most recent trends in the specialty-specific costs of professional liability insurance.
- These are the same malpractice premium data that were used in the development of revised malpractice GPCIs in the November 7, 2003 final rule.

We were unable to obtain a nationally representative sample of 2003 malpractice premium data for the following two reasons:

- The premium data that we collected from the private insurance companies had to “match” the market share data that were provided by the respective State Departments of Insurance (DOI). Because none of the State DOI had 2003 market share information at the time of this data collection, 2003 premium data were not usable; and
- The majority of private insurers were not amenable to releasing premium data to us. In the majority of instances, the private insurance companies would release their premium data only to the State Department of Insurance.

Discussions with the industry led us to conclude that the primary determinants of malpractice liability costs remain physician specialty, level of surgical involvement, and the physician's malpractice history. Malpractice premium data were collected for the top 20 Medicare physician specialties measured by total payments. Premiums were for a \$1 million/\$3 million mature claims-made policy (a policy covering claims made, rather than services provided during the policy term). We attempted to collect premium data from all 50 States, Washington, D.C., and Puerto Rico. Data were collected from commercial and physician-owned insurers and from joint underwriting associations (JUAs). A JUA is a State government-administered risk pooling insurance arrangement in areas where commercial insurers have left the market. Adjustments were made to reflect mandatory patient compensation funds (PCFs) (funds to pay for any claim beyond the statutory amount, thereby limiting an individual physician's liability in cases of a large suit) surcharges in States where PCF participation is mandatory. The premium data collected represent at least 50 percent of physician malpractice premiums paid in each State.

For 2001, we collected premium data from 48 States (for purposes of this discussion, State counts include



Washington, D.C. and Puerto Rico). We were unable to obtain premium data from Kentucky, New Hampshire, New Mexico, and Washington D.C. To calculate a proxy for the malpractice premium data for these four areas in 2001, we began with the most current malpractice premium data collected for these areas, 1996 through 1998 (the last premium data collection that was undertaken). We calculated an average premium price (using 1996 through 1998 data) for all States except Kentucky, New Hampshire, New Mexico, and Washington, D.C. Similarly, we calculated an average premium price for the 1999 through 2001 period for all States except Kentucky, New Hampshire, New Mexico, and Washington, D.C. We calculated the percentage change in these premium prices as the percent difference between the 1999 to 2001 calculated average premium price and the 1996 to 1998 calculated average premium price. We then applied this percentage change to the weighted average 1996 to 1998 malpractice premium price for these four areas to arrive at a comparable 1999 to 2001 average premium price.

For 2002, we were able to obtain malpractice premium data from 33 States. Many State Departments of Insurance had not yet obtained premium data from the primary insurers within their States at the time of this data collection. For those States for which we were unable to obtain

malpractice premium data, we calculated a national average rate of growth for 2002 and applied this national rate of growth to the weighted average premium for 2001 to obtain an average premium for 2002 for each county for which we were unable to obtain malpractice premium data for 2002.

We projected premium values for 2003 based on the average of historical year-to-year changes for each locality (when locality level data were available) or by State (when only statewide premium data projections were available). First, we calculated the percentage changes in the premiums from the 1999 through 2000, 2000 through 2001, and 2001 through 2002 periods for each payment locality. Next, we calculated the geometric mean of these three percentages and applied the mean to the 2002 premium to obtain the forecasted 2003 malpractice premium. We used the geometric mean to calculate the forecasted 2003 premium data because the geometric mean is commonly used to derive the mean of a series of values that represent rates of change. Because the geometric mean is based on the logarithmic scale, it is less impacted by outlying data. Alternative methods, such as linear extrapolation tended to yield more extreme values that were the result of outlying data.

Malpractice insurers generally use five-digit codes developed by the Insurance Services Office (ISO), an advisory body serving property and casualty insurers, to classify physician specialties into different risk classes for premium rating purposes. ISO codes classify physicians not only by specialty, but in many cases also by whether or not the specialty performs surgical procedures. A given specialty could thus have two ISO codes, one for use in rating a member of that specialty who performs surgical procedures and another for rating a member who does not perform surgery. We use our own system of specialty classification for payment and data purposes. It was therefore necessary to map Medicare specialties to ISO codes and insurer risk classes. Different insurers, while using ISO codes, have their own risk class categories. To ensure consistency, we used the risk classes of St. Paul Companies, one of the oldest and largest malpractice insurers. Although St. Paul Companies have recently terminated writing professional liability insurance policies at the time of this data collection they were still the largest and most nationally representative writer of professional liability insurance policies in the nation. The crosswalks for Medicare specialties to ISO codes and to the St. Paul risk classes used are reflected in Table 4.

Some physician specialties, nonphysician practitioners, and other entities (for example, independent diagnostic testing facilities) paid under the physician fee schedule could not be assigned an ISO code. We crosswalked these specialties to similar physician specialties and assigned an ISO code and a risk class. These crosswalks are reflected in Table 5.

In the development of the proposed resource-based malpractice RVU methodology, we considered two malpractice premium-based alternatives for resource-based malpractice RVUs: the dominant specialty approach and the specialty-weighted approach.

#### Dominant Specialty Approach

The dominant specialty approach bases the malpractice RVUs upon the risk factor of only the dominant specialty performing a given service as long as the dominant specialty accounted for at least 51 percent of the total utilization for a given service. When 51 percent of the total utilization does not comprise the dominant specialty, this approach uses a modified specialty-weighted approach. In this modified specialty-weighted approach, two or more specialties are collectively defined as the dominant specialty. Starting with the specialty with the largest percentage of allowed services, the modified

specialty-weighted approach successively adds the next highest specialty in terms of percentage of allowed services until a 50 percent threshold is achieved. The next step is to sum the risk factors of those specialties (weighted by utilization) in order to achieve at least 50 percent of the total utilization of a given service and then to use the factors in the calculation of the final malpractice RVU.

The dominant specialty approach produces modest increases for some specialties and modest decreases for other specialties. The largest increase for any given specialty, over the specialty-weighted approach, is less than 1.5 percent of total RVUs, while the largest decrease for any given specialty is less than 0.5 percent of total RVUs. The dominant specialty approach also fails to account for as much as 49 percent of the utilization associated with a given procedure.

#### Specialty-Weighted Approach

The approach that we adopted in the November 1999 final rule and proposed to use for 2005 bases the final malpractice RVUs upon a weighted average of the risk factors of all specialties performing a given service. The specialty-weighted approach ensures that all specialties performing a given service are accounted for in the

calculation of the final malpractice RVU. Under the proposed methodology, we--

- Compute a national average premium for each specialty.  
Insurance rating area malpractice premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by the total county RVUs (as defined by Medicare claims data), which were divided by the malpractice GPCI applicable to each county to standardize the relative values for geographic variations. If the malpractice RVUs were not normalized for geographic variation, the locality cost differences (as reflected by the GPICs) would be counted twice. The product of the malpractice premiums and standardized RVUs is then summed across specialties for each county. This calculation is then divided by the total RVUs for all counties, for each specialty, to yield a national average premium for each specialty. As stated previously, we used an average of the 3 most current years, 2001 to projected 2003 malpractice premiums, in our calculation of the proposed malpractice RVUs. See Table 6 for a display of the average premiums for the top 20 Medicare specialties;
- Calculate a risk factor for each specialty. Differences among specialties in malpractice premiums are a direct

reflection of the malpractice risk associated with the services performed by a given specialty. The relative differences in national average premiums between various specialties can be expressed as a specialty risk factor. These risk factors are an index calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest average premium, nephrology. The risk factors used in the development of the resource-based malpractice RVUs are displayed in Table 7;

- Calculate malpractice RVUs for each code. Resource-based malpractice RVUs were calculated for each procedure. In order to calculate malpractice RVUs for each code, we identified the percentage of services performed by each specialty for each respective procedure code. This percentage was then multiplied by each respective specialty's risk factor as calculated in Step 2. The products for all specialties for the procedure were then summed, yielding a specialty-weighted malpractice RVU reflecting the weighted malpractice costs across all specialties for that procedure. This number was then multiplied by the procedure's work RVUs to account for differences in risk-of-service. Since we were unable to find an acceptable source of data to be used in

determining risk-of-service, work RVUs were used. We welcome any suggestions at any time for alternative data sources to be used in determining risk-of-service.

Certain specialties may have more than one ISO rating class and risk factor. The surgical risk factor for a specialty was used for surgical services and the nonsurgical risk factor for evaluation and management services. Also, for obstetrics/gynecology, the lower gynecology risk factor was used for all codes except those obviously surgical services, in which case the higher, surgical risk factor was used.

Certain codes have no physician work RVUs. The overwhelming majority of these codes are the technical components (TCs) of diagnostic tests, such as x-rays and cardiac catheterization, which have a distinctly separate technical component (the taking of an x-ray by a technician) and professional component (the interpretation of the x-ray by a physician). Examples of other codes with no work RVUs are audiology tests and injections. Nonphysicians, in this example, audiologists and nurses, respectively, usually furnish these services. In many cases, the nonphysician or entity furnishing the TC is distinct and separate from the physician ordering and interpreting the test. We believe it is appropriate for



the malpractice RVUs assigned to TCs to be based on the malpractice costs of the nonphysician or entity, not the professional liability of the physician.

Our proposed methodology, however, would result in zero malpractice RVUs for codes with no physician work, since we proposed the use of physician work RVUs to adjust for risk-of-service. We believe that zero malpractice RVUs would be inappropriate because nonphysician health practitioners and entities such as independent diagnostic testing facilities (IDTFs) also have malpractice liability and carry malpractice insurance. Therefore, we proposed to retain the current charge-based malpractice RVUs for all services with zero work RVUs. We also solicited comments and suggestions for constructing resource-based malpractice RVUs for codes with no physician work.

- Rescale for budget neutrality. The law requires that changes to fee schedule RVUs be budget neutral. The current resource-based malpractice RVUs and the proposed resource-based malpractice RVUs were constructed using entirely different malpractice premium data. Thus, the last step in this process is to adjust for budget neutrality by rescaling the proposed malpractice RVUs so that the total proposed resource-based malpractice RVUs equal the total current resource-based malpractice RVUs.

The proposed resource-based malpractice RVUs for each procedure were then multiplied by the frequency count for that procedure to determine the total resource-based malpractice RVUs for each procedure. The total resource-based malpractice RVUs for each procedure were summed for all procedures to determine the total fee schedule proposed resource-based malpractice RVUs. The total fee schedule proposed resource-based malpractice RVUs were compared to the total current resource-based malpractice RVUs. The total current and proposed malpractice RVUs were equal and, therefore, budget neutral. Thus, no adjustments were needed to ensure that expenditures remained constant for the malpractice RVU portion of the physician fee schedule payment.

The proposed resource-based malpractice RVUs were shown in Addendum B of the August 5, 2004 proposed rule. The values did not reflect any final budget-neutrality adjustment, which we stated would be made in the final rule based upon the more current Medicare claims data. The malpractice RVUs identified in this final rule did not require the application of a scaling factor to retain budget neutrality.

Because of the differences in the sizes of the three fee schedule components, the implementation of the updated

resource-based malpractice RVUs has a smaller payment effect than the previous implementation of resource-based practice expense RVUs. On average, work represents about 52.5 percent of the total payment for a procedure, practice expense about 43.6 percent of the total payment, and malpractice expense about 3.9 percent of the total payment. Thus, a 20 percent change in practice expense or work RVUs would yield a change in payment of about 8 to 11 percent. In contrast, a corresponding 20 percent change in malpractice values would yield a change in payment of only about 0.6 percent.

**TABLE 4 :**

Medicare Code	Medicare Description	ISO code		Risk Class		St. Paul's Description
		Surgery	Other	Surgery	Other	
1	General practice	80117	80420	4	1	Family/Gen. Practitioners - No Obstetrical
2	General surgery	80143	80143	5	5	Surgery General
3	Allergy/Immunology	80254	80254	1A	1A	Allergy
4	Otolaryngology	80159	80265	3	1	Otorhinolaryngology
5	Anesthesiology	80151	80151	5A	5A	Anesthesiology
6	Cardiology	80281	80255	2	1	Cardiovascular Disease
7	Dermatology	80472	80256	5	1A	Dermatology
8	Family practice	80117	80420	4	1	Family/Gen. Practitioners - No Obstetrical
10	Gastroenterology	80104	80241	3	1	Gastroenterology
11	Internal medicine	80284	80257	2	1	Internal medicine
13	Neurology	80288	80261	2	2	Neurology
14	Neurosurgery	80152	80152	8	8	Surgery Neurology
16	Obstetrics/Gynecology	80167	80244	4	1	Gynecology
18	Ophthalmology	80114	80263	2	1	Ophthalmology
20	Orthopedic surgery	80501	80501	5	5	Surgery Orthopedic - excluding Spinal Surgery
20	Orthopedic surgery	80154	80154	6	6	Surgery Orthopedic - including Spinal Surgery
22	Pathology	80292	80266	2	1A	Pathology
24	Plastic and reconstructive surgery	80156	80156	5	5	Surgery Plastic
25	Physical medicine and rehab	80235	80235	1	1	Physical medicine and rehab
26	Psychiatry *	80492, 80431	80249	2	1A	Psychiatry
28	Colorectal surgery	80115	80115	3	3	Surgery Colon and Rectal
29	Pulmonary Disease	80269	80269	1	1	Pulmonary Disease
30	Diagnostic radiology **	80280	80253	2	2	Radiology
33	Thoracic surgery	80144	80144	6	6	Surgery Thoracic
34	Urology	80145	80145	2	2	Surgery Urological
36	Nuclear medicine	80262	80262	1	1	Nuclear medicine

Medicare Code	Medicare Description	ISO code		Risk Class		St. Paul's Description
		Surgery	Other	Surgery	Other	
37	Pediatric medicine	80293	80267	2	1	Pediatrics
38	Geriatric medicine ***	80276	80243	2	1	Geriatrics
39	Nephrology ***	80287	80260	2	1	Nephrology
40	Hand surgery	80169	80169	5	5	Surgery Hand
44	Infectious disease	80279	80246	2	1	Infectious disease
46	Endocrinology ***	80272	80238	2	1	Endocrinology
65	Physical therapist (independent)	80235	80235	1	1	Physical medicine and rehab
66	Rheumatology	80252	80252	1	1	Rheumatology
67	Occupational therapist (independent)	80235	80235	1	1	Occupational Medicine
77	Vascular surgery	80146	80146	6	6	Surgery Vascular
78	Cardiac surgery	80141	80141	6	6	Surgery Cardiac
82	Hematology	80278	80245	2	1	Hematology
83	Hematology/oncology	80473	80473	1	1	Oncology
84	Preventive medicine	80231	80231	1	1	General Preventive Medicine
92	Radiation Oncology ****	80425	80425	2	2	Radiation Therapy
93	Emergency medicine	80157	80102	5	4	Emergency Medicine
98	Gynecologist/oncologist	80167	80244	4	1	Gynecology

Note: For specialties with multiple risk classifications depending on the level of surgical involvement, the highest level of surgery for each specialty was selected for the "surgery" ISO and risk class; and the lowest level of surgery was selected for the "nonsurgery" ISO and risk class.

Note: If a specialty has only one risk classification the same classification was used for both surgery and nonsurgery..\*The ISO codes for surgery for Psychiatry represents Psychiatry - shock therapy.

\*\*St. Paul's is the only one of the five companies that has a "major invasive" procedures ISO Code for Radiology; therefore, the "minor invasive procedures" ISO Code is being used as the highest level of surgery.

\*\*\*St. Paul's is the only one of the five companies that has a "major surgery" ISO Code for Geriatrics, Nephrology, and Endocrinology; therefore, the minor Surgery" ISO Code is being used as the highest level of surgery.

\*\*\*\*Medical Protective's Description was used as St. Paul's does not provide specific medical malpractice insurance for Radiation Therapy.

**TABLE 5:**

<b>Medicare Code</b>	<b>Unassigned Medicare Specialty</b>	<b>Crosswalk Specialty</b>
12	Osteopathic Manipulative Therapy	Family Practice
32	Anesthesiologist Assistant	Anesthesiology
35	Chiropractic	Physical medicine and rehab
41	Optometry	Ophthalmology
43	Certified Registered Nurse Assistant	All Physicians
47	Physiological Laboratory (independent)	All Physicians
48	Podiatry	All Physicians
50	Nurse Practitioner	All Physicians
62	Psychologist	Psychiatry
68	Clinical Psychologist	Psychiatry
69	Clinical Laboratory	All Physicians
70	Multi-Specialty Clinic or Group Practice	All Physicians
74	Radiation Therpay Center	Radiation Oncology
76	Peripheral Vascular Disease	Vascular Surgery
79	Addiction Medicine	Psychiatry
80	Licensed Clinical Social Worker	Psychiatry
81	Critical Care (Intensivists)	All Physicians
85	Maxillofacial Surgery	Plastic Surgery
86	Neuropsychiatry	Psychiatry
89	Certified Clinical Nurse Specialist	All Physicians
90	Medical Oncology	Internal Medicine
91	Surgical Oncology	General Surgery
94	Interventional Radiology	Radiology
96	Optician	Ophthalmology
97	Physician Assistant	All Physicians

TABLE 6:

ISO	Specialty	2001 Average	2002 Average	2003 Average	1996-1998 Average	2001-2003 Average <sup>1</sup>	Annual Trend <sup>2</sup>	Specialty MGPCI <sup>3</sup>	Normalized 2001-2003 Premium <sup>4</sup>	Risk Factor <sup>5</sup>
80269	Pulmonary disease	12,574	13,456	14,541	9,508	13,524	7.30%	1.027	13,168	2.14
80280	Diagnostic radiology	15,807	16,783	17,997	12,372	16,862	6.39%	0.997	16,913	2.75
80284	Internal medicine	14,395	15,714	16,985	11,836	15,698	5.81%	1.028	15,270	2.48
80274	Gastroenterology	14,347	15,398	16,643	11,745	15,463	5.65%	1.017	15,204	2.47
80143	General surgery	33,163	36,004	39,059	27,825	36,075	5.33%	0.957	37,696	6.13
80423	General practice	13,325	14,479	15,731	11,234	14,512	5.25%	0.943	15,389	2.50
80288	Neurology	16,206	17,330	18,629	13,726	17,388	4.84%	1.032	16,849	2.74
80114	Ophthalmology	13,064	14,103	15,317	11,209	14,161	4.79%	0.997	14,204	2.31
80152	Neurosurgery	64,724	70,125	76,060	57,701	70,303	4.03%	0.952	73,848	12.00
80281	Cardiology	14,798	15,836	17,085	13,204	15,906	3.79%	1.021	15,579	2.53
80145	Urology	18,701	20,253	21,931	16,958	20,295	3.66%	0.999	20,315	3.30
80159	Otolaryngology	21,720	23,127	24,794	19,990	23,214	3.04%	0.997	23,284	3.78
80154	Orthopedic w/ spinal	40,384	43,758	47,321	38,584	43,821	2.58%	0.955	45,886	7.46
80144	Thoracic surgery	39,538	43,200	47,249	38,812	43,329	2.23%	1.020	42,479	6.91
80282	Dermatology	11,046	11,549	12,375	10,650	11,657	1.82%	1.020	11,428	1.86
80260	Nephrology <sup>6</sup>	8,408	9,290	10,142	n/a	9,280	n/a	0.999	9,289	1.51
80146	Vascular surgery	39,391	42,660	46,211	n/a	42,754	n/a	1.014	42,164	6.85
80141	Cardiac surgery	37,802	40,498	43,722	n/a	40,674	n/a	0.921	44,163	7.18
80425	Radiation oncology	13,800	14,755	15,976	n/a	14,844	n/a	0.995	14,918	2.43
80102	Emergency medicine	20,671	22,672	24,733	n/a	22,692	n/a	0.974	23,298	3.79

<sup>1</sup> A simple average of figures for 2001, 2002, and 2003.<sup>2</sup> Annualized average growth rate between 1996 - 1998 and 2001 - 2003.<sup>3</sup> An average of locality malpractice GPCIs using specialty-specific malpractice RVUs as weights.

<sup>4</sup> 2001 - 2003 premium divided by specialty MGPCI.

<sup>5</sup> (Normalized 2001 - 2003 Premium, .9289) x 1.51.

<sup>6</sup> Nephrology is set to 1.51 to be consistent with the risk factor taken from the rating manuals.

n/a signifies that the premium data was not available.

**TABLE 7:**

<b>Medicare Code</b>	<b>Medicare Description</b>	<b>Nonsurgical Risk Factor</b>	<b>Surgical Risk Factor</b>
01	General practice	1.79	4.26
02	General surgery	6.13	6.13
03	Allergy/Immunology	1.00	1.00
04	Otolaryngology	1.45	3.78
05	Anesthesiology	2.84	2.84
06	Cardiology	1.45	2.53
07	Dermatology	1.00	1.86
08	Family practice	1.79	4.26
10	Gastroenterology	2.05	3.49
11	Internal medicine	2.05	2.48
12	Osteopathic Manipulative Therapy	1.79	4.26
13	Neurology	2.52	2.74
14	Neurosurgery	12.00	12.00
16	Obstetrics/Gynecology	2.15	5.63
18	Ophthalmology	1.24	2.31
20	Orthopedic surgery w/o Spinal	8.06	8.06
20	Orthopedic surgery with Spinal	8.89	8.89
22	Pathology	1.72	2.09
24	Plastic Surgery	6.92	6.92
25	Physical Med & Rehab	1.26	1.26



<b>Medicare Code</b>	<b>Medicare Description</b>	<b>Nonsurgical Risk Factor</b>	<b>Surgical Risk Factor</b>
26	Psychiatry	1.11	3.08
28	Colorectal surgery	4.08	4.08
29	Pulmonary disease	2.14	2.14
30	Diagnostic radiology	2.07	2.75
32	Anesthesiologist Assistant	2.84	2.84
33	Thoracic surgery	6.91	6.91
34	Urology	3.30	3.30
35	Chiropractic	1.26	1.26
36	Nuclear medicine	1.66	1.66
37	Pediatric medicine	1.76	2.42
38	Geriatric medicine	1.35	2.17
39	Nephrology	1.51	1.96
40	Hand surgery	4.71	4.71
41	Optometry	1.24	2.31
43	Certified Registered Nurse Assistant	3.04	3.71
44	Infectious disease	1.55	2.09
46	Endocrinology	2.03	2.09
47	Physiological Laboratory (independent)	3.04	3.71
48	Podiatry	3.04	3.71
50	Nurse Practitioner	3.04	3.71
62	Psychologist	1.11	3.08
65	Physical therapist (independent)	1.26	1.26
66	Rheumatology	2.11	2.11
67	Occupational therapist	1.11	1.11
68	Clinical Psychologist	1.11	3.08
69	Clinical Laboratory	3.04	3.71

<b>Medicare Code</b>	<b>Medicare Description</b>	<b>Nonsurgical Risk Factor</b>	<b>Surgical Risk Factor</b>
70	Multi-Specialty Clinic or Group Practice	3.04	3.71
74	Radiation Therapy Center	2.43	2.43
76	Peripheral Vascular Disease	6.85	6.85
77	Vascular surgery	6.85	6.85
78	Cardiac surgery	7.18	7.18
79	Addiction Medicine	1.11	3.08
80	Licensed Clinical Social Worker	1.11	3.08
81	Critical Care (Intensivists)	3.04	3.71
82	Hematology	1.77	2.26
83	Hematology/oncology	2.05	2.11
84	Preventive medicine	1.26	1.26
85	Maxillofacial Surgery	6.92	6.92
86	Neuropsychiatry	1.11	3.08
89	Certified Clinical Nurse Specialist	3.04	3.71
90	Medical Oncology	2.05	2.48
91	Surgical Oncology	6.13	6.13
92	*Radiation oncology/therapy	2.43	2.43
93	Emergency medicine	3.79	4.55
94	Interventional Radiology	2.07	2.75
96	Optician	1.24	2.31
97	Physician Assistant	3.04	3.71
98	Gynecologist/oncologist	2.15	5.63

Note: If a specialty has only one risk classification, the same classification was used for both surgery and nonsurgery.

Note: For specialties with multiple risk classifications depending on the level of surgical involvement, the highest level of surgery was selected for surgery risk factor and the lowest level of surgery was selected for nonsurgery risk factor.

Note: CPT codes 59000-59899 were assigned the obstetrics risk factor (11.30) while all other OB/GYN procedures were assigned the gynecology surgical risk factor.

Comments and Responses

We received public comments on several malpractice issues. The comments and our responses are stated below.

Comment: Several comments were received that requested revisions to the data sources utilized in the development of resource-based malpractice RVUs. Specifically, commenters requested that we remove utilization for assistant-at-surgery claims from the calculation of resource-based malpractice RVUs because the utilization of assistant-at-surgery services artificially lowers the average risk associated with surgical services. Additionally, we also received comments that raised questions related to the ISO crosswalks and resulting risk factors that we used.

Response: We agree that assistants at surgery should not be reflected in the malpractice RVUs because they are not primarily responsible for performing the surgical procedures, and we are removing the assistant-at-surgery utilization, and associated risk factors, from the data that are used to calculate the resource-based malpractice RVUs. The inclusion of the lower assistant-at-surgery risk factors into the overall determination of some complex surgical services artificially lowers the average risk

factor and resulting resource-based malpractice RVUs of these services.

Regarding the ISO Classifications and resulting risk factors that were applied to specialties, the majority of comments received did not offer substantive reasons or alternative methodologies for the proposed ISO crosswalks. We derived the ISO crosswalks, and resulting risk factors, based upon the review by both our contractor and CMS medical officers. Due to the lack of substantive alternatives in the comments received, we will retain the crosswalks that were proposed in the August 4, 2004 proposed rule (see Table 7) with the exception of orthopedic surgery and dermatology.

Comment: Several commenters believed that the August 2004 proposed rule that established risk factors of 7.46 for orthopedic surgery with spinal and 8.06 for orthopedic surgery without spinal were counterintuitive and needed revision.

Response: We agree with these comments and have revised the orthopedic surgery with spinal risk factor to reflect the risk factor identified in the rating manuals (8.89). In the proposed rule, the risk factors for orthopedic surgery with spinal and without spinal were taken from two separate sources (premium data and rating

manuals, respectively) thus causing the anomalous result. See Table 7 for the revised orthopedic surgery risk factors.

Comment: Two commenters, including the American College of Dermatology believe that the use of the higher risk class of major surgery is inappropriate for dermatological services as the typical dermatological practice does not encompass major surgery but instead focuses on minor surgery in the office setting.

Response: We agree with these comments and will use the minor surgery and no-surgery risk classifications for dermatological services. See Table 7 for the revised dermatology risk factors. The impact of removing the assistant at surgery claims and revising the risk factor associated with orthopedic surgery with spinal is an 0.9 percent increase for neurosurgery and a 0.4 percent increase for orthopedic surgery over the malpractice RVUs shown in proposed rule. The effect of replacing the major surgery risk factor with the minor surgery risk factor for dermatology is a 0.9 percent decrease in total payments relative to the proposed rule.

Comment: One commenter states that the resource-based malpractice RVU methodology underestimates the cost of PLI for physicians who perform obstetric and gynecologic

services. According to the commenter, eighty percent of OB/GYNs perform both obstetric and gynecologic services yet the risk factor for most services these physicians provide to Medicare beneficiaries is based on the much lower premiums paid by physicians who offer only gynecologic services.

Response: Although obstetricians and gynecologists' malpractice premiums can be appreciably different, most Medicare OB/GYN services are gynecological. Therefore, all Medicare OB/GYN procedures will be assigned a gynecology risk factor except in those instances where the service provided is clearly obstetrical in nature. CPT codes in the range of 59000 - 59899 are clearly obstetrical services and use the obstetrics risk factor (11.30).

Comment: One commenter felt that it was inappropriate to assign 0.00 malpractice RVUs to services that have physician work and have historically had a small amount of malpractice RVUs associated with them.

Response: We agree with this comment and will adjust these services in the final rule. All payable fee schedule services have some amount of PLI associated with their performance.

Comment: One commenter requested that we consider the implementation of the resource-based malpractice expense

RVUs interim until the agency has worked with the medical community to ensure that the data and methodology utilized to calculate the malpractice RVUs are appropriate.

Response: We are continuing to work with the medical community to ensure that the methodology and data used to calculate the malpractice RVUs appropriately reflect the actual resource costs associated with professional liability insurance for physicians. Section 1848(c)(2)(B)(i) of the Act states that the Secretary is required to review the relative values not less often than every 5 years. If substantive information becomes available subsequent to the publication of the final malpractice RVUs, the statute allows us flexibility to review that information for possible inclusion in future malpractice RVU updates.

Comment: Several commenters requested that we use a methodology that would only account for the dominant specialty in the calculation of the service-specific resource-based malpractice RVUs. Commenters stated that a dominant specialty approach would be consistent with the "typical" service approach that we use throughout the resource-based physician payment system. Commenters also feel that a dominant specialty approach would more



appropriately reflect the actual premium resource costs associated with the performance of individual services.

Response: We continue to believe that accounting for all specialties that perform a given service is the more appropriate and equitable methodology in establishing resource-based malpractice RVUs. Basing payment upon all specialties that perform a given service ensures that the actual professional liability insurance resource costs of all specialties are included in the calculation of the final malpractice RVUs. Using only the dominant specialty does not capture the true resource costs associated with a given service and under a relative value based system, results in the redistribution of RVUs based upon only partial data.

The dominant specialty approach is particularly vulnerable for calculating resource-based malpractice RVUs in services that are multi-disciplinary in nature. An example that illustrates the potentially distorting effect of the dominant specialty approach on multi-disciplinary services is the specialty utilization associated with a level III established office visit. Although over 35 different specialties perform a significant number of these services, a dominant specialty approach would base the malpractice RVUs on approximately 2 specialties. High risk

specialties such as neurosurgery, thoracic surgery, general surgery, and obstetrics and gynecology, which account for a small percentage of the total utilization but a large amount of total dollars, would no longer factor into the calculation of the malpractice RVU for this service. These four specialties alone account for nearly \$300 million of the total dollars associated with a level III established office visit. The effect of removing these four high-cost, high-risk specialties from the calculation of the malpractice RVUs for this service would be an overall decrease in the malpractice RVUs, because the calculation would be based upon lower-cost, lower-risk specialties.

We disagree that a dominant specialty approach is consistent with the typical service approach used in the RUC survey process. Irrespective of the specialty performing a given service, we require that the typical service be the measurement tool for the calculation of final payments. The typical service approach utilized in the RUC survey process has never referred to the typical specialty performing a service, but instead to the typical type of service furnished. This typical service would encompass such things as the condition of the patient, the extent of the work, the staff needed to accomplish the

service, and the respective resource inputs associated with the typical service.

We will continue to work with the RUC PLI Workgroup to identify alternatives to the dominant specialty approach. One alternative that we are currently exploring with the RUC PLI Workgroup is removing aberrant data from low utilization services.

Comment: One commenter suggested that we determine the exponential rate of growth in the PLI premium data from 2001 through 2003 to predict the 2004 premium data. This commenter believes that we should use only this predicted 2004 premium data in the calculation of resource-based malpractice RVUs.

Response: We disagree with the commenter's recommendation that predicted 2004 professional liability insurance premium data be utilized in the calculation of resource-based malpractice RVUs. The data sources that are currently used in the calculation of the 2005 resource-based malpractice RVUs consist of actual 2001 and 2002 premium data (when available) and projected 2003 premium data. Professional liability insurance has proven to be the most volatile data source that is used in the calculation of resource-based physician fee schedule RVUs.

For this reason, we believe that it is inappropriate to use only one year of projected premium data.

Comment: Various specialty organizations request that we work with the RUC's Professional Liability Insurance (PLI) Workgroup to ensure that the medical community has input into the refinement of the malpractice RVUs.

Response: Over the course of the past year, we have been working with the RUC PLI Workgroup to solicit input on the methodology and data sources utilized to calculate resource-based malpractice RVUs. We continue to actively participate in the PLI Workgroup to keep both the workgroup and the various specialty organizations aware of our progress in the development and refinement of resource-based malpractice RVUs. We have forwarded all requested contractor reports, which outline both our methodology and data sources, to the RUC for review and comment. We agree with these comments and plan to continue our cooperative relationship with the RUC PLI Workgroup and various specialty organizations to ensure that the necessary specialty organizations are involved with both the premium collection efforts and the development and refinement of resource-based malpractice RVUs.

Comment: Tail coverage is designed to cover any claims that may be made against a new employee for services

furnished on behalf of his or her old employer during the time that he or she is employed by the new employer. Several commenters suggested that we incorporate the cost of tail coverage in the determination of PLI annual premium data.

Response: Although we agree with the commenters that it might be desirable to use tail coverage premium data in addition to the annual premium data that are currently used in the revisions to resource-based malpractice RVUs, we have been unable to identify a nationally representative source of tail coverage premium data. We are continuing to work with the RUC PLI Workgroup, the AMA, and the various specialty organizations to identify a nationally representative source of tail coverage premium data for future rulemaking.

Comment: One commenter recommended that professional liability insurance data for all specialties should be used rather than the data from the top 20 Medicare specialties.

Response: Although it might be desirable to obtain premium data from every conceivable specialty in the practice of medicine, it is not possible to obtain this scope of data under the time constraints associated with collecting the most current premium data. In order to conduct surveys that collect the maximum amount of premium

data from all geographic areas without being too intrusive to the State Departments of Insurance and private insurance companies, we chose to limit the scope of the data collection to the top 20 Medicare specialties. Further, utilizing PLI data from the top 20 Medicare specialties encompasses 80 percent of fee schedule services.

Comment: Several commenters requested that we use data from the Physician Insurers Association of America (PIAA) in the development of resource-based malpractice RVUs. This commenter further requested that we provide concise requirements for those data collection efforts.

Response: We did explore the use of data from PIAA in the development of resource-based malpractice RVUs. Unfortunately, the PIAA does not include actual physician claims-made premium data by insurer and specialty classification. The information that was available from PIAA ranged from insured demographics information to medical malpractice claims trends.

Regarding our criteria for premium data collection efforts, we have shared the criteria for those premium data collection efforts with the RUC PLI Workgroup.

Comment: Several commenters recommended that the malpractice RVUs should remain stable. Commenters suggested that any budget neutrality adjustments, positive

or negative, that might occur due to the 5-year review of malpractice RVUs should be made to the conversion factor and not to the malpractice RVUs.

Response: We acknowledge the comments that suggest that any adjustments for budget neutrality not be performed on the RVUs, but we note that any budget neutrality adjustments to the RVUs do not change the relative relationship among the values for the services but instead uniformly change all relative values. Regarding malpractice RVUs specifically, malpractice RVUs are by nature not "stable." When the malpractice RVUs are reviewed and updated, the malpractice RVUs associated with all services could potentially change. Additionally, for 2005, we are mandated by statute to apply at least a 1.5 percent increase to the conversion factor. Thus, if the budget neutrality associated with updated malpractice RVUs were negative, it would not be possible to ensure budget neutrality and comply with the statutory 1.5 percent update.

Comment: One commenter recommended that the exceptions to the surgical risk factor be modified to include coding changes since the initiation of the resource-based malpractice RVUs in 2000. The previous update to the malpractice RVUs made service-specific

exceptions, whereby certain codes were assigned the higher surgical risk factor in the calculation of their final malpractice RVU. The commenter specifically requested that due to CPT coding modifications, the following codes should also receive this same coding modification and receive the greater of their actual average risk factor or the risk factor for cardiac catheterization: 92973-92974, 93501-93533, 93580-93581, 93600-93613, and 93650-93652.

Response: In order to retain the exceptions that were identified in the previous malpractice RVU update for this new series of services, we will assign the greater of the actual average risk factors or the risk factor for cardiac catheterization services.

Comment: Several commenters agreed with our use of the work RVUs as the best available data source for adjusting the malpractice RVUs for risk of service. These commenters noted, as we did, that the work RVUs are not a perfect proxy for risk of service, but are the best available source at this time. Commenters requested that we continue our use of work RVUs as the adjuster to malpractice RVUs for risk of service, but also requested that we be responsive to potential anomalies that may be identified.



Response: We agree with these comments and look forward to continuing our work with the various organizations to identify all potential anomalies in the malpractice RVUs.

Comment: One commenter expressed concern that, although malpractice premiums have increased for all specialty practices, some specialty practices will experience a decline in payments as a result of the 5-Year Review of malpractice RVUs. This commenter suggested that additional dollars need to be added to the system to account for rising PLI costs.

Response: The impact of the malpractice RVU revisions on an individual specialty organization is not a direct reflection of the increases or decreases in their malpractice premiums but instead reflects increases or decrease in a specific state's premiums as compared to the national average. In some instances, specialty organizations might have experienced slight increases in their respective malpractice premiums since the last malpractice RVU update, but these increases have occurred at a slower rate than the national average increase for all specialty organizations. The result is a negative impact on these specialties. Specialty organizations that have

increased at a rate higher than the national average will experience positive impacts.

Comment: One commenter believes that additional dollars should be added to the Medicare physician fee schedule to account for escalating professional liability insurance premiums.

Response: The Medicare Economic Index (MEI) is the device by which additional dollars are added to the physician fee schedule. For 2005, the cost category associated with professional liability insurance has increased by 23.9 percent. However, for 2004 and 2005, section 601 of the MMA established an update of 1.5 percent.

Comment: The American College of Radiology (ACR) commented that there is an imbalance between the distribution of malpractice RVUs to the professional component and technical component of a service. The ACR requested that we work with ACR staff to identify alternative methodologies for the more appropriate valuation of technical component services.

Response: Physician work RVUs are used to adjust for risk of service. Because, technical component services do not have physician work RVUs, they are still valued using charge-based RVUs instead of the resource-based malpractice

RVU methodology. We look forward to working with the ACR and other interested specialty organizations to examine alternative methodologies that would allow technical component services to also reflect resource-based malpractice RVUs.

#### Final Decision

We are implementing the revised 2005 malpractice RVUs as proposed with the modifications noted in the discussions above. Additionally, we are continuing to work with the AMAs RUC to--

- Consider the appropriateness of a dominant specialty approach;
- Identify the most current nationally representative professional liability insurance premium data;
- Review the current ISO crosswalks; and
- Review aberrant data patterns in low-utilization services for possible inclusion in a future rulemaking cycle.

#### D. Coding Issues

##### 1. Change in global period for CPT code 77427, Radiation treatment management, five treatments

This code was included in the November 2, 1999 physician fee schedule final rule (64 FR 59380) and was effective for services beginning January 1, 2000. In that

rule, and subsequent rules, we have applied a global indicator of "xxx" to this code, meaning that the global concept does not apply. It was brought to our attention that this global indicator is incorrect and that the code should be assigned a 90-day global period because the RUC valuation of this service reflected a global period of 90 days which we had accepted. Therefore, we proposed to correct the global indicator for this service to reflect a global period of 90 days (090).

Comment: Specialty organizations representing radiation oncology and radiology as well as individual physicians and providers, and the AMA, all expressed concern about this proposal to change the global period for CPT code 77427. The commenters stated that this code is universally recognized as a recurring service that can be provided multiple times during a course of radiation. This code is usually submitted once for each group of five treatments (or fractions) and represents substantial services furnished during that group (typically 1 week) of five treatments. Commenters believe this proposed change would—

- Contradict the current CPT definitions;
- Not reflect the process of care for radiation;
- Countervene the essence of the RUC valuations; and
- Negate the guidelines that we previously issued.

Because a change in the global period could have a significant impact on the process of care for radiation oncology, commenters urged us to withdraw this proposal or to delay implementation until there is further discussion with the specialty organizations and the RUC, and clarification of billing matters related to this proposed change are provided.

Response: Based on the concerns raised by the commenters, we are not changing the global period for this service as proposed.

#### Result of Evaluation of Comments

We are retaining the global period of "xxx" for CPT code 77427.

#### 2. Requests for Adding Services to the List of Medicare Telehealth Services

As discussed in the proposed rule (69 FR 47510), section 1834(m) of the Act defines telehealth services as professional consultations, office and other outpatient visits, and office psychiatry services defined as of July 1, 2000 by CPT codes 99241 through 99275, 99201 through 99215, 90804 through 90809, and 90862. In addition, the statute requires us to establish a process for adding services to, or deleting services from, the list of telehealth services on an annual basis. In the CY 2003 final rule, we established a process for adding to or

deleting services from the list of Medicare telehealth services (67 FR 79988). This process provides the public an opportunity on an ongoing basis to submit requests for adding a service. We assign any request to add a service to the list of Medicare telehealth services to one of the following categories:

- Category 1: Services that are similar to office and other outpatient visits, consultation, and office psychiatry services. In reviewing these requests, we look for similarities between the proposed and existing telehealth services in terms of the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.
- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face "hands on" delivery of the same service.

Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to a face-to-face delivery of the requested service.

Requests for adding services to the list of Medicare telehealth services must be submitted and received no later than December 31st of each calendar year to be considered for the next proposed rule. For example, requests submitted in CY 2003 are considered for the CY 2005 proposed rule. For more information on submitting a request for addition to the list of Medicare telehealth services, visit our web site at [www.cms.hhs.gov/physicians/telehealth](http://www.cms.hhs.gov/physicians/telehealth).

We received the following public requests for addition in CY 2003:

- Inpatient hospital care (as represented by CPT codes 99221 through 99223 and 99231 through 99233).
- Emergency department visits (as defined by CPT codes 99281 through 99285).
- Hospital observation services (as represented by CPT codes 99217, 99218 through 99220).
- Inpatient psychotherapy (as defined by CPT codes 90816 through 90822).

- Monthly management of patients with end-stage renal disease (ESRD), (as represented by HCPCS codes G0308 through G0319).
- Speech and audiologist services (as defined by CPT code range 92541 through 92596).
- Case management (as identified by CPT codes 99361 and 99362)
- Care plan oversight services (as represented by CPT codes 99374 and 99375).

After reviewing the public requests for addition, we proposed to add ESRD-related services as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318 to the list of Medicare telehealth services. However, we specified that the required clinical examination of the vascular access site must be furnished face-to-face “hands on” (without the use of an interactive telecommunications system) by a physician, certified nurse specialist (CNS), nurse practitioner (NP), or physician’s assistant (PA). An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit Monthly Capitation Payment (MCP) code and the 4 or more visit MCP code.



Moreover, we proposed to add the term "ESRD-related visits" to the definition of Medicare telehealth services at \$410.78 and \$414.65 as appropriate.

We did not propose to add any additional services to the list of Medicare telehealth services for CY 2005.

For further information on the addition to the list of telehealth services, see the **Federal Register** dated August 5, 2004 (69 FR 47510).

Inpatient Hospital Care, Hospital Observation Services, Inpatient Psychotherapy, and Emergency Department Services

Comment: We received conflicting comments on our proposal not to add inpatient hospital care, hospital observation services, inpatient psychotherapy, and emergency department services to the list of approved telehealth services. For example, one professional society supported our proposal not to add inpatient hospital care, hospital observation services, inpatient psychotherapy, and emergency department services to the list. That commenter believes conclusive efficacy data is necessary before adding the aforementioned services. Likewise, an association representing emergency department management agreed that emergency department visits should not be added to the list of Medicare telehealth services. That commenter believes that hospitals in rural areas have

physicians with sufficient experience to handle the complexities of emergent care.

An association representing family physicians agreed with our proposal not to add inpatient hospital care and hospital observation services. However, they disagreed with our proposal not to add emergency department visits to the list of Medicare telehealth services. The commenter stated that emergency department visits should not be assigned to category 2 based on the acuity of the patient. The commenter believes that the range of potential acuity is the same in the emergency room as it is in the office setting and noted that office and other outpatient visits are currently on the list of Medicare telehealth services. A professional society encouraged us to reexamine the request to add inpatient hospital care, observation services, and inpatient psychotherapy to the list of Medicare telehealth services in the future.

Response: We agree that the acuity for some patients may be the same in the emergency department as in a physician's office. However, we also believe that more acutely ill patients are more likely to be seen in the emergency department. Although telehealth is an acceptable alternative to face-to-face "hands on" patient care in certain settings, the potential for misdiagnosis and/or

mismanagement, with more serious consequences, exists in high acuity environments like the emergency department when telehealth is used as a replacement for an onsite physician or practitioner. The practice of emergency medicine often requires frequent patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. We do not have evidence suggesting the use of telehealth could be a reasonable surrogate service for this type of care. In the absence of sufficient evidence that illustrates that the use of a telecommunications system produces similar diagnoses or therapeutic interventions as would the face-to-face delivery of inpatient hospital care, emergency department visits, hospital observation services, and inpatient psychotherapy, we do not plan to add these services to the list of approved telehealth services. As discussed in the proposed rule, we believe that the current list of Medicare telehealth services is appropriate for hospital inpatients, emergency room cases, and patients designated as observation status. If guidance or advice is needed in these settings, a consultation may be requested from an appropriate source.

Comment: A telehealth association and a telehealth network requested that we clarify what consultation codes

could be used for hospital inpatients, emergency room cases, and patients designated as observation status.

Response: The appropriate consultation code depends on the admission status of the beneficiary. When the beneficiary is an inpatient of a hospital, the physician or practitioner at the distant site bills an initial or follow-up inpatient consultation as described by CPT codes 99251 through 99263. For the hospital observation setting and emergency department, the appropriate office or other outpatient consultation code is CPT codes 99241 through 99245.

Comment: Some commenters believe that hospital inpatient care, inpatient psychotherapy, observation services, and emergency department visits should all be assigned to category 1 because they are clinically the same as a consultation. Moreover, the commenters expressed their opinion that a telecommunications system would not substitute for an in-person practitioner for the requested hospital services.

Response: We agree that the key components of a consultation are similar to inpatient hospital care, observation services, and emergency department visits. However, a consultation service is distinguished from the requested hospital services because it is provided by a

physician or practitioner whose opinion or advice regarding evaluation and management of a specific problem is requested by another physician or appropriate source. The ongoing management of the patient's condition remains the responsibility of the practitioner who requested the consultation. As discussed in our response to another comment, a consultation may be provided as a Medicare telehealth service for hospital inpatients, emergency room cases, and patients designated in observation status.

In furnishing a consultation as a telehealth service, the physician at the distant site provides additional expertise, to ensure optimal patient outcomes. For consultation services, a practitioner is available to manage the patient at the originating site. However, adding the requested hospital services would permit a telecommunications system to be used as a substitute for an onsite practitioner because the physician or practitioner at the distant site assumes responsibility for the ongoing management of the patient's condition.

End Stage Renal Disease- Monthly Management of Patients on Dialysis

Comment: Many commenters, including a telehealth association, a nephrology nurses association, a renal physicians association, a health system, a community

hospital, a telemedicine law group, and others applauded our proposal to add the ESRD-related services with 2 or 3 visits per month and ESRD-related services with 4 or more visits per month to the list of Medicare telehealth services. For example, two commenters believe that adding these services will help provide dialysis patients living in rural areas sufficient access to nephrology specialists and will save both patients and practitioners a significant amount of travel time. Additionally, many commenters expressed strong support for not permitting the visit that includes a clinical examination of the vascular access site to be added to the list of Medicare telehealth services and agreed that this exam should be furnished in person.

Response: We agree with the comments.

Comment: With regard to furnishing ESRD-related visits under the MCP, a nephrology association suggested that we permit the use of e-mail and telephone conferencing for one year. The commenter believes this grace period would enable physicians and originating sites to acquire the necessary technology and execute their implementation plans. Additionally, an association of kidney patients questioned whether telehealth services would be available to ESRD patients in non-rural areas.

Response: Services added to the list of Medicare telehealth services are subject to the requirements and conditions of payment in the law and regulations. Under the Medicare telehealth provision, the use of an interactive audio and video telecommunications system that permits real-time interaction between the patient, physician or practitioner at the distant site, and telepresenter (if necessary) is a substitution for the face-to-face requirements under Medicare. Electronic mail systems and telephone calls are specifically excluded from the definition of an interactive telecommunications system. Moreover, we do not have the legislative authority to expand the geographic areas where telehealth services may be furnished. Telehealth services may only be furnished in non-Metropolitan Statistical Area counties or rural health professional shortage areas.

Comment: An association representing kidney patients questioned whether we plan to evaluate the provision of telehealth services to ESRD patients to determine best practices.

Response: We believe that most physicians and practitioners will use telehealth services for providing additional visits required under the MCP as appropriate to manage their patients on dialysis. However, we would

welcome specific data on best practice methods for furnishing ESRD-related services as telehealth services.

Comment: Some commenters indicated a belief that the ESRD-related services were assigned to category 2 for review. For example, one telehealth group believed that a discrepancy exists between the rationale we used to add ESRD-related services to the list of telehealth services and our decision not to add inpatient hospital care, observation services, inpatient psychotherapy, and emergency department visits. The commenter stated that ESRD-related services were added in the absence of randomized clinical trials or comparison studies and mentioned that the same level of evidence was submitted for ESRD-related services as for other requests (for example, inpatient hospital services). The commenter requested clarification on the method used to assign services to category 1 or category 2.

Response: As discussed in the proposed rule, the MCP represents a range of services provided during the month, including various physician and practitioner services, such as the establishment of a dialyzing cycle, outpatient evaluation and management of the dialysis visit(s), telephone calls, and patient management as well as clinically appropriate physician or practitioner visit(s)



during the month. At least one of the visits must include a clinical examination of the vascular access site furnished face-to-face, "hands-on" by a physician, CNS, NP, or PA.

We considered the outpatient evaluation and management of the dialysis visits to be similar to an office visit and other outpatient visits currently on the list of Medicare telehealth services. However, we believe that the clinical examination of the vascular access site is not similar to the existing telehealth services, and, therefore, it meets the criteria for a category 2 request. We did not propose to add a comprehensive visit including a clinical examination of the vascular access site, to the list of Medicare telehealth services because the requestor did not provide comparative analyses illustrating that the use of a telecommunications system is an adequate substitute for a face-to-face clinical examination of the vascular access site. However, as discussed in the proposed rule, we do believe that the subsequent visits to monitor the patient's condition met our criteria for approving a category 1 request. For category 1 services, we look for similarities between the proposed and existing telehealth services in terms of the roles of, and interactions among, the

beneficiary, the physician or practitioner at the distant site, and, if necessary, the telepresenter.

Therefore, we proposed that the MCP physician, that is, the physician or practitioner responsible for the evaluation and management of the patient's ESRD, and other practitioners within the same group practice or employed by the same employer or entity, may furnish additional ESRD-related visits as telehealth services using an interactive audio and video telecommunications system. However, for purposes of billing the MCP, at least one visit must include a clinical examination of the vascular access site, and must be furnished face-to-face, "hands on" by a physician, CNS, NP, or PA each month.

Comment: One commenter requested that we allow a physician or surgeon located at the originating site (who is not the MCP physician) to furnish ESRD-related visits involving the clinical examination of the vascular access site. The commenter stated that having a physician or surgeon skilled in vascular access management available to work in coordination with the MCP physician is necessary for geographically remote areas such as Alaska and in severe weather conditions. The commenter believes that this type of arrangement is well suited for telehealth.

Response: The MCP physician may use another physician to provide some of the visits during the month however, the non-MCP physician must have a relationship with the billing physician such as a partner, employees of the same group practice or an employee of the MCP physician, for example, the physician at the originating site is either a W-2 employee or 1099 independent contractor.

Case Management and Care Plan Oversight (Team Conferences and Physician Supervision)

A telehealth association and a network of clinics requested clarification on--

- The scope of authority relating to the addition of services that do not require a face-to-face encounter with the patient; and
- Whether our policy for care plan oversight is similar to the interpretation of an x-ray and other services that do not require a face-to-face encounter.

Additionally, a neurological society urged us to reconsider our decision not to add medical team conferences to the list of telehealth services. The commenter argued that adding medical team conferences as a telehealth service would improve the quality of the care plan and save time for all physicians involved in the patient's care.

Response: We add services to the list of Medicare telehealth services that traditionally require a face-to-face physician or practitioner encounter. The use of an interactive audio and video telecommunications system, permitting real time interaction between the beneficiary, physician or practitioner at the distant site, and telepresenter (if necessary) is a substitute for face-to-face requirements under Medicare. Services not requiring a face-to-face encounter with the patient that may be furnished through the use of a telecommunications system are already covered under Medicare. As discussed in chapter 15, section 30 of the Medicare Benefit Policy Manual, payment may be made for physicians' services delivered via a telecommunications system for services that do not require a face-to-face patient encounter. The interpretation of an x-ray, electrocardiogram, electroencephalogram and tissue samples are listed as examples of these services. The Medicare Benefit Policy Manual may be found on our web site at <http://www.cms.hhs.gov/manuals/> by selecting the internet-only manuals link.

Medical team conferences and monthly physician supervision do not require a face-to-face encounter with the patient, and, thus, a telecommunications system may be

used to accomplish them. However, Medicare payment for CPT codes 99361, 99362, and 99374 are bundled; no separate payment is made under the Medicare program for these services, and CPT code 99375 (physician supervision; 30 minutes or more) is invalid for Medicare payment purposes. We pay for monthly physician supervision as described by HCPCS codes G0181 and G0182.

Process for Adding Services to the List of Medicare Telehealth Services

Comment: We received conflicting comments on our process for adding services to the list of Medicare telehealth services. For example, a surgeons' association supported the evidence-based approach for adding category 2 services. However, a school of medicine and a telemedicine and electronic health group believe that we should consider changing our categorical system for adding a service to the list of Medicare telehealth services, specifically, in relation to the requested hospital services for hospital inpatients, emergency room cases, and patients designated as observation status.

One of the commenters believes that the decision to use a telehealth system should be up to the physician or practitioner at the distant site. The commenter argues that, if the physician or practitioner at the distant site

is not comfortable in making a clinical judgment, the patient may be asked to travel to the physician's office for further examination.

Moreover, the commenter contends that the nature of telehealth services is not well suited for clinical trials and that the evidence that we require under category 2 may never be obtained because of the lack of reimbursement. As an alternative, the commenters recommended a method of review that considers—

- Clinical utilization of the requested telehealth service;
- The opinions of physicians and practitioners furnishing the telehealth service; and
- The opportunity for the physicians and practitioners to prove the service is being delivered appropriately via telecommunications system.

Response: We believe that the current method for reviewing requests for addition already considers the criteria mentioned by the commenter. The process for adding services to the list of Medicare telehealth services provides the public an ongoing opportunity to propose services that they believe are appropriate for Medicare payment. Requestors may submit data showing that patients who receive the requested service via telecommunications

system are satisfied with the service delivered and that the use of a telecommunications system does not change the diagnosis or therapeutic interventions for the requested service. Additionally, we believe that having different categories of review allows us to add requested services that are most like the current telehealth services (for example, office visits, consultation, and office psychiatry) without subjecting these requests to a comparative analysis.

Since establishing the process to add services to the list of Medicare telehealth services, we have added the psychiatric diagnostic interview examination and have proposed specific ESRD-related services for the CY 2005 rule.

Comment: One commenter recommended that we replace the term face-to-face with "in-person". The commenter believes that the term "in-person" is a better description of an encounter where the practitioner is in the same physical location as the beneficiary.

Response: The commenter's suggestion to use the term "in-person" to describe an encounter where the physician or practitioner and the beneficiary are physically in the same room has been noted. We will consider the commenter's

suggestion as we discuss Medicare telehealth payment policy in the future.

Report to Congress

Comment: An audiology society and a language and hearing association strongly believe that most audiology services and speech therapy can be furnished remotely as telehealth services. To that end, many commenting groups and associations requested that we complete the report to Congress (as required by section 223(d) of the BIPA) and urged us to recommend adding speech language pathologists and audiologists as medical professionals that may provide and receive payment for Medicare telehealth services.

Moreover, in light of the proposed addition of ESRD-related services to the list of telehealth services, many of these same commenters along with a nephrology society requested that we recommend adding dialysis facilities to the list of originating sites. One commenter requested that we add the patient's home to the definition of an originating site.

Response: The report to Congress on additional sites and settings, practitioners, and geographic areas that may be appropriate for Medicare telehealth payment is under development. We are considering the suggestions raised by



the commenters as we formulate our recommendations to the Congress.

#### Result of Evaluation of Comments

We are adding ESRD-related services as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318 to the list of Medicare telehealth services. However, we will require that the complete assessment must include a face-to-face clinical examination of the vascular access site furnished "hands on" (without the use of an interactive telecommunications system) by a physician, clinical nurse specialist, nurse practitioner, or physician's assistant. An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit MCP code and the 4 or more visit MCP code. Additionally, we are adding the term "ESRD-related visits" to the definition of Medicare telehealth services at \$410.78 and \$414.65, as appropriate.

#### 3. National Pricing of G0238 and G0239 Respiratory Therapy Service Codes.

In the 2001 final rule, we created the following three G codes for respiratory therapy services:

- G0237 Therapeutic procedures to increase strength or endurance of respiratory muscles, face-to-face, one-on-one, each 15 minutes (includes monitoring).

- G0238 Therapeutic procedures to improve respiratory function, other than ones described by G0237, one-on-one, face-to-face, per 15 minutes (includes monitoring).
- G0239 Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).

We assigned RVUs to one of the codes (G0237), and indicated that the other two codes (G0238 and G0239) would be carrier-priced. Since the services represented by these codes are frequently being performed in comprehensive outpatient rehabilitation facilities (CORFs), paid under the physician fee schedule through fiscal intermediaries, there has been some uncertainty surrounding the payment for the carrier-priced services. We believe assigning RVUs to G0238 and G0239 will provide needed clarity. Since these services are typically performed by respiratory therapists, we did not assign physician work to G0237, and we did not propose work RVUs for either G0238 or G0239.

Therefore, we proposed to value nationally the practice expense for these services using the nonphysician work pool. We proposed to crosswalk practice expense RVUS for G0238 to those for G0237 based on our belief that the

practice expense for the activities involved is substantially the same for both services.

For G0239, we believe a typical group session to be 30 minutes in length and to consist of 3 patients.

Therefore, for the practice expense RVUs for G0239, we proposed using the practice expense RVUs of G0237 reduced by one-third to account for the fact that the service is being provided to more than one patient simultaneously and each patient in a group can be billed for the services of G0329.

We also proposed a malpractice RVU of 0.02, the malpractice RVU assigned to G0237, for these two G-codes.

Comment: Commenters supported the national pricing for these 2 G-codes, G0238 and G0239. However, these organizations disagree with our RVU assignment. Specifically, most commenters disagreed with the lack of physician work RVUs and also believed that the malpractice RVU is inadequate to reflect the costs associated with the delivery of the services. These organizations contend that pulmonary rehabilitation services "include a physician-directed individualized plan of care using multidisciplinary qualified health professionals to enhance the effective management of pulmonary diseases and resultant functional deficits." They believe that

beneficiaries may receive pulmonary rehabilitation services at physician offices, outpatient departments of acute care hospitals, CORFs and rehabilitation clinics. The commenters noted that physicians and qualified nurse practitioners (NPs) and PAs order, supervise, and approve the plans of care for patients receiving respiratory therapy services, irrespective of the delivery setting.

Because respiratory rehabilitation is often furnished in a physician office, these organizations believe the malpractice RVU assigned is inadequate to account for the physician involvement and requested that a more appropriate risk factor be used.

Response: Because we believe that respiratory therapists (RTs) typically deliver these services, it would be inappropriate to assign a physician work RVU to these services. The malpractice RVU of 0.02 is similar to RVUs of therapeutic procedures delivered by physical and occupational therapists for similar services, including procedures performed one-on-one and in groups. We believe that the 0.02 malpractice RVU fairly represents the risk value inherent in the provision of these procedures. However, because the commenters expressed concerns about work and malpractice RVUs, we are assigning these RVUs on an interim basis, and we are requesting that the RUC or

HCPAC consider this series of three G-codes at an upcoming meeting.

Because RTs cannot directly bill Medicare for their services, these G-codes can only be billed as incident to services in physician offices and outpatient hospital departments or as CORF services. When performed in the CORF setting, these services must be delivered by qualified personnel, that is, RTs and respiratory therapy technicians, as defined at §485.70. The CORF benefit requires the physician to establish the respiratory therapy plan of care and mandates a 60-day re-certification for therapy plans of care, including physical therapy (PT), occupational therapy (OT), speech language pathology (SLP), and respiratory therapy. As we stated in the December 31, 2002 final rule, we believe that specially trained professionals (that is, registered nurses, physical therapists and occupational therapists) can also provide these services.

These respiratory therapy G-codes were designed to provide more specific information about the medically necessary services being provided to improve respiratory function and to substitute for the physical medicine series of CPT codes 97000 through 97799, except when services are

furnished and meet all the requirements for physical and occupational therapy services.

Comment: While three commenters voiced concerns about the significant undervaluing of these codes, one commenter noted that the practice expense RVUs fail to recognize the intensity of services and the cost of monitoring and other equipment associated with providing these services.

Response: We agree that the practice expenses, particularly the equipment, for G0237 and G0238 are not equivalent and that there are more resources required to provide the medically necessary services of G0238. The necessary monitoring equipment referenced by commenters were considered at the time G0327 was originally valued. The appropriate direct inputs will be added to the practice expense database. However, we identified the omission of therapeutic exercise equipment for G0238 and G0239 and we will also add this to the practice expense database.

#### Result of Evaluation of Comments

We are assigning practice expense and malpractice RVUs to G0238 and G0239 and will add the additional items to the practice expense database. These codes are being valued in the nonphysician work pool as proposed. We will also ask the RUC or HCPAC to consider these codes.

4. Bone Marrow Aspiration and Biopsy through the Same Incision on the Same Date of Service.

In the August 5, 2004 rule, we proposed a new add-on G-code, G0364 (proposed as G0XX1): Bone marrow aspiration performed with bone marrow biopsy through same incision on same date of service. The physician would use the CPT code for bone marrow biopsy (38221) and G0364 for the second procedure (bone marrow aspiration).

We believe that there is minimal incremental work associated with performing the second procedure through the same incision during a single encounter. We estimated that the time associated with this G-code is approximately 5 minutes based on a comparison to CPT code 38220 bone marrow aspiration which has 34 minutes of intraservice time and a work RVU of 1.08 work when performed on its own. We proposed 0.16 work RVUs for this new add-on G-code and malpractice RVUs of 0.04 (current malpractice RVUS assigned to CPT code 38220). For practice expense, we proposed the following practice expense inputs:

- Clinical staff time: Registered nurse-5 minutes Lab technician-2 minutes
- Equipment: Exam table

We also proposed a ZZZ global period (code related to another service and is always in the global period of the

other service) for this add-on code since this code is related to another service and is included in the global period of the other service.

In the August 5, 2004 proposed rule, we also stated that if the two procedures, aspiration and biopsy, are performed at different sites (for example, contralateral iliac crests, sternum/iliac crest or two separate incisions on the same iliac crest), the -59 modifier, which denotes a distinct procedural service, is appropriate to use and Medicare's multiple procedure rule will apply. In this instance, the CPT codes for aspiration and biopsy are each being used.

Comment: Many commenters supported creation of this G code; however, all commenters stated that the time for this procedure (5 minutes) was substantially underestimated. Commenters recommended increasing the added incremental time associated with the aspiration to 15 minutes. One commenter noted that this time is needed for the actual aspiration procedure, approving the quality of the aspiration, collecting flow cytometry and chromosome studies, preparing additional slides, ordering appropriate lab tests on the slides, and performing the added recordkeeping and documentation. Another commenter provided a detailed description of the activities involved



in this procedure. Commenters also recommended that the practice expense input for the nurse assisting with the procedure should be increased to 15 minutes.

Response: We continue to believe that the proposed 5 minutes of physician time, 5 minutes of registered nurse time, and 2 minutes of lab technician time reflect the additional effort involved when a bone marrow aspiration is performed in conjunction with a bone marrow biopsy through the same incision during a single encounter. It is our understanding that some of the activities attributed to the additional 15 minutes of physician work generally are performed by ancillary staff, for example, preparing slides. While we appreciate the information provided, we believe that the majority of the effort and specific tasks discussed are accounted for in the CPT code for bone marrow biopsy (38221) which is the primary code being billed.

Comment: Two physician specialty societies, representing radiologists and interventional radiologists, questioned the need for the proposed code, because the multiple surgical discount rule that reduces payment for a subsequent lower valued service applies, thereby taking into account any savings in physician work. If we choose to proceed with the proposal, the commenter recommended the RVUs be consistent with those determined using the current

values for CPT codes 38220 and 38221 and the multiple surgical discount rule.

Response: One of the primary reasons for our proposal for this G-code was that we believe that, even with the application of the multiple procedure reduction, we would be overpaying for these services when they are performed on the same day, at the same encounter and using the same incision.

#### Result Of Evaluation of Comments

We are finalizing our proposal and using new G-code G0364, Bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service. Payment is based on the work and malpractice RVUs and practice expense inputs proposed and the global period for this service is "ZZZ".

#### 5. Q Code for the Set-Up of Portable X-Ray Equipment

The Q-code for the set-up of portable x-ray equipment, Q0092, is currently paid under the physician fee schedule and is assigned an RVU of 0.33. In 2004, this produces a national payment of \$12.32. This set-up code encompasses only a portion of the resources required to provide a portable x-ray service to patients. In 2003, portable x-ray suppliers received total Medicare payments of approximately \$208 million. More than half of these payments (approximately \$116 million) were for portable x-ray

transportation (codes R0070 and R0075). The portable x-ray set-up code (Q0092) generated approximately \$19 million in payments. The remainder of the Medicare payments for portable x-ray services (approximately \$73 million) were for the actual x-ray services themselves.

As discussed in the August 5, 2004 proposed rule, the Conference Report accompanying the Consolidated Appropriations Bill, H.R. 2673, (Pub. L. 108-199, enacted January 23, 2004) urged the Secretary to review payment for this code, and the portable x-ray industry has also requested that we reexamine payments for this code.

Q0092 is currently priced in the nonphysician work pool. At the time we modeled this change for the proposed rule, removing this code from the nonphysician work pool had an overall negative impact on payments to portable x-ray suppliers (as a result of decreases to radiology codes that remain in the nonphysician work pool) and a negative impact on many of the codes remaining in the nonphysician work pool. An alternative to national pricing of portable x-ray set-up would be to require Medicare carriers to develop local pricing as they do currently for portable x-ray transportation. We requested comments on whether we should pursue national pricing for portable x-ray set-up outside of the nonphysician work pool or local

carrier pricing for 2005, or whether we should continue to price the service in the nonphysician work pool.

Comment: Most commenters recommended removing portable x-ray from the nonphysician work pool, using the "existing data" from the American College of Radiology (ACR) supplemental practice expense survey as the practice expense per hour proxy. However, the National Association of Portable X-Ray Suppliers (NAPXP) requested additional time to review information they received from us just 3 days before the close of the comment period. This association requested that they be allowed to submit supplemental comments.

Response: ACR requested that we delay incorporating their survey data for 1 year. Using the data for one code, as proposed by commenters, would be inconsistent with that request. We believe it is inappropriate to use the new survey data for this code but no other code. Even if we removed the set-up code from the nonphysician work pool and calculated its practice expense RVU using the ACR data, the increase in payment for the portable x-ray set-up code would be largely offset by lower payment for x-ray services. Payments for other services in the nonphysician work pool would also decline affecting other specialties, such as radiology, radiation oncology, cardiology, allergy,

audiology and others. Further, the portable x-ray set-up code is yet to be refined, and we believe that the 45 minutes of staff time that is used to determine its value is likely overstated. We believe it is preferable to address refinement of the code and pricing the service outside of the nonphysician work pool together. Therefore, in 2005, we are continuing to price this service within the nonphysician work pool.

The NAPXP requested more time to review the data we supplied them. NAPXP's comment implying that we withheld "data" from them is simply wrong. In an effort to explain the theoretical reasons for our statements that removing this service from the nonphysician work pool could lower overall payments to portable x-ray suppliers, we prepared an illustration for another association as a follow-up request after a meeting, where we were asked to explain the our proposed rule analysis. The explanation contained no new data. Moreover, we provided the explanatory information to NAPXP as soon as they requested it. Since the information NAPXP complains about was illustrative only, we do not believe NAPXP has been prejudiced in any way. Moreover, we are willing to explain the information to NAPXP and to consider any comments they may have as we consider changes to the practice expense methodology for 2006.

#### 6. Venous Mapping for Hemodialysis

In the August 5, 2004 rule, we proposed a new G-code (G0XX3: Venous mapping for hemodialysis access placement (Service to be performed by operating surgeon for preoperative venous mapping prior to creation of a hemodialysis access conduit using an autogenous graft). Autogenous grafts have longer patency rates, a lower incidence of infection and greater durability than prosthetic grafts. Use of autogenous grafts can also result in a decrease in hospitalizations and morbidity related to vascular access complications. We stated that creation of this G-code will enable us to distinguish between CPT code 93971 (Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study) and G0XX3 in order to allow us to track use of venous mapping for quality improvement purposes.

We also proposed that this G-code be billed only by the operating surgeon in conjunction with CPT codes 36819, 36821, 36825, and 36832 and that we would not permit payment for CPT code 93971 when this G-code is billed, unless code CPT 93971 was being performed for a separately identifiable clinical indication in a different anatomic region.

We proposed to crosswalk the RVUs for the new G-code from those of CPT code 93971 and also assigned this new

G-code a global period of "XXX," which means that the global concept does not apply.

Comment: Commenters representing specialty societies and individual providers were generally supportive of the proposal for this new code, but expressed the following three primary concerns:

- Commenters did not agree with restricting this code to the operating surgeon, stating that such a restriction could limit access and serve as a barrier in providing this service. They also stated that this proposed restriction is not reflective of current practice, since nonsurgeons often perform this procedure.
- Commenters did not agree with the proposed descriptor. They indicated that the proposed descriptor did not reflect the procedure as it is now performed and suggested (a) alternate wording, such as "vascular mapping," "autogenous AV fistula," and "prosthetic graft," "vessel mapping;" (b) that two G-codes should be created to distinguish between a complete bilateral and unilateral or limited studies. Other commenters noted that the proposal did not distinguish between mapping by venography or ultrasound (duplex), and some commenters suggested creating an additional G-code to distinguish between these procedures.

- Commenters stated that the comparison to CPT code 93971 in the proposed rule undervalues the service. While there are differences, the closer analogue in terms of time and resources required is CPT code 93990, Duplex scans of hemodialysis access.

Response: We proposed the G-code to create the opportunity for us to analyze the relationship between venous mapping utilization and fistula formation.

Based on the comments we received, we are revising the code descriptor to enable clinicians, other than the operating surgeon, who provide care to ESRD patients the opportunity to bill for this service.

We believe that vessel mapping requires the assessment of the arterial and venous vessels in order to provide the information necessary for the creation of an autogenous conduit. Therefore, we are also revising payment for this code and will crosswalk it to CPT code 93990 for work, malpractice, and practice expense RVUs because these RVUs more appropriately reflect the work and resources of this new G-code. The G-code and descriptor for this service will be G0365, Vessel mapping of vessels for hemodialysis access (Services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous



outflow). This code can only be used in patients who have not had a prior hemodialysis access prosthetic graft or autogenous fistula and is limited to two times per year.

We will not permit separate payment for CPT code 93971 when this G-code is billed, unless CPT code 93971 is being performed for a separately identifiable indication in a different anatomic region. We also note that other imaging studies may not be billed for the same site on the same date of service unless an appropriate "KO" modifier indicating the reason or need for the second imaging study is provided on the claim form.

We will follow the utilization closely this year to better understand whether this code is used as intended.

### **III. Provisions Related to the Medicare Modernization Act of 2003**

#### **A. Section 611—Preventive Physical Examination**

Section 611 of the MMA provides for coverage under Part B of an initial preventive physical examination (IPPE) for new beneficiaries, effective for services furnished on or after January 1, 2005, subject to certain eligibility and other limitations.

In the August 5, 2004 proposed rule, we described a new §410.16 (Initial preventive physical examination: conditions for and limitations on coverage) that would

provide for coverage of the various IPPE services specified in the statute. As provided in the statute, this new coverage allows payment for one IPPE within the first 6 months after the effective date of the beneficiary's first Part B coverage period, but only if that coverage period begins on or after January 1, 2005. To implement the statutory provisions, we proposed definitions of the following terms:

- Eligible beneficiary;
- An initial preventive physical examination;
- Medical history;
- Physician;
- Qualified NPP;
- Social History, and
- Review of the individual's functional ability and level of safety.

In keeping with the language of section 611 of the MMA, we defined the term "eligible beneficiary" to mean individuals who receive their IPPEs within 6 months after the date of their first Medicare Part B coverage period, but only if their first Part B coverage period begins on or after January 1, 2005. This section also defines the term "Initial Preventive Physical Examination" to mean services

provided by a physician or a qualified NPP consisting of:

(1) A physical examination (including measurement of height, weight, blood pressure, and an electrocardiogram, but excluding clinical laboratory tests) with the goal of health promotion and disease detection; and (2) Education, counseling, and referral for screening and other covered preventive benefits separately authorized under Medicare Part B.

Specifically, section 611(b) of the MMA provides that the education, counseling, and referral of the individual by the physician or other qualified NPP are for the following statutory screening and other preventive services authorized under Medicare Part B:

- Pneumococcal, influenza, and hepatitis B vaccine and their administration;
- Screening mammography;
- Screening pap smear and screening pelvic exam services;
- Prostate cancer screening services;
- Colorectal cancer screening tests;
- Diabetes outpatient self-management training services;
- Bone mass measurements;

- Screening for glaucoma;
- Medical nutrition therapy services for individuals with diabetes or renal disease;
- Cardiovascular screening blood tests; and
- Diabetes screening tests.

Based on the language of the statute, our review of the medical literature, current clinical practice guidelines, and United States Preventive Services Task Force (USPSTF) recommendations, we interpreted the term "initial preventive physical examination" for purposes of this benefit to include all of the following service elements:

1. Review of the individual's comprehensive medical and social history, as those terms are defined in proposed §410.16(a);
2. Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument, which the physician or other qualified NPP may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process;

3. Review of the individual's functional ability and level of safety, as described in proposed §410.16(a), (that is, at a minimum, a review of the following areas: hearing impairment, activities of daily living, falls risk, and home safety), based on the use of an appropriate screening instrument, which the physician or other qualified NPP may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is further defined through the NCD process;
4. An examination to include measurement of the individual's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate by the physician or qualified NPP, based on the individual's comprehensive medical and social history and current clinical standards;
5. Performance and interpretation of an electrocardiogram;
6. Education, counseling, and referral, as appropriate, based on the results of the first five elements of the initial preventive physical examination; and
7. Education, counseling, and referral, including a written plan provided to the individual for

obtaining the appropriate screening and other preventive services, which are separately covered under Medicare Part B benefits; that is, pneumococcal, influenza, and hepatitis B vaccines and their administration, screening mammography, screening pap smear and screening pelvic examinations, prostate cancer screening tests, colorectal cancer screening tests, diabetes outpatient self-management training services, bone mass measurements, screening for glaucoma, medical nutrition therapy services, cardiovascular (CV) screening blood tests, and diabetes screening tests.

The proposed “medical history” definition includes the following elements:

- Past medical history and surgical history, including experience with illnesses, hospital stays, operations, allergies, injuries, and treatment.
- Current medications and supplements, including calcium and vitamins.
- Family history, including a review of medical events in the patient’s family, including diseases that may be hereditary or place the individual at risk.

The proposed "physician" definition means for purposes of this provision a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

The proposed "qualified nonphysician practitioner" for purposes of this provision means a PA, NP, or clinical nurse specialist (CNS) (as authorized under sections 1861(s)(2)(K)(i) and 1861(s)(2)(K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in regulations at §410.74, §410.75, and §410.76).

The proposed "social history" definition includes, at a minimum, the following elements:

- History of alcohol, tobacco, and illicit drug use.
- Work and travel history.
- Diet.
- Social activities.
- Physical activities.

The proposed definition of "Review of the individual's functional ability and level of safety" includes, at a minimum, a review of the following areas:

- Hearing impairment.
- Activities of daily living.
- Falls risk.
- Home safety.

We also proposed conforming changes to specify an exception to the list of examples of routine physical examinations excluded from coverage in § 411.15(a)(1) and §411.15(k)(11) for IPPEs that meet the eligibility limitation and the conditions for coverage that we are specifying under §410.16, Initial preventive physical examinations.

With regards to the issue of payment for the IPPE, in the August 5, 2004 proposed rule we stated that there is no current CPT code that contains the specific elements included in the IPPE and proposed to establish a new HCPCS code to be used for billing for the initial preventive examination. As required by the statute, we indicated that this code includes an electrocardiogram, but does not include the other previously mentioned preventive services that are currently separately covered and paid under the Medicare Part B screening benefits. When these other preventive services are performed, they must be identified using the existing appropriate codes.

Proposed payment for this code was based on the following:

- Work RVUs: We proposed a work value of 1.51 RVUs for G0344 (G0XX2 in proposed rule) based on our determination that this new service has equivalent



resources and work intensity to those contained in CPT E/M code 99203, new patient, office or other outpatient visit (1.34 RVUs), and CPT code 93000 electrocardiogram, complete (0.17 RVUs), which is for a routine ECG with the interpretation and report.

- **Malpractice RVUs:** For the malpractice component of G0344, we proposed malpractice RVUs of 0.13 in the nonfacility setting based on the malpractice RVUs currently assigned to CPT code 99203 (0.10) and CPT code 93000 (0.03). In the facility setting, we proposed malpractice RVUs of 0.11 based on the current malpractice RVUs assigned to CPT code 99203 (0.10) and 93010 (an EKG interpretation with a value of 0.01).
- **Practice Expense RVUs:** For the practice expense component of G0344, we proposed practice expense RVUs of 1.65 in the nonfacility setting based on the practice RVUs assigned to CPT code 99203 (1.14) and CPT code 93000 (0.51). In the facility setting, we proposed practice expense RVUs of 0.54 based on the practice expense RVUs assigned to CPT code 99203 (0.48) and 93010 (0.06).

Because some of the components for a medically necessary Evaluation and Management (E/M) visit are reflected in this new G code, we also proposed, when it is appropriate, to allow a medically necessary E/M service no greater than a level 2 to be reported at the same visit as the IPPE. That portion of the visit must be medically necessary to treat the patient's illness or injury or to improve the function of a malformed body member and should be reported with modifier -25. We also stated the physician or qualified NPP could also bill for the screening and other preventive services currently covered and paid by Medicare Part B under separate provisions of section 1861 of the Act, if provided during this IPPE.

The MMA did not make any provision for the waiver of the Medicare coinsurance and Part B deductible for the IPPE. Payment for this service would be applied to the required deductible, which is \$110 for CY 2005, if the deductible is not met, and the usual coinsurance provisions would apply.

#### Analysis of and Response to Comments

We specifically solicited public comments on the definition of the term "initial preventive physical examination," with supporting documentation. For example, we indicated that we chose not to define the term,

"appropriate screening instrument," for screening individuals for depression, functional ability, and level of safety, as specified in the rule, because we anticipated that the examining physician or qualified NPP may want to use the test of his or her choice, based on current clinical practice guidelines. We believe that any standardized screening test for depression, functional ability, and level of safety recognized by the American Academy of Family Physicians, the American College of Physicians-American Society of Internal Medicine, the American College of Preventive Medicine, the American Geriatrics Society, the American Psychiatric Association, or the USPSTF, or other recognized medical professional group, would be acceptable for purposes of meeting the "appropriate screening instrument" provision. We asked that commenters making specific recommendations on this or any related issue provide documentation from the medical literature, current clinical practice guidelines, or the USPSTF recommendations.

We received 71 public comments on the proposed rule regarding IPPE. Commenters included national and State professional associations, medical societies and medical advocacy groups, hospital associations, hospitals, managed care plans, physicians, senior advocacy groups, health care

manufacturers, and others. Although a number of commenters expressed concern that the proposed rule was too prescriptive and not sufficiently targeted to prevention, a large majority of the commenters enthusiastically supported most of the coverage provisions of the proposed rule. Many of the commenters, however, suggested clarification and revision of the rule in a number of different areas, including the proposed definitions of "initial preventive physical examination," "physician," and "qualified nonphysician practitioner." Commenters also raised questions regarding other issues, such as those relating to the need for us to educate Medicare beneficiaries and providers with respect to the new benefit, and to monitor the implementation of the new benefit. Finally, commenters offered suggestions and questions with regards to payment issues, evaluation and management services (E/M) and coinsurance and Part B deductible issues.

A summary of the comments and our responses are presented below.

Comment: A number of commenters expressed concern that in the proposed rule, we had gone beyond the coverage criteria that were specified in the statute for the new benefit. They noted that the additional criteria was too prescriptive and would only add confusion and an additional

burden for physicians in determining what medical services are necessary for each beneficiary they evaluate. Several commenters indicated that while the proposed definition for the scope of the benefit was well-intentioned, the beneficiary's physician or other provider was the best person to determine what medical services are necessary in providing a thorough physical and to be responsive to the individual's age, gender, and particular health risks. In general, they suggested that we not interfere in a physician's judgment by attempting to standardize by Federal regulations the specific medical services to be included under the new benefit.

Response: Section 611 of the MMA defines the scope of the IPPE benefit as physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure and an electrocardiogram) with the goal of health promotion and disease detection, as well as certain education, counseling, and referral services with respect to other statutory screening and preventive services also covered under the Medicare statute. We believe that the statutory parenthetical language, (including measurement of height, weight, and blood pressure and an electrocardiogram) recognizes that other services could be contained within the IPPE benefit. We are

using the authority under section 1871(a) of the Act through the rulemaking process to provide clarity as to the specific services that are to be included under the new benefit.

We believe that adding these additional services will help to ensure that a full and complete IPPE is provided to each beneficiary who chooses to take advantage of the service and that all beneficiaries who decide to do this are treated in a relatively uniform manner throughout the country. With an estimated 200,000 individuals expected to enroll in Medicare Part B each month starting in January 2005, who will be eligible to receive the IPPE benefit, we believe that it is paramount that we promulgate a minimum list of required services important to the goals of health promotion and disease detection that must be included in the new benefit, and we are specifying those service elements in the final rule.

The "Initial Preventive Physical Examination" Definition (IPPE) (§ 410.16(a))

Comment: Three commenters indicated that this new benefit presents a unique opportunity to offer Medicare beneficiaries with a visit focused on prevention at the start of their Part B enrollment. They suggested, that we shift our focus in service element 1 of the definition of

the new IPPE from a comprehensive to a more targeted priority list of modifiable risk factors, screening tests, and immunizations that are supported by the strongest evidence of effectiveness, and have been proven to improve the health of beneficiaries.

Response: We agree that the intent of the new benefit is to deliver clinical preventive services that are accepted and effective in helping to keep people healthy and reduce the burden of disease whenever possible. Therefore, we agree to revise the language in service element 1 to read as follows: "Review of the individual's medical and social history with particular attention to modifiable risk factors for disease."

Comment: Three commenters indicated that the collection of information on a beneficiary's social history such as social activities, work and travel history, is a distraction and is not needed by the physician or other qualified NPP who is performing the preventive physical examination. The commenters suggest that we eliminate the proposed definition and not require the collection of this information.

Response: We agree that information on work and travel history, and social activities may not be necessary for purposes of the new preventive physical examination and

thus we are removing those elements from the minimum requirements for the "social history" definition. However, we believe it is important to retain three elements of the Social history definition in the final rule and they will be reflected in that document as follows:

- History of alcohol, tobacco, and illicit drug use.
- Diet.
- Physical activities.

Comment: Several commenters requested that we add language to service element 1 to allow practitioners to ascertain information from individuals about additional disease or other diagnoses such as including questions regarding past diagnoses or treatment of cancer, diabetes, elevated blood sugar, height loss, previous fractures, and medical conditions that may increase a person's risk of coagulopathic disorders such as deep venous thrombosis (DVT).

Response: In applying our definition of "past medical history" we expect that physicians and qualified NPPs performing the IPPE will be able to ask about an array of medical illnesses, including prior diagnoses and treatment of conditions such as cancer, diabetes, risk factors for osteoporosis such as height loss or previous fractures, and history of coagulopathic disorders such as DVT. Therefore,



we do not see a need to expand the proposed definition as the commenters have suggested, and we have decided to leave it unchanged in the final rule.

Comment: Three commenters asked us to add language to either service element 1 or 3 to allow practitioners to screen individuals for memory impairment.

Response: Currently, the USPSTF has found insufficient evidence to recommend for or against routine screening for dementia with standardized instruments in asymptomatic persons. However, the USPSTF notes that patients with problems in performing daily activities should have their mental status evaluated and clinicians should remain alert for possible signs of declining cognitive function. We included as part of the definition for service element 3, "Review of the individual's functional ability and level of safety," a review of the patient's activities of daily living. While not exhaustive, this review will primarily aid physicians in identifying a patient's problems with regard to performing these activities and the role cognitive impairment may play in these deficits.

Comment: One commenter proposed that we not use the NCD process to revise the content of the IPPE in the future. The NCD process would be too slow or cumbersome

to allow us to keep the content of the examination consistent with current clinical practice.

Response: For service elements 2 and 3, which discuss the future use of the NCD process in determining appropriate screening instruments we will delete the following: "unless the appropriate instrument is defined through the NCD process." We will add language that states available standardized screening tests must be recognized by national medical professional organizations.

Comment: Several commenters requested that we clarify our intent as to whether the depression screening assessment in service element 2 will include consideration of the potential for depression as well as an assessment of an individual's current depression status. Another commenter asked us to clarify our intent with respect to the use of a screening instrument for persons with a current diagnosis of depression.

Response: We agree with the commenters that the regulation language on depression screening needs to be clarified. We are revising service element 2 to read "review of the individual's potential (risk factors) for depression, including current or past experience with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a

current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.”

Comment: Three commenters expressed the view that the proposed screening tests for falls risk and home safety in service element 3 were not supported by direct scientific evidence, and should be dropped from the IPPE benefit in the final rule.

Response: Falls are among the most common and serious problems facing elderly persons. They are associated with considerable morbidity such as hip fractures and overall reduced level of functioning. The USPSTF also notes that falls are the second leading cause of unintentional injury deaths in the United States. The death rate due to falls increases as a person ages. According to the National Center for Injury Prevention and Control, approximately one-half to two-thirds of all falls occur in and around a person's home. Therefore, discussing with patients home safety tips may reduce some home hazards. In addition, the USPSTF recommends counseling patients on specific measures to reduce the risk of falling, although direct evidence of effectiveness has not yet been established. Therefore, we believe that questioning and counseling patients to

determine their risk of falling and home safety is warranted as part of the IPPE benefit.

Comment: Several commenters from the audiology community have asked us to clarify the meaning of the proposed requirement in service element 3, which includes (among other things) a review of any hearing impairment. In addition, several commenters have requested that we clarify whether a hearing assessment is required as part of service element 3, or whether questions (or a questionnaire) advanced to an individual about any possible hearing problems would suffice for purposes of this part of the new benefit. The commenters ask for provider flexibility in meeting this requirement.

Response: The regulatory intent of service element 3 is that we expect that the physician or qualified NPP will engage in a dialogue with patients concerning these issues by asking the individual appropriate questions or using a written questionnaire to address hearing impairment, activities of daily living, falls risk, and home safety. We do not intend for actual screening instruments such as audiometric screening tests to be used. After questioning the individual, if abnormalities are identified, additional follow-up services may be warranted and may include education, counseling, and referral (if appropriate.)

Therefore, we are revising the language of service element 3 to read "review of the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire which the physician or qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national medical professional organizations."

Medically necessary diagnostic hearing tests, including hearing and balance assessment services, performed by a qualified audiologist are covered as other diagnostic tests under section 1861(s)(3) of the Act and would be separate from the new IPPE benefit. These services may be appropriate when a physician or other qualified NPP orders a diagnostic hearing test for the purpose of obtaining information necessary for the physician's diagnostic evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. However, coverage of this testing is excluded by virtue of section 1862 (a)(7) of the Act when the diagnostic information required to determine the appropriate medical or surgical arrangement is already known to the physician, or the diagnostic services are performed only to determine the need for the

appropriate type of hearing aid. For further information about the application of the hearing test exclusion to diagnostic hearing tests and payment for these services, we suggest review of section 80.3 to 80.3.1 of the Medicare Benefit Policy Manual.

Comment: Several commenters suggested that we expand the services to be included as part of service element 4 that was proposed for coverage under the IPPE benefit to include: (1) palpitation/auscultation of carotid arteries; (2) palpitation/auscultation of abdominal aorta; and (3) the ankle-brachial index (ABI) test for peripheral arterial disease (PAD).

Response: Currently, routine screening of asymptomatic persons for carotid artery stenosis via palpation/auscultation of the carotid arteries or carotid ultrasound is not recommended by organizations such as the USPSTF, which provides guidelines on this issue. Therefore, we are not adding routine screening of asymptomatic individuals for carotid artery stenosis to service element 4 in the absence of evidence of the effectiveness of the screening. In addition, the USPSTF has determined that there is insufficient evidence to recommend for or against routine screening of asymptomatic adults for abdominal aortic aneurysm (AAA) by

palpation/auscultation or ultrasound of the abdominal aorta so we are not adding that type of screening to service element 4.

Finally, the USPSTF does not recommend routine screening for PAD in asymptomatic persons. However, they also state that clinicians, should be aware of symptoms and risk factors for PAD and evaluate patients accordingly. Therefore, routine screening for PAD with the use of the ABI will not be required as part of the initial preventive physical examination.

Comment: One commenter asked for clarification on whether the proposed regulatory language “and other factors deemed appropriate by the physician or qualified nonphysician practitioner,” as specified in service element 4, would permit inclusion of coverage of a screening for chronic obstructive pulmonary disease (COPD) through spirometric testing under the IPPE benefit.

Response: The intent of this language for the actual physical examination portion of the IPPE benefit is to leave to the discretion of the physician or other qualified NPP whether to perform commonly utilized physical examination measures such as auscultation of the heart or lungs on a particular patient, if needed. Spirometry as a screening test for COPD, however, would not be considered

to fall within the scope of the physical examination element of the IPPE benefit.

Comment: A number of commenters suggested that we add an assessment of abdominal obesity or alternatively the calculation of the body mass index (BMI) to the vital signs part of service element 4 to help in determining if an individual is at risk for a heart attack, diabetes, or other medical problems.

Response: By requiring measurement of height and weight as part of the IPPE in element 4 (an examination to include measurement of an individual's height, weight, blood pressure), we believe that the physician or other qualified NPP performing the IPPE will use that information to determine an individual's BMI if necessary.

Comment: Three commenters expressed concern about the wide latitude given to physicians and other qualified NPPs providing the IPPE benefit to select whichever screening test they prefer to use in connection with the assessment of visual acuity. The commenters believe that setting vague boundaries around what constitutes an appropriate screening instrument could open the door for inappropriate use of preventive services. To avoid this, the commenters recommend narrowly defining the appropriate screening



instrument for visual acuity in service element 4 by specifying the use of the Snellen test for that purpose.

Response: We agree that the Snellen test is a widely available test used to assess a person's visual acuity. Other similarly available tests for visual acuity also exist, however, and may convey similar results for individual physicians and other clinicians. While we expect that many physicians will utilize the Snellen test in assessing a beneficiary's visual acuity for the purpose of this new benefit, we are not mandating the use of the Snellen test or any other specific visual acuity test in order to meet the requirements of element 4 in the final rule.

Comment: One commenter noted that the proposed rule allows for coverage of the assessment in service element 4 of "other factors as deemed appropriate based on the individual's comprehensive medical and social history." The commenter expressed the view that the quoted language might result in the possibility that virtually any patient's abnormality identified during the preventive physical examination might lead to further evaluation of the patient and a cascade of diagnostic workup of questionable health benefit to the patient and potentially of great cost to the Medicare program. In view of these

concerns, the commenter recommended using more restrictive language that would allow for additional assessment of other factors only when they are supported by evidence-based clinical practice guidelines.

Response: Our purpose in proposing the specific quoted language referenced in service element 4 was to allow for the physician or other qualified NPP to perform a limited physical examination of those key elements such as height, weight, blood pressure, and a visual acuity screen that may be important in detecting disease. However, we have specified that additional physical examination measures may be performed if deemed appropriate based on the issues identified by the physician or other clinician in the review of service elements 1 to 3. While we will not specify in the final rule that these additional measures must be supported by evidence-based practice guidelines, we will state that the practitioner performing the preventive examination follow current clinical standards and those guidelines, of course, may include the evidence-based guidelines referenced by the commenter.

Comment: One commenter recommends that we include in our guidelines for the IPPE benefit information that informs the physician or other qualified NPP of: (1) the need to refer patients to occupational therapists when a

more extensive evaluation of activities of daily living, falls risk, and home safety is warranted; and, (2) when, such referrals would be medically appropriate.

Response: As part of the final rule, service element 6 of the IPPE benefit will require, education, counseling, and referral, as appropriate, based on the individual's results of the previous 5 elements of the IPPE benefit. However, appropriate referral of a patient to an occupational therapist is left to the discretion of the physician or other qualified NPP who is treating the patient for the medical problem that is identified, subject to contractors' medical necessity review. We do not believe there is a need for us to issue guidelines to our contractors on this point.

Comment: Several commenters indicated that they were concerned about use of the term "counseling" in service elements 6 and 7 of the definition of the IPPE because it lacked sufficient clarity. The commenters indicated that counseling may include varying amounts of time depending upon the intensity of the type of service provided, the ability of the individual receiving the counseling to understand the information that is being communicated, etc. The commenters suggested that either we not use the term counseling or clarify its meaning in the final rule.

Response: Use of the term counseling in connection with service element 7 is mandated by section 611 of the MMA, and thus, it is appropriate to use the term in the final rule. However, we would like to clarify this issue in connection with both service elements 6 and 7 of the new benefit. In most cases, we do not expect that the physician or other qualified NPP performing the service should need to spend more than a few minutes of brief education and counseling with a new beneficiary on appropriate topics as required by element 7. Nonetheless, it is possible that it may be necessary to spend more than a few minutes on the education and counseling required by element 6. As the commenters have indicated, the education and counseling required may involve varying amounts of time depending upon the medical problem or problems that are being considered, based on the results of elements 1 to 5, and the intensity of the service that is believed to be medically necessary at that time.

Comment: Three commenters indicated that they support proposed service element 6 on "education, referral, and counseling deemed appropriate based on the results of the review and evaluation of services," in service elements 1 to 5 because it offers an unprecedented opportunity to counsel beneficiaries about health behaviors (for example,

stopping smoking, losing weight). Nonetheless, they were concerned about possible over-utilization of services that might result from that provision, and suggest that we clarify that these education, counseling and referral efforts be concordant with evidence-based practice guidelines.

Response: We will not specify in the final rule that education, counseling, and referral efforts must be consistent with evidence-based practice guidelines. We expect that physicians and other qualified NPPs will provide appropriate education, counseling, and referral that utilizes evidence-based practice guidelines and current clinical standards. In addition, follow-up care obtained outside of the IPPE Benefit must be reasonable and necessary based on Section 1862(a)(1)(A) of the Act.

Comment: A number of commenters requested that we clarify the written plan provision of service element 7 that was included in the proposed rule. Several commenters indicated that two problems they see with this requirement are: (1) it is not clearly defined and thus could impose a significant burden on physicians and other clinicians, if it is not more carefully written; and, (2) it does not acknowledge that alternative mechanisms may already be in place that could better facilitate coordination of care for

these beneficiaries than the proposed written plan requirement. For example, one commenter suggests that some physicians and other clinicians may currently be using electronic technology to track the delivery of preventive services and should not be required to file written plans. Instead, the commenter recommends that we craft language to require physicians to demonstrate a system for ensuring that beneficiaries receive recommended screening and preventive services and allow physicians flexibility to determine the design and medium that such a system would employ.

Response: We agree that the term written plan may not offer a sufficiently clear description of our intentions in requiring the physician or other qualified NPP who also performs the IPPE to carry out the statutory mandate that eligible beneficiaries be provided with education, counseling, and referral for screening and other preventive services described in section 1861(w)(2) of the Act. Our intent in the proposed rule was that each physician or other qualified NPP provide their eligible beneficiaries at the time of the examination with appropriate education, counseling, and referral(s), including a brief written plan such as a checklist, which is provided to the beneficiary for obtaining the appropriate screening and/or other

preventive services that are covered as separate Medicare Part B benefits to which he or she is entitled. We acknowledge that physicians or qualified NPPs may have an alternative mechanism in place to ensure that beneficiaries receive recommended screening and other preventive services that does not provide for a written plan to be provided to the beneficiary. However, the intent of the written plan requirement is to promote and encourage beneficiary participation in the health care process by making them aware, briefly in writing of the screening and prevention services for which they are entitled under the Medicare Part B program.

In conclusion, we will revise service element 7 to read "education, counseling, and referral, including a brief written plan such as a checklist, be provided to the individual for obtaining appropriate screening and other preventive services, which are separately covered under Medicare Part B benefits."

The "Physician" Definition (§410.16(a))

Comment: One commenter expressed concerns regarding the definition of a physician. The commenter expressed concern that the proposed rule limits the type of practitioner who is considered qualified to perform the new preventive physical examination. The commenter states that

this restriction was not specified by the Congress in section 611 of the MMA or its accompanying conference committee report, and suggests that it should be revised to allow all practitioners, including doctors of podiatric medicine, who are defined as a physician under section 1861(r) of the Act, to be considered qualified to perform the preventive physical examination.

Response: Section 611 of the MMA amended the statute to provide that payment for the IPPE must be made under the Medicare physician fee schedule, as provided in section 1848(j)(3) of the Act, but it did not specifically define what type of physician is eligible for performing those examination. In developing the proposed rule on which physicians are considered qualified to perform the IPPE, we considered the various types of physicians that are identified in section 1861(r)(2), (r)(3), (r)(4), and (r)(5) of the Act. These include doctors of dental surgery, doctors of podiatric medicine, doctors of optometry, and chiropractors, whose scope of medical practice is generally limited by State law to a particular part (or parts) of the human anatomy.

These state licensing restrictions would likely make it difficult for those practitioners to perform all of the services required. Based on this information, we are



leaving the definition of a physician unchanged in the final rule.

The "Qualified Nonphysician Practitioner" Definition

(§410.16(a))

Comment: One commenter indicated concern that in the proposed rule certified nurse-midwives (CNMs) are not eligible to furnish the new preventive physical examinations, but physicians and certain other NPPs are eligible to provide those services to Medicare beneficiaries. The commenter indicates that CNMs are fully qualified to provide physical examination and checkups covered by the statute and that they do so on a daily basis as a basic component of the care they provide their clients. The commenter states that we may be constrained by the statute as enacted by Congress on this subject, but suggests that we should review the issue and if possible revise the proposed rule to include CNMs among those who are considered to be eligible to provide the new service in the final rule.

Response: Section 611 of the MMA amended the statute to provide that in addition to physicians certain NPPs, that is, PAs, NPs, and CNS (as authorized under section 1861(s)(2)(K)(i) and (ii) of the Act, and defined in section 1861(aa)(5) of the Act, or in regulations at

\$410.74, \$410.75, and \$410.76) will be able to furnish the new preventive physical examination to eligible beneficiaries effective January 1, 2005. Thus, Congress did not specifically authorize CNMs to perform the IPPE. Unless CNMs are able to qualify as one of these other types of NPPs designated by the statute for purposes of the new IPPE benefit, they will not be eligible to provide this service to beneficiaries for Medicare Part B coverage purposes.

#### Other Issues

Comment: One commenter requested that we clarify application of the proposed IPPE definition to managed care plans where preventive physical examinations are available to Medicare enrollees on an annual basis and they are not limited to a one-time benefit. Generally in the case of managed care plans, it is indicated that the extent of their typical annual preventive examination is determined by the enrollee's physician or other treating physician, depending upon the patient's history and clinical indications. The commenter asks that we allow managed care plans greater flexibility in providing their Medicare enrollees with the various service elements described in the proposed rule. Alternatively, the commenter requests that we clarify in the final rule that managed care plans

will need to provide their Medicare enrollees with all elements of the new benefit only if requested to do so by a particular Medicare enrollee.

Response: Section 611 of the MMA requires that IPPEs be made available to all Medicare beneficiaries who first enroll in Medicare Part B on or after January 1, 2005, and who receive that benefit within 6 months of the effective date of their initial Part B coverage period. The new statute does not allow for any exceptions to be made to the coverage of IPPEs for beneficiaries who are members of managed care plans. In fact, section 1852(a) of the Act provides that generally each managed care plan must, at a minimum, provide to its Medicare members all of those items and services (other than hospice care) for which benefits are available under Parts A and B for individuals residing in the area served by the plan. Nonetheless, if a particular Part B member of the plan chooses not to take advantage of the IPPE benefit, for example, because it would duplicate an annual preventive physical exam that has already been provided to that member, the plan would not be obligated to provide the IPPE to that member.

Comment: One commenter noted that while the screening benefits listed in paragraph (A)(1) on **Federal Register** page 47514 (vol. 69, No.150) includes "(5)

colorectal cancer screening test," the list of screening benefits described in the same section, paragraph (7) on page 47515 does not include that type of cancer screening test. The commenter requests that we include colorectal cancer screening in the list of screening services described on page 47515 of the Physician Fee Schedule Proposed Rule and any other sections of any proposed rule in which covered screening benefits are listed to ensure there is no confusion regarding what services should be discussed with patients during the IPPE.

Response: We agree with the commenter that there was an error of omission relative to colorectal cancer screening in the language in the preamble to the proposed rule in the list of screening benefits described on page 47515 of the Physicians Fee Schedule, and we have corrected that oversight in this final rule.

Comment: One commenter requests that we clarify the part of the definition of the IPPE (service element 7) that refers to the provision of education, counseling, and referral of the individual for coverage of bone mass measurements by adding the term "Dual Energy X-Ray Absorptiometry" (DEXA) to that provision. The commenter states that DEXA testing is the most accurate method available for diagnosis of osteoporosis and that early

detection of this condition paramount for preventing further bone loss and eventual fractures. The commenter is concerned that unless this is clarified in the final rule, local Medicare contractors may exclude coverage for the DEXA test as part of the IPPE benefit.

Response: Our existing regulations governing bone mass measurements are published in §410.31. While we agree that the DEXA scan is a very commonly used method for the initial diagnosis of osteoporosis, we do not believe that it would be appropriate to add any specific reference to the DEXA test in the IPPE definition because it may be perceived as endorsing one test over another. We do not believe this would be appropriate. Physicians and other qualified NPPs who perform IPPE services may provide appropriate education, counseling, and referral of their Medicare patients for the bone density tests. The counseling and referral may include choosing the appropriateness of the diagnostic modalities for the particular patient.

Comment: A number of commenters have asked us to provide information to Medicare physicians and qualified NPPs performing the IPPE for appropriate referral of their patients when treatment or a more extensive evaluation of patients is needed as part of service element 6.

Response: As part of the final rule, under service element 6, providers are required to furnish their patients with education, counseling, and referral, as appropriate, based on the individual's results of service elements 1-5 of the IPPE service. However, appropriate referral of a patient, of course, is left to the discretion of the physician or other qualified NPP who is treating the patient for the medical problem that is identified.

Comment: One commenter asked us how we plan to monitor the effectiveness of the IPPE benefit over the next several years.

Response: As indicated in the final rule, we have established unique billing codes for the IPPE service which physicians and other qualified NPPs must use in billing Medicare Part B for the new service. Establishing those codes will allow us to monitor over time the extent to which the eligible Medicare Part B population is utilizing the new service, which will be of interest to our program administrators, members of the Congress, and the general public.

Comment: One commenter asked how providers of IPPE services will know if a particular beneficiary is eligible to receive the new benefit due to the statutory time and coverage frequency (one-time benefit) limitations.

Response: The statute provides for coverage of a one-time IPPE benefit that must be performed for new beneficiaries by qualified physicians or certain specified NPPs within the first 6 months period following the effective date of the beneficiary's first Part B coverage. Since physicians or other qualified NPPs may not have the complete medical history for a particular new beneficiary, including information on possible use of the one-time benefit, these clinicians are largely relying on their own medical records and the information the beneficiary provides to them in establishing whether or not the IPPE benefit is still available to a particular individual and was not performed by another qualified practitioner. Since a second IPPE will always fall outside the definition of the new Medicare benefit, an advance beneficiary notice (ABN) need not be issued in those instances where there is doubt regarding whether the beneficiary has previously received an IPPE. The beneficiary will always be liable for a second IPPE no matter when it is conducted. However, for those instances where there is sufficient doubt as to whether the statutory 6-month period has lapsed, the physician or other qualified NPP should issue an ABN indicating that Medicare may not cover and pay for the service. If the physician or other qualified NPP does not

issue an ABN and Medicare denies payment because the statutory time limitation for conducting the initial IPPE has expired, then the physician or other qualified NPP may be held financially liable.

Comment: Several commenters asked that we provide explicit instructions and guidelines, respectively, to providers and beneficiaries regarding the details of what will be included in the new benefit, the eligibility requirements, and how providers must bill Medicare for the new service.

Response: Medicare will release appropriate manual and transmittal instructions and information from our educational components for the medical community, including a MedLearn Matters article and fact sheets like the "2005 Payment Changes for Physicians and Other Providers: Key News From Medicare for 2005". The medical community can join this effort in educating physicians, qualified NPPs, and beneficiaries by distributing their own communications, bulletins or other publications.

In addition, we have specifically included information on the new IPPE benefit in the 2005 version of the Medicare and You Handbook and the revised booklet, Medicare's Preventive Services. A new 2-page fact sheet on all of the new preventive services, including the IPPE benefit, is



currently under development, and a bilingual brochure for Hispanic beneficiaries will also be available in the new future. This information will be disseminated by our regional offices, State Health Insurance Assistance Programs (SHIPs), and various partners at the national, State, and local levels. Information on the new benefit will also be made available to the public through medicare.gov, the cms.gov partner website, 1-800-MEDICARE, numerous forums hosted by CMS, and conference exhibits and presentations.

Comment: Many of the major physician specialty societies believe the payment, as proposed, is undervalued for what is believed to be a labor-intensive IPPE. They request that we use the existing CPT preventive medicine services code series rather than creating a new G-code. These codes have higher RVUs than the office or other outpatient visit code 99203. For example, preventive medicine services visit code 99387 has total nonfacility RVUs of 4.00 while the corresponding value for 99203 is 2.58.

Response: The existing CPT preventive medicine services codes (99381 - 99397) are not covered by Medicare. In accordance with section 1862(a)(1)(A) of the Act that requires us to pay only for services that are reasonable

and necessary for the treatment of an illness or injury or to improve the function of a malformed body member, we have not covered E/M visits for screening purposes.

The IPPE is intended to target selected modifiable risk factors and secondary prevention opportunities shown by evidence to improve the health and welfare of the beneficiary, and is less focused on a comprehensive physical examination compared to the typical service provided in accordance with CPT code 99397. We equated the resources anticipated with this service to the existing new office or other outpatient visit. For CPT code 99203 the RUC survey data shows 53 physician minutes (including pre-service time, intra-service time and post-service time) with 51 minutes of staff time. We believe the IPPE will reflect these time approximations. We will be looking at the data and consulting with the medical community after initial experience with this new benefit to determine if this payment has been valued appropriately.

Comment: Two commenters suggested that we allow the IPPE either on a yearly basis or every decade after the initial evaluation.

Response: The IPPE was specifically legislated as a one time only benefit for the beneficiary newly enrolled in the Medicare program. This visit familiarizes the

beneficiary with a physician or qualified NPP who will highlight the assessments available to help prevent and detect disease and also make available the educational, counseling and referral opportunities to the new Medicare recipient. Our policy anticipates physicians will make appropriate and individualized referrals for the beneficiary. Expanding the number of routine physicals would require additional legislation (See section 1862 (a) (7) of the Act).

Comment: Many commenters asked if the IPPE may be provided without performing the EKG at the same visit. They asked to have the EKG component unbundled from the evaluation and management component that had been specified in the proposed rule for the IPPE service since a physician may not have the equipment and capability of providing EKG services to their patients in the office suite or clinic. Additionally, others asked if a physician would be denied payment for the IPPE if the screening EKG was not performed because a diagnostic EKG was performed in a recent visit or if a diagnostic EKG was warranted at the IPPE visit.

Response: Section 611 of the MMA does require a screening EKG to be performed as part of the IPPE visit. We recognize that there are a number of primary care physicians or other clinicians furnishing the service who

may want to refer their beneficiaries to outside practitioners or entities for performance and interpretation of the EKG service rather than performing it themselves. Therefore, if an individual physician or other qualified NPP does not have the capacity to perform the EKG in the office suite, then alternative arrangements will need to be made with an outside physician or other entity in order to make certain that the EKG is performed. In circumstances where the primary care physician or qualified NPP refers the beneficiary to an outside physician or entity for the EKG service, we expect that the primary care physician or qualified NPP will incorporate the results of the EKG into the beneficiary's medical record to complete the IPPE. Both components of the IPPE, the examination portion and the EKG, must be performed for either of the components to be paid. Billing instructions for physicians, qualified NPPs and providers will be issued. In order to address these potentially occurring scenarios to complete the IPPE and EKG we have created the following HCPCS codes:

- G0344: Initial preventive physical examination; face-to-face visit services limited to new beneficiary during the first six months of Medicare enrollment

- G0366: Electrocardiogram, routine ECG with at least 12 leads with interpretation and report, performed as a component of the initial preventive physical examination

A physician or qualified NPP performing the complete service would report both G0344 and G0366.

- G0367: tracing only, without interpretation and report, performed as a component of the initial preventive physical examination
- G0368: interpretation and report only, performed as a component of the IPPE

RVUs for payment for these new HCPCS codes will be crosswalked from the following CPT codes:

- G0344 will crosswalk from CPT code 99203 (Office or other outpatient visit)
- G0366 will crosswalk from CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report)
- G0367 will crosswalk from CPT code 93005 (Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report)

- G0368 will crosswalk from CPT code 93010  
(Electrocardiogram, routine ECG with at least 12  
leads; interpretation and report only)

Note that HCPCS codes G0366 and G0367 are not payable under the physician fee schedule in the facility setting.

To comply with MMA the IPPE must include the EKG regardless of whether a diagnostic EKG was recently performed. An EKG performed by the physician or qualified NPP during the IPPE visit must be reported with HCPCS code G0366. Medicare does not cover a screening EKG alone.

Comment: One commenter asked if physicians and qualified NPP who see patients in Federally Qualified Healthcare Centers (FQHCs) will be able to provide and bill under the FQHC all-inclusive rate.

Response: Physicians and other qualified NPPs in RHCs and FQHCs may provide this new benefit and follow normal procedures for billing for RHCs and FQHC services. Payment for the professional services will be made under the all-inclusive rate.

Comment: Many physician specialty societies did not agree with our proposal to limit the level of a medically necessary E/M visit when performed and billed with the IPPE. They contend that most Medicare patients, even if

known to their physician, come to the IPPE visit with multiple chronic problems often necessitating immediate evaluation and treatment at a level of care equal to a level 4/5 E/M visit code. They also state that current Medicare policy does permit a medically necessary E/M visit at whatever level is appropriate when the noncovered preventive medicine services (CPT codes 99381 - 99397) are performed. They ask that we eliminate the restriction for the level of service for a medically necessary E/M visit performed at the same visit as the IPPE visit.

Response: The physician will need to schedule time with the beneficiary identifying the available preventive and educational opportunities. A level 2 new or established patient office or other outpatient visit code was proposed because we believe there is a substantial overlap of practice expense, malpractice expense and physician work in both history taking and examination of the patient with the IPPE and another E/M service. We do not want to prohibit the use of an appropriate level of service when it is necessary to evaluate and treat the beneficiary for acute and chronic conditions. At the same time, we believe the physician is better able to discuss health promotion, disease prevention and the educational opportunities available with the beneficiary when the

health status is stabilized and the beneficiary is physically receptive.

We will remove the restriction limiting the medically necessary E/M service to a level 2 visit code. CPT codes 99201 through 99215 may be used depending on the circumstances and appended with CPT modifier -25 identifying the E/M visit as a separately identifiable service from the IPPE code G0344 reported.

We do not believe this scenario will be the typical occurrence and, therefore, we will monitor utilization patterns for the level 4/5 new or established office or other outpatient visit codes being reported with the IPPE. If there are consistent data that demonstrate high usage of level 4/5 E/M codes we may need to revise the policy.

Comment: Two commenters asked if we would permit separate payment for a digital rectal exam (DRE) when performed on the same day as the initial preventive physical examination.

Response: Currently Medicare does not make separate payment for DRE (code G0102) when performed on the same day as an E/M service. We will maintain the current policy and not pay separately for a DRE performed during the IPPE visit. A DRE is usually furnished as part of an E/M service and is bundled into the payment for an E/M service



when a covered E/M service is furnished on the same day as a DRE. It is a relatively quick and simple procedure and if it is the only service furnished or is provided as part of an otherwise noncovered service it would be payable if coverage requirements are met.

Comment: Several commenters requested guidance on documentation.

Response: It is expected that the physician will use the appropriate screening tools. As for all E/M services, the 1995 and 1997 E/M documentation guidelines must be followed for recording information in the patient's medical record. The screening tools used, EKG documentation, referrals and a written plan for the patient also must be included in the patient's medical record. These forms and methods of documentation mirror those that would be used in typical physician practice with patient visits and do not add an additional burden to the physician.

Comment: Several commenters expressed concern that the non-waived deductible and coinsurance will be a disincentive to the beneficiary having the IPPE. They are concerned that some beneficiaries will not avail themselves of the opportunity of the IPPE visit because of the beneficiary's cost share.

Response: The MMA did not waive the deductible and coinsurance, therefore, we must implement the provision as written.

Result of Evaluation of Comments

In view of the comments, we have decided to make several revisions in §410.16(a) relative to service elements 1, 2, and 3. We are revising §410.16(a)(1)(i) language in service element 1 to read as follows: "Review of the individual's medical and social history with particular attention to modifiable risk factors for disease."

We are clarifying the regulation language on depression screening (service element 2) by revising §410.16(a)(1)(ii) to specify that review of the individual's potential (risk factors) for depression, including current or past experience with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations. To allow for a certain amount of provider flexibility in meeting the requirements of the regulatory intent of

service component 3 we are revising §410.16(a)(1)(iii) to specify that review of the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire, which the physician or qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national medical professional organizations.

To clarify the requirements of the regulatory intent of service component 7 we are revising §410.16(a)(1)(vii) to specify that education, counseling, and referral, including a brief written plan such as a checklist be provided to the individual for obtaining the screening and other preventive services for the individual that are covered as separate Medicare Part B benefits.

The "social history" definition in the final rule will be revised to include 3 elements:

- History of alcohol, tobacco, and illicit drug use.
- Diet.
- Physical activities.

With regard to payment of the IPPE, we will use the new HCPCS codes and payment will be based on the RVUs of the CPT codes crosswalked as stated above. We will not finalize our proposal to allow a medically necessary E/M

service no greater than a level 2 to be reported at the same visit as the IPPE.

B. Section 613—Diabetes Screening

Section 613 of the MMA adds section 1861(yy) to the Act and mandates coverage of diabetes screening tests.

The term "diabetes screening tests" is defined in section 613 of the MMA as testing furnished to an individual at risk for diabetes and includes a fasting blood glucose test and other tests. The Secretary may modify these tests, when appropriate, as the result of consultations with the appropriate organizations. In compliance with this directive, we consulted with the American Diabetes Association, the American Association of Clinical Endocrinologists, and the National Institute for Diabetes and Digestive and Kidney Diseases.

1. Coverage

We proposed in §410.18 that Medicare cover—

- A fasting blood glucose test; and
- Post-glucose challenge tests; either an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, or a 2-hour post-glucose challenge test alone.

We would not include a random serum or plasma glucose for persons with symptoms of uncontrolled diabetes such as

excessive thirst or frequent urination in this benefit because it is already covered as a diagnostic service. This language is not intended to exclude other post-glucose challenge tests that may be developed in the future, including panels that may be created to include new diabetes and lipid screening tests. We also would include language that would allow Medicare to cover other diabetes screening tests, subject to a NCD process.

The statutory provision describes an "individual at risk for diabetes" as having any of the following risk factors:

- Hypertension.
- Dyslipidemia.
- Obesity, defined as a body mass index greater than or equal to 30 kg/m<sup>2</sup>.
- Previous identification of an elevated impaired fasting glucose.
- Previous identification of impaired glucose tolerance.
- A risk factor consisting of at least two of the following characteristics:
  - + Overweight, defined as a body mass index greater than 25 kg/m<sup>2</sup>, but less than 30.
  - + A family history of diabetes.

- + A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.
- + 65 years of age or older.

For individuals previously diagnosed as diabetic, there is no coverage under this statute.

The statutory language directs the Secretary to establish standards regarding the frequency of diabetes screening tests that will be covered and limits the frequency to no more than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

We proposed that Medicare beneficiaries diagnosed with pre-diabetes be eligible for the maximum frequency allowed by the statute, that is, 2 screening tests per 12 month period. We defined "pre-diabetes" as a previous fasting glucose level of 100-125 mg/dL, or a 2-hour post-glucose challenge of 140-199 mg/dL. This definition of pre-diabetes was developed with the assistance of the American Association of Clinical Endocrinologists, concurs with the Centers for Disease Control and Prevention (CDC) definition, and complements the definition of diabetes that we published November 7, 2003 (68 FR 63195).

## 2. Payment

We proposed to pay for diabetes screening tests at the same amounts paid for these tests when performed to diagnose an individual with signs and symptoms of diabetes. We would pay for these tests under the clinical laboratory fee schedule. We proposed to pay for these tests under CPT code 82947 Glucose; quantitative, blood (except reagent strip), CPT code 82950, post glucose dose (includes glucose), and CPT code 82951 Glucose; tolerance test (GTT), three specimens (includes glucose). To indicate that the purpose of the test is for diabetes screening, we would require that the laboratory include a screening diagnosis code in the diagnosis section of the claim. We proposed V77.1 special screening for diabetes mellitus as the applicable ICD-9-CM code for this purpose. Because laboratories are required and accustomed to submitting diagnosis codes when requesting payment for testing, we believe including a screening diagnosis code is appropriate for this benefit.

Comment: One commenter questioned whether there is statutory authority to expand eligibility for individuals. Adding that, section 613 of the MMA gives authority for additional test and frequency, not additional individuals.

Response: There is no statutory authority to expand eligibility for individuals. Section 613 of the MMA

establishes coverage for beneficiaries who are at risk for developing diabetes. Beneficiaries who are pre-diabetic fall within 1861(yy) (2) (D) or (E) and are at an increased risk for developing diabetes. This increased risk separates them from the general at-risk population and requires the course of their care to be managed closer and more frequently.

For individuals not meeting the "pre-diabetes" criteria, we proposed that one diabetes screening test be covered per individual per year.

Comment: Several comments were received that recommended we provide physicians with clear guidance about Medicare's covered services to help patients control their diabetes. The commenters also asked that we inform providers about other covered services, such as Hgb1AC tests, that will help patients avoid painful diabetes-related complications.

Response: We will be releasing two publications. The Dear Doctor Package publication, which includes the "2005 FACT SHEET", will be sent to the contractors on a CD on or about October 15, 2005 and distributed to the providers by November 15, 2005. The Medicare Coverage of Diabetes Services and Supplies publication was originally written in 2002. It was revised in 2003 to update the Part B premium



amount and is being revised again this year to update the premium amount and to include any information relevant to the MMA. This document will be available on the CMS website and at 1-800-MEDICARE.

Comment: We received several comments suggesting that screening should not require a physician's prescription or referral in order to be covered under Medicare Part B. This approach would follow the successful precedent established by us with other screening tests such as mammograms.

Response: The legislative history on mammography did result in us allowing self-referral for mammograms. However, Medicare rules have required that laboratory tests for screening or other diagnoses must be ordered by licensed health care practitioners, specifically physicians, PAs, NPs, or CNSs.

Comment: Comments were received recommending that the final rule include coverage of one annual diabetes screening for all Medicare beneficiaries.

Response: The benefit of screening all Medicare beneficiaries is not supported by current evidence. We plan risk-based frequency limitations of coverage for diabetes screening based upon the statute requirements. Furthermore, we believe beneficiaries with pre-diabetes may

warrant a more frequent follow-up and this is permitted at the professional judgment of the health care practitioner.

Comment: We received a few comments suggesting the addition of the C-peptide test, as it is sometimes useful in Type 1 or Type 2 diabetes.

Response: We believe that C-peptide testing is appropriate for diagnostic evaluation, but not for screening. It is currently covered under the general lab benefit as a diagnostic test when it is medically necessary.

Comment: The American Society for Clinical Pathology (ASCP) has urged us to add CPT 82950 glucose; post glucose dose (includes glucose). This test is more frequently used to screen for diabetes. GTT is a more definitive test usually requested when questionable results from random, fasting or postprandial glucose levels are obtained. As written, the proposed rule appears to exclude 82950 as a screening test.

Response: We appreciate attention being drawn to the apparent exclusion of CPT code 82950, which was not our intention and we have corrected that omission.

Comment: A commenter suggested that due to increased incidence of obesity in recent years that family history of

diabetes be defined as persons with Type 2 Diabetes in one or more first or second-degree relatives.

Response: The comments received did not provide a clear consensus on the definition of family history of diabetes. Thus the definition of family history of diabetes will be left to the professional judgment of the treating physician or qualified non-physician practitioner based on the beneficiary's medical history and best practice standards.

Comment: The American Clinical Laboratory Association (ACLA) believes that the other codes on the NCD routine screening list that currently result in a diabetes denial on the basis of routine screening should be covered under the new diabetes screening benefit.

Response: We believe the majority of individuals who will seek care under this benefit will conform to the V77.1 code. We are willing to review a sample of claims and determine if other specific codes are appropriate code for this benefit. Codes that need to be considered for this new benefit can be brought to our attention through the national coverage determination process for laboratories.

Comment: A comment was received recommending that the proposed rule be clarified to refer to a "fasting blood glucose test" rather than a "fasting plasma glucose test"

since the CPT code does not differentiate between blood and plasma.

Response: We agree with the recommendation to change the term "fasting plasma glucose test" to "fasting blood glucose test".

Comment: A comment was received recommending additional diabetes screening tests be added through a less formal process of consultation with manufacturers, health care providers, patients, and other stakeholders, as contemplated by Congress. The commenter further stated that the NCD process is complex and time consuming, delaying the coverage of new tests.

Response: We believe the evidence-based NCD process is an effective process to review and analyze items and services as potential benefits for Medicare beneficiaries. Because the NCD process allows for public comment before we make any changes, we believe this is the appropriate process for any future changes. Further, we may not be able to accept every stakeholder's recommendation because of instructional, coding, or claims issues which must be resolved before any benefit can be implemented.

Result of Evaluation of Comments:

Our review of the comments has led to the elimination of the word "plasma" from the term "fasting plasma glucose

test.” The word “plasma” will be replaced with the term “blood”. We have corrected the unintentional omission of CPT code 82950, post glucose dose (includes glucose) as a diabetes screening test. The providers and beneficiaries are reassured that there will be clear guidance on covered services by way of two publications: The Dear Doctor Package, which includes the “2005 Fact Sheet” and Medicare Coverage of Diabetes Services and Supplies. We continue to promote healthcare practitioner autonomy with our policy of risk-based frequency limitations on items and services provided to our beneficiaries. We recognize the differing opinions with regard to the usage of the NCD process to review potential new items and services such as new diabetes screening tests for our beneficiaries. To provide transparency, timeliness and fairness, a formal process is necessary. Historically, the NCD process has been open to all interested parties and has proven to be an effective process.

Based on reasoning from the responses to the comments we received, at this time we will not be accepting the following suggestions.

- Reversing policy requiring a physician’s or a qualified non-physician’s prescription or referral for diabetes screening tests.

- Providing coverage of one annual diabetes screening test for all Medicare beneficiaries.
- Adding coverage of C-peptide test as a screening test.
- Bypassing the current NCD process for a less formal process to add additional diabetes screening tests.

C. Section 612—Cardiovascular Screening

Section 612 of the MMA adds section 1861(xx) to the Act and provides for Medicare coverage of cardiovascular (CV) screening blood tests for the early detection of CV disease or abnormalities associated with an elevated risk for that disease effective on or after January 1, 2005.

Upon reviewing the USPSTF reports, the scientific literature and comments of professional societies, trade associations, the industry, and the public, we proposed in the August 5, 2004 Federal Register, that the benefit for CV screening would include the use of three clinical laboratory tests to detect early risk for CV disease. Since the three tests, a total cholesterol, a HDL-cholesterol, and a triglycerides test, could be ordered as a lipid panel or individually, the frequency was limited to one of each individual test or combination as a panel every 5 years.

When we researched the benefit, some scientific experts proposed that the use of only the total cholesterol test as a single test every 2 years was adequate. After reviewing the literature and comments, we concluded that each test in the lipid panel is important since each test predicts the risk for CV disease independently. It would be prudent, therefore, to promote the benefit as three separate tests every 5 years. The decision to limit the frequency to 5 years, rather than more frequent testing every 2 years was due to information found in the Clinical Considerations of the USPSTF which indicate that the cholesterol values of elderly persons, who are the majority of the Medicare population, change slowly as they age. We also proposed that any changes to the list of tests could be made after a review of recommendations by the USPSTF and the use of the NCD process.

We proposed that for the claims processing and payment system, the coding of the tests would be made using the CPT codes available for the lipid panel or the three tests individually coded with the use of V codes to identify the tests were ordered for screening purposes. We also stated that we would pay for these CV screening tests at the same amounts paid for these tests to diagnose an individual with signs of CV disease and that these would be paid under the

clinical laboratory fee schedule. The proposed coverage requirements were set forth in new §410.17.

In response to the proposed rule, we received letters and emails from 28 commenters representing professional societies, trade groups, the industry, and individuals, who wrote on 26 different issues. One commenter represented 14 medical societies. Each commenter had many concerns and the comments were grouped into 26 areas of concern.

Comment: Three commenters expressed concern that many laboratories perform direct measurement LDL reflexively when triglycerides exceed certain parameters. The commenters are concerned that if screening direct measurement LDL is statutorily excluded then the Medicare beneficiaries would be liable for these tests without prior notice.

Response: Section 410.32 requires that tests be ordered by a treating physician and used in the management of the patient. We have interpreted this provision to restrict the furnishing of reflex testing to situations where it is clear that the physician is ordering reflex testing at specific parameters and where the physician has an option to order the test without the reflex portion. Thus, laboratories must offer physicians the ability to order a lipid panel without the option to perform the



direct measurement LDL. We strongly encourage physicians to order lipid panels without the direct measurement LDL reflex option to protect Medicare beneficiaries from incurring a charge for this service without advanced notice.

If the screening lipid panel results indicate a triglyceride level that indicates the need for a direct measurement LDL, the physician may order this test once the results of screening lipid panel are reported. The NCD for lipid testing includes coverage of direct measurement LDL for patients with hyperglyceridemia.

[[http://www.cms.hhs.gov/mcd/viewncd.asp?ncd\\_id=190.23&ncd\\_version=1&show=all](http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=190.23&ncd_version=1&show=all)]

We do not require the patient to physically return to the treating physician for an office visit and ordering of subsequent testing. Physicians may order such tests based on the results of the CV screening. The Medicare law and regulations do not prohibit the use of the same sample of blood to be used for direct measurement LDL following a lipid panel with very high triglycerides. Laboratories may archive the initial specimen and use it for subsequently ordered medically necessary direct measurement LDL.

Comment: One commenter suggested that if the direct LDL cholesterol is included in the CV risk screening

benefit, we must provide guidance to laboratories regarding whether or not the direct LDL must be billed with the -59 modifier for the charge to be reimbursed.

Response: Since the direct LDL cholesterol is not being added to the CV screening benefit, there is no change to the billing.

Comment: One commenter requested that the V codes (V81.0, V81.1, and V81.2) be added to the Lipid NCD and that the NCD Edit Software be modified to accept these V codes (V81.0, 81.1, and 81.2) on a frequency basis.

Response: The Laboratory NCD Edit Module will be modified to accept the V codes for matching the CPT codes with the ICD-9-CM code for those tests within the lipid NCD that are part of this statutory benefit. The entire lipid NCD is not open for modification. The frequency is determined by the NCD process and implemented through changes to the claims processing system to edit the patient history and coding.

Comment: One commenter asked that Medicare contractors provide explicit instructions to physicians to provide the necessary V codes (or their corresponding narratives) since screening is normally non-covered.

Response: We will release the appropriate manual, transmittal instructions and information from our

educational components for the medical community including a MedLearn Matters article and fact sheets such as the "2005 Payment Changes for Physicians and Other Providers: Key News From Medicare for 2005." Laboratories can join this effort to educate physicians and beneficiaries by distributing their own communication, bulletins or other publications. Some of this information will also be part of the "Welcome to Medicare Preventive Services Package."

Comment: Three commenters recommended that high sensitivity C-reactive protein (hsCRP) be considered as a test for this benefit since the AHA and CDC issued a Class IIa recommendation stating that hsCRP measurements for risk stratification add important information to the "classic" cholesterol and HDL measurement. They cited that given Congressional intent, we should include this measure in its list of "approved" screening tests and, if not, that we immediately request that USPSTF conduct a formal review of hsCRP as a screening test. Four commenters recommended the addition of the ABI test. Another requested the inclusion of the 12-lead ECG, the echocardiogram, and tests for carotid artery disease. Another requested the coverage of blood pressure screening. Finally, another commenter suggested that we allow the broadest access and maximize the potential for tests.

Response: We appreciate the commenters' suggestions to include hsCRP and the other tests. In our efforts to develop the proposed rule, many tests were considered for inclusion in the list of screening tests for this benefit. There was insufficient evidence to include any additional tests beyond the lipid panel tests. The information we received in the development of the proposed rule did not support the inclusion of these additional tests but we invite the public to submit scientific literature for our consideration. Other new types of CV screening blood tests may be added under this new screening benefit if we determine them appropriate through a subsequent NCD.

[68 FR 55634 (Sept 26, 2003) or  
<http://www.cms.hhs.gov/coverage/8a.asp>]

Comment: Two commenters recommended that we add HCPCS codes for the Lipid Panel and components as waived tests since they are performed in physician offices and other sites with Clinical Laboratory Improvement Amendments (CLIA) Certificates of Waiver.

Responses: Under CLIA, a facility with a CLIA certificate of waiver can only perform those tests that are approved by the FDA as waived tests. We update the list of waived tests and their appropriate CPT codes on a quarterly basis through our program transmittal process. When we

program the claims system to look for the AMA CPT codes for Lipid Panel or any of the three tests which make up the panel, the system will recognize those waived tests performed using the same code plus the QW modifier that are medically necessary.

Comment: Two commenters requested clarification of the frequency limits for the three tests considered for this benefit. They asked if we would cover: (1) a lipid panel; (2) one or more component tests making up the lipid panel once every 5 years; or (3) each of the 4 HCPCS codes listed every 5 years.

Response: The intent of the benefit is to screen for CV disease. Since we believe most physicians would order the Lipid Panel as a single test, our intention was to cover the panel. We recognize that physicians may have different approaches to reaching their decision to treat, and therefore, we have to make available the possibility that physicians could order the individual tests which make up the panel. No matter how the physician(s) order the tests, our intention is to cover each of the 3 component tests (that is, a total cholesterol, a triglycerides test, and an HDL cholesterol) once every 5 years.

Comment: Two commenters asked that we clarify the reasons for having V codes for screening tests added from

the MMA rather than the past practice of developing G codes (unique HCPCS codes; temporary codes). This commenter believed that the change to V codes would cause confusion to the databases like the Physician/Supplier Procedure Summary Master File. This confusion would result in improperly filed provider claims and this would lead to a different and confusing method of processing claims.

Response: The decision to use ICD-9-CM codes rather than continue to add G codes was made because we try to utilize existing coding structures where possible and create G codes if there is a specific programmatic need. The laboratory community has lobbied against the use of G codes for a few years. Also the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Standardization Requirements are working toward phasing out G codes, which are CMS only codes. The claims processing and editing systems are expected to be adjusted to manage this change.

Comment: Five commenters questioned the reasons for establishing limits on the frequency of this benefit since this places great legal, administrative, and financial burden for providers to manage this type of information. One commenter suggested the use of a hit that

beneficiaries would receive and redeem for testing so laboratories would not need to keep records.

Response: The statute requires a frequency limit. Since laboratories may not have the complete medical history for individuals, including their history of CV screening tests, they are largely relying on the physician's order in establishing whether the test is medically necessary and covered by Medicare. However, relying on the physician's order does not provide the laboratory with proof that the CV screening test is medically necessary since the beneficiary may be treated by multiple physicians who may have ordered these tests independently within the 5 year coverage window. If the laboratory has sufficient doubt, the laboratory may issue an Advanced Beneficiary Notice (ABN) to the beneficiary indicating that Medicare may not cover the CV screening test. If the laboratory does not issue an ABN to the beneficiary who has received more than one CV screening test during the previous five years, the laboratory may be financially liable for the cost of the test. Laboratories are not required to issue an ABN if the physician has already issued one.

In addition, section 40.3.6.4(C) titled "Frequency Limited Items and Services" of Chapter 30 of Pub 100-4 of

the "Internet Only Manual" provides additional guidance for those instances where Medicare has imposed frequency limitations on items or services. This section instructs providers that the provider may routinely give ABNs to beneficiaries and that whenever such a routine ABN is provided to a beneficiary, the ABN must include the frequency limitation as the reason for which Medicare will deny coverage.

Comment: Several commenters, including the ACR and the SIR, offered their assistance to us when we determine whether noninvasive testing for CV disease is necessary.

Response: Since the organizations that suggested noninvasive tests for inclusion in this benefit provided the materials for our review, it is not necessary for us to seek outside assistance. We appreciate the commenters' offer of assistance.

Comment: Four commenters suggested that the CV screening benefit stipulate an age for the population to be tested. We reviewed the USPSTF recommendation that promoted testing for men 35 years and older and women 45 years and older. The commenters believe this age range should be lowered to include those aged 20 years and older and asked us to consider including younger people in this benefit.



Response: The statutory change for this benefit did not include an age for the person to be tested. While some of the USPSTF recommendations included an age or an age range, none was selected for the proposed rule. Since the majority of the individuals in Medicare are generally 65 and older, the belief was that we are looking at an older population rather than concentrating our resources on the younger beneficiaries who may also be disabled and Medicaid eligible or could be eligible for other services due to other complications of CV disease. While there may be individuals younger than 65 years of age that could benefit from this testing, this benefit is intended for those entitled to Medicare. Therefore, any patient entitled to Medicare would be covered for this benefit as specified in this rule.

Comment: One commenter noted that if the patient did not fast for the screening test (fasting may be difficult for some patients), the calculation of LDL cholesterol may be inaccurate. This commenter recommended that for screening purposes, an alternative to repeating the full lipoprotein profile in the fasting state would be a follow-up direct measurement of LDL cholesterol.

Response: If a patient cannot fast and the physician believes the patient's medical history and circumstances

suggest the beneficiary is at risk of CV disease, then any additional testing beyond an initial screening would need to be done under the diagnostic clinical laboratory benefit. Under the screening benefit, a repeated full lipoprotein profile (fasting) or a second LDL cholesterol (fasting) would not be covered for anyone who failed to fast when they had their first set of tests.

Comment: Several commenters suggested that the tests that the USPSTF approves for CV screening blood tests be automatically adopted and covered by Medicare for the purposes of this benefit. We would not need to use the NCD process to add tests to this benefit. Immediate adoption of USPSTF recommendations will remove us from our own lengthy review.

Response: While the USPSTF process is well established, we believe it is prudent to review any recommendations from the USPSTF before implementing them. In the proposed rule, we asked the public how we should make changes for this benefit. Because the national coverage determination process allows for public comment before we make any changes, we believe this is the most appropriate basis for any future changes. Further, we may not be able to accept every USPSTF recommendation because

of instructional, coding or claims issues that must be resolved before any benefit can be implemented.

Comment: Several commenters questioned whether the screening benefit for CV disease included noninvasive tests or whether it was limited only to blood tests. Further, they recommended that the adoption of noninvasive tests be tied to recommendations of the USPSTF or to an NCD.

Response: We interpreted this portion of the screening benefit to permit noninvasive tests for which there was a blood test recommended by the USPSTF (for example, there is a blood test for cholesterol and if a noninvasive test was developed that detected characteristics of cholesterol, could provide a meaningful (comparison) result and accurate reading) then the noninvasive test could be considered for inclusion in the screening benefit. Noninvasive tests would not be immediately included but would be subject to a review before adoption. When it is time to consider the addition of tests or changes to the list of tests, we will consider any changes through an NCD. This benefit is not limited only to blood tests.

Comment: One commenter recommended that we include a fasting blood glucose test as part of the CV screening blood benefit and that we cover this test every 2 years for

beneficiaries over 45 and for younger beneficiaries who are obese or have a family history of diabetes. Fasting blood glucose is inherently a CV screening test because diabetes carries increased risk of CV disease.

Response: While some people who have diabetes exhibit other factors associated with CV disease, we do not see the necessity to adjust the CV screening benefit to include a fasting blood glucose test. The diabetes screening benefit should be able to identify these individuals. Medicare does not plan to duplicate tests when they are available through other screening programs.

Comment: One commenter requested the inclusion of V70.0 for routine examination to be added as one of the ICD-9-CM codes to be covered for screening for CV screening blood tests. They asked that the NCD on lipid panel be reviewed for any codes that were previously denied as routine screening in the past, and that these codes be considered for inclusion under this new benefit.

Response: We believe the majority of individuals who will seek care under this benefit will fit the V81.0, V81.1, or V 81.2 codes. We are willing to review a sample of claims and determine if V70.0 is an appropriate code for this benefit. At this time, we are unable to add V70.0 to the instructions being cleared. Codes that are to be

considered for this new benefit must be brought to our attention through the national coverage determination process for laboratories.

Comment: One commenter suggested that the proposed §410.17 include reference to whether beneficiaries will incur out-of-pocket costs for CV screening blood tests.

Response: Section §410.17 is specific to coverage instructions for screening tests for the early detection of CV disease. We do not believe it is necessary to revise §410.17 to include payment instructions. We have indicated that Medicare would pay for the tests under the clinical laboratory fee schedule. Currently under this payment system, beneficiaries do not incur copayments and deductibles in accordance with section 1833(a)(1)(D)(i) of the Act, and is included in instructions at Medicare Claims Processing Manual, Pub. 100-04, chapter 16, §30.2.

Comment: Two commenters asked us to clarify why we chose 5 years as the timeframe for the benefit, rather than the 2 years allowed by the statute.

Response: Our primary goal was to allow testing for the population that needed to be screened. In the preamble to the proposed rule, we stipulated that the Clinical Considerations of the USPSTF indicate, while screening may be appropriate in older people, repeated screening is less

important because lipid levels are less likely to increase after age 65. Screening individuals more often than necessary might lead to unnecessary expenses and treatment. The scientific literature indicates that lipid levels in the elderly are fairly stable. Therefore, we proposed screening once every 5 years and have not received sufficient evidence to change this position.

Comment: Two commenters suggested that a two-tiered benefit be developed that would allow lipid profile screening tests at least every 5 years for beneficiaries when risk factors are not evident and a second group be screened at least every 2 years. The second group would include individuals who have modifiable risk factors (for example, tobacco smoking, high blood pressure, physical inactivity, obesity, and diabetes mellitus) and non-modifiable risk factors (such as age, gender, race, and family history).

Response: While the CV screening benefit could be expanded to include individuals other than those mentioned in the proposed rule, preventive benefits were added to the Medicare Program on a limited basis as science and technology permit them. Since some of the individuals in the second group already would be screened through the IPPE and the Diabetes Screening Benefit, we are not developing a

second tier at this time. We believe expanding this to a second tier would waste precious resources of time and money and not contribute to lowering the risk factors for individuals with CV disease.

Comment: One commenter questioned why we proposed to use the NCD process as the method of making changes to the list of tests covered by the CV screening blood test benefit. The commenter wrote that the MMA does not require that the NCD process be utilized. They indicated that there is no need for us to conduct our own assessment since a thorough evaluation of the test was to be done by the USPSTF in determining that the test is one that it recommends. The commenter objected to the use of the NCD process for consideration of new tests because of the significant delays that mark this process. The commenter also stated that all that would be needed for us to approve the coverage of additional CV screening tests is the recommendation of the USPSTF.

Response: In establishing the benefit for CV screening blood tests, the Congress gave the Secretary the authority to determine which tests would be covered by this benefit. We do not believe it would be proper to delegate this function to USPSTF or any other entity. In the proposed rule, we proposed the tests to be covered for the

new benefit when it becomes effective January 1, 2005 and at the same time, we offered the NCD process for changes to this benefit. We proposed that future tests would be added after reviewing the recommendations of the USPSTF and the use of the NCD process. The NCD process actually has several methods for evaluating which tests we may eventually cover. The NCD process includes an application for a new coverage issue, a reconsideration of an existing policy, or a coding change for laboratory tests. We believe the use of the NCD process is a worthwhile endeavor since it is a public process and less time consuming than rulemaking. The use of an NCD is authorized by Section 1871 of the Act.

Comment: One commenter suggested that we include triglycerides as a test for the CV screening blood test benefit since the 2001 USPSTF recommendations for screening for lipid disorders associated with CV disease only includes measurement of total cholesterol and high-density lipoprotein cholesterol (HDL-C).

Response: We have included the triglycerides test as one of the tests for screening for CV disease. For some individuals, triglycerides may detect a risk factor for CV disease. That is why it was more prudent to select a lipid profile that includes the three tests (total cholesterol,



HDL-C, and the triglycerides) rather than to indicate the use of individual tests with different test intervals and different ordering patterns.

Comment: One commenter requested that the frequency limit for lipid testing of 5 years be waived if the patient develops a risk factor, such as diabetes, a marked weight gain, etc. in the interval.

Response: A patient screened for lipid testing could also meet the requirements for screening under the diabetes screening benefit. If a patient developed further risk factors which negate the need for continued screening under the CV screening blood test benefit, their additional signs or symptoms would probably cause the person to need to seek treatment which would be covered under other benefits including diagnostic clinical laboratory testing.

Comment: One commenter questioned whether §410.16 that permits qualified nurse practitioners and others to order CV screening tests under the physical examination (section 611 of the MMA) is inconsistent with §410.17 that requires that the laboratory tests be ordered by the treating physician (§410.32(a)).

Response: Section 410.16 addresses services by NPs because of conforming changes made in section 611(d) of the MMA. Section 410.32(a)(3) permits certain NPPs to furnish

services that would be physicians' services if furnished by a physician and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit. We believe that the statute permits the use of NPPs to order tests described under §410.17 without a change in the statute. The general rule for laboratory tests is that the tests must be ordered by the treating physician and in the instance of screening tests, the treating NPP may be regarded as a physician for this purpose.

Comment: One commenter believed that screening every 5 years was too long a period between tests and that the data we collect be used to allow more frequent testing.

Response: We have heard from commenters that the frequency limitation of keeping records for the 5 years is difficult because of storage, access and retrieval, and orders from multiple physicians. Change in the frequency (that is, the number of times a patient can be tested during a given timeframe) will be considered if the scientific literature supports it. We do not believe we are permitted to change the frequency based solely upon the logistical difficulties in collecting, consolidating, and maintaining administrative data. Modifying the benefit to permit more frequent testing will not resolve these

administrative difficulties. However, we will take this recommendation under advisement as we continue to consider the associated clinical data, but will not make any changes for the final rule.

Comment: One commenter requested that blood be removed from the title of this benefit for the final rule. The commenter believed the narrow focus on blood would restrict the types of tests that would be administered for detecting CV disease.

Response: In developing the proposed rule, we included blood in the title of this benefit to be consistent with the history of this benefit and to distinguish the tests in the benefit. We believe that noninvasive tests could be covered and this benefit is not limited only to blood tests.

Comment: One commenter suggested that the CV screening benefit include an appropriate screening instrument. As with depression, the examining physician has a test based on clinical practice guidelines to use as a tool for assessing the patient. Since the American Heart Association (AHA) and the ACC Guidelines for PAD are expected to be published in 2005, the commenter is requesting that we adapt the patient assessment and include these guidelines under the CV screening benefit.

Response: Since the publication of the AHA and ACC Guidelines has not taken place, it would be difficult to evaluate this document and how physicians would use this in the course of examining a patient. Physicians may use their best judgment for how they assess an individual patient and whether additional specific tests from the AHA and ACC guidelines would be more helpful than what is already included in the screening benefit for CV disease is not something we can conclude at this time. The NCD process is available when additional tests should be considered.

#### Result of Evaluation of Comments

After reviewing all the comments, we have plans to include the V codes (V81.0, V81.1 and V81.2) in the Laboratory Edit Module, and to release manual and transmittal instructions and information to smooth the transition for the new benefit. Providers who routinely give ABNs to beneficiaries must include in the ABN that the frequency limitation is the reason for which Medicare will deny coverage. A patient who has an ABN and exceeds the frequency limitation may incur out-of-pocket charges. We will finalize the changes to §410.17 as proposed.

#### D. Section 413—Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments

[If you choose to comment on issues in this section, please include the caption "HPSA Zip Code Areas" at the beginning of your comments.]

Section 413(a) of the MMA provides a new 5 percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs). The MMA added a new section 1833(u) of the Act that provides for paying primary care physicians furnishing services in a primary care scarcity county and specialty physicians furnishing services in a specialist care scarcity county an additional amount equal to 5 percent of the amount paid for these services.

Section 1833(u) of the Act defines the two measures of physician scarcity as follows:

1. Primary care scarcity areas--determined by the ratio of primary care physicians to Medicare beneficiaries. A primary care physician is a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist.
2. Specialist care scarcity areas--determined by the ratio of specialty care physicians to Medicare beneficiaries. The specialist care PSA ratio includes all physicians other than primary care physicians as defined in the definition of primary care scarcity areas.

To identify eligible primary care and specialist care scarcity areas, we ranked each county by its ratio of physicians to Medicare beneficiaries. In accordance with the statute, in the list of primary care and specialist care scarcity counties, only those counties with the lowest ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties were considered eligible for the 5 percent incentive payment. In accordance with the section 1833(u) of the Act, we also treated a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification) as an equivalent area (that is, equal to a full county).

Consistent with section 1833(u)(4)(C) of the Act, all PSAs were assigned their 5-digit zip code area so that we may automatically provide the 5 percent incentive payment to eligible physicians. For zip codes that cross county boundaries, we used the dominant county of the postal zip code (as determined by the U.S. Postal Service) to identify areas eligible to receive the 5 percent payment. Section 1833(u)(4)(C) of the Act also requires us to publish a list of eligible areas as part of the proposed and final physician fee schedule rules for the years for which PSAs are identified or revised and to post a list of PSAs on our

website. See Addenda J and H for the zip codes of primary care and specialist care PSAs. The PSA lists by zip code and county are also available on our website at [www.cms.hhs.gov/providers/bonuspayment](http://www.cms.hhs.gov/providers/bonuspayment). Since we are publishing these lists for the first time in this final rule with comment period, we are accepting comments for 60 days after the date of publication of this regulation on the zip codes and counties qualifying as physician scarcity areas and will address the comments in next year's fee schedule.

In addition to creating of the 5 percent PSA incentive payment, section 413 of the MMA amended section 1833(m) of the Act to mandate that we pay the 10 percent health professional shortage areas (HPSA) incentive payment to eligible physicians in full county HPSAs without any requirement that the physician identify the HPSA area. We can only achieve this result by assigning zip codes to eligible areas. See Addenda I and K for the lists of eligible primary care and mental health HPSAs by zip code. Consistent with the Act, we have also posted a list of links on our website at [www.cms.hhs.gov/providers/bonuspayment](http://www.cms.hhs.gov/providers/bonuspayment) to assist those physicians located in eligible areas where automation is not feasible, that is, the eligible area could not be assigned a zip code.

In the August 5, 2004 proposed rule, we proposed conforming changes to our regulations to add §414.66 to

provide a 5 percent incentive payment to eligible physicians furnishing covered services in eligible PSAs. We also proposed conforming changes to our regulations to add §414.67 to codify the 10 percent incentive payment to eligible physicians furnishing covered services in eligible HPSAs, established under the Omnibus Budget Reconciliation Act of 1987 (OBRA) (Pub. L. 100-203), previously implemented through manual issuance.

We received 23 letter comments on the bonus payment provisions of section 413 of the MMA. A summary of those comments and our responses follows:

Comment: One commenter questioned the rationale behind using zip codes for the purpose of identifying eligible areas for physician bonuses. The commenter believes that zip codes are less accurate than political boundaries (counties, census civil divisions, and census tracts).

Response: The statute requires the identification of PSAs on a county basis, except for rural areas (using the Goldsmith Modification). At this time, we can only determine physician scarcity for Goldsmith areas at the zip code level since the Medicare beneficiary data is currently unavailable at the census tract level.

Automation of physician bonus payments can only be achieved by assigning zip codes to eligible areas. That



is, the zip code place of service is the only data element reported on the Medicare claim form that would allow automation.

Comment: A commenter believes that our proposal to identify qualified PSAs and HPSAs by zip code for automatic payment purposes is problematic because zip codes cross county lines. The commenter suggested that a more user-friendly option would be to add a county identifier to the claim form.

Response: The addition of a county code would not resolve the issue of identifying the claims that would have a bonus because not all designated HPSAs and PSAs are full counties. We cannot identify, for an automated payment, services furnished in counties that are only partially designated and Goldsmith areas that are not full counties. In addition, there currently is no place on the standard electronic claims form to accommodate the entry of a county code.

Comment: A commenter requested clarification regarding circumstances when automation of bonus payments is not feasible.

Response: When the boundaries of zip code areas precisely overlay with the boundaries of eligible HPSAs and PSAs, automation of bonus payments is feasible. In other

words, eligible physicians furnishing services to Medicare patients within these zip code areas will automatically receive their bonus payments. We can also automate bonus payments within zip code areas that cross outside of qualified county boundaries as long as the zip code, as determined by the U.S. Postal Service, is dominant to the qualified scarcity county. We cannot automate bonus payments when boundaries of zip code areas only partially coincide with the boundaries of HPSAs and PSAs.

Comment: One commenter requested clarification regarding the application of the billing modifier in determining physician eligibility. The commenter inferred from the proposed rule that, if the zip code is not posted as a qualified area, an eligible physician could still receive a bonus payment if a modifier is used.

Response: Eligible physicians furnishing covered services in a portion of an eligible PSA, which cannot be properly assigned a zip code to permit automation of the bonus payment, would need to include the new physician scarcity modifier on the Medicare claim in order to receive the bonus payment. Lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus are available on our website at

[www.cms.hhs.gov/providers/bonuspayment](http://www.cms.hhs.gov/providers/bonuspayment). If a service is provided in a zip code area that is not listed on the automated payment files, but is within a designated physician scarcity county, the physician must submit the "AR" billing modifier with the service in order to receive the bonus payment. Separate lists for the primary care PSAs and the specialty care PSAs are provided on our website for both the automated zip codes and the counties.

Comment: A commenter requested clarification on what ratios would be used to identify PSAs. The Health Resources and Services Administration (HRSA) uses a national ratio of 3,500:1, or 3,000:1 if high needs are shown. The commenter requested information on which ratios would be used to determine PSAs for specialty providers, and whether the ratios would be different for different specialty care providers.

Response: Only those counties with the lowest primary care ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties will be considered eligible for the 5 percent incentive payment. In other words, we ranked each county by its ratio of physicians to beneficiaries and then designated counties as scarcity areas with the lowest ratios until 20 percent of the Medicare population was reached. A separate specialist

physician ratio was calculated to identify specialist care PSAs using the same methods stated. The statutory mandate precludes us from adopting a national physician-to-patient ratio similar to the HPSA designations. By statute, the 20 percent population threshold must serve as the qualifying condition for all counties/rural areas.

For calculating the ratios, section 1833(u)(6) of the Act, as added by the MMA, defines a primary care physician as a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist. In accordance with the statute, all other physicians were grouped together as specialists for purposes of determining the specialist care PSA list.

Comment: A commenter requested clarification regarding the frequency of updating the eligible zip code list for automatic HPSA bonus payments and its impact on otherwise eligible physicians.

Response: Determination of zip codes eligible for automatic HPSA bonus payment will be made on an annual basis, and there will not be any mid-year updates. We will effectuate revisions made to designations by HRSA the following year for purposes of automatic bonus payments. Consequently, if HRSA changes to the HPSA designations remove physicians in those areas from receiving automatic

payment, the zip code areas will remain eligible until the next year when we remove the zip code from our approved list.

Eligible physicians furnishing covered services in newly-designated HPSAs are permitted to add a modifier to their Medicare claims to collect the HPSA incentive payment until our next annual posting of eligible zip codes for automation of bonus payments. In cases where a zip code cannot be properly assigned to the newly-qualified HPSA, physicians furnishing services in the area must continue to bill for the incentive payments using the appropriate modifier.

Comment: A commenter requested that we provide FQHCs with the 5 percent PSA incentive payment. Since the statute does not explicitly exclude other physicians' services (that are billed on an all-inclusive basis), such as those provided in FQHCs or RHCs, the commenter stated that we should extend the new 5 percent bonus payment to FQHC physicians.

Response: As defined in section 1861(aa) of the Act, FQHC and RHC services are not physicians' services, even though physicians' services are frequently a component of the services furnished in these facilities. The services are rather identified as FQHC services. Therefore,

services furnished by these providers are not eligible for the incentive payment.

Comment: A commenter has questioned our proposal not to apply the new 5 percent physician incentive payment to the technical component of physicians' services. The commenter stated that extending the new bonus payment to both the professional and technical component of the physicians' services is consistent with Congressional intent and would simplify claims processing.

Response: Section 1833(u) of the Act provides for incentive payments for physicians' services furnished in PSAs. We note that the statute contains two definitions of physicians' services. The first, which appears at section 1861(q) of the Act, defines physicians' services as "professional services performed by physicians including surgery, consultation, and home, office, and institutional calls." The second, which refers to services paid under the physician fee schedule, is found at section 1848(j)(3) of the Act and contains a broader definition of physician services. However, that definition applies only for purposes of section 1848 of the Act.

Since the incentive payment is not included in section 1848 of the Act, the definition of physicians' services specified in section 1861(q) of the Act is the definition

that applies. Thus, we believe the best reading of the statute is that only professional services furnished by physicians are eligible for incentive payments.

Comment: A commenter recommended that we extend the HPSA bonus payment to all physicians, regardless of their specialty, when their services are furnished within a mental health HPSA. The commenter believes there is no statutory basis to limit incentive payments just to psychiatrists within mental health HPSAs.

Response: We provide HPSA bonus payments in primary medical care HPSAs to all physicians regardless of specialty (including psychiatrists) in light of the fact that there is significant overlap between primary medical care HPSAs and mental health HPSAs. Furthermore, most primary medical HPSAs, especially in rural areas, also have shortages of specialists. Consequently, there is no apparent need to distinguish between physician specialties within primary medical care HPSAs for determining physician eligibility for bonus payment purposes. However, in the situation where the mental health HPSA does not overlap with a primary medical care HPSA, we allow only psychiatrists to collect the incentive payment. Within these stand-alone mental health HPSAs, there is an adequate supply of physicians for the provision of medical services

and a shortage only of those providing mental health services. Therefore, it would be inconsistent with the HPSA incentive payment provisions, as well as an inappropriate use of the Medicare Trust Fund, to pay bonuses to physicians who furnish medical services in service areas without shortages of primary medical services.

Comment: A commenter requested that we count only those practicing physicians who treat Medicare patients when determining the ratio of beneficiaries to practicing physicians. To count all practicing physicians, including those who do not treat Medicare patients would undermine the intent of the provision.

Response: The statute does not permit us to count only Medicare participating physicians to determine PSAs. The statute explicitly requires that we calculate the primary and specialist care ratio by the number physicians in the active practice of medicine or osteopathy within the county or rural area. Therefore, we must include in the physician tally all actively practicing physicians when determining PSAs.

Comment: A commenter asked that we clarify our methods for determining the number of primary care and specialty care physicians to calculate the



physician-to-beneficiary ratio for identifying PSAs. The commenter suggested that we use only the number of practicing physicians when determining the beneficiary to physician ratio, that is, distinguish between licensed physicians and practicing physicians when determining ratios of primary care and specialty care since some physicians continue to be licensed after they retire.

Response: As required by section 413 of the MMA, the determination of eligible PSAs is based on the ratio of "active practice" physicians to Medicare beneficiaries within a county or rural area (using the Goldsmith Modification). The physician data source used in calculating scarcity areas is contained in the following:

- The 2001 Physician Characteristics file; and
- The 2001 Physician Address file.

These data are a compilation of:

- The December 2001 AMA Master file;
- The December 2001 American Osteopathic Association (AOA) Physician file; and
- The National Health Service Corps 2001 participant listing.

These physician data files allow for the identification of the physician's active status. Some of the key status

indicators to identify practicing physicians include "clinically active" and "Federal employment" status. Clinically active status was determined using the type of practice, professional employment, and major professional activity fields from AMA and AOA. For example, determining non-active status is based on physicians who--

- (1) Are involved in administration, medical teaching, research, and other non-patient care activities; or
- (2) Have self-identified as fully retired or otherwise inactive.

We believe that the indicator field of "fully retired or otherwise inactive" addresses the specific issue of a physician maintaining his or her license after he or she retires.

Comment: A commenter expressed concern about our use of the AMA database to determine the number of licensed physicians engaged in direct patient care in each State. The commenter claims that the AMA database overstates the number of practicing physicians in the State of California by at least 10,000 physicians. In light of this concern, the commenter stated that we should use State medical board licensing information rather than the AMA database in determining the physician counts.

Response: The physician data source used in calculating scarcity areas is contained in the 2001 Physician Characteristics file and the 2001 Physician Address file. These data are a compilation of the December 2001 AMA Master file, the December 2001 AOA Physician file, and the National Health Service Corps 2001 participant listing. We made the decision to use the AMA Master file as well as the other files as the sources of physician data in scarcity calculations because there is no other adequate source of national physician data. It may be possible to obtain physician data from each individual State agency, but doing so would entail considerable administrative and technical difficulties. Furthermore, methods of gathering and compiling data may be inconsistent in different States. State agencies may vary greatly in terms of the methods used to update physician databases, the frequency of updates, how the data are stored, the type of information collected, and so forth. In addition, States may use their own classification systems for physician specialties, types of practice, and other key information, and these systems may change over time.

Comment: A commenter encouraged us to implement similar incentive payment programs for non-physician

practitioners, for example, Certified Registered Nurse Anesthetists and physician assistants.

Response: We do not have the authority to provide bonus payments to non-physicians. Sections 1833(m) and 1833(u) of the Act authorize bonus payments only to physicians.

Comment: A commenter requested that we immediately publish the already identified PSAs by zip code and specify the specialties in short demand within each eligible PSA.

Response: Lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus, are now available on our website at [www.cms.hhs.gov/providers/bonuspayment](http://www.cms.hhs.gov/providers/bonuspayment). See Addenda J and H for the zip code list of PSAs for primary care and specialist care.

We have forwarded to the Health Resources and Services Administration the request for identification of specialties in short supply within PSAs. That Agency has responsibility for physician manpower issues.

Comment: A commenter requested that the list of scarcity areas should be made interim in the final fee schedule rule in order to give physicians sufficient time to review and comment on the proposal.

Response: Although we made these lists public on our website on October 1, 2004, we will accept comments for 60 days after the date of publication of this regulation on the zip codes and counties qualifying as physician scarcity areas and will address the comments in next year's fee schedule.

Comment: A commenter expressed appreciation for our effort to fairly implement the incentive payments to physicians in scarcity areas. As this new incentive payment program is implemented, physicians must be informed that this bonus is available, and it must be simple for them to receive the bonus.

Response: We have already made available on our website at [www.cms.hhs.gov/providers/bonuspayment](http://www.cms.hhs.gov/providers/bonuspayment) the lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus. We have also issued a Medlearn article to educate the physician community regarding Medicare physician incentive payment programs. For a copy of this provider education article go to: [www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0449.pd](http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0449.pd). Lastly, Medicare's contractors have established their own website links for the HPSA incentive payment program to

facilitate the payment of these bonuses to eligible physicians.

Comment: A commenter expressed support of our proposed changes relating to incentive payments for services provided in areas designated as HPSAs and PSAs. The commenter also commended us for our prompt implementation of section 413 of the MMA. Another commenter expressed appreciation that the new 5 percent incentive is available to specialists in counties with short supply of these physicians.

Response: We appreciate this positive feedback from the provider community.

Comment: A commenter has questioned the rationale for our policy of imposing, as a condition of eligibility, the requirement that the specific location at which the service is furnished must be considered a HPSA or PSA. Since physicians do not always reside in the county where they provide services, identifying PSAs on one basis and paying for them on another basis may be problematic.

Response: According to section 1833 of the Act, we make bonus payments for physicians' services furnished in an eligible HPSA or PSA. Thus, the place of service controls the availability of the bonus. A physician providing a service in his or her office, a patient's home,

or in a hospital may receive the incentive payment only if the service occurs within an eligible shortage or scarcity area.

Comment: One commenter believes that podiatric physicians, who are considered specialists, should be among those eligible to receive the additional 5 percent incentive payment.

Response: Section 1833(u) of the Act, as added by the MMA, specifically defines "physician" as one described in section 1861(r)(1) of the Act. Therefore, we do not have authority to make bonus payments to podiatrists.

Commenter: A commenter expressed concern that our systems had trouble implementing the HPSA bonuses under Method II for Critical Access Hospital (CAH) participation, and some providers have waited more than two years for increased Medicare payments.

Response: Although some fiscal intermediaries may not have been accustomed to processing physician claims, these systems were updated and the problems resolved as of July 1, 2004.

Comment: A commenter from California requested that physicians who provide Medicare services only through managed care not be included in our calculations. The commenter believes that including physicians who only treat

managed care patients in the count to determine physician scarcity areas will lead to a gross overstatement of the number of physicians available to provide care to fee-for-service Medicare patients.

Response: We do not believe that we have the legal authority to exclude managed care physicians from the ratio calculations. Moreover, excluding managed care physicians in the county-wide physician tally would not change PSAs in California based on our calculations. In fact, excluding the managed care physicians would make five eligible areas ineligible.

#### Result of Evaluation of Comments

We are finalizing \$414.66 and \$414.67 as proposed. We are accepting public comments on the zip code areas.

#### E. Section 303—Payment for Covered Outpatient Drugs and Biologicals

##### 1. Average Sales Price (ASP) Payment Methodology

##### a. Background

Medicare Part B covers a limited number of prescription drugs and biologicals. For the purposes of this proposed rule, the term “drugs” will hereafter refer to both drugs and biologicals. Medicare Part B covered drugs generally fall into the following three categories:

- Drugs furnished incident to a physician’s service.



- Durable medical equipment (DME) drugs.
- Drugs specifically covered by statute (for example, immunosuppressive drugs).

Section 303(c) of the MMA revises the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303(c) of the MMA amends Title XVIII of the Act by adding section 1847A, which establishes a new ASP drug payment system. In 2005, almost all Medicare Part B drugs not paid on a cost or prospective payment basis will be paid under this system.

The new ASP drug payment system is based on data submitted to us quarterly by manufacturers. Payment amounts will be updated quarterly based on the manufacturer's ASP calculated for the most recent calendar quarter for which data are available. We intend to implement the quarterly pricing changes through program instructions or otherwise, as permitted under Section 1847A(c)(5)(C). For calendar quarters beginning on or after January 1, 2004, the statute requires manufacturers to report their ASP data to us for almost all Medicare Part B drugs not paid on a cost or prospective payment basis. Manufacturers' submissions are due to us not later than 30 days after the last day of each calendar quarter.

The methodology for developing Medicare drug payment allowances based on the manufacturer's submitted ASP data is described in this final rule and reflected in final revisions to the regulations at §405.517 and new Subpart K in part 414. Several comments discussed aspects of the manufacturers' calculation of ASP that are beyond the scope of this final rule. We did not propose any changes to the regulations concerning the manufacturer's calculation of ASP. We also received other comments regarding the use of the least costly alternative (LCA) methodology when pricing drugs, and requests for new HCPCS codes for drugs and coverage of compounded drugs. These comments are also outside the scope of this final rule. We did not propose any changes to the LCA policy, the HCPCS process, or coverage of compounded drugs.

b. Provisions of the Final Rule

i. The ASP Methodology

Effective 2005, payment for certain drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005 will be based on an ASP methodology.

As described in section 1847A(b)(3)(A) of the Act for multiple source drugs and section 1847A(b)(4)(A) for single source drugs, the ASP for all drug products included within

the same billing and payment code [or HCPCS code] is the volume-weighted average of the manufacturers' average sales prices reported to us across all the NDCs assigned to the HCPCS code. Specifically, section 1847A(b)(3)(A) of the Act and section 1847A(b)(4)(A) of the Act require that this amount be determined by--

- Computing the sum of the products (for each National Drug Code assigned to those drug products) of the manufacturer's average sales price and the total number of units sold; and
- Dividing that sum by the sum of the total number of units sold for all NDCs assigned to those drug products.

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment allowance for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the HCPCS code. This payment allowance is subject to applicable deductible and coinsurance. The payment limit is also subject to the two limitations described below in section III.E.1.b.v of this preamble concerning widely available market prices and average manufacturer prices in the Medicaid drug rebate program. As described in section 1847A(e) of the Act, the payment limit may also be adjusted in response to a public health emergency under section 319 of the Public Health Service

Act in which there is a documented inability to access drugs and a concomitant increase in the price of the drug which is not reflected in the manufacturer's average sales price.

Section 1847A(b) (1) (B) of the Act requires that the Medicare payment allowance for a single source drug HCPCS code be equal to the lesser of 106 percent of the average sales price for the HCPCS code or 106 percent of the wholesale acquisition cost of the HCPCS code. This payment allowance is subject to applicable deductible and coinsurance. The payment limit is also subject to the two limitations described below in section III.E.1.b.v concerning widely available market prices and average manufacturer prices in the Medicaid drug rebate program. As described in section 1847A(e) of the Act, the payment limit may also be adjusted in response to a public health emergency under section 319 of the Public Health Service Act.

Comment: One commenter suggested that we implement the ASP methodology on a pilot basis prior to a national rollout. A physician interest group recommended that we delay the implementation of the ASP payment system for at least one year. The interest group stated that we should inform physicians of the ASP for all covered drugs before

the final rule is issued and allow physicians to comment on the proposed rates after an informed and complete review process.

Response: The law requires that the new ASP-based drug pricing system be implemented January 1, 2005. The January 1, 2005 prices will be based on the data submitted to us no later than 30 days after the end of the third calendar year quarter of 2004. Given the requirements surrounding the timing of the promulgation of the physician fee schedule final rule, we will not have the January 1, 2005 prices available before the publication of the final rule. However, our goal is to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the January 1, 2005 effective date of those rates.

Comment: A provider asked that we earmark funds to enable physicians to transition from the AWP-15 percent payment system to the ASP + 6 percent payment system.

Response: We do not have statutory authority to create such a transition fund.

Comment: One commenter stated that the ASP plan does not account for price increases in a timely manner. Another commenter expressed concern that because ASP modifications lag by at least two calendar quarters, market

prices would not be reflected in a drug's payment limit for at least six months after a pricing adjustment.

Response: The ASP methodology is based on average sales prices reported by manufacturers quarterly. Manufacturers must report to us no later than 30 days after the close of the quarter. We implement these new prices through program instructions or otherwise at the first opportunity after we receive the data, which is the calendar quarter after receipt.

Comment: Some commenters expressed concern that the ASP + 6 percent payment methodology would discourage providers from using generic drugs and would increase the tendency to use newer or more expensive agents.

Response: It is true that the higher the average sales price of a drug, the greater amount of money represented by 6 percent of that price. However, Section 1847A specifies that payment is at 106 percent of ASP. The law requires the use of the new ASP + 6 percent payment system except in the limited instances described below in Sections V and VI.

Comment: Several commenters suggested that we should establish a mechanism to provide the public with an opportunity to identify errors in the ASP-based payment rates before the start of the calendar quarter in which the

rates are effective. They believe that this mechanism would minimize errors by permitting posting of the rates several weeks prior to the effective date.

Response: Our goal is to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the effective date of those rates.

Comment: A physician specialty group recommended that we use our inherent reasonableness authority to increase drug payments up to 15 percent where necessary to make the Medicare payment level sufficient to cover the price of drugs charged by specialty distributors that service the physician office market.

Response: We do not have sufficient data to determine whether our inherent reasonableness authority would apply in this instance. Even if our inherent reasonableness authority were triggered, our data are insufficient to determine whether the adjustment the commenters request would be appropriate.

Comment: Several commenters urged us to weigh the full range of potential consequences to patient care, especially in the oncology setting, with the implementation of the ASP payment methodology. They recommended that we take into consideration concerns such as the potential inability of providers to purchase drugs below the new reimbursement rate, the inability of oncologists to provide access to important under-reimbursed support services, and the disproportionate impact of these changes on rural providers

necessitating a shift in care of sick cancer patient from community settings to the hospital. Some commenters suggested that we place a form on its website enabling beneficiaries to identify access problems. One commenter suggested that we perform a 1-year monitoring study to evaluate the quality of care issues and delay implementation until the results of the study are known.

Response: Although we do not expect access problems under the new ASP + 6 percent payment system, we will be monitoring patient access through our 1-800-MEDICARE line, regional office staff, claims analysis, and other environmental scanning activities. We will work with Congress if access issues arise. The law requires that the new ASP-based drug pricing system be implemented January 1, 2005.

Comment: Several commenters expressed concern regarding the statements on joining group purchasing organizations (GPOs) to improve their purchasing power. They indicate that the size of the discount is based on the individual GPO member's purchases, not the combined purchases of the GPO members. Thus, membership in a GPO would not necessarily result in a greater discount. They also point out that retail pharmacies do not have access to GPO purchasing arrangements. One commenter requested that we offer more tangible suggestions for obtaining drugs at



the ASP plus 6 percent price other than encouraging physicians to participate in purchasing groups.

Response: The law requires that the new ASP-based drug pricing system be implemented January 1, 2006. A recent survey of oncology practices performed by the American Society of Clinical Oncology indicated that the purchase price of drugs is not necessarily driven by practice size. It would appear that smaller purchasers are on average sometimes able to achieve similar drug pricing to larger purchasers. The OIG is conducting a study due not later than October 1, 2005, on the ability of different size physician practices in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs at 106 percent of the average sales price. We are currently conducting another MMA-mandated study of sales of drugs to large volume purchasers that is due not later than January 1, 2006. We will seek to work with physicians, providers, and suppliers on ways to encourage prudent purchasing, including to the extent practicable the dissemination of information on lower cost suppliers of Medicare Part B drugs. We would welcome suggestions on ways to accomplish this goal.

Comment: One commenter suggested that classes of trade should be taken into account when establishing ASP

payment rates.

Response: The law does not permit the exclusion of or differentiation by classes of trade in the calculation of the ASP payment rates, except for the specific statutory exceptions described in the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act. The statute specifies a payment rate of 106 percent of ASP.

Comment: A drug manufacturer urges us to reject any requests to publish the NDC-specific ASPs as the publishing of the rates would facilitate inappropriate conduct.

Response: The law does not permit the disclosure of NDC level ASPs in a form that discloses the identity of a specific manufacturer or prices charged by the manufacturer except in accordance with Section 1927(b)(3)(D) of the Act. That provision permits the disclosure of such data as the Secretary determines to be necessary to effectuate the provisions of section 1847A of the Act.

v. Limitations on ASP

Section 1847A(d)(1) of the Act states that "The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the

Inspector General, in consultation with the Secretary, determines to be appropriate.” Section 1847A(d)(2) of the Act states that “Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with--

- The widely available market price for such drugs and biologicals (if any); and
- The average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.”

Section 1847A(d)(3) of the Act states that “The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).” Section 1847A(d)(3)(B) states that “the term “applicable threshold percentage” means--

- In 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and
- In 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the

Secretary may specify for the widely available market price or the average manufacturer price, or both."

Section 1847A(d) (3) (C) of the Act states that "If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of--

- The widely available market price for the drug or biological (if any); or
- 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological."

Comment: One commenter urged us to provide further guidance on the widely available market price (WAMP) methodology, specifically how the OIG will compare ASP to WAMP. The commenter also requested guidance on how WAMP will be determined in the case of multiple drugs represented by a single J-code. Other commenters stated

that we should provide greater guidance for how it will substitute WAMP for ASP. These commenters also suggested that we provide guidance on how it will treat quarterly oscillations between ASP and WAMP.

Response: The OIG is developing its methodology regarding the widely available market price. Because the determination of WAMP is within OIG's purview, we believe it is premature to address the implementation issues prior to the OIG establishing its methodology and conducting its first review.

Comment: Several commenters recommend that we make adjustments where there is a disparity between the ASP-based payment limit and the physician acquisition cost. These commenters recommended that we raise the payment rate if the WAMP is higher than ASP.

Response: Section 1847A of the Act does not provide authority to increase the ASP-based payment system based on the review of the OIG.

vi. Payment Methodology in Cases Where the Average Sales Price During the First Quarter of Sales is Unavailable

Section 1847A(c)(4) of the Act states that "In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not

sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on--

- The wholesale acquisition cost; or
- The methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals."

Comment: Several commenters requested that we provide guidance on how the payment rate for a new drug in its second calendar quarter will be determined. They recommend that we utilize the same methodology for the 2nd quarter payment as for the 1st quarter; that is, use the WAC or methodologies in effect on November 1, 2003.

Response: Pursuant to section 1847A(c)(4) of the Act, during an initial period (not to exceed a full calendar quarter) where data on prices for sales for a drug are not sufficiently available from the manufacturer to compute an ASP, we will pay based on WAC or the methodologies in effect on November 1, 2003 for a limited period. This time period will start on the date that sales of the drug begin and end at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales.

c. Payment for Influenza, Pneumococcal, and Hepatitis B Vaccines

Section 1841(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of the average wholesale price (AWP) of the drug. The AWP payment rates for these vaccines will be updated quarterly. No commenters objected.

d. Payment for Drugs Furnished During 2005 in Connection With the Furnishing of Renal Dialysis Services if Separately Billed by Renal Dialysis Facilities

Section 1881(b)(13)(A)(ii) of the Act indicates that payment for a drug furnished during 2005 in connection with the furnishing of renal dialysis services, if separately billed by renal dialysis facilities, will be based on the acquisition cost of the drug as determined by the Inspector General(IG) report to the Secretary required by section 623(c) of the MMA or, insofar as the IG has not determined the acquisition cost with respect to a drug, the Secretary shall determine the payment amount for the drug. In the report, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs," the IG found that, on average, in

2003 the four largest chains had drug acquisition costs that were 6 percent lower than the ASP of 10 of the top drugs, including erythropoietin. A sample of the remaining independent facilities had acquisition costs that were 4 percent above the ASP. Based on this information, the overall weighted average drug acquisition cost for renal dialysis facilities is 3 percent lower than the ASP. Therefore, we proposed that payment for a drug or biological furnished during 2005 in connection with renal dialysis services and separately billed by renal dialysis facilities will be based on the ASP of the drug minus 3 percent. We proposed to update this quarterly based on the ASP reported to us by drug manufacturers.

We received numerous comments regarding our proposed payments rate of ASP minus 3 percent. Those comments and responses are provided below.

Comment: Commenters questioned the basis for our decision to pay for separately reimbursed drugs at a rate of ASP minus three percent. These commenters stated that ASP minus 3 percent was not acquisition cost as determined by OIG and did not reflect the acquisition cost relationship between these drugs. Some commenters questioned the relationship between the ASP definition used by the OIG and the current definition. Commenters stated



that we should base the payment rates on the acquisition cost of each drug as reported by the OIG updated to 2005 rather than an ASP-based formula. Some commenters indicated that the acquisition cost should be updated to 2005 and suggested an update using the same annual factor used for budget neutrality calculations. For drugs not included in the OIG report, some commenters suggested that we use the same methodology for most other Medicare Part B drugs, namely ASP plus 6 percent. Commenters indicated we should consider two tiers of payment based on provider size to minimize the discrepancy between large and small providers or in the absence of two tiers base the payment on the acquisition cost of the facilities not owned or managed by the four largest providers. Commenters also asked for clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital based ESRD facilities since these drugs historically were not paid based on AWP but rather based on reasonable cost.

Response: We agree with the commenters who suggested we base the 2005 payment rates for separately billable ESRD drugs on the actual dollar value of the acquisition costs as determined by the IG rather than the acquisition costs relative to the ASP. We also agree that we should update the IG acquisition costs to calculate 2005 rates. After

consideration of the available price data, we have determined that the Producer Price Index (PPI) for prescription preparations is the most appropriate price measure for updating EPO and other separately billable drugs from 2003 to 2005. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) for prescription drugs reflects price changes at the retail stage. Because EPO and many of the separately billable drugs used by dialysis facilities are purchased directly from the manufacturer, the use of a price index that measures wholesale rather than retail prices is more appropriate. The PPI for prescription drugs is the measure used in the various market baskets that update Medicare payments to hospitals, physicians, skilled nursing facilities, and home health agencies. In addition, the PPI for prescription drugs was recommended for use in the proposed composite rate market basket detailed in the 2003 Report to Congress.

Based on historical data through the second quarter of 2004, we used the Global Insight Inc. forecast of the PPI for prescription drugs to determine the update factors for 2004 and 2005. We feel the use of an independent forecast,

in this case from Global Insight Inc., is superior to using the Naational Health Expenditure projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases for Medicare prospective payment systems.

We also agree with those commenters who suggested that the drugs not contained in the IG study should be paid at ASP plus 6 percent. We believe it is appropriate for the payment amount for these drugs when separately billed by ESRD facilities during 2005 to be the same as the payment amount for other entities that are paid by Medicare on other than a cost or prospective payment basis. We do not agree with commenters that we should establish separate drug payment rates for large and small providers. For reasons discussed in the section of this final rule on the ESRD composite rate, we believe it is appropriate to establish a single add-on payment to the composite rate and therefore appropriate to establish the same drug payment rates for both large and small providers. We do not believe it is appropriate to base the payment amount on only the higher acquisition cost of the facilities not owned or managed by the four largest providers and not take into account the acquisition costs of the largest four providers who represent the majority of the drug

expenditures. Section 1881(b)(13)(A)(ii) of the Social Security Act refers to "the acquisition cost of the drug or biological" and not the acquisition costs of the drug or biological. In accordance with the statute and our understanding of Congressional intent for 2005, we believe it is more appropriate to base the 2005 payment amounts on a weighted average of the acquisition costs of the four largest providers and the other facilities rather than base the 2005 payment amounts solely on the acquisition costs of the other facilities.

In response to the commenters who requested clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities, we did not propose changes to the reasonable cost payment basis for these drugs. The OIG did not study separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities and accordingly, we did not propose to change the payment basis for these drugs.

e. Payment for Infusion Drugs Furnished through an Item of DME

In 2005, section 1841(o)(1)(D)(i) of the Act requires that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent

of the average wholesale price for that drug in effect on October 1, 2003. No commenters objected.

## 2. Drug Administration Payment Policy and Coding Effective in 2005

Section 1848(c)(2)(J) of the Act (as added by section 303(a) of the MMA) requires the Secretary to promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for those services, taking into account levels of complexity of the administration and resource consumption. According to section 1848(c)(2)(B)(iv) of the Act (as amended by section 303(a) of the MMA), any changes in expenditures in 2005 or 2006 resulting from this review are exempt from the budget neutrality requirement of section 1848(c)(2)(B)(ii) of the Act. The statute further indicates that the Secretary shall use existing processes for the consideration of coding changes and, to the extent changes are made, shall use those processes to establish relative values for those services. The Secretary is also required to consult with physician specialties affected by the provisions that change Medicare payments for drugs and drug administration.

The AMA's CPT Editorial Panel established a workgroup, with representatives from affected specialties that met earlier this year to develop recommendations to the CPT

Editorial Panel in August. Based on these recommendations, that panel adopted several new drug administration codes and revised several existing codes. Subsequently, the AMA's Relative Value Update Committee (RUC) met at the end of September to make recommendations to us on the practice expense resource inputs and work relative values for the new and revised drug administration codes.

We indicated in the proposed rule that we would consider whether it is necessary for us to make coding changes effective January 1, 2005 through the use of G-codes (because the 2005 CPT book will have already been published), and we requested public comment. As described in detail below, we are establishing new G-codes for 2005 that correspond with the new CPT codes that will become active in 2006. These new G-codes are interim until 2006.

The new CPT codes can be categorized into the following three categories of drug administration services: infusion for hydration; nonchemotherapy therapeutic/diagnostic injections and infusions other than hydration; and chemotherapy administration (other than hydration) which includes infusions/injections. There are some important changes in the new codes relative to current drug administration coding. The infusion of substances such as monoclonal antibody agents or other biologic

response modifiers is reported under the chemotherapy codes, instead of the nonchemotherapy infusion codes, as is currently the case. There are also new codes in both the chemotherapy and nonchemotherapy sections for reporting the additional sequential infusion of different substances or drugs.

As we stated in the proposed rule, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue. We also note that the MMA requires the Medicare Payment Advisory Commission (MedPAC) to study how the changes in payments for drugs and drug administration affect other specialties.

We received many comments on various aspects of coding and payment for drug administration services in response to the proposed rule. We are also responding below to comments we received on the January 7, 2004 interim final rule with comment period that announced the provisions of section 303 of the MMA affecting drug administration services that took effect in 2004 (69 FR 1094). Specifically, section 303 of the MMA required the following changes in 2004: a transitional adjustment that increases

payments for specific drug administration services by 32 percent in 2004 (and 3 percent in 2005); establishing work RVUs for certain drug administration services equal to the work RVUs for a level 1 office medical visit for an established patient; the incorporation of supplemental survey data in the calculation of the practice expense RVUs for drug administration codes; and allowing oncologists to bill for multiple drug administrations by the 'push' technique on a single day.

Comment: Many commenters supported the efforts to promptly evaluate existing drug administration codes to ensure accurate reporting and billing for services. They support our proposal to use G-codes until the new CPT codes are active. They asked us to adopt the recommendations of the CPT Editorial Panel for new drug administration codes.

Response: We appreciate the support of the commenters of all of the efforts to expeditiously review and update these codes. We also would like to specifically recognize the efforts of the CPT Editorial Panel's Drug Administration Workgroup to develop the new CPT codes, the Editorial Panel for its consideration and approval of the new codes, and the RUC for its similar efforts to develop recommendations for the inputs for the new codes.

We have reviewed the recommendations of the CPT Editorial Panel and, with one exception noted below, agree



with their new and revised codes for drug administration for 2005. Because the new CPT codes will not be included in the 2005 CPT, we have decided to establish G-codes, where applicable. At this time, we anticipate these new G-codes will be temporary until the new CPT codes become active January 1, 2006.

A listing of the old CPT codes and their corresponding G-codes are in the table below. Some of the old CPT codes will correspond to more than one G-code, and there are codes that will allow physicians to bill for services that previously did not have a code or were bundled into other services.

The drug administration codes are divided into three categories: infusion codes for hydration; codes for therapeutic/diagnostic injections and ; and chemotherapy administration codes. The descriptions of the codes below are taken primarily from the AMA CPT Editorial Panel. We are including these specific descriptions here in order to provide as much information as possible about the new G-codes prior to their implementation on January 1, 2005. However, we anticipate that we will issue further instructions regarding the appropriate use of these G-codes, including clarifications, interpretations, and other modifications to the following guidance (apart from the G-

codes themselves) as part of any instructions issued through a subregulatory process.

The codes for hydration (G0345 and G0346 in the table below) are for reporting hydration intravenous (IV) infusions consisting of a prepackaged fluid and electrolytes. These codes are not used to report infusion of drugs or other substances. The codes for chemotherapy administration are to be used for reporting the administration of non-radionuclide anti-neoplastic drugs, and anti-neoplastic agents provided for treatment of noncancer diagnoses, or substances such as monoclonal antibody agents and other biologic response modifiers. The remaining codes are for reporting injections and infusions for all drug administrations that were previously reported using CPT codes 90780-90788, 96400, and 96408-96414 (other than those described above as hydration or chemotherapy).

**TABLE 8:** Comparison of old CPT codes to G codes

#### Hydration

Old CPT	G Code	Descriptor
90780	G0345	Intravenous infusion, hydration; initial, up to one hour
90781	G0346	each additional hour, up to eight (8) hours

## Injections and Infusions (Non-Chemotherapy, other than hydration)

Old CPT	G Code	Descriptor
90780	G0347	Intravenous infusion, for therapy/diagnosis, initial, up to one hour
90781	G0349	additional sequential infusion, up to one hour
90781	G0348	each additional hour, up to eight (8) hours
N/A	G0350	Concurrent infusion

Old CPT	G Code	Descriptor
90782	G0351	Therapeutic or diagnostic injection
90783	N/A	intra-arterial
90784	G0353	intravenous push, single or initial substance/drug
N/A	G0354	each additional sequential intravenous push
90788	N/A	Intramuscular injection of antibiotic
90799	N/A	Unlisted injection or infusion

## Chemotherapy Administration

Old CPT	G Code	Descriptor
96400	G0355	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96400	G0356	hormonal anti-neoplastic
96405	N/A	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	N/A	intralesional, more than 7 lesions
96408	G0357	intravenous, push technique, single or initial substance/drug
96408	G0358	intravenous, push technique, each additional substance/drug
96410	G0359	Chemotherapy administration, intravenous infusion technique; Up to one hour, single or initial substance/drug
96412	G0360	each additional hour, one to eight (8) hours
96414	G0361	initiation of prolonged chemotherapy infusion
96412	G0362	each additional sequential infusion, up to one hour
96420	N/A	Chemotherapy administration, intra-arterial; push technique
96422	N/A	infusion technique, up to one hour
96423	N/A	infusion technique, each additional hour, one to eight hours
96425	N/A	infusion technique, initiation of prolonged infusion (more than eight hours)
96440	N/A	Chemotherapy administration into pleural cavity
96445	N/A	Chemotherapy administration into peritoneal cavity
96450	N/A	Chemotherapy administration into CNS
96520	N/A	Refilling and maintenance of portable pump
N/A	G0363	Irrigation of implanted venous access device for drug delivery systems
96530	N/A	Refilling and maintenance of implantable pump
96542	N/A	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous

	reservoir, single or multiple agents
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The following coding guidance is based on the CPT Editorial Panel's explanatory language for the new CPT codes. As noted above, we plan to issue further guidance as needed.

Infusions that were previously reported under CPT code 90780 (non-chemotherapy infusion, 1st hour) will be billed under one of three G-codes beginning January 1, 2005. The first hour of a hydration infusion will be billed under G0345. The first hour of infusion of a nonchemotherapy drug other than hydration will be billed under G0347. The first hour of infusion of anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents and other biologic response modifiers is billed under G0359.

Similarly, services that were previously reported under CPT code 90781 (non-chemotherapy infusion, each additional hour) will be billed under one of four G-codes beginning January 1, 2005. Each additional hour of a hydration infusion will be billed under G0346. Each additional hour of a nonchemotherapy infusion will be billed under G0348. Currently, if a second (or other subsequent) nonchemotherapy drug is administered sequentially, the physician would bill code 90781 for the additional hour of infusion. Under the new G-codes, the

physician will bill G0349, the sequential administration of a second or subsequent nonchemotherapy drug. In addition, each additional hour of the infusion of anti-neoplastic agents for the treatment of noncancer diagnoses or substances such as monoclonal antibodies and other biological modifiers is billed under G0360.

Injectons that were previously billed under CPT code 90782 will now be billed under HCPCS code G0351. Physicians should use HCPCS code G0352 for injections previously billed under CPT code 90783. Nonchemotherapy drugs administered by IV push (currently using CPT code 90784) should now be billed under HCPCS code G0353. The CPT book does not currently contain a code for physicians to bill a second (or other subsequent) nonchemotherapy drug administered by IV push. The CPT Editorial Panel created a new code for each additional nonchemotherapy drug administered by IV push. For 2005, the physician should bill HCPCS code G0354.

The CPT coding system will be deleting code 90788 (Intramuscular injection of antibiotic) in 2006. We are maintaining CPT code 90788 as an active code until it is changed in the CPT coding system and instructions are provided on the code to bill in its place beginning January 1, 2006.

Chemotherapy injections, previously billed under the CPT code 96400, will now be billed using one of two new G-codes. For injection of nonhormonal anti-neoplastic drugs, the physician should bill HCPCS code G0355. For injection of hormonal anti-neoplastic drugs, the physician should bill HCPCS code G0356. CPT is not recommending any changes to CPT codes 96405 (Chemotherapy administration; intralesional, up to and including 7 lesions) and 96406 (more than 7 lesions), and these codes will remain active for Medicare in 2005.

Chemotherapy drugs administered by IV push (currently billed under CPT code 96408, or, if the drug meets the expanded definition of chemotherapy including monoclonal antibodies or other biologic response modifiers, currently billed under CPT code 90784) should be billed using G0357 for the initial drug administered. In 2004, Medicare paid for the second (or other subsequent) chemotherapy drug administered by IV push under CPT code 96408. CPT will be establishing a code that recognizes the resource inputs associated with each additional chemotherapy drug administered by IV push. For 2005, the analogous code to bill the second (or other subsequent) chemotherapy drug administered by IV push is G0358.

The first hour of chemotherapy administration, previously billed under CPT code 96410, should now be billed under CPT code G0359. Each additional hour of chemotherapy (previously billed under CPT code 96412) should now be billed under CPT code G0360. CPT is also recommending a new code for the first hour of a different chemotherapy drug administered sequentially by infusion. If a second chemotherapy drug is administered sequentially, the physician should bill for HCPCS G0362 for the first hour of infusion of the second drug. All additional hours (up to eight total hours) of chemotherapy infusion should be billed using HCPCS code G0360. Prolonged chemotherapy infusions (8 hours or more, previously billed under code 96414) should be billed in 2005 using HCPCS code G0361.

For three codes (G0350, G0354, G0363), the table above has an "N/A" listed in the "Old CPT" column, meaning there were no CPT codes that existed explicitly for these services. These services will now be billable under the new coding system. For instance, CPT will be establishing a code for a "concurrent infusion." A concurrent infusion refers to the simultaneous infusion of two nonchemotherapy drugs. We are using temporary code G0350 for this service. Code G0350 is an add-on code. It must be reported as an "add-on" or with another code and our payment reflects the

incremental resources associated with infusing the second drug. For example, if two nonchemotherapy drugs are infused concurrently, the physician bills G0347 for the initial drug infused and G0350 as an add-on.

As indicated above, HCPCS code G0354 is a new code for each additional sequential nonchemotherapy drug administered by IV push. HCPCS code G0354 is also an add-on code. In general, G0354 will be an add-on to G0353. However, it is possible that a nonchemotherapy drug administered by IV push may follow the administration of a chemotherapy drug administered by IV push, and HCPCS code G0354 would then be an add-on to HCPCS code G0357.

HCPCS code G0363 is a new code for irrigation of an implanted venous access device. There is currently no code to describe this service. Medicare will pay for G0363 if it is the only service provided that day. If there is a visit or other drug administration service provided on the same day, payment for this service is bundled into payment for the other service.

We are creating the following new add-on G-codes: G0346, G0348, G0349, G0350, G0354, G0358, G0360 and G0362. As indicated above, add-on codes must be billed with other codes, and our payment reflects the incremental resources associated with providing the additional service. The



initial codes that these add-on codes could potentially be billed with include: G0345, G0347, G0353, G0357 and G0359. If a combination of chemotherapy, nonchemotherapy drugs, and/or hydration is administered by infusion sequentially, the initial code that best describes the service should always be billed irrespective of the order in which the infusions occur.

Comment: In the January 7, 2004 interim final rule with comment, we revised our payment policy for pushes of chemotherapy drugs to allow for payment of multiple pushes of different chemotherapy agents in one day. A commenter asked that we revise our policy for multiple pushes of nonchemotherapy agents, to allow multiple billings on a single day.

Response: The CPT/RUC recommendations address this comment. New codes have been created to account for the resources associated with multiple chemotherapy and nonchemotherapy drugs administered by IV push. HCPCS code G0353 is used for the initial IV push of a nonchemotherapy drug, while HCPCS code G0354 is used for each additional push of a nonchemotherapy drug. For chemotherapy drugs administered by IV push, HCPCS code G0357 is used for the first drug administered, while HCPCS code G0358 is used for each additional drug.

We also note that existing CPT codes 90782-90788 (Therapeutic, prophylactic or diagnostic injections) currently have a status indicator of "T", which means that payment for the service is bundled unless it is the only service billed by the physician for the patient that day. However, based on the RUC recommendations and the resulting values for the injection services, we are making the status indicator on HCPCS codes G0351 - G0354 an "A", which will allow them to be separately paid even if another physician fee schedule service is billed for the same patient that day.

Comment: A commenter stated that, given the increased work and practice expense RVUs for drug administration codes, it follows that both the work and practice expense RVUs for the immunization administration codes (90471, 90472, 90473, and 90474) should also be increased. The commenter argued that the service involved in administering vaccines is more intense/complex than the service involved in the drug infusion codes.

Response: We agree with the commenter that the physician work and practice expenses associated with administering injections are similar to immunizations. In addition, we would point out that we currently pay for vaccine administrations (G0008-G0010) based on crosswalking

the RVUs to CPT code 90471. Therefore, any changes to the physician work and practice expense RVUs for code 90471 would also affect payments for vaccine administrations.

Because we agree these services should be similar in the amount of physician work involved, we are assigning the physician work value recommended by the RUC for code 90782 (G-code G0351) to code 90471 and HCPCS G-codes G0008-G0010. We are combining the utilization data for all of these codes to determine a single practice expense RVU that will be applied to each of these codes.

We are also assigning a work RVU of 0.15 to code 90472. Codes 90473 (Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)) and 90474 (Each additional vaccine (single or combination vaccine/toxoid)) are currently not covered. We are changing the status of these codes to "R", or restricted, meaning they are payable under some circumstances after carrier review. These codes will be carrier priced.

Comment: If a patient receives chemotherapy infusions, CPT code 96410 is used to report the infusion of the first drug up to one hour. Chemotherapy drugs are usually administered sequentially. Thus, if a patient receives the administration of a second chemotherapy drug

at the same treatment session, CPT code 96412 is used to report the infusion of the second drug for each additional hour of infusion. In 2004, the national payment, including the transitional payment adjustment of 32 percent, for CPT code 96410 is \$217. The comparable payment for CPT code 96412 is \$48.

Commenters pointed out that this policy does not take into account the levels of complexity of administration and resource consumption. The administration of multiple drugs requires additional preparation time, supplies, and patient education, not currently accounted for in CPT code 96412.

Response: The CPT/RUC recommendations addressed this issue. We are implementing new code G0362, Chemotherapy administration, intravenous technique; each additional sequential infusion, up to one hour. This code will allow, effective January 1, 2005, physicians to begin to bill for the first hour of chemotherapy of the second chemotherapy drug administered.

Comment: Several commenters requested clarification that the changes to the drug administration codes resulting from the CPT changes and our G-codes would be exempted from budget neutrality by the provision at section 1848(c)(2)(B)(iv)(III), as added by MMA section 303(a)(1). This provision stipulates that the evaluation of the

existing drug administration codes described above as leading to the interim G-codes and the new CPT codes for 2006, is to be exempt from budget neutrality.

Response: The commenters are correct that the additional expenditures that result from the interim G-code changes we are implementing in this rule are exempt from budget neutrality.

Comment: Several commenters asked that we continue payment for drug administration codes at the 2004 levels, which included the 32 percent transitional payment adjustment, instead of paying at the 3 percent transitional payment adjustment for 2005, or adopt other measures. For example, commenters suggested temporary codes to offset the large reductions that would otherwise go into effect in 2005.

Response: Section 303(a)(4) of the MMA is very specific on the application of the transitional payment adjustments in 2004 and 2005. We do not have the legal authority to continue payments based on the 2004 payment levels. In 2005, the transitional adjustment percentage for drug administration decreases from 32 percent to 3 percent. No transitional percentage is applied in 2006 or subsequent years.

Comment: One commenter requested additional temporary G-codes to offset the payment reductions for oncologists that would otherwise go into effect in 2005. According to this commenter, the payment amount associated with each of these codes would be a percentage add-on amount sufficient to offset the reductions in drug margins and payments for drug administration services.

Response: We have worked extensively with the major associations representing oncologists and their patients to ensure that Medicare continues to pay appropriately for these extremely critical services. The payment changes we made for 2004, the new G-codes, and allowing additional payment for injections and additional infusions, either have already increased, or will increase, payments for drug administration services. The impacts of these changes are discussed extensively in the impact analysis section of this final rule.

In addition, as we indicated above, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue.

Comment: One commenter expressed concern that the reductions in payments to oncologists described in the proposed rule could make it difficult, if not impossible, for many patients to continue to access cancer care in nonhospital community settings.

Response: As noted above, we have taken several steps to increase payments for drug administration services in this final rule. We recognize that oncology patients in the Medicare population undergoing chemotherapy face serious and unique issues and problems related to quality of care throughout the life cycle of their disease process; from the time of first diagnosis, through treatment, until the patient experiences an end to medical (including hospice) care. Patients, national cancer organizations, and medical providers have identified certain factors that they believe affect the comfort and ultimately the care for cancer patients in the physician office setting.

We believe that the goals and objectives of optimal treatment include reviewing and analyzing pain control management, minimization of nausea and vomiting, explaining treatment options, outlining existing chemotherapy regimens, assessing quality of life, assessing patient symptoms and complaints, supporting and educating caregivers, and avoidance of unnecessary Emergency

Department visits and inpatient hospitalizations. Further, we believe that clinicians armed with appropriate assessments can proactively intervene with medical treatment and nonmedical assistance to help ameliorate some of the distressing and unpleasant, but frequent and predictable, events that may accompany certain cancers and chemotherapeutic regimens used to combat cancer.

The Secretary has been given the authority under sections 402(a)(1)(B) and 402(a)(2) of the Social Security Act Amendments of 1967 (Pub. L. 90-248), as amended, to develop and engage in experiments and demonstration projects to provide incentives for economy, while maintaining or improving quality in provision of health services. In order to identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population, we will initiate a one-year demonstration project for CY 2005. While we encourage optimal care in all facets of treatment, the focus of the demonstration project will be on three areas of concern often cited by patients: pain control management, the minimization of nausea and vomiting, and the reduction of fatigue.

Practitioners participating in the project must provide and document specified services related to pain



control management and minimization of nausea and vomiting, and the reduction of fatigue. To facilitate the collection of this information, we have established 12 new G-codes to be reported by program participants.

G-codes for Assessment of Nausea and/or Vomiting

**G9021:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level one: not at all (for use in a Medicare-approved demonstration project)

**G9022:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level two: a little (for use in a Medicare-approved demonstration project)

**G9023:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level three: quite a bit (for use in a Medicare-approved demonstration project)

**G9024:** Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level four: very much (for use in a Medicare-approved demonstration project)

G-Codes for Assessment for Pain

**G9025:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare-approved demonstration project)

**G9026:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare-approved demonstration project)

**G9027:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment level three: quite a bit (for use in a Medicare-approved demonstration project)

**G9028:** Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project)

G-Codes for Assessment for Lack of Energy (Fatigue)

**G9029:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of

chemotherapy administration, assessment level one: not at all. (for use in a Medicare approved demonstration project)

**G9030:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level two: a little. (for use in a Medicare approved demonstration project)

**G9031:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level three: quite a bit. (for use in a Medicare approved demonstration project)

**G9032:** Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level four: very much. (for use in a Medicare - approved demonstration project)

The codes correspond to four patient assessment levels ("not at all," "a little," "quite a bit," or "very much") for each of the following three patient status factors: nausea and/or vomiting; pain; and lack of energy (fatigue).

These levels, based on the Rotterdam scale, were chosen since they appear to be less burdensome for the practitioner and more easily understood by the patient. Participating practitioners must bill the applicable G-codes for each patient status factor (that is, one G-code each for patient comfort assessment factors: nausea and/or vomiting; pain; and fatigue) assessed during a chemotherapy encounter in order to receive payment under the demonstration. A G-code for each patient status factor must appear on the claim for payment to be made under the demonstration project. A patient chemotherapy encounter is defined as chemotherapy administered through intravenous infusion or push, limited to once per day. During the course of the demonstration, an additional payment of \$130 per encounter will be paid to participating practitioners for submitting the patient assessment data as described above.

Any office-based physician or nonphysician practitioner operating within the State scope of practice laws who takes care of and administers chemotherapy to oncology patients in an office setting is eligible to participate in this demonstration project. By billing the designated G-codes, the practitioner self-enrolls in the

project and agrees to all of the terms and conditions of the demonstration project.

This information will help us to work with those who care for cancer patients to determine ways to improve the quality of care and quality of life for patients as demonstrated by measuring objective parameters and the medical response to those standardized measurements. The evaluation of the project will be based on data reported to us by the practitioners and the use of our administrative claims data to examine Emergency Department visits and inpatient hospitalizations.

We anticipate that further information regarding this demonstration project will be forthcoming after publication of this final rule.

Comment: Commenters pointed out that, under the MMA, we added physician work RVUs to specified drug administration codes equivalent to a level 1 established office visit. They indicated that we should also have increased the practice expense inputs for the same drug administration codes to account for the practice expense inputs associated with a level 1 established office visit.

Response: Section 1848(c)(2)(H)(iii) of the Act (as added by 303(a)(1)(B) of the MMA) specified that we increase the work RVUs for drug administration services

equal to the work RVUs for a level 1 established patient office visit (CPT code 99211). As indicated in the January 7, 2004 *Federal Register* (69 FR 1093), we established work RVUs of 0.17 for specific CPT codes that met the statutory definition of "drug administration services."

However, the legislation did not direct us to also increase the practice expense RVUs of the drug administration codes to include the clinical staff time associated with a level 1 office visit. The practice expense inputs of the existing CPT codes for drug administration were refined in 2002. We believe the recommendations from the PEAC included the typical clinical staff time associated with each drug administration service.

The CPT Editorial Panel approved new and revised codes for drug administration services for 2005. Depending upon the service, the RUC is recommending work RVUs for the new drug administration codes that may equal, exceed or be less than 0.17. Although section 1848(c)(2)(H)(iii) of the Act requires that the work RVUs for drug administration services shall equal those of a level 1 office medical visit, new subparagraph (J) requires the Secretary to "promptly evaluate existing drug administration codes for

physicians' services". The statute further indicates that the "Secretary shall use existing processes for the consideration of coding changes and ... in establishing relative values..."

Because we typically use the CPT and RUC processes to establish codes and relative values, we believe the statute gives us authority to establish work RVUs at a level other than those of a level 1 established patient office visit. Therefore, for 2005, we are accepting the RUC recommendations for the interim G-codes even though they result in work RVUs that are different than 0.17.

Comment: Several organizations and physicians commented that the Medicare payments for the chemotherapy codes do not include payment for many services provided by an oncology practice. These services include support services such as nutrition counseling, social work services, case management, psychosocial counseling, and educational services provided by an oncology nurse to the patient.

Response: Under certain circumstances, Medicare does make explicit payment for clinical social worker and medical nutrition therapy services. Medicare can pay separately for the services of clinical psychologists (CPs), clinical social workers (CSWs), and nurse

practitioners (NPs), clinical nurse specialists (CNS) and physician assistants (PAs).

CPs can bill directly for services and supplies they are legally authorized by the State to perform that could also be furnished by a physician or incident to a physician's service. Payment for CP services is made at 100 percent of the physician fee schedule for services they are authorized to provide that are comparable to those of a physician.

CSWs can furnish services for the diagnosis and treatment of mental illnesses that they are legally authorized by the State to provide. Payment for CSW services is made at 75 percent of the CP fee schedule, which is 100 percent of the physician fee schedule.

NPs, CNSs and PAs can bill for mental health services consistent with their authority under law to furnish physician services. They may also bill for services furnished incident to their own professional services that fall under the State scopes of practice. Payment for these services is made at 85 percent of the physician fee schedule. Medicare will pay for medical nutrition therapy services provided by a registered dietitian or nutrition professional for a beneficiary with diabetes or renal disease. Based on a comment on our August 20, 2003 proposed



rule (68 FR 50428), we understand that social worker services could involve different tasks ("helping patients with their health insurance, filling and refilling prescriptions") than those that are explicitly paid for by Medicare. However, we believe Medicare does pay for these services indirectly through the practice expense RVUs for drug administration services. If these services are typically provided to cancer patients, we believe the RUC could consider whether it is possible for resource inputs for these types of staff to be incorporated into the new drug administration codes. We also believe that the RUC could consider whether these types of staff activities are unique to physicians who provide drug administration or if they apply to other physicians' services as well.

Comment: Current CPT code 96412 (infusion techniques, one to 8 hours, each additional hour) is an add-on code, billed in addition to the primary code, 96410 (the first hour of chemotherapy). There is no national coding policy that explains how this add-on code is to be reported if less than a full hour of chemotherapy infusion is provided. A commenter pointed out that the Medicare carriers have different policies for reporting this service. Some carriers require the infusion to extend at least 16 minutes into the subsequent hour before an add-on code can be

billed, and others impose a 31 minute requirement. The commenter asked that we establish a uniform policy for the carriers to follow.

Response: The CPT Editorial Panel addressed this issue as part of its review of the drug administration codes. Effective in 2006, the add-on code is to be used for "infusion intervals of greater than thirty minutes beyond one hour increments". We are adopting this policy for chemotherapy administration codes furnished on or after January 1, 2005.

Comment: The nonchemotherapy subcutaneous injection is currently reported and paid under CPT code 90782, while a chemotherapy subcutaneous injection is currently reported under CPT code 96400. Some commenters recommended that we permit billing for nonchemotherapy injections for cancer patients to be made under CPT code 96400. They believe this code more appropriately reflects the practice expenses related to supportive care for chemotherapy.

Response: The CPT Editorial Panel explicitly addressed this issue by creating separate drug administration codes for hydration, nonchemotherapy infusions and injections, and chemotherapy infusions and injections. It further expanded the definition of chemotherapy to include those drugs where the resource

costs associated with the drug administration are similar to those administered as anti-neoplastics. Other drugs administered in support of chemotherapy, such as anti-emetics and drugs to prevent anemia, are billed using the injection code, G0351, which replaces CPT code 90782 (consistent with the CPT recommendations). We have reviewed the practice expense inputs for this code from the RUC and accepted their recommendation.

Comment: Some commenters asked that complex non-oncology infusions, such as Remicade, be paid at the same level as chemotherapy infusions. They indicate that these nonchemotherapy infusions have similar complexity and resource use as chemotherapy infusions.

Response: The CPT recommendations address this issue. The codes for chemotherapy administration are for reporting the administration of non-radionuclide, anti-neoplastic drugs, anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents, and other biologic response modifiers.

Comment: Some commenters inquired about the recognition of a severe drug reaction management code that could be used during the administration of high complexity biologic medications and less frequently during other drug administrations or chemotherapy services. While the CPT

Drug Administration Workgroup supported the creation of a severe drug reaction management code, the CPT Editorial Panel did not approve this code.

Response: We recognize that considerable physician effort may be required to monitor and attend to patients who develop significant adverse reactions to chemotherapy drugs, or otherwise have complications in the course of chemotherapy treatment. Physicians may not be aware that these services can be billed using existing CPT codes. The following scenarios are examples where existing codes may be used in addition to the routine billing for the physician's care of a cancer patient:

- Bill for the Physician Visit. If a patient has a significant adverse reaction to drugs during a chemotherapy session and the physician intervenes, the physician could bill for a visit in addition to the chemotherapy administration services.
- Bill for the Higher-Level Physician Visit. If the patient had already seen the physician prior to a chemotherapy session for a problem that is unrelated to the supervision of the administration of chemotherapy drugs, the physician may bill a visit for a significant adverse drug reaction. The total time, resources, and complexity of the physician's

interaction with the patient may justify a higher level of visit service.

- Bill for a Prolonged Service. If the patient had a physician visit prior to the chemotherapy session and experienced a significant adverse reaction to drugs on the same day, the physician can bill a prolonged service code in addition to the physician visit.

There are several code combinations to use depending on the number of minutes involved. The physician must have a face-to-face encounter with the patient and must spend at least 30 minutes beyond the threshold or typical time for that level of visit for the physician to bill for the prolonged service code.

- Bill for Critical Care Service. If the patient had a physician visit prior to the chemotherapy session and experienced a life-threatening adverse reaction to the drugs, the physician could bill for a critical care service in addition to the visit if the physician's work involves at least 30 minutes of direct face-to-face involvement managing the patient's life-threatening condition. Examples of life-threatening conditions are: central nervous failure, circulatory failure, shock, renal, hepatic, metabolic, and/or respiratory failure.

These instructions are published here for informational purposes, and we anticipate that we will issue further instructions regarding the appropriate use of these G-codes including clarifications, interpretations and other modifications to the following guidance as part of any instructions issued through a subregulatory process.

Comment: The American Urological Association (AUA) commented in response to the January 7, 2004 interim final rule to ask us to include the following codes in the MMA-mandated evaluation of existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services: CPT codes 11980, 11981, 11982, 11983, 51700, 51720, 54200, 54231, and 54235. The AUA asked that we consider applying the transitional adjustment payment to these codes for 2005.

Response: We presented these codes to the CPT Drug Administration Workgroup. After subsequent discussion with representatives of the AUA, the AUA withdrew these codes from consideration by the workgroup.

These codes are not subject to the "transitional adjustment payment provision because they are not included in the definition of "drug administration codes."

Comment: Ophthalmologists frequently perform the procedure photodynamic therapy (CPT code 67221 and 67225)

by infusing the drug Visudyne. While separate payment is allowed for the drug, the infusion is considered an integral part of the photodynamic therapy code. Thus, the physician is not allowed to bill a separate code for the infusion of the drug.

According to one commenter, Visudyne is also a drug used in cancer chemotherapy. The commenter pointed out that when Visudyne is provided for photodynamic therapy, ophthalmologists incur drug administration costs similar to oncologists who use infused drugs.

The AAO asked why we did not include CPT codes 67221 and 67225 among the drug administration codes that benefited under the MMA.

Response: In this instance, the infusion of the drug is an integral part of the surgical procedure and it was valued by the RUC and CMS that way. The code of which it is a part is not considered a drug administration code under section 303 of the MMA.

### 3. Blood Clotting Factor

For clotting factors furnished on or after January 1, 2005, we proposed to establish a separate payment of \$0.05 per unit to hemophilia treatment centers, homecare companies and other suppliers for the items and services associated with the furnishing of blood clotting factor.

Section 303(e)(1) of the MMA requires the Secretary, after review of the January 2003 report to the Congress by the Comptroller General of the United States, to establish a furnishing fee for the items and services associated with the furnishing of blood clotting factor.

Based on a review of the Government Accountability Office (GAO) report and data received from various clotting factor providers, we proposed a furnishing fee in order to cover the administrative costs associated with supplying the clotting factor. As outlined in the MMA, any separate payment amount established may include the mixing and delivery of factors, including special inventory management and storage requirements, as well as ancillary supplies and patient training necessary for the self-administration of these factors. The MMA states that, in determining the separate payment, the total amount of payments and these separate payments must not exceed the total amount of payments that would have been made for the factors if the amendments in section 303 of the MMA had not been enacted. As indicated in the GAO report, "[w]hen Medicare's payment for clotting factor more closely reflects acquisition costs, we recommend that the Administrator establish a separate payment for providers based on the costs of delivering clotting factor to Medicare beneficiaries."



Effective upon implementation of the ASP-based payment rates, payment for blood clotting factors will more closely reflect acquisition costs, since payment will be based on the average sales price as reported by drug manufacturers plus 6 percent.

Therefore, we stated in the August 5, 2004 proposed rule that in the absence of additional data we believe that a furnishing fee of \$0.05 per unit for the cost of delivering clotting factor is an appropriate amount. However, we also sought updated data and comments on the GAO report, as well as information on the fixed and variable costs of furnishing clotting factor. We recognized that there may be alternatives to a fee, which varies entirely based on the number of units of clotting factor furnished. We indicated we would closely examine all data and information submitted in order to make a final determination with respect to the appropriateness of the \$0.05 per unit amount.

We received comments from various sources including, but not limited to, hemophilia treatment centers, hemophilia coalitions, and other suppliers of clotting factors regarding our request for additional data and information on the appropriateness of our proposed fee. The comments and responses are provided below.

Comment: Many commenters recommended that we incorporate cost information received from homecare providers and any updated cost data from hemophilia treatment centers in determining the separate furnishing fee payment amount for 2005. The commenters cited an industry-sponsored survey of full-service hemophilia homecare companies that recommended a furnishing fee of \$0.20 per unit. This survey collected CY 2003 data from three hemophilia homecare suppliers that the commenter indicated supplied 42 percent of all Medicare hemophilia patients. Commenters also stated that the GAO report was inadequate to serve as the basis for determining the separate payment for clinically appropriate items and services related to furnishing blood clotting factor. They questioned the accuracy of the recommended payment range in the GAO report, given what they viewed as an insufficient sample size; that is, the GAO report received data from only 4 hemophilia treatment centers and lacked any cost data from national or regional full-service hemophilia homecare providers. These commenters also indicated that the GAO survey may have included homecare companies that purchase clotting factor at a lower price through the Public Health Service's 340B program. More information on the 340B program is available on the Health Resources and

Services Administration's website at <http://bphc.hrsa.gov/opa/howto.htm>. The commenters also stated that the GAO report focused solely on estimating providers' blood clotting factor delivery costs, which the GAO defined as inventory management, storage, shipping, and the provision of ancillary supplies. According to the commenters, the MMA directed us to establish a separate payment for items and services related to the furnishing of blood clotting factor that takes into consideration a wider range of items and services than the delivery costs addressed in the GAO report, for example patient education.

Response: We agree with the commenters that full-service hemophilia homecare companies provide services that may be of benefit to Medicare beneficiaries with hemophilia, such as disease and patient management activities. However, we do not believe that the scope of the furnishing fee includes these services. As noted above, Section 303(e) specifies the items and services that may be taken into consideration in setting the furnishing fee. Disease and patient management activities are not included in the items and services specified in Section 303(e). However, these activities may be more appropriately addressed through a future phase of the new Medicare Chronic Care Improvement Program.

The new Medicare Chronic Care Improvement Program is an important component of the MMA and demonstrates a commitment to improving and strengthening the traditional fee-for-service Medicare program. This program is the first large-scale chronic care improvement initiative under the Medicare fee-for-service program. We will select organizations that will offer self-care guidance and support to chronically ill beneficiaries. These organizations will help beneficiaries manage their health and adhere to their physicians' plans of care, and help ensure that they seek or obtain medical care that they need to reduce their health risks. More information regarding this program is available on the CMS website at <http://www.cms.hhs.gov/medicarereform/ccip/>.

With regard to the other costs identified in the comments and in the industry-sponsored survey, we also do not believe the scope of a furnishing fee includes costs associated with sales and marketing. We do not believe it is appropriate to build an explicit profit margin into the furnishing fee, but rather have the margin associated with the furnishing fee result from efficient furnishing of clotting factor. We agree with the commenters that the GAO report did not include amounts for education and that these are appropriate for the furnishing fee. Therefore, after

removing the costs associated with sales and marketing, an explicit profit margin, and patient management, the resulting figure from the homecare survey is \$0.14 per unit of clotting factor. We are establishing the furnishing fee for 2004 at \$0.14 per unit of clotting factor. For years after 2005, the MMA specifies that the furnishing fee for clotting factor must be updated by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

Comment: One commenter recommended that the beneficiary's 20 percent coinsurance not be applicable to this separate payment. The commenter indicated that the additional financial burden would limit many beneficiaries' access to this lifesaving product.

Response: Under provisions designed to protect the Medicare program from fraud and abuse, a broad waiver of beneficiary cost sharing of the type the commenter recommends would not be permitted. However, we make no statement regarding the applicability of existing statutory and regulatory provisions that may allow for the waiver of cost sharing in certain cases.

#### 4. Supplying Fee

Section 1842(o)(6) of the Social Security Act requires the Secretary to pay a supplying fee (less applicable

deductible and coinsurance) to pharmacies for immunosuppressive drugs described in section 1861(s)(2)(J) of the Act, oral anticancer chemotherapeutic drugs described in section 1861(s)(2)(Q) of the Act, and oral anti-emetic drugs used as part of an anticancer chemotherapeutic regimen described in section 1861(s)(2)(T) of the Act, as determined appropriate by the Secretary. In the interim final rule published on January 7, 2004 (69 FR 1084), we considered this fee to be bundled into the current payment for these drugs for 2004 and did not establish a separately billable supplying fee.

Effective January 1, 2005, we proposed to establish a separately billable supplying fee of \$10 per prescription for immunosuppressive drugs, oral anti-cancer chemotherapeutic drugs and oral anti-emetic drugs. We based this proposed fee on information provided by retail chain pharmacies on the costs of supplying these drugs to non-Medicare patients combined with steps to reduce the administrative burden associated with billing Medicare.

We also sought data and information on the additional services pharmacies provide to Medicare beneficiaries, the extent to which oral drugs can be furnished without these additional services and the extent to which such services are covered under Medicare. Additionally, we requested

comments concerning whether the supplying fee should be somewhat higher during the initial month following a Medicare beneficiary's transplant to the extent that additional resources are required for example, due to more frequent changes in prescriptions for immunosuppressive drugs.

Comment: Several commenters stated that they were not in a position to determine whether the proposed \$10.00 supplying fee was adequate since they did not know the actual 2005 payment rates for Part B drugs. These commenters indicated that the supplying fee needed to cover return on investment, the costs of supplying the drugs, and make up for any differences between the product costs and the ASP based payment for the drug. Some commenters indicated that aside from the adequacy of the ASP-based payment for the drug, a \$10.00 supplying fee appeared to be too low. These commenters indicated that the average cost to a retail pharmacy to dispense a non-Medicaid third party or cash paying prescription ranges anywhere from \$7.50-\$8.00. The commenters indicated that Medicare should pay at least \$2.00-\$2.50 more per prescription since costs associated with supplying Medicare prescriptions are higher.

We received a comment from a large retail pharmacy indicating that a supplying fee of \$25 would be adequate to cover the higher costs of dispensing Medicare Part B oral drugs.

We received comments from specialty immunosuppressive pharmacies that included information from a recent survey of their supplying costs. The survey indicated that the cost for specialty pharmacies to dispense Medicare Part B immunosuppressants is \$35.48 per prescription. The specialty immunosuppressive pharmacies indicated that they provide services not typically provided by retail chain drug stores or large mail-order pharmacy benefit management companies. These services include direct patient care through pro-active pharmacist contact, expeditious processing and turnaround of medication orders, direct billing of Medicare and coordination of benefits on behalf of transplant patients to reduce the costs to the patients, and maintaining expensive immunosuppressant in stock to ensure timely receipt when needed by beneficiaries. These pharmacies also indicated that the retail chains typically do not supply immunosuppressive drugs or file Medicare claims.

Several commenters indicated that the lack of on-line adjudication for Medicare claims was one of the major



drivers, among other reasons, for the additional costs of supplying Medicare prescription.

Response: We agree that the cost of supplying Medicare Part B oral drugs is higher than many other payers because of the lack of on-line adjudication for Medicare Part B oral drug claims. Due to operational issues, we do not anticipate the establishment of an on-line adjudication system in the near future. Accordingly, we believe it is appropriate to establish a supplying fee higher than the fees paid by some other payers with on-line adjudication. We note that many other payers with on-line adjudication have fees in the range of \$5-\$10 per prescription. We note that this is consistent with the approximately \$8 cost for non-Medicaid dispensing stated by some commenters and described earlier. Other than administrative costs associated with billing Medicare Part B for oral drugs, we do not agree with commenters that the supplying fee for these drugs should exceed the dispensing fees of other payers because we do not believe there are other significant differences between supplying Medicare Part B and other oral drugs. We also do not agree that the supplying fee should include product costs. Product costs are paid through the ASP + 6 percent drug payment system. For the additional burden associated with billing Medicare

Part B for oral drugs, we note the commenters who suggested an additional fee of approximately \$2 for Medicare billing costs. Added to the \$8 non-Medicaid fee described above, this would result in a supplying fee of approximately \$10. We also note the survey of the specialty immunosuppressive pharmacies that indicated Medicare claims processing costs of approximately \$8. This same survey also indicated total personnel costs of approximately \$9, a portion of which we assume is attributable to the additional work associated with Medicare billings because the comments indicated Medicare billing was labor-intensive. Using the \$5 to \$10 figures for payers with on-line adjudication described above, the specialty pharmacy data on Medicare claims processing costs and personnel costs, we developed a range of possible supplying fees based on the specialty pharmacy data. Depending upon the portion of the personnel costs associated with Medicare billings, this would result in a supplying fee between a minimum of \$13 ( $= \$5 + \$8$ ) and a maximum of \$27 ( $= \$10 + \$8 + \$9$ ). The comment of the large chain pharmacy recommending a \$25 supplying fee indicated that this amount would be adequate to cover the costs of supplying Medicare Part B drugs including the additional costs of processing Medicare claims; however, this amount included a margin for profit. We do not

believe it is appropriate to build an explicit profit margin into the supplying fee, but rather have the margin associated with the supplying fee result from efficient supplying of these drugs. Although the profit margin included in the \$25 was not explicitly stated in the comment, if we assume a 5 percent margin, then a supplying fee of approximately \$24 would cover the large chain pharmacy's costs of supplying Medicare Part B drugs. We are not indicating that 5 percent is an appropriate margin.

There was variability in the submitted comments with respect to an appropriate supplying fee. On the low end, analysis of the submitted comments would indicate a supplying fee of \$10. On the high end, the analysis would indicate a supplying fee of \$27. Given the variability in the values and assumptions included in various calculations, we do not think it is appropriate to simply take the rounded midpoint of this range, \$19, as the supplying fee. However, we do not think it appropriate to take the maximum amount of this range, \$27, given that it is unlikely that all of the personnel costs indicated in the specialty pharmacy survey are related to the costs of billing for oral Medicare Part B drugs. The amount in the comment from the large chain pharmacy, after adjusting for a possible profit margin, or \$24, is consistent with our

belief that not all of the additional personnel costs identified in the specialty pharmacy survey are related to the costs of billing for oral Medicare Part B drugs. We are therefore establishing a per prescription supplying fee of \$24 as the value consistent with both the large retail pharmacy comment (after making an adjustment for built-in profit margins) and the higher end of the broad range of the specialty pharmacy survey. Although we believe that a \$24 supplying fee coupled with the ASP-based drug payment will not result in any access problems for Medicare beneficiaries, we will monitor access as we implement the new ASP-based payment system.

Comment: Some commenters recommended that we update the supplying fee annually. Some commenters indicated this fee should be updated by the average annual increase in the costs of pharmacies supplying these drugs to Medicare beneficiaries (costs such as rent, utilities and salaries), but no less than the increase in the medical care inflation index for the most recent twelve months for which it can be calculated before the next calendar year.

Response: We will study the issue of appropriate future increases for the supplying fee and proceed, as necessary, through notice and comment rulemaking.

Comment: A specialty organization suggested that we develop a sliding supplying fee, which would be calculated as a percentage of the cost that the pharmacy incurred in acquiring a particular drug.

Response: We do not agree that the supplying fee should vary by product costs. Product costs are paid through the ASP based drug payment system.

Comment: Several commenters agreed with our suggestion to increase the supplying fee in the first month following a transplant, but recommended that we extend this increase to at least the first 3 months following the transplant. One commenter suggested that extra resources are associated with frequent changes in prescriptions during the initial month following a beneficiary's organ transplant. One commenter recommended a fee of \$50 for an initial prescription fill. However, one commenter advocated against a supplying fee that distinguished between new and refill prescriptions stating that it would be impractical, of questionable benefit and would discourage long-term pharmacy-patient relationships as pharmacy providers would only have an incentive to serve patients in the short term.

Response: We agree that additional costs are most likely to occur nearer the time when the beneficiary has a

transplant. In order to recognize these costs, we are establishing a higher supplying fee of \$50 for the supplying of the initial oral immunosuppressive prescription in the first month after a beneficiary has a transplant because the costs of supplying immunosuppressives are likely to be higher immediately following a transplant, when the practitioner is adjusting the dose of immunosuppressive drugs. With regard to the comment opposing higher supplying fees for new patients regardless of their transplant date, we agree with the commenter that it would result in inappropriate incentives and are not implementing any such fee.

Comment: Commenters recommended that the supplying fee should account for the different prices paid by pharmacies and physicians, recognizing that these are separate classes of trade that may not have access to comparable pricing. Thus, we should increase the supplying fee associated with providing and overseeing the use of oral anti-cancer drugs.

Response: We do not agree that the supplying fee should vary by product costs. Product costs are paid through the ASP based drug payment system.

Comment: Commenters recommended that we extend the supplying fee to physicians that directly supply covered

oral anti-cancer, immunosuppressive and oral anti-emetic drugs to patients, as well as create a dose management and compliance fee for physicians that prescribe oral chemotherapy products. These commenters state that we could use the premise that the MMA does not provide a definition of the word "pharmacy" and we could permit payment of a supplying fee to include a physician acting in the capacity of a pharmacist. Alternatively, commenters suggested that we use its inherent reasonableness authority to extend the supplying fee to physicians.

Response: Given our current understanding of Congressional intent, we do not believe it would be appropriate to pay a supplying fee to physicians. Moreover, we do not have sufficient data to determine whether our inherent reasonableness authority would apply in this instance. However, we will study these issues further.

## 5. Billing Requirements

In the proposed rule, we proposed the following changes to certain billing requirements and clarified policy for other billing requirements in an effort to reduce a pharmacy's costs of supplying covered immunosuppressive and oral chemotherapy drugs to Medicare beneficiaries:

- Original signed order. We clarified Medicare's policy regarding the necessity of an original signed order before the filling of a prescription. According to the Medicare Program Integrity Manual (section 5.1 of Chapter 5), which addresses the ordering requirement for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), including drugs, most DMEPOS items can be dispensed based on a verbal order from a physician. A written order must be obtained before submitting a claim, but that written order may be faxed, photocopied, electronic, or pen and ink. The order for the drug must specify the name of the drug, the concentration (if applicable), the dosage, and the frequency of administration. The clarification of this requirement should reduce a pharmacy's costs of supplying covered immunosuppressive and oral drugs to Medicare beneficiaries to the extent that pharmacies are currently applying an original signed prescription requirement.

Comment: Commenters recommended that a prescription be filled and billed based solely on a verbal order from a physician and an actual signed written prescription should not be necessary before billing.

Response: The policy that allows dispensing based on a verbal order but requires a written order for billing



applies to all DMEPOS items. This policy balances fraud and abuse concerns with prompt dispensing of DMEPOS items to beneficiaries. We point out that the written order from the physician can be faxed, photocopied, electronic, or pen and ink. We currently allow pharmacies to accept electronic prescriptions from physicians.

- Assignment of Benefits Form. We proposed to eliminate use of the Assignment of Benefits form for Part B items and services, including drugs, where Medicare payment can only be made on an assigned basis. For Part B covered oral drugs, this would be a means of reducing a pharmacy's costs of supplying these drugs to Medicare beneficiaries. Currently, pharmacies must obtain a completed Assignment of Benefits form in order to receive payment from Medicare. This requirement increases a pharmacy's cost of supplying covered drugs to Medicare beneficiaries, as other payers do not impose this requirement. Thus, we do not believe that it is necessary for an assignment of benefits form to be filled out for drugs covered under Part B, since payment for them can only be made on an assignment-related basis.

Comment: Some commenters suggested that the Assignment of Benefits form be eliminated for diabetic supplies dispensed by pharmacy suppliers.

Response: Our proposal to eliminate the Assignment of Benefits form applied to services where Medicare payment can only be made on an assigned basis. That is not the case with diabetic supplies. Thus, we are not eliminating the AOB form for diabetic supplies.

- DMERC Information Form (DIF). The DIF is a form created by the DMERC Medical Directors that contains information regarding the dates of the beneficiary's transplant and other diagnosis information. This form is a one-time requirement that pharmacies must complete in order to receive payment. Since section 1861(s)(2)(J) of the Act no longer imposes limits on the period of time for coverage of immunosuppressive drugs, we believe that the information on transplant diagnosis can be captured through other means (for example, diagnosis codes on the Part B claim form).

Comment: Several commenters applauded our efforts to eliminate use of the DIF in an effort to reduce the cost that the billing requirements imposed. These commenters asked that we ensure that this requirement is applied uniformly by all the DMERCs.

Response: We appreciate the support regarding the elimination of the DIF form. Action is being taken to eliminate the DIF form, including accommodating systems issues and providing for notifications. We anticipate

resolution of issues to occur soon and elimination would occur next year.

- Other Billing Issues. We also received other comments regarding other billing issues related to the supplying of immunosuppressive, oral anti-cancer, and oral anti-emetic drugs.

Comment: Commenters suggested that we allow physicians to bill the carrier when oral drugs are provided directly by the physician in his office rather than having the physician bill the DMERC for the oral anti-cancer drug. Others stated that we should allow for billing for pharmaceutical products to be conducted on current electronic platforms, because "batch billing" creates operational and patient care problems, and adds significant participation costs. Commenters also stated that we should eliminate the requirement for a diagnosis code to be present on the prescription; while, at the same time, adopt the usage of the physician's DEA number instead of the UPIN number when submitting claims.

Response: We thank the commenters for identifying these issues. We plan to examine these aspects of billing.

## 6. Shipping Time Frame

In the proposed rule, we highlighted the fact that the guidelines regarding the time frame for subsequent

deliveries of refills of DMEPOS products had been revised. Effective February 2, 2004, the shipping of refills of DMEPOS products may occur "approximately" on the 25<sup>th</sup> day of the month in the case of a month's supply. In the proposed rule, we emphasized the word "approximately"; while we indicated that normal ground service shipping would allow delivery in 5 days, if there were circumstances where ground service could not occur in 5 days, the guideline would still be met if the shipment occurs in 6 or 7 days. This change should eliminate the need for suppliers to utilize overnight shipping methods and would permit the shipping of drugs via less expensive ground service.

F. Section 952 – Revision to Reassignment Provisions

As discussed in the August 5, 2004 proposed rule, section 1842(b)(6)(A)(ii) of the Act, as amended by section 952 of the MMA, allows, in many circumstances, a physician or NPP to reassign payment for Medicare-covered services, regardless of the site of service, providing there is a contractual arrangement between the physician or NPP and the entity through which the entity submits the bill for those services. Thus, the services may be provided on or off the premises of the entity receiving the reassigned payments. The MMA Conference Agreement states that entities that retain independent contractors may

enroll in the Medicare program. The expanded exception created by section 952 of the MMA applies to those situations when an entity seeks to obtain the medical services of a physician or NPP.

Section 952 of the MMA states that reassignment is permissible if the contractual arrangement between the entity that submits the bill for the service and the physician or NPP who performs the service meets the program integrity and other safeguards as the Secretary may determine to be appropriate. The Conference Agreement supports appropriate program integrity efforts for entities with independent contractors that bill the Medicare program, including joint and several liability (that is, both the entity accepting reassignment and the physician or NPP providing a service are both liable for any Medicare overpayments). The Conference Agreement also recommends that physician or NPPs have unrestricted access to the billings submitted on their behalf by entities with which they contract. We incorporated these recommended safeguards in a change to the Medicare Manual, implementing section 952 of the MMA that was published on February 27, 2004. In the August 5, 2004 rule, we proposed to revise §424.71 and §424.80 to reflect these safeguards, as well as the expanded exception established by section 952 of the

MMA.

Section 952 of the MMA revises only the statutory reassignment exceptions relevant to services provided in facilities and clinics (section 1842(b)(6)(A)(ii) of the Act). Section 952 of the MMA does not alter an individual or entity's obligations under any other applicable Medicare statutes or regulations governing billing or claims submission.

In addition, physician group practices should be mindful that compliance with the physicians' services exception and the in-office ancillary services exception to the physician self-referral prohibition in section 1877 of the Act requires that a physician or NPP who is engaged by a group practice as an independent contractor may provide "designated health services" to the group practice's patients only in the group's facilities. See the definition of physician in the group at 42 C.F.R. § 411.351.

We also cautioned that parties must be mindful that contractual arrangements involving reassignment may not be used to camouflage inappropriate fee-splitting arrangements or payments for referrals. In the August 5, 2004 proposed rule, we solicited comments on potential program vulnerabilities and on possible additional program

integrity safeguards to guard against those vulnerabilities.

Comment: We received positive comments for the proposed changes to the reassignment rules from two physician associations and one association representing non-physician practitioners.

Response: We are pleased to receive positive feedback to the changes to the reassignment rules. We believe these changes balance the need to respond to the changing business arrangements in the delivery of health care services with the need to protect the Medicare trust funds from fraudulent and abusive billing practices.

Comment: An association representing emergency medicine physicians and numerous members of that association commented that requiring independent contractor physicians to have unrestricted access to the billings submitted on their behalf is not sufficient to ensure such access. The commenters requested that we revise our regulations to require the entity submitting the bills to provide duplicates of the Medicare remittance notices (which indicate the services billed and the amounts paid for those services) to the independent contractor physicians. Some of the commenters requested that we require independent contractor physicians to receive

itemized monthly reports of the claims submitted and remittances received on their behalf.

Response: We believe that requiring independent contractors to have unrestricted access to the billings submitted on their behalf is sufficient to satisfy the independent contractors' need to review the claims information.

We recognize that some independent contractors may not wish to receive copies of all bills submitted on their behalf. It would place an unnecessary burden on entities if we require them to furnish duplicate remittance notices to independent contractors on a routine basis. Similarly, it would place a significant burden on our claims processing systems if we were obligated to provide duplicate remittance notices to those who have reassigned their payments. We note that the method and frequency of obtaining access to billing records is an issue that the independent contractor and the entity to which the independent contractor is reassigning payments can resolve in their written contract.

Comment: A commenter asked whether or not the new reassignment exception (which essentially expanded or revised the previous exceptions pertaining to independent contractors), established by section 952 of the MMA, is



available when one entity contracts with a second entity, which in turn contracts with a physician or non-physician practitioner to furnish services for the first entity.

Response: We refer to this situation as an indirect contractual arrangement between the independent contractor furnishing the service and the entity doing the billing and receiving payment (excluding billing agents). Thus, the reassignment is between the individual furnishing the service and the entity receiving the reassigned benefits. Indirect contractual arrangements were permissible prior to passage of section 952 of the MMA and remain permissible. The CMS-855-R enrollment form would need to be completed by the entity receiving the reassigned benefits and the person furnishing the service. In accordance with section 952 of the MMA, the contractual arrangement and any program integrity safeguard requirements deemed appropriate by the Secretary are between the independent contractor and the entity receiving the reassigned payments, with the program integrity safeguards applying to both parties. If the parties involved also wish to include the intermediary entity in a similar contract, and apply standards identical or similar to the program integrity safeguards to their arrangement, they have that option; but, it is not required

or necessary to comply with the exception to the reassignment prohibition for contractual arrangements.

Comment: Several members of the Congress urged us not to delay the enrollment process of providers or suppliers while implementing section 952 of the MMA.

Response: We do not expect any delays in provider or supplier enrollment to result from implementing the reassignment provisions of this regulation. We are sensitive to the need for an efficient and timely enrollment process. If the new reassignment exception results in the submission of a particularly high volume of claims, or if a Medicare contractor has to process a large number of new enrollment applications, it is possible that delays may occur in some cases. A provider or supplier whose enrollment was delayed must contact the appropriate Medicare contractor's provider or supplier enrollment office to discuss the reasons for the delay.

Comment: A trade association of physician specialists asked that we clarify our definitions of onsite and off-site services. This trade association also requested that we further describe the potential program vulnerabilities that the revised Medicare reassignment exception might create.

Response: We consider onsite services to be services of an independent contractor that are performed in space owned or leased by the entity billing and receiving the reassigned payments. We consider offsite services to be services of an independent contractor that are performed in space that is not owned or leased by the entity billing and receiving the reassigned payments, that is, services performed off the premises.

The Congress originally passed the prohibition on reassignment provision due to experience with fraudulent and abusive billing practices. As we discussed in the preamble to the August 5, 2004 proposed rule, the new reassignment exception for contractual arrangements will potentially permit myriad relationships and financial arrangements. Some of these relationships may have the potential to increase fraudulent and abusive billing practices that the reassignment rules were designed to prevent. We also stated in the proposed rule that the new reassignment exception does not alter an individual's or entity's obligations under existing Medicare statutes and regulations (for example, the physician self-referral prohibition, the anti-kickback statute, purchased diagnostic test rules, incident to rules, etc.).

Comment: Several commenters expressed concern over the recent growth of so-called pod, salon, turnkey, mini-mall, or condo labs, especially since section 952 of the MMA appears to liberalize the Medicare reassignment rules.

As we understand the situation, some entities have created a building or a floor of a building that contains a number of cubicles, each of which is equipped with a microscope and other supplies that enable a pathologist to go to a particular cubicle or pod to analyze any tissue sample that is submitted by the group practice that rents pod space on a full-time basis. Apparently, some of the owners of these anatomical laboratories assert that each pod is a centralized location for a laboratory that is owned by a group practice. Other owners assert that each pod serves as an offsite office of a pathologist who works for a group practice as an independent contractor.

These entities market their services to specialists in certain disciplines, such as gastroenterology, urology, and dermatology, which rely on a high volume of anatomic pathology services. The commenters stated that these lab arrangements are subject to excess, waste, and abuse, including, but not limited to: (a) generation of medically unnecessary biopsies; (b) kickbacks; (c) fee-splitting;

and, (d) referrals that would otherwise be prohibited under the physician self-referral statute.

The commenters agree with us that safeguards are necessary to prevent the increased incidence of fraudulent and abusive billing practices resulting from the new reassignment exception for contractual arrangements. To reach the goal of closing any loophole for excess, waste, and abuse opened by the new independent contractor reassignment exception, the commenters provided several suggestions. One commenter recommends that we add language to proposed §424.80(d) that would prohibit a physician from making a reassignment to another physician, under the independent contractor exception, if the physicians do not practice in substantially the same medical specialty. This limitation would not apply if the entity accepting the assignment is a bona fide multi-specialty physician practice, meaning that it employs (on a W-2 basis) physicians who regularly practice in two or more specialties of medicine.

The commenters believe that the regulations need to state more clearly that all requirements of the purchased diagnostic test rules and purchased test interpretation rules need to be met. In other words, the commenters want

to prevent the new reassignment exception from applying to services furnished by independent contractor pathologists.

These commenters are urging us to review these practices to see if they fail to meet existing obligations under the physician self-referral prohibition or anti-kickback statute. The commenters believe that these business arrangements are exploiting the in-office ancillary services exception and other exceptions to the physician self-referral prohibition.

Response: We appreciate comments that specify situations where fraud and abuse may occur and propose solutions to prevent such occurrences. While we decline to incorporate the commenters' suggested regulatory revisions at this time, we share the commenters' concerns. We will be paying close attention to this issue, and may initiate future rulemaking to address arrangements that are fraudulent or abusive.

To respond to commenters' concerns, we are amending the regulations governing reassignment at §424.80(a) to clarify that nothing in §424.80 alters an individual or entity's obligations under other Medicare statutes or rules, including, but not limited to, the physician self-referral prohibition (section 1877 of the Act), the anti-kickback statute (section 1128(B)(b)(1) of the Act), the

regulations regarding purchased diagnostic tests, and regulations regarding services and supplies provided incident to a physician's services.

In response to the concerns expressed by the commenters, we wish to further expand on the fact that section 952 of the MMA did not affect the obligation of an individual or entity to comply with the physician self-referral prohibition (section 1877 of the Act and the corresponding regulations). As stated in the proposed rule, "physician group practices should be mindful that compliance with the in-office ancillary services exception to the physician self-referral prohibition requires that a physician who is engaged by a group practice on an independent contractor basis must provide services to the group practice's patients in the group's facilities. As noted in the Phase I physician self-referral final rule (66 FR 887), 'we consider an independent contractor physician to be 'in the group practice' if: (1) he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities; (2) the contract contains compensation terms that are the same as those that apply to group members under section 1877(h)(4)(iv) of the Act or the contract fits in the personal services exception; and, (3) the contract complies

with the reassignment rules...' See also 66 FR 886." This test is specified at §411.351 in the definition of physician in the group practice, which contains a premises requirement independent of the reassignment rules.

In addition, the use of independent contractors at off-premises locations may impact the ability of a group practice to meet the definition of a group practice at §411.352 for purposes of complying with section 1877 of the Act. Accordingly, some group practices may need to be careful about the number of physician-patient encounters that independent contractors perform off-premises to ensure that they meet the 75 percent patient-physician encounters test as set forth in §411.352(h).

We will continue to monitor compliance with the reassignment rules and we will analyze the impact of the physician self-referral prohibition on "pod" labs. If we determine that changes to the physician self-referral prohibition are necessary, these changes will be made in a separate rulemaking document.

Comment: We received a number of comments and recommendations from three organizations that utilize the services of independent contractor emergency department physicians. One of the three organizations represents management companies that employ independent contractor



emergency department physicians. The commenters believe that the changes to the reassignment rules necessitated by section 952 of the MMA should be implemented in a manner that does not impose additional burdens on the Medicare enrollment process. They believe that implementation of the proposed regulations could impede the enrollment process. They expressed concern that amendments to current contracts might be necessary to incorporate the program integrity safeguards included in the proposed regulations. Since they believe requiring contract amendments would be burdensome and costly to hospitals, they are urging us not to require parties to amend their contracts to reflect the program integrity safeguards that we proposed.

Response: We do not believe that implementation of the proposed regulations will impede the enrollment process. Our proposed regulations would not require parties to amend their contracts to reflect the program integrity safeguards. We plan to include the program integrity safeguard requirements on the CMS-855-R enrollment form. The program integrity safeguards will apply to arrangements entered into pursuant to the new reassignment exception for contractual arrangements, regardless of whether the parties reference the safeguards in their contracts.

Comment: Three commenters representing groups that utilize independent contractor emergency physicians strongly oppose our implementation of the two proposed program integrity safeguard requirements: (1) joint and several liability/responsibility for Medicare overpayments; and (2) unrestricted access to the billings for services provided by independent contractors. The commenters believe that establishing program integrity safeguards is premature and that we should first formally assess the need for such safeguards. These commenters also ask us to clearly define joint and several liability/responsibility. They express concern over our attempt to impose joint and several liability/responsibility on both the contracting entity and practitioner furnishing the services and note that the CMS-855-R enrollment form certification holds the enrolling provider or supplier responsible for any Medicare overpayments. The commenters argue that we should impose these program integrity safeguards on employer/employee relationships if we are going to impose them on contractual arrangements. The commenters ask how we would monitor compliance with joint and several liability/responsibility. The commenters also have concerns about regulating access to claims submitted by an entity for services furnished by an independent contractor. In their view, this type of

requirement should be part of the compliance programs of entities and employers rather than mandated as part of the reassignment rules.

Response: We disagree with the commenters' assertion that it is premature to implement the proposed program integrity safeguards. Section 952 of the MMA specifically authorizes the Secretary to implement program integrity safeguards. Further, in the Conference Report to the MMA, the Congress specifically highlighted the two program integrity safeguards that we have proposed.

Our assessment of the need for program integrity safeguards is based upon prior experience with certain types of entities and their subsidiary billing companies. For example, on April 6, 2000, Lewis Morris, Assistant Inspector General for Legal Affairs, Office of Inspector General (OIG), U.S. Department of Health and Human Services, testified before the House Committee on Commerce, Subcommittee on Oversight and Investigations regarding Medicare and third-party billing companies. Mr. Morris of the OIG detailed the upcoding activities of two firms that provided billing services for entities contracting with emergency department physicians. One firm paid \$15 million and the other paid \$15.5 million to settle their respective liabilities. Moreover, as we have noted, we have received

numerous comments from physicians stating that they have been prevented from seeing the Medicare remittance notices for services they furnished, on penalty of termination.

In addition, we understand the commenters' concerns that if the Agency plans to implement the two proposed program integrity safeguards, we should apply these same program integrity safeguards to employees, as well as to independent contractors. Joint and several responsibility/liability and unrestricted access to billings may or may not be appropriate for employees and employers as it is for the parties involved in contractual arrangements. CMS will study this issue further, and if necessary will address it in a separate rulemaking document.

We use the words responsibility and liability interchangeably, and in the context of claims filing and payment, they both have the same meaning. We define joint and several liability/responsibility to mean that both the person furnishing a service and the entity billing for that service (and to which payments have been reassigned) can be held liable or responsible for any errors in billing that result in a Medicare overpayment, including, but not limited to, upcoding and billing for services never rendered.

We will monitor the program integrity safeguards as we monitor all other program integrity requirements. We also believe that entities and independent contractors will report violations to us, since both may be held responsible for any Medicare overpayments. If an independent contractor is refused access to the billings submitted on his or her behalf, the independent contractor may report this to the appropriate Medicare contractor.

Comment: An organization representing entities that use independent contractor emergency department physicians believes if we retain the proposed program integrity requirements, then these requirements should be clarified and included in other reassignment exceptions and in other Medicare conditions of participation.

Response: It is our goal to have the program integrity requirements identified and included on the appropriate CMS-855-R enrollment form. As we have discussed above, while we will study whether it is appropriate to extend the program integrity safeguards to employer/employee relationships, we do not believe it is necessary to include the program integrity requirements in other reassignment exceptions (or in other Medicare conditions of participation) at this time.

Comment: Three commenters representing organizations that use independent contractor emergency physicians recommend that we revise our definition of entity to specifically identify the types of entities that are listed in the Conference Report to section 952 of the MMA. They believe that our existing definition which defines entity as a person, group or facility enrolled in the Medicare program is ambiguous and inconsistent with Congressional intent. Therefore, they are recommending that we add the language to the definition that specifies that an entity includes but is not limited to, a hospital, clinic, medical group, a physician practice management organization, or a staffing company. One of the commenters opposes stating that entities need to be enrolled in Medicare in the definition of entity because the commenter believes it is not necessary to include such information in the regulations on reassignment. This commenter believes that instructions on enrollment should be addressed in an enrollment regulation. The commenter also states that our current reassignment regulation does not define facility as a hospital or other institution enrolled in the Medicare program. These groups believe that their proposed definition of entity more accurately reflects the language from the Statement of the Managers filed by the MMA

Conference Committee and is included in the Conference Report (Conference Agreement). Finally, these groups do not believe that a definition of entity is necessary, since we do not define employer in the reassignment regulations definition section.

Response: We continue to believe that our definition of entity in the proposed rule is appropriate. We believe that defining entity as a person, group, or facility that is enrolled in Medicare encompasses all entities that are allowed to bill and receive payment from Medicare, and does not prevent those entities that were specifically identified in the Conference Report from benefiting from the new contractual arrangement reassignment exception. We will not specifically include a staffing company in the definition of entity because a staffing company cannot enroll in Medicare as a staffing company. Staffing companies can enroll as either a group practice or clinic, depending on how they are licensed or allowed to do business in the state where they are located. We further believe that a definition of entity is necessary to distinguish between entities that are allowed to reassign their right to payment and to receive reassigned payments from entities that are not allowed to reassign their right to payment or to receive reassigned payments (for example,

billing agents, entities that provide services under arrangements, and substitute physicians, (for example, locum tenens physicians or physicians working on a reciprocal basis) all of which are not required to enroll in Medicare).

Comment: Three commenters representing organizations that use independent contractor emergency physicians found our use of the term supplier confusing when denoting the physician or non-physician practitioner that contracts with an entity and reassigns his or her right to bill and receive payment. Specifically, the commenters found the proposed revision to §424.80(c) (Prohibition on reassignment of claims by suppliers) confusing because it refers to a hospital or facility as the supplier of services for purposes of the reassignment revision when Medicare already has regulations that separately define provider and supplier. The commenters recommend that we clarify our intent regarding the use of the term supplier.

Response: In instances of reassignment, the supplier is the person furnishing the service and reassigning his or her right to bill and receive payment to another entity. This is consistent with our definition of supplier in §400.202. In our proposed revision to §424.80(c), we state that the employer or entity is considered to be the



supplier of the services for subparts C, D, and E of this part, subject to the provisions of paragraph (d) of the section. Once a supplier reassigns his or her right to receive Medicare payments, the entity receiving the reassigned payments essentially takes the place of the supplier. We have revised §424.80(c) to reflect the new contractual arrangement reassignment exception. The existing §424.80(c) includes the same formulation and we have simply proposed to replace the words "facility" and "system" with "entity," because the new exception for payment to an entity under a contractual arrangement now replaces the previous exceptions for payment to a facility or health care delivery system.

Comment: Three commenters that use independent contractor emergency physicians expressed concern about our statement in the preamble to the proposed rule that the new reassignment exception may create fraud and abuse vulnerabilities, which may not become apparent until the program has experience with the range of contractual arrangements permitted by the new reassignment exception. These groups do not believe that the new reassignment exception will result in an increase in violations of the types addressed in the preamble to the proposed rule. The groups also disagree with our statement in the preamble to

the proposed rule that contractual arrangements with independent contractor physicians may be used to camouflage inappropriate fee-splitting arrangements or payment for referrals. These groups state that Medicare does not govern fee-splitting arrangements, that policing such arrangements is a matter of State law, and that Medicare reassignment policy has no direct effect on this issue. They question why we have expressed concern over potential violations of the physician self-referral prohibition, because section 952 of the MMA does not affect or otherwise change the obligation of providers and suppliers to comply with the physician self-referral prohibition and its accompanying regulations.

Response: The Congress originally passed the prohibition on reassignment provision because of increasing fraud and abuse in billing practices. Since the new reassignment exception has expanded the circumstances under which suppliers can reassign their right to receive Medicare payments, we are concerned that the potential exists for an increased incidence of fraud and abuse, which may not become apparent until the program has experience with the range of contractual arrangements permitted by the new reassignment exception. Fee-splitting arrangements may violate the physician self-referral prohibition and the

anti-kickback statute. Preventing fraudulent and abusive billing practices continues to be the primary purpose of the reassignment rules, even as they are amended to reflect changing practices in the delivery of health care.

We agree that section 952 of the MMA does not change the obligations of providers and suppliers under the physician self-referral prohibition, and all other Medicare statutes and regulations. We are incorporating this clarification in §424.80(a).

Comment: Three organizations that use independent contractor emergency physicians raised procedural concerns regarding the timing of the final rule, which is effective January 1, 2005. The commenters claim that providers and suppliers do not have time to comply with the new program integrity safeguards. They are asking us to provide providers and suppliers with an additional time frame of at least six months for compliance with the program integrity safeguards, if they are finalized. They recommend that we make the new safeguards applicable to enrollment applications submitted on or after the effective date of the final rule.

Response: We do not believe additional time is necessary for compliance with the program integrity safeguards. Providers and suppliers will not have to amend

contracts to include the proposed program integrity requirements. Thus, enrollment applications are not affected by this regulation. The program integrity safeguards will be effective on the effective date of this final rule and these requirements will be applicable to all Medicare providers and suppliers affected by the section 952 change to the reassignment rules.

Comment: One commenter believes that the public comment period for this rule was shortened to 50 days instead of the 60-day comment period required by statute. The proposed rule was published in the **Federal Register** on August 5, 2004 and the public comment period ended at 5:00 pm on September 24, 2004.

Response: While the law requires that we provide a 60-day public comment period and that the notice of proposed rulemaking be published in the **Federal Register**, it does not require that the date of **Federal Register** publication be the first day of the comment period. The two requirements are independent. We post the proposed rule on our website on the date of display of the proposed rule at the Office of the Federal Register, satisfying the requirement for a 60-day comment period. By making the proposed rule available on the CMS website (as well as at the Office of the Federal Register), we provided the public

with access to not only the proposed rule, but also to all of the supporting files and documents cited in the proposed rule in a manner that can be used for analysis. We note that the computer files posted on the website can be used for independent analysis. Therefore, we believe that beginning the comment period for the proposed rule with the display date at the Office of the Federal Register, and posting the proposed rule and data files on the CMS website on the display date, fully complies with the statute and provides a far better opportunity for the public to have meaningful input than the past practice under which the comment period began with the publication date in the **Federal Register**, a week or longer after the display date and no other data in any other form was furnished.

G. Section 642—Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home

In the August 5, 2004 proposed rule, we stated that for dates of service beginning on or after January 1, 2004, Medicare would pay for IVIG administered in the home. The benefit is for the drug and not for the items or services related to the administration of the drug when administered in the home, if deemed medically appropriate. The implementing instructions for this benefit were provided in a transmittal released on January 23, 2004. We received

several comments regarding this new benefit. The comments and our responses are provided below.

Comment: Several commenters expressed concern regarding the lack of coverage for the items and services needed to administer IVIG. These commenters urged us to use our authority to pay for the items that are necessary for the effective use of IVIG.

Response: The MMA provided coverage for the approved pool plasma derivative for treatment in the home; however, new section 1861(zz) of the Act specifically precludes coverage for the items and services related to the administration of the derivative.

Comment: The commenter stated that on January 23, 2004, we released a transmittal implementing the new IVIG coverage. The transmittal contained the following language: "for coverage of IVIG under this benefit, it is not necessary for the derivative (IVIG) to be administered through a piece of durable medical equipment." Commenters stated that this language has resulted in the denial of coverage of IVIG for patients because providers are using the rationale that it is medically unnecessary to infuse IVIG through an infusion pump and therefore IVIG is medically unnecessary. The commenters recommended that we issue a new transmittal

stating that IVIG is to be covered even when administered through durable medical equipment (DME), as determined necessary by a physician.

Response: It was not our intention to deny any beneficiary the coverage of IVIG in the home. It appears that the sentence that references the use of DME for the administration of IVIG is both confusing and misleading. Therefore, we will issue a new transmittal removing the apparent DME restriction.

#### Result of Evaluation of Comments

We are finalizing the proposed revisions to \$410.10 without alteration.

#### H. Section 623—Payment for Renal Dialysis Services

Section 623 of the MMA amended section 1881(b) of the Act and directed the Secretary to revise the current renal dialysis composite rate payment system. The MMA included several major provisions that require the development of revised composite payment rates for ESRD facilities.

The following is a summary of the proposed revisions to the composite payments rate methodology implementing provisions in section 623 of the MMA that are required to be effective January 1, 2005.

- The proposed rule provides for a 1.6 percent increase to the current composite payment rates effective January 1, 2005.
- The proposed rule included an add-on to the composite rate for the difference between current payments for separately billable drugs and payments based on a revised drug pricing methodology using acquisition costs. For purposes of this adjustment, in the proposed rule, we defined acquisition costs as the ASP minus 3 percent. We proposed a single adjustment to the composite payment rates for both hospital-based and independent facilities, equal to 11.3 percent.
- In the proposed rule, we discussed the reinstatement of the ESRD exceptions process for pediatric facilities as provided in section 623(b) of MMA. The statute defines pediatric ESRD facilities as renal facilities at least 50 percent of whose patients are under age 18. Since April 1, 2004, we have accepted ESRD composite rate exception requests from ESRD facilities that believe they qualify for exceptions as pediatric ESRD facilities.
- Section 1881(b) (12) (D) of the Act, added by section 623(d) (1) of the MMA gives the Secretary discretionary



authority to revise the current wage indexes and the urban and rural definitions used to develop them. In the proposed rule, we proposed to take no action at this time to revise the current composite rate wage indexes. Because of the potential payment implications of recently revised definitions of urban areas, we believe further study is required.

- The proposed rule described the proposed methodology for a case-mix adjustment to a facility's composite payment rate based on the statutorily required limited number of patient characteristics. We used co-morbidity data for all Medicare ESRD patients obtained from the Form CMS-2728, supplemented with co-morbidity information obtained from Medicare claims. We measured the degree of the relationship between specified co-morbidities and ESRD facility per treatment costs, controlling for the effects of other variables, using standard least square regression. The source of the per treatment costs was the Medicare cost report. The result, after all necessary statistical adjustments, was a set of eight case-mix adjustment factors based on age, gender, AIDS, and peripheral vascular disease (PVD). Section 623(d)(1) of the MMA requires that aggregate payments under the case-mix adjusted composite payment system be budget neutral. Therefore, the proposed rule provided an adjustment 0.8390 to be

applied to a facility's composite payment rate to account for the effects of the case-mix adjustments.

A. Composite Rate Increase

The current composite payment rates applicable to urban and rural hospital-based and independent ESRD facilities were effective January 1, 2002. Section 623(a)(3) of the MMA requires that the composite rates in effect on December 31, 2004 be increased by 1.6 percent. The updated wage adjusted rates were published in Tables 18 and 19 of the proposed notice.

The tables reflected the updated hospital-based and independent facility composite rate of \$132.41 and \$128.35, respectively, adjusted by the current wage index. The rates shown in the tables do not include any of the basic case-mix adjustments required under section 623 of the MMA.

Comment: Although there were no specific comments on the 1.6 percent adjustment, several commenters wanted to emphasize the importance of providing an annual adjustment to the composite rate in order to recognize the increased costs that face renal dialysis facilities. They stated that failure to increase the composite rate on a regular basis has caused dialysis providers to suffer a significant loss of income from their Medicare reimbursement and that dialysis facilities are the only Medicare entities that do not receive a statutorily mandated annual increase in their reimbursement rates.

Response: We do not have the authority to establish an annual update to the composite payment rates. Section 4201(a)(2) of Pub. L. 101-508 effectively froze the methodology for calculation of the rates, including the data and definitions used as of January 1, 1991. Since that time, the Congress has set the composite payment rate for ESRD services furnished to Medicare beneficiaries. As a result, we do not have the authority to update the composite payment rate.

B. Composite Rate Adjustments to Account for Changes in Pricing of Separately Billable Drugs and Biologicals

Section 623(d) of MMA provides for an add-on to the composite rate for the difference between current payments for separately billable drugs and payments based on a revised drug pricing methodology using acquisition costs.

In the proposed notice we proposed to pay for separately billable ESRD drugs using ASP minus 3 percent based on the average relationship of acquisition costs to average sales prices from the drug manufacturers as outlines in the OIG report. We developed the proposed drug add-on adjustment using the ASP minus 3 percent drug prices. As discussed below, the drug add-on adjustment for this final rule is based on average acquisition costs for the top ten ESRD drugs updated to 2005 and ASP plus 6

percent for the remaining separately billable ESRD drugs. See section III.E, Payment for Covered Outpatient Drugs and Biologicals, for a discussion of the final payment methodology for ESRD separately billable drugs.

In the proposed notice, we outlined the methodology and data used to develop the proposed drug add-on adjustment to the composite rate of 11.3 percent for both hospital-based and independent ESRD facilities. Since the composite rate payment for hospital-based facilities is higher than the composite rate for independent facilities, the proposed adjustment results in a higher payment rate for hospital-based facilities. The 2005 composite rates (including the 1.6 percent increase) would be \$132.41 for hospital-based facilities and \$128.35 for independent facilities with the hospital-based facilities' rate higher by \$4.06. We found this result consistent with section 1881(b)(7) of the Act, which requires that our payment methods differentiate between hospital-based facilities and others. We also indicated that the proposed methodology for making this drug add-on adjustment to the composite rate is designed to ensure that the aggregate payments to ESRD facilities for separately billable drugs would be budget neutral with what would have been paid absent the MMA provisions.

The proposed rule also discussed an alternative approach that produced separate adjustments to the composite rate of 2.7 percent for hospital-based and 12.8 percent for

independent facilities. In contrast to a single add-on, separate add-on adjustments would result in a significantly higher composite payment rate for independent facilities than hospital-based facilities, of \$8.79 more per treatment.

Comment: We received many comments from independent facilities, chain organizations and groups objecting to our proposal to establish a single add-on adjustment to the composite payment rate. Several commenters expressed concern that since hospital-based facilities are paid reasonable cost for their separately billed drugs other than EPO, those facilities should receive an adjustment based only on the spread related to EPO payments. They stated that our proposal to spread the drug savings to all facilities does not comply with the provision in the statute that they believe is intended to hold facilities harmless with respect to their drug payment profit margins. The commenters also contend that since hospital-based facilities already receive about \$4.00 per treatment more than independent facilities, they should not share in the drug add-on adjustment for other than their specific EPO usage.

Response: As we indicated in the proposed rule, we believe that the statutory language supports one uniform drug add-on adjustment to composite payment rates set forth

in section 1881(b)(7) of the Act after updating by 1.6 percent. The provision speaks of one "difference between payment amounts" and "acquisition costs...as determined by the Inspector General." It is reasonable to infer that the Congress intended us to compute one "difference" based only on the payment amounts under sections 1842(o) and 1881(b)(11) of the Act.

Although the language of section 1881(b)(7) contemplates differential composite rates for hospital-based facilities and 623(d) contemplates existing composite rates as the starting point for application of the new rate adjustments prescribed under section 1881(b)(12)(A) of the Act, the MMA language does not suggest that these adjustments would be applied differentially across facilities. Otherwise, all of the adjustments, including case-mix and budget neutrality would have to be developed separately based on facility type.

We note that the amount of the drug add-on has decreased significantly from the proposed rule as a result of our revised policy of paying for ESRD drugs for 2005. Since the drug payment amounts increased, the amount of the drug add-on to the composite rate decreased. The resulting drug add-on amount is now 8.7 percent.

We also note that there is not a significant difference in composite rates for independent facilities

under single and separate add-ons. With a single add-on of 8.7 percent, the 2005 composite rate for independent facilities would be \$139.52. Under a separate add-on approach, the 2005 composite rate for independent facilities would be \$140.93, a difference of \$1.41 or about 1 percent before taking other considerations into account. This difference is about 27 percent less than the difference based on the approach and figures in the proposed rule.

While a composite rate difference of \$1.41 is important, such difference does not take into account two other factors: (1) Since Medicare's 2005 payments for ESRD drugs will be a weighted average of the acquisition costs determined by the Inspector General, the payment amounts for the most utilized ESRD drugs (such as EPO) will be significantly higher than payment based on ASP-3 percent; and (2) Beginning with 2005, Medicare will pay separately for syringes that are currently included in the EPO payments.

With separate add-ons, the composite rate for the independent facilities would be \$7.33 higher than the composite rate for hospital-based facilities. However, the composite rate for hospital-based facilities would be \$10.33 lower under separate add-ons than under a single add-on

approach. We believe the current difference in composite rates where the hospital-based rate is about \$4.00 higher than the independent facility rate would effectively be preserved with a single add-on and significantly reversed with separate add-ons.

Finally, we note that a key purpose of the MMA legislation was to eliminate the cross-subsidization of composite rate payments by drug payments. If the composite rate was inadequate before the MMA provision, it was inadequate for both hospital-based and independent facilities. As such, increasing the composite rate by relatively greater amounts for independent facilities than hospital-based facilities would place the latter facilities at a competitive disadvantage relative to the former facilities.

Comment: One comment from a drug manufacturer suggested that in order to preserve high quality care to ESRD patients and prevent cost shifting behavior, we should require a facility to provide the full range of separately reimbursable drugs and biologicals in order to receive the drug add-on adjustment.

Response: We do not believe the statute permits imposing such a requirement as a condition for receiving the add-on adjustment to the composite rate. However,



other regulations require that ESRD facilities provide appropriate care to each patient based on a plan of care that would include the administration of medically necessary drugs as prescribed by the patient's dialysis physician.

#### 1. Growth Factors Used to Update Drug Expenditures and Prices

Comment: One commenter noted that, in the proposed rule, we updated the 2004 ASP drug prices to 2005 prices by using the projected annual growth factor for National Health Expenditures prescription drugs of 3.39 percent. This commenter wanted to know why we did not use the actual growth factors for separately billable drugs that are furnished by ESRD facilities to ESRD patients. The commenter states that this factor is currently running about 39 percent.

Response: After consideration of the available price data, as discussed in the section on payment for ESRD separately billable drugs, we have determined that the Producer Price Index (PPI) for prescription preparations is the most appropriate price measure for updating EPO and other separately billable drugs from 2003 to 2005. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at

the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) for prescription drugs reflects price changes at the retail stage. Because EPO and many of the separately billable drugs used by dialysis facilities are purchased directly from the manufacturer, the use of a price index that measures wholesale rather than retail prices is more appropriate. The PPI for prescription drugs is the measure used in the various market baskets that update Medicare payments to hospitals, physicians, and skilled nursing facilities, and home health agencies. In addition, the PPI for prescription drugs was recommended for use in the proposed composite rate market basket detailed in the 2003 Report to the Congress.

Based on historical data through the second quarter of 2004, we used the Global Insight Inc. forecast of the PPI for prescription drugs to determine the update factors for 2004 and 2005. We feel the use of an independent forecast, in this case from Global Insight Inc., is superior to using the NHE projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases for Medicare prospective payment systems.

Comment: One comment questioned the 3 percent growth rate that we used in the proposed rule to estimate

2005 Medicare AWP payment amounts for purposes of calculating the drug add-on amount. Specifically, the commenter asked whether the 3 percent figure represented the AWP growth trends for all drugs as opposed to the AWP growth trends for only ESRD separately billable drugs and biologicals. The commenter also asked for clarification of the timeframe used to establish the historical trend.

Several comments also expressed concern that we used a 10-quarter average as an approximation for 2002 expenditures, and as a result, the projected 2005 drug expenditures were understated. These comments strongly recommended that we establish an accurate baseline using actual 2002 expenditures. A study performed for commenters by an industry consultant was cited as confirming that our base year estimate is materially below actual drug spending computed using CMS's 2002 Outpatient Five Percent Standard Analytic File (SAF). Commenters were also concerned that the drug add-on does not reflect the true difference between payments under the current system and acquisition costs described by the OIG.

Response: We have taken all these comments into consideration and have re-evaluated our 2005 projection of aggregate ESRD facility drug expenditures. We did not use an average over 10 quarters to determine aggregate drug

payments. The 10 quarters of data were used only to establish historical growth trends. However, we determined that our estimates of aggregate drug payment amounts were in fact understated because they did not include deductibles and coinsurance. Since drug payment rates are set at 100 percent of the allowable payment, we incorrectly calculated the aggregate drug payment for 2005. We revised our calculation to ensure that we capture the allowable payment before deductible and coinsurance are removed. In addition, we updated our estimates to incorporate the June 2004 update to the 2003 standard analytical file. The 3 percent growth represents our best estimate of the expected growth rate in AWP prices. In addition, due to numerous coding changes for the various ESRD drugs, we were unable to do direct comparisons for each of the AWP prices from year-to-year. Therefore, we believe the 3 percent inflation factor we used to update the AWP prices is appropriate.

Comment: One comment expressed concern that the projected number of dialysis treatments in 2005 would be overstated if home peritoneal dialysis (PD) treatments for home patients are included because facilities do not bill for non-EPO drugs in that setting.

Response: Since ESRD facilities also receive composite rate payments for their Method I home patients, the drug add-on would also apply to composite rate payments for those patients. Therefore, it is appropriate for us to count those treatments in projecting the number of dialysis treatments for computation of the drug add-on amount. We did not, however, count treatments attributable to Method II home patients since payment for these patients is made based on reasonable charges as opposed to the composite rate.

Comment: One comment from a patient organization raised concern that the add-on provision would remove any incentives the current payment policy creates for facilities to provide separately billable drugs and biologicals to dialysis patients. This comment suggested that we establish new clinical guidelines or indicators to ensure that dialysis patients receive necessary drugs and biologicals. This commenter also asked whether we have longer term plans to revise payment for dialysis treatment and ancillary services.

Response: We share this commenters concern that changes in payments to dialysis facilities could produce perverse incentives for dialysis facilities to skimp on care to ESRD patients. In order to ensure that patients

continue to receive quality care, we are revising the ESRD facility conditions for coverage so that they are more patient-centered and outcome-oriented. We will publish proposed ESRD conditions by the end of 2004.

We note that section 623 of MMA also requires us to develop a bundled, case-mix adjusted payment system and report to the Congress by October 1, 2005. This section also requires the establishment of a demonstration to test the revised payment system over a 3-year period beginning January 1, 2006.

## 2. Update Methodology for Drug Add-on Adjustment in 2006

Comment: Several commenters recommended that we publish the methodology that we intend to use to update the drug add-on component of the basic case-mix adjusted payment amounts, beginning in 2006, and that we provide the opportunity for public comment.

Response: We did not propose a mechanism for updating the 2006 payments in this document since this rule addresses payment for 2005. It is our intent to publish a proposed rule in mid-2005 to address payment changes for 2006. The public will be given an opportunity to comment on those proposals at that time.

## 3. Computation of Final Drug Add-on Adjustment to the Composite Payment Rate

To develop the final drug add-on adjustment we used historical total aggregate payments for separately billed ESRD drugs for half of 2000 and all of 2001, 2002 and 2003. For EPO, these payments were broken down according to type of ESRD facility (hospital-based versus independent). We also used the 2003 data on dialysis treatments performed by these two types of facilities over the same period. I.

#### 2005 Average Acquisition Payment (AAP) Amounts

The OIG report contained 2003 average acquisition costs for the top ten drugs supplied by the four largest dialysis chain organizations and by a sample of those facilities not managed by the four largest chain organizations. According to the OIG report, these ten drugs accounted for about 98 percent of total expenditures for separately billed drugs furnished by ESRD facilities. The report also indicated that payment to the four largest dialysis chains accounted for 73 percent of Medicare drug reimbursement in 2002. Therefore, we weighted the average acquisition costs using a 73-27 split. As discussed earlier, we then updated the 2003 weighted average acquisition costs to arrive at the 2005 AAP amounts by using the PPI for prescription drugs. These factors were 4.81 percent and 3.72 percent for 2004 and 2005, respectively.

**TABLE 9:**

	2003 Average Acquisition Costs	2005 Average Acquisition Payment Amounts
Epogen	\$8.98	\$9.76
Calcitriol	0.88	0.96
Doxercalciferol	2.39	2.60
Iron dextran	10.07	10.94
Iron sucrose	0.34	0.37
Levocarnitine	12.53	13.63
Paricalcitol	3.68	4.00
Sodium ferric glut	4.55	4.95
Alteplase, Recombinant	29.19	31.74
Vancomycin	2.74	2.98

**II. Estimated 2005 Medicare Payment Amounts Based on 95****Percent of AWP**

We estimated what Medicare would pay for ESRD drugs in 2005 if the MMA had not been enacted. We adjusted the first quarter 2004 Medicare payment amounts (95 percent of AWP), based on the prices from the January 2004 Single Drug Pricer, for drugs other than EPO, to estimate 2005 prices by using an estimated AWP growth of 3 percent. As discussed earlier, these growth factors are based on historical trends of AWP pricing over years. We did not increase the price for Epogen since payment was maintained at \$10.00 per thousand units prior to MMA.

**TABLE 10:**



Drugs	Estimated 2005 Pre-MMA Medicare Payment Amounts
Epogen	\$10.00
Calcitriol	1.42
Doxercalciferol	5.67
Iron dextran	18.45
Iron sucrose	0.68
Levocarnitine	35.23
Paricalcitol	5.49
Sodium ferric glut	8.42
Alteplase, Recombinant	37.80
Vancomycin	7.24

### **III. Dialysis Treatments**

We updated the number of dialysis treatments based on 2003 data by actuarial projected growth in the number of ESRD beneficiaries. Since Medicare covers a maximum of three treatments per week, utilization growth is limited, and therefore any increase in the number of treatments will be due to enrollment. In 2005, we project there will be a total of 34.8 million treatments performed.

### **IV. Estimated Drug Spending**

We updated the total aggregate 2003 Epogen drug spending for hospital-based and independent facilities using historical trend factors. For 2004 and 2005, we increased the 2003 spending levels by trend factors of 1.0 percent for hospital-based facilities and by 10.0 percent for independent facilities based on historical growth from 2000 to 2003.

We also updated the aggregate AWP based spending for separately billed drugs, other than EPO, for independent facilities by using the 10 percent growth factor for Epogen. Since aggregate spending in this category show extremely varied growth in recent history, we could not establish a clear growth trend. For this reason we decided to apply the Epogen growth rate to the other separately billed drugs. Given the problems establishing growth trends for the other drugs, plus the fact the expenditures for Epogen account for about 70 percent of the total spending for the top ten ESRD drugs, we believe this approach to updating all of the separately billed drugs is appropriate.

Additionally, we deducted 50 cents for each administration of Epogen from the total Epogen spending for both hospital based and independent facilities, to account for payment for syringes that is currently included in the EPO payments. Payment for syringes used in administering EPO will be made separately beginning January 1, 2005. In 2005, we estimate that the total spending for syringes associated with the administration of Epogen will amount to \$1.6 million for hospital-based facilities and \$27 million for independent facilities. For 2005, we estimate that the total spending for Epogen provided in hospital-based facilities will be \$210 million, and \$2.913 billion for

drugs provided in independent facilities (\$2.003 billion for Epogen and \$910 million for other drugs).

#### **V. Add-On Calculation and Budget Neutrality**

For each of the ten drugs in the previous tables, we calculated the percent by which 2005 AAP amounts are projected to be different from the payment amounts under the pre-MMA system. For Epogen, this amount is 2 percent. We applied this 2 percent figure to the total aggregate drug payments for Epogen in hospital-based facilities, resulting in a difference of \$5 million.

Since the top 10 ESRD drugs will be paid at 2005 AAP amounts and the remainder will be paid at ASP plus six percent, we then calculated a weighted average of the percentages by which AAP amounts would be below current Medicare prices, for the top 10 drugs, and the percentage by which ASP plus 6 percent would be below current Medicare payment amounts. For other than the top ten drugs, we do not have detailed data on expenditures for drugs billed by ESRD facilities. Therefore, we computed the percentage by which ASP plus 6 percent is below the estimated 2005 pre-MMA payment amounts for those drugs, using the average of the comparable ASP prices for the top 10 ESRD drugs. This procedure resulted in a weighted average of 13 percent by which the overall revised 2005 drug payment amounts

applicable to independent facilities is projected to be less than the 2005 estimated pre-MMA system (that is, 95 percent of AWP). We then applied the 13 percent weighted average to total aggregate drug spending projections for independent facilities, producing a projected difference of \$385 million.

Combining the 2005 estimates of \$5 million and \$385 million, for a total of \$390 million and then distributing this over a total projected 34.8 million treatments would result in a add-on to the per treatment composite rate of 8.7 percent. We estimate that an 8.7 percent adjustment to the ESRD composite payment rate would be needed to achieve budget neutrality with respect to drug expenditures for ESRD facilities.

#### A. Patient Characteristic Adjustments

As explained in the proposed rule, the current ESRD composite payment rates are not adjusted for variation in patient characteristics or case-mix. Section 623(d)(1) of the MMA added section 1881(b)(12)(A) of the Act to require that the outpatient dialysis services included in the composite rate be case-mix adjusted. Specifically, the statute requires us to establish a basic case-mix adjusted prospective payment system for dialysis services. Also, the statute requires adjustments under this system for a

limited number of patient characteristics. In the proposed notice, we described the development of the methodology for the proposed patient characteristic case-mix adjusters required under the MMA.

In summary, we proposed to use a limited number of patient characteristics that explain variation in reported costs for composite rate services, consistent with the legislative requirement. The proposed adjustment factors are as follows:

**TABLE 11:**

	Age	Adjustment factor
Female	<65 years	1.11
	65-79 years	1.00
	>79 years	1.16
Male	<65 years	1.21
	65-79 years	1.17
	>79 years	1.23
AIDS		1.15
PVD		1.07

Although the magnitude of some of the patient-specific case-mix adjustments appears to be significant, facility level variation in case-mix is limited because of the overall similarity of the distribution of patients among the eight case-mix classification categories across facility classification groups.

We received a significant number of comments regarding the case-mix adjustment factors, which are summarized in this section with our corresponding responses.

1. Sample Data Used to Develop the Basic Case-Mix System

Comment: Comments regarding the sample or universe used to derive the proposed basic case-mix adjustments in the proposed rule expressed concerns about the size of the sample, the number of hospitals and freestanding facilities included, as well as the number of facilities excluded from the data.

Response: We used the database established by our contractor to develop the basic case-mix system in the proposed rule. Facility cost report data were matched to the corresponding facility billing data to insure that the sample reflected the most valid and reliable data available. The specific methodology used to develop the database is discussed in Kidney Epidemiology and Cost Center's (KECC's) Phase I report. The Phase I report entitled: "An Expanded Medicare Outpatient End Stage Renal Disease PPS - Phase I" is available on the University of Michigan website: [www.sph.umich.edu/kecc](http://www.sph.umich.edu/kecc). The contractor has been updating the data files for subsequent phases of their research and is beginning to analyze these data for the bundled prospective payment system. The data used for

the basic case-mix proposed system were also assessed in terms of consistency. Data from 2000, 2001, and 2002 were examined separately as well as combined to determine if there were consistent trends over the 3-year period. The data were updated to include the latest 2002 data that was available as of September 2004. The updated data reflect an increase of approximately 10 percent in the number of facilities represented in the database.

Comment: Several comments expressed concerns regarding the timeliness of the data used to develop the proposed case-mix measures. These concerns focused on the availability of cost reports for 2002. In the proposed notice we acknowledged we were delayed in obtaining cost reports for 2002 and that the final rule would reflect the most recent data on the number of cost reports available.

Response: Table 12 indicates the number of dialysis facilities with at least one cost report for 2000 to 2002. This table also reflects the availability of the most recent cost reports data for 2002 and reflects an increase from the proposed rule of an additional 564 cost reports for the independent facilities in 2002.

**TABLE 12:**

	2000	2001	2002

Independent Facilities	3034	3067	3072
Hospital-based Facilities	476	470	456

The availability of cost reporting data may be delayed because of a number of factors including late submissions by facilities and necessary reconciliation and verification of data by fiscal intermediaries prior to submission to our data systems. The comment on delays and availability of data is also related to concerns expressed by other comments regarding the reporting of co-morbid conditions. Several comments addressed potential inconsistencies in facility reporting of co-morbid conditions, specifically with the impact of the variation of the reporting of AIDs noted in the 2000 data compared to other years. This variation, coupled with the potential incompleteness of the 2002 data, led us to examine options for selecting the time period to be used for determining the case-mix adjustments.

In this final rule, we have decided to use combined data for the 3-year period 2000 - 2002, to determine the case-mix adjustment factors. The use of combined data enables us to eliminate any impact caused by annual variation in reporting, delays in the availability of administrative files, and overemphasizing the predictive significance of selected variables, because case-mix



variables are combined and averaged over a 3-year period, thus representing a more stable database.

Comment: Several comments focused on the number of facilities that were excluded from the study sample in the development of the proposed case-mix adjustments. For the proposed regulation, we excluded from our sample facilities where cost report data could not be matched to claims data and vice versa, or where key data elements were missing. In addition we excluded outlier facilities (those with high or low average costs, or high or low proportions of co-morbid conditions.) Data from small facilities (fewer than 20 patients) and those with existing composite rate exceptions were also excluded.

Response: We concurred with the recommendation to reassess the sample. For the final rule, we are including, within the sample, data for facilities with existing exceptions. However, we have continued to exclude data for small facilities, outliers, and facilities with missing or unusable data. Missing data excluded approximately 11 percent of the sample, and not including small facilities or outlier facilities eliminated approximately 9 percent of the study sample.

We did not accept the suggestion that smaller sized facilities were proxies for rural facilities, however, and

we will continue to study the rural and urban issue in future research and in updates to the wage index.

Overall, including those facilities with exceptions provides a more robust study sample. In this way any effects on the case-mix values due to fluctuations in the data from year to year are greatly diminished.

Comment: Several commenters objected that the database used to develop the basic case mix was not available. One commenter indicated that not having the data made it difficult to evaluate the impact of the proposed case-mix variables on specific facilities.

Response: The database developed for the basic case-mix system is the same database that was developed by the University of Michigan for the ongoing research project to develop a bundled payment system. This database was compiled using our administrative data. We make available for purchase data available in the form of public use files or standard analytic files. Commenters can use the same data files that were used by the University of Michigan to develop the database used. The proposed rule provides the factors necessary to determine impact on individual facilities based on the case-mix within that facility. In addition, we have expanded our discussion of the impact of the case-mix adjustments and have provided a more detailed

example to assist facilities in evaluating the impact of the case mix on their specific facilities.

## 2. Including Co-morbid Conditions in the Case-mix Adjustment

Comment: A number of comments expressed concerns regarding the coding of co-morbid conditions. Some comments acknowledged that limited time has been spent by ESRD facilities in coding multiple conditions. Some stressed that training should be provided to ensure that facilities understand this reporting requirement. One commenter attributed the proposed delay in implementation of the case-mix adjustments to potential difficulties in coding co-morbid conditions and in integrating these coded conditions into the payment.

Response: We considered the commenters concerns regarding incorporating co-morbid conditions and the findings from analyzing more recent data. Although our regression modeling suggests that the inclusion of co-morbidities in the case-mix system would be appropriate, we are concerned that the data available to determine patient level co-morbidities may not accurately reflect diagnoses relevant to the dialysis patient population. Therefore, in this final rule we are not including co-morbidities as case-mix adjustments. As discussed later in this section,

we are establishing the case-mix adjustments based on the following variables: age, body mass index (BMI) and body surface area (BSA). More recent analysis of the data and clinical concerns expressed regarding the inclusion of AIDs and selected PVD diagnoses support this decision. However, while co-morbid conditions are not currently part of the basic case-mix system, we encourage all facilities to more thoroughly report and code co-morbid conditions on their claims. This will enable appropriate refinements to the basic case-mix adjustments and also provide a better database from which we can develop case-mix measures for a bundled payment system.

Comment: One commenter representing a chain of ESRD facilities stated that we overstated the prevalence of patients with peripheral vascular disease (PVD). The commenter maintained that overstating the incidence of PVD in the ESRD outpatient population results in an overstatement of the offset for budget neutrality because of the proposed 1.07 case-mix adjuster for PVD patients, thereby decreasing the otherwise applicable composite payment rate prior to case-mix adjustments. The commenter identified 51 diagnoses from the list of PVD diagnosis codes included in the proposed rule that he believed were either not reflective of PVD in ESRD patients, were not

usually considered as a cause of PVD in ESRD patients, or were poorly differentiated clinically and could occur even in the absence of PVD. The commenter believed that these 51 diagnoses should be excluded from our list of PVD diagnoses for purposes of determining the case-mix and budget neutrality adjustments to the composite payment rates. Another commenter pointed out that there is substantial clinical disagreement about the definition of PVD and that the ESRD claims data presently do not contain sufficient information to implement the proposed PVD adjustor.

Response: The selection of specific co-morbid conditions for purposes of adjusting the composite payment rates to reflect the patient characteristics associated with cost differences across facilities is an important issue, and we appreciate the commenter's suggestions. However, we disagree with the recommendation that we exclude certain diagnoses because they are not usually considered a cause of ESRD in patients. We believe that whether a particular co-morbid condition caused the onset of ESRD is irrelevant. The important factor is whether a particular co-morbid condition is associated with facility differences in composite rate costs, regardless of their role in the etiology of ESRD.

We agree with the commenter's suggestion that diagnoses which can occur in the absence of PVD will be excluded for purposes of applying a case mix adjustment based on PVD. In addition, there is apparent disagreement among clinicians as to whether certain diagnoses are reflective of PVD in ESRD patients, and we will try to achieve as much consensus as possible before proceeding to implement a case mix adjuster which purports to reflect PVD. Accordingly, we are eliminating the case mix adjustment for PVD as set forth in the proposed rule. We point out that further analyses with more restricted sets of diagnostic codes revealed that the omitted codes were still strong predictors of costs. We intend to revisit the issue of appropriate co-morbidity adjustments as we continue our research to develop the bundled ESRD payment system.

We point out that our case mix model that included PVD explained about 35.7 percent of the variation in facility composite rate costs. By comparison, our model using five age groups without co-morbidities explains about 35.6 percent of the cost variations. Although PVD was a statistically significant case mix variable, its contribution to the model's performance overall in explaining facility differences in costs was minimal.

While co-morbidity adjustments will be excluded under the basic case mix adjusted composite payment system, accuracy in the reporting of co-morbid conditions on the bills will become increasingly important because of the likelihood that a bundled ESRD payment system will include co-morbidities associated with differences in patient resource consumption.

Comment: Two commenters recommended that we exclude AIDS as a co-morbidity warranting case-mix adjustment. These commenters stated that because of State laws requiring that a patient's AIDS status be kept confidential, most facilities do not know whether their patients have AIDS. This does not pose a risk to other patients or caregivers because of the universal precautions which dialysis facilities are required to use in order to prevent exposure and infection.

Response: Because the claims data contain primarily the patient's primary diagnosis, AIDS is not likely to be recorded as a claims diagnosis for outpatient dialysis patients. Requiring the recording of the AIDS diagnosis on the bills would create powerful incentives for ESRD facilities to circumvent confidentiality restrictions. In those States with AIDS confidentiality requirements, the diagnosis is not likely to be recorded at all. Given the

relatively low incidence of AIDS patients in the outpatient dialysis population, the fact that facilities in States with AIDS confidentiality requirements would be potentially disadvantaged if AIDS were included as a payment adjuster, and the fact that the relationship between AIDS and dialysis costs was not stable from year to year, we have decided to eliminate AIDS as a basis for case-mix adjustment to the composite payment rates at the present time.

### 3. Case-Mix Adjustment for Gender

Comment: One commenter suggested that we eliminate gender as one of the patient characteristic variables used to case-mix adjust the composite payment rates. The commenter stated that gender was essentially a surrogate for differences in height and weight measures that would yield a superior case-mix adjustment.

Response: Although height and weight are much better predictors of facility variation in composite rate costs, these data were only available on the Form CMS 2728, not on the bills submitted for payment. Accordingly, we used gender as a surrogate measure in proposing adjustments, because gender is reported on the outpatient bill (for example, UB92 or the equivalent electronic form). However, the National Uniform Billing Committee has approved the use



of two new value codes for reporting weight and height (A8 - weight in kilograms, A9 - height in centimeters) on the billing forms effective January 1, 2005.

The mandatory reporting of height and weight permits the development of case mix measures that reflect both variables, such as BMI and BSA, each of which are superior to weight alone as predictors of resource use. Given the impending availability of height and weight data on the outpatient dialysis bill, we examined the predictive power of weight, BMI, and BSA in lieu of gender based on data reported on the Form 2728 from 2000 through 2002. We found that both BMI and BSA are superior predictors to weight alone and that BSA, coupled with a variable for low BMI, is the best predictor of facility differences in composite rate costs. Accordingly, we have eliminated gender in this final rule as a patient classification variable for purposes of case mix adjustment. Instead we are substituting BSA, and a variable for low BMI, each of which are explained in another section of this final rule.

#### 4. Age Groupings Used in Proposed Case-Mix Adjustment

Comment: Several comments indicated that the proposed age groups were too broad. Some of the comments recommended that we create more age categories for purposes of the case-mix adjustments.

Response: In the proposed rule we established three age categories for example: less than 65, 65-79, and greater than 79. In reassessing the study sample and the proposed case mix adjusters, we also explored the age categories. We concur with the comments to expand the number of age categories. For the final rule, there will be five age groupings. These are: 18-44, 45-59, 60-69, 70-79, and 80+. Patients under 18 are discussed in the following section on pediatrics. We believe that the revisions to the age groupings more accurately describe the distribution of the patient population and reflect more refined predictors of age for payment purposes.

Comment: One commenter asked what would happen under our proposed adjustment if during the course of a month, an ESRD patient's age changed and they cross the line into another case-mix adjustment factor. For example, on August 15 a 64-year-old ESRD patient turns 65. They questioned how is this situation is handled and is the age used as of the last day of the month.

Response: We believe it is appropriate to handle this situation as it is handled for enrollment. Thus, for a month when the patient has a birthday that puts him or her into another age category, the first of the month would be the effective date of the patient's new age category.

#### 5. Case-Mix Adjustment for Pediatric Patients

Comment: Several commenters expressed concern over the lack of a case-mix adjustment for pediatric ESRD patients. The commenters stated that although section 623(b) of the MMA provided for an exception process for pediatric ESRD facilities, qualification for a pediatric exception is limited to those facilities where pediatric patients (those under age 18), comprise at least 50 percent of the caseload. The commenters pointed out that ESRD pediatric patients are unusually resource intensive and costly and are widely scattered among facilities, most of which would not qualify as pediatric facilities under the definition set forth in the statute. The commenters recommended that we develop a case-mix adjuster for pediatric ESRD patients using other data sources.

Response: Using the same regression methodology described in the proposed rule, we attempted to develop a case-mix adjuster for outpatient ESRD patients under age 18. However, based on the approximately 600 Medicare

patients for whom bills were available each year from 2000 through 2002, the results were highly variable, statistically unstable, and therefore inappropriate for development of a case-mix adjuster in accordance with the proposed rule's methodology. However, because of the costliness of pediatric ESRD patients, we believe that an alternative case-mix adjustment is warranted, particularly for those facilities, which do not meet the definition of a pediatric facility under section 623(b) of the MMA.

As the commenter correctly pointed out, some facilities would not qualify for consideration for the pediatric exception provided in the law because their pediatric caseload does not constitute 50 percent of their patients. These facilities may still incur substantial costs for the treatment of pediatric ESRD patients. Pending the development of more refined case-mix adjustments that are more sensitive to individual variation in treatment costs under a fully bundled ESRD PPS, we are providing for a single adjustment to a facility's otherwise applicable composite payment rate, developed based on the methodology described below, for outpatient ESRD pediatric treatments. We want to emphasize that the pediatric adjustment factor resulting from this methodology is intended to be a temporary measure. It will only apply

until we can develop an adjustor under the bundled ESRD PPS that is more similar with the case-mix adjustments that would apply to non-pediatric ESRD patients.

During the period from November 1, 1993 to the present time, we identified 19 hospital-based and one freestanding ESRD facility, each of which sought and received an atypical services exception based on the higher costs incurred for the treatment of outpatient pediatric patients. For each of these facilities we obtained the number of treatments at the time the exception was submitted and determined the unadjusted composite payment rate that would have applied beginning January 1, 2005 without regard to any exception amount, that is, each facility's unadjusted composite payment rate was inflated to January 1, 2005 to reflect the statutory increases of 1.2 percent effective January 1, 2000, 2.4 percent effective January 1, 2001, and 1.6 percent effective January 1, 2005.

We then subtracted the inflated January 1, 2005 unadjusted composite rate from each facility's composite payment rate, including the exception amount granted, to obtain the estimated amount of the exception projected to 2005. This amount was multiplied by the number of treatments previously provided, summed for all 20

facilities, and then divided by the number of treatments for all 20 providers to yield an average atypical services exception amount per treatment. The average exception amount for ESRD facilities that received exceptions due to their pediatric caseload, adjusted to 2005, was \$86.79 per treatment. The average unadjusted composite payment rate for these same 20 facilities projected to 2005, similarly weighted by the number of treatments, was \$139.32. Thus, the average composite payment rate adjusted to January 1, 2005, including the average exception amount of \$86.79, was  $\$139.32 + \$86.79$  or \$226.11. Because the average exception amount was calculated from facilities located in areas with differing wage levels, we converted the average pediatric exception amount to a ratio,  $\$226.11/\$139.32$  or 1.62.

This is the case-mix adjustment factor that will be applied to each facility's composite payment rate per treatment for outpatient maintenance dialysis services furnished to pediatric patients. This includes both in-facility and home dialysis. Applying the adjuster multiplicatively in this manner recognizes the wage index variation in labor costs among urban and rural areas built into the composite rates. Notwithstanding this case-mix adjustment per treatment for ESRD pediatric patients, facilities who otherwise qualify as a pediatric facility

under section 623(b) of the MMA will be permitted to seek an exception to this rate if they believe their circumstances warrant a higher payment rate under the atypical services exception provisions set forth in the regulations. We intend the pediatric adjustment factor of 1.62 to be a temporary measure. We anticipate its elimination once the case-mix methodology that will apply in the context of the bundled ESRD PPS is developed. We want the same methodology to apply to both pediatric and non-pediatric ESRD patients.

#### 6. Facility Level Control Variables Used in the Proposed Regression Model

In developing the regression model used to derive the case-mix adjustments, we included variables reflective of facility characteristics. Because facility characteristics do account for differences in facility composite rate costs, we included them in the regression model through the use of facility control variables, so that the patient characteristic case-mix adjusters are not distorted. The facility control variables included the wage index, facility size (based on the annual number of treatments), facility status as hospital-based or freestanding, percent of patients with urea reduction ratios greater than or equal to 65 percent, chain ownership, year of cost report,

and percent of pediatric patients treatments. These variables were not used to calculate the basic case-mix adjustment factors.

Comment: One comment questioned the inclusion of the proportion of patients with urea reduction ratios (URRs) greater than 65 as a facility control variable in the least squares regression model used to develop the case-mix adjustment factors. The comment maintained that because a patient's URR may be correlated with other co-morbid conditions, the coefficients for the variables tested in the model might be distorted. The comment recommended an evaluation of the degree of association between URR and the main co-morbid conditions to determine the extent of any multicollinearity. The comment further stated that if URR is appropriate as a facility control variable, then other surrogates of dialysis efficiency, such as standardized mortality ratio and proportion of patients with hemoglobin readings above specified target levels, should also be considered as control variables.

Response: We believe that case-mix adjustments to the composite payment rate must be determined by patient and not by facility characteristics. To the extent that facility differences in costs are statistically explained by facility and not patient characteristics, we account for



them in the regression model through the use of control variables, so that the potential case-mix adjusters are not distorted. Facility control variables were not used to develop the adjustment factors to the composite payment rates.

For example, chain affiliation, facility size, and status as a hospital-based or freestanding facility were associated with statistically significant differences in facility costs. However, it would be inappropriate to object the payment rates based on a facility belonging to a particular chain, or based on the number of annual treatments.

To test for multicollinearity, that is, to ensure that each co-morbidity tested for inclusion in the regression model was not correlated with other variables, we ran a correlation matrix. The correlation matrix included URR. URR was found not to correlate with any of the co-morbidities tested; in statistical parlance, it was orthogonal. Accordingly, low URR was not a surrogate of co-morbidity. Therefore, we believe it was appropriate to treat URR as a quality of care outcome measure at each facility. The effect of using URR as a facility control variable was to ensure that the case-mix adjustment factors were not distorted for facilities with similar URR

outcomes. For example, if larger patients receive lower doses of dialysis, not controlling for URR could impart a downward bias on the coefficient for patient size. The comment also suggested the use of other variables as facility control variables such as standardized mortality ratio (SMR) and hemoglobin count. Because SMR standardizes or controls for the effect of case mix on the ratio, we would have to ensure consistency in the reporting of specified co-morbidities on the bills in order to ensure the validity of each facility's SMR. That consistency currently does not exist. Facilities are only required to report hematocrit/hemoglobin on the claims available for those patients receiving erythropoietin (EPO). However, because the proportion of patients receiving EPO is high, the use of hematocrit/hemoglobin as another outcome facility control variable is feasible, but mainly in the context of the bundled payment system. Since the drugs and lab tests associated with anemia management are paid outside the composite payment rate, hematocrit/hemoglobin level would not be appropriate as a control variable applicable to composite rate costs.

#### 7. Propriety of Case-mix Adjustment

Comment: Several commenters expressed reservations about our proceeding with the implementation of a case-mix

adjustment to the composite payment rates using the methodology set forth in the proposed rule. One commenter cited the May 19, 2004 report prepared by the KECC of the University of Michigan, which pointed out that the proposed case-mix variables collectively explained less than 1 percent of the facility variation in composite rate costs, although the addition of facility control variables increased this proportion to about 33 percent. One commenter stated that the low explanatory power of the proposed case-mix variables indicated that they do not accurately predict cost variation and are flawed. The commenter suggested that we defer applying a case-mix model until the results of the demonstration project mandated under section 623(e) of the MMA are available.

Response: We would have preferred to develop a case-mix adjustment in the context of a bundled outpatient ESRD PPS. In a fully bundled PPS, which section 623(f) of the MMA anticipates, routine and separately billable dialysis related services, drugs, and clinical laboratory tests would be included in the payment bundle. KECC's previous research revealed that, for separately billable services, case-mix explained about 23 percent of the variation in cost across dialysis facilities. (See Hirth, et al., Is Case-Mix Adjustment Necessary for an Expanded Dialysis

Bundle?, Health Care Financing Review, 2003, 24, pages 77-88).

However, the enactment of Pub. L. No. 108-173 foreclosed the option of deferring implementation of a casemix adjusted composite rate based on a limited number of patient characteristics effective January 1, 2005. We do not believe that the statutory directive set forth in section 623(d) of the MMA permits us to defer the development of a basic case-mix measure, one based on a "limited number of patient characteristics."

We do not agree with the statement that, because the proposed case-mix adjusters collectively account for about 1 percent of the facility variation in composite rate costs, the variables used are fundamentally flawed. In fact, when data is combined over three years, each of the proposed case-mix variables is highly significant statistically, despite the low proportion of facility variation in costs explained. A more important indicator of the importance of the case mix factors identified is the size of the adjustments. If the identified case mix variables did not have a meaningful relationship with costs, the magnitude of the adjustment factors would be insignificant or trivial. They are not. As explained in this final rule, based on our analysis of the comments we

received, we have revised the case-mix variables used to adjust the composite payment rates. Our research to develop a statistically robust clinically coherent case-mix measure in the context of the fully bundled ESRD PPS will continue.

#### 8. Alternative Case-mix Variables

Comment: Several commenters suggested alternative case-mix variables which they believe account for patient differences in resource consumption and would better distinguish facility differences in composite rate costs. The patient characteristics proposed by commenters included quarterly serum albumin values, cancer, limb amputation, gastrointestinal disorders, body mass index, weight, revised age groupings, hypertension, duration of dialysis treatment, and others. The commenters indicated that, based on their clinical judgment, the suggested factors were more likely to be predictors of variability in the cost of care than the proposed AIDS and PVD co-morbidities. A few commenters recommended a delay in the implementation of the case-mix adjusted composite payment rates pending evaluation of the suggested variables. A number of comments indicated that BMI was a significant predictor of cost and recommended that BMI be included in the case-mix

adjustment. Another commenter recommended BSA be examined as a potential case-mix predictor.

Response: We appreciate all of the comments we received proposing alternative case-mix variables. We welcome suggestions for case-mix refinement based on sound clinical judgment, especially when analyses including separately billable ESRD services are performed as our research for development of the bundled ESRD payment system progresses. However, we point out, that unless the existence of a suggested co-morbidity or patient characteristic could be determined from either the Form CMS 2728 or claims data which could be linked to a specific ESRD dialysis patient, we were unable to evaluate its potential to predict facility differences in composite rate costs. Furthermore, unless a patient characteristic can be reported on the UB 92 claim form (or the equivalent electronic version), it cannot be used to adjust a facility's composite payment rate. These limitations eliminate for consideration many of the commenters' suggested alternative patient characteristic variables.

Nonetheless, our regression model evaluated 35 patient characteristics including weight, BMI, BSA, seven types of cancer, diabetes, chronic obstructive pulmonary disease, four types of heart disease, and race. Co-morbidities

selected for inclusion in the model with significant negative coefficients were removed from subsequent iterations of the stepwise regression model. The inclusion of such co-morbidities would have resulted in reductions in the otherwise applicable composite rate payments. Because we can now require the reporting of height and weight on the claim form beginning January 1, 2005, we have adopted the commenters' suggestions to use either BMI or BSA as a predictor variable. We selected BSA and low BMI because they improve the model's ability to predict the costs of composite rate service compared to using BMI or weight alone. In addition, we have increased the number of age groups from three to five and eliminated gender as a payment variable entirely.

As explained later in the "Implementation Date" section, we do not believe it would be appropriate to further delay the implementation of the basic case-mix adjustment. We proposed delaying implementation of the case-mix payments until April 1, 2005 in order to ensure all systems, programming, and other operational requirements are in place. Between publication of this final rule and the implementation date, we will conduct training programs to ensure that facilities understand both

the payment methodology and reporting requirements necessary to ensure appropriate payment to ESRD facilities.

#### 9. Continuing Research to Develop a More Fully Bundled Case-mix System

Comment: Several comments requested additional detail regarding the continuing research for the development of a more fully bundled system.

Response: The research activities for the fully bundled system have focused on updating the database. Research efforts since the passage of MMA have focused on supporting the Congressional mandate for the development of a limited number of case-mix variables. Following the publication of this rule, we anticipate that the emphasis will return to the development of a bundled prospective payment system that includes bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. This research will be reflected in an October 1, 2005 Report to the Congress.

In addition, the MMA requires us to establish the fully case-mix adjusted demonstration which will bundle into the payments both separately billable drugs and biologicals and clinical labs. Both the Report to the Congress and the demonstration will be supported by continuing research.



## 10. Body Measurements as Case-Mix Adjusters

In the proposed rule, we had discussed the importance of the BMI as a measure of resource consumption related to the composite payment rate. At that time, our analysis indicated that patients with very low or high BMI were more costly to treat. At the time of the publication of the proposed rule, we had no mechanism to obtain indicators for height and weight on the claims form. We had indicated that we would be exploring adding height and weight to the bills.

Comment: A number of commenters endorsed the use of low BMI as an appropriate surrogate for the severity of morbid conditions associated with malnourishment in the dialysis population, and some suggested that a BMI below 20.0 kg/m<sup>2</sup> is generally considered in the underweight range. In addition, we also received comments regarding the inclusion of a measure of BSA.

Response: We concur with the comments to include BMI and BSA as case-mix adjusters reflecting patient characteristics that explain variation in the reported costs for composite rate services. We have obtained approval to collect both height and weight on the bill through the use of two new value codes. ESRD facilities will be required to report height and weight using these value codes, so that payment can be based on the case-mix adjusted composite rate payment system on April 1, 2005.

For the implementation of the basic case-mix payments, we are providing an adjustment for low BMI, that is, any patient with a BMI less than 18.5 kg/m<sup>2</sup>. We included this variable because our regression analysis indicated that those patients who are underweight and malnourished consume more resources than other patients. Although we received one comment suggesting defining low BMI as 20 kg/m<sup>2</sup>, we chose the measure of low BMI that is consistent with the CDC and NIH definition for malnourishment. Furthermore, our exploration of alternative BMI thresholds did not improve the model's ability to predict the costs of composite rate services.

In addition, we are providing case-mix adjustments based on BSA. Our research into this body measurement indicated that BSA (meters<sup>2</sup>) is a good predictor of composite rate resource consumption. We examined all of the formulas for BSA. While we found very little differences between the formulas in predictive power, we are adopting the Dubois and Dubois formula for BSA since our literature search revealed that this particular formula was the most widely known and accepted. This formula is:

$$BSA = W^{0.425} * H^{0.725} * 0.007184$$

(DuBois D. and DuBois, EF. "A Formula to Estimate the Approximate Surface Area if Height and Weight be Known": Arch. Int. Med. 1916 17:863-71.),

where  $w$  and  $h$  represent weight in kilograms and height in centimeters, respectively.

In addition, we explored a number of options for setting the reference values for the BSA. We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on this analysis, we are setting the reference point at a BSA of 1.84 (the average BSA among dialysis patients in 2002). By setting the reference point at the average BSA, the adjusters will reflect the relationship of a specific patient's BSA to the average BSA of all patients. Therefore, some adjusters will be greater than 1.0 and some will be less than 1.0. In this way, we are able to minimize the magnitude of the budget neutrality offset to the composite payment rate.

The following presents an example of the method for calculating patient level multipliers that were derived from the coefficients resulting from the regression model that includes control variables, expanded age groups, BSA, and an indicator for low BMI ( $<18.5 \text{ kg/m}^2$ ). The model excluded small facilities, and outliers.

Case-mix adjuster = Age factor \* low BMI factor \* BSA factor

Although we could have selected any increment, we believed an increment of 0,1 provided and appropriate degree of precision of the calculation of the exponent used to compute the BSA case-mix adjustment. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.84 divided by 0.1. The BSA adjustment factor of 1.037 is then exponentiated based on the calculated BSA factor as  $1.037^{((BSA - 1.84)/0.1)}$

For Example:

The case-mix adjuster for a 47-year old person who is underweight (BMI<18.5 kg/m<sup>2</sup>) and has a body surface area of 2.0 m<sup>2</sup> is calculated by using the 1.84 BSA reference point:

Age Factor = 1.055

Low BMI Factor = 1.112

BSA Factor =  $1.037^{((2.0-1.84)/0.1)} = 1.037^{(1.6)} = 1.060$

Case-Mix Adjuster = 1.055 \* 1.112 \* 1.06 = 1.244

The resulting case-mix adjustment factor of 1.244 for this patient would be applied to the facility's composite payment rate that is adjusted for area wage index, drug add-on, and budget neutrality.

## 11. Budget Neutrality for Case-Mix Adjustment

Section 1881(b)(12)(E)(i) of the Act, as added by section 623(d)(1) of the MMA, requires that the basic case-mix adjusted composite rate system be designed to result in the same aggregate amount of expenditure for such services, as estimated by the Secretary, as would have been made for 2005 if that paragraph did not apply. Therefore, the patient characteristics case-mix adjustment required by section 623(d)(1) of the MMA must result in the same aggregate expenditures for 2005 as if these adjustments were not made.

In order to account for the payment effect related to the case-mix adjustment, we proposed to standardize the composite rate by dividing by the average case-mix modifier of 1.1919. The proposed budget neutrality adjustment to the composite rate was 0.8390. However, we were not able to simulate case-mix effects at the bill level because comorbidities are generally not reported on the ESRD bill. We still intend to refine our case-mix adjustments once we have more complete patient data on the ESRD bill. In this final rule, we have refined our adjustment for budget neutrality related to the case-mix factor. We simulated payment for each ESRD provider by applying a facility-specific case-mix multiplier to the composite rate applicable for that facility. Since the pediatric case-mix adjustment was developed outside the regression model, we simulated payments separately for those treatments. The results of these two computations were then combined to arrive at the

total case-mix adjusted payments. We also simulated payment for each provider as if they did not receive any case-mix adjustments. We then compared the total simulated payments with case-mix adjustment to total simulated payments without case-mix adjustment. The resulting budget neutrality adjustment to the composite rate is 0.9116.

B. Revised Patient Characteristic Adjustments

The following section discusses in detail the final case-mix adjustments to the ESRD composite rate payment.

In summary, based on the comments that we received on the proposed case-mix and additional analyses prepared by our contractor, KECC, in this final rule, we are modifying the proposed case-mix adjustments. We have broadened the number of age groups to include five age categories and added low BMI and BSA as measures. We have also included a specific case-mix adjustment for pediatric patients under age 18. We excluded the proposed categories gender and co-morbid conditions. We will be using a limited number of patient characteristics for the basic case mix system; however, we believe that these adjustments adequately explain variation in the reported costs per treatment for the composite rate services consistent with the legislative requirement. The adjustment factors for the basic case mix are listed in Table 13 below.

**TABLE 13:**

Variable	Multiplier
Age      Pediatrics <18 **	1.62
18-44	1.223
45-59	1.055
60-69	1.000
70-79	1.094
80+	1.174
Body Surface Area (per 0.1 Δ BSA of 1.84)	1.037
Low BMI (<18.5 kg/m <sup>2</sup> )	1.112

\*\* BSA and BMI adjustment do not apply to pediatric patients.

The following table illustrates the average case-mix adjustment by type of provider based on the 2002 data that was used to develop the adjustment factors.

**Table 14:**

Facility Type	Average Case-Mix Adjustment
All	1.0967
Independent	1.0963
Hospital-Based	1.0990
Urban	1.0957
Rural	1.1009
Small (<5k treatments/yr.)	1.1027
Medium (<5-10k treatments/yr.)	1.0995
Large (>10k treatments/yr.)	1.0947
Non-Profit	1.1004

For-Profit

1.0957

As illustrated in table 14, regardless of the type of provider, the projected average case-mix adjustments for patient characteristics do not vary significantly.

#### C. Rural Facilities

Comments: Some commenters focused on the potential impact the revised composite rate payment system could have on rural facilities. They were initially concerned that excluding small facilities from the overall sample actually reflected the elimination of rural facilities from the sample. As a means of resolving this issue, they suggested that a rural facility exception be restored.

Response: The MMA provision for composite rate exceptions limited the availability of exceptions only to pediatric facilities. To the extent that a qualifying pediatric facility is located in a rural area, it would be able to apply for an exception to its composite payment rate.

#### D. Dual Eligible Dialysis Population

Comment: One commenter expressed concerns regarding potential impact on the dual eligible population, specifically with respect to coverage of deductibles and coinsurance amounts. Concern was expressed regarding the



impact of this proposal on the Medicaid population on a state-by-state basis.

Response: We recognize that this is an important issue for ESRD facilities and can be particularly problematic for chain organizations that own facilities in multiple States. While we cannot direct States for payment for dual eligible beneficiaries, we will take appropriate action to ensure that States are aware of the changes we are implementing so they can take steps to adjust their payments for dual eligible dialysis patients.

#### E. Budget Neutrality

Section 623(d)(1) of the MMA added section 1881(b)(12)(E)(i) of the Act, which requires that the basic case-mix adjusted composite rate system be designed to result in the same aggregate amount of expenditure for services, as estimated by the Secretary, as would have been made for 2005 if that paragraph did not apply. Therefore, the drug add-on adjustment and the patient characteristics case-mix adjustment required by section 623(d)(1) of the MMA must result in the same aggregate expenditures for 2005 as if these adjustments were not made.

For the proposed drug payment add-on adjustment, we indicated in the proposed rule that the methodology we used to estimate the difference between the current and proposed

drug payments was designed so that aggregate payments would be budget neutral.

In addition, the proposed rule provided for a budget neutrality adjustment to the composite payment rate of 0.8390 to account for the affects of the proposed case-mix adjustments on aggregate expenditures.

Comment: We received a number of comments concerning our application of the budget neutrality provision of section 623 of MMA. Specifically, many comments suggested that we did not comply with Congressional intent that facilities would be held harmless by this provision, that is, that facilities would not receive lower payments than they otherwise would have.

Response: Section 623 of MMA requires that aggregate payments in 2005 not exceed payments that would otherwise be paid. The budget neutrality provision is to ensure that total aggregate payments from the Medicare trust fund will not increase or decrease as a result of changes in the payment methodology. As with other Medicare payment systems, changes in the payment mechanism will result in the redistribution of Medicare dollars across facilities. There is no provision (nor any implication) in section 623 of the MMA that guarantees that individual facilities would

receive the same amount of payment under a case-mix adjusted system as they did previously.

The final budget neutrality adjustment to the ESRD composite payment rate applicable to the case mix adjustments (including the pediatric adjustment) is 0.9116. Also in the proposed rule, the calculation of the drug add-on adjustment was designed to ensure budget neutrality with respect to aggregate drug payments.

#### F. Geographic Index

Comment: Several comments expressed disappointment that we did not propose revisions to the current outdated wage indexes reflected in the composite payment rates, despite the discretionary authority set forth in section 623(d)(1) of the MMA to replace them. These comments stated that this decision likely would have the greatest impact on facilities located in high cost and high wage areas, where competitive labor market pressures are more pronounced. Comments generally were in favor of using the most up-to-date information available for developing a revised composite rate wage index.

Response: The wage index currently used in the composite rates is a blend of two wage index values, one based on hospital wage data from fiscal year 1986 and the other developed from 1980 data from the Bureau of Labor

Statistics. The wage index is calculated for each urban and rural area based on 1980 U.S. Census definitions of metropolitan statistical areas (MSAs) and areas outside of MSAs. Restrictions apply to the wage index values used to develop the composite payment rates. Payments to facilities in areas where labor costs fall below 90 percent of the national average, or exceed 130 percent of that average, are not adjusted below the 90 percent or above the 130 percent level. This effectively means that facilities located in areas with wage index values less than 0.90 are paid more than they would receive if we fully adjusted for area wage differences. Conversely, facilities in locales with wage index values greater than 1.30 are paid less than they would receive if we fully adjusted payment for these higher wage levels.

We agree that the current ESRD composite rate wage indexes, and the definitions of the geographic areas on which they are based, need to be updated. On June 6, 2003, OMB issued Bulletin 03-04, which announced new geographic areas based on the 2000 Census. The extent to which we use the new OMB geographic definitions, incorporate them into the various prospective payment systems (PPSs) we administer, and whether we rely on hospital wage and employment data to develop new composite rate wage index

values will have the potential to significantly redistribute payments among ESRD facilities.

In the August 11, 2004 **Federal Register** (69 FR 48916), we announced how we were revising the hospital wage index used in connection with inpatient PPS. Although one comment stated that we should adopt the same wage index used in connection with the inpatient PPS, several of the hospital wage index revisions stem from specific provisions of law (for example, geographic reclassification of hospitals) and would not necessarily be appropriate to apply to a revised ESRD wage index for the composite payment rates. Because of the discretion afforded the Secretary in developing a new wage index for ESRD payment purposes, we are carefully assessing the propriety and payment implications of policy options before recommending revisions to the current measure. We will not take action to replace the current composite rate wage index at this time. We point out that, in accordance with section 623(d)(1) of the MMA, any revisions to the wage index ultimately adopted must be phased in over a multiyear period.

G. Payment Exceptions and the Revised Composite Payment Rate

1. Application of Statutory Increases to Exception Amounts

Comment: Several comments were critical of our policy of not applying increases to composite rates, mandated by the Congress, to amounts paid under exceptions. The comments maintained that this policy is inequitable, precludes the proper application of inflation updates to costs that we had recognized as appropriate in granting the exception, and over time erodes the value of the exception because of the cumulative impact of an effective "historical freeze."

Response: The commenters are correct that we have only applied the Congressionally mandated statutory increases to the basic wage index adjusted composite payment rates, not to exception payments. For example, a provider which was authorized a \$12.00 atypical services exception amount per treatment in addition to its otherwise applicable composite payment rate of \$125.00 effective August 12, 2000 would not be entitled to the 2.4 percent increase applicable to composite rate payments on January 1, 2001, because its exception rate of \$137.00 exceeded its basic rate of \$125.00 increased by 2.4 percent or \$128.00. While the commenter believes that our policy

of not applying the Congressional mandated increases to exception amounts is unfair, we believe that the policy is consistent with the law. Section 422(a)(2)(C) of SCHIP, enacted December 21, 2000, states as follows in pertinent part:

Any exception rate under such section in effect on December 31, 2000...shall continue in effect so long as such rate is greater than the composite rate as updated...

Thus, the statute seems to distinguish between an exception rate and the composite rate, as "updated" by the Congress. The clear implication of the text is that the exception rate is not so updated. Accordingly, we believe that our policy of not applying mandated composite rate increases to exception amounts is consistent with the statute. Moreover, we point out that section 422(a)(2) of SCHIP prohibited the granting of new exceptions and that we are providing facilities the option of either retaining their exception rates, or at any time, electing payment under the case-mix adjusted composite payment rates. We do not believe providers, given this option, will be disadvantaged.

## 2. Home Dialysis Training Exceptions

Comment: We received comments asking for clarification concerning home dialysis training exceptions

since the proposed rule only addressed exceptions in a very general way. They stated that the rule proposes that each facility with an exception rate would compare their exception rate to the new basic case-mix adjusted prospective payment and then decide if it wishes to withdraw the exception rate and be subject to the basic case-mix adjusted composite rate. The commenters stated that this language does not consider a facility that would choose to accept the basic case-mix adjusted prospective payment for its chronic treatments, but continue its exception rates for the training of home patients. The home training exception is the most widely used exception and provides a higher rate for the higher cost of training a patient in fewer than the maximum number of allowed treatments.

Response: We agree and are providing that a home training exception rate may be continued. Facilities with home training exceptions will be able to retain their current exception training rates as well as take advantage of the case-mix adjusted rate for non-training dialysis.

### 3. New Exception Window

Comment: One commenter requests that a new "exceptions window" for pediatric facilities be opened in early 2005. It will not be until after this rule is final



that its members will be able to determine the exact impact of this new methodology on their operations.

Response: Section 623(b) of MMA reinstated exceptions for qualifying pediatric facilities defined as facilities with at least 50 percent of their patients under 18 years of age. The current exception window for pediatric facilities closed on September 27, 2004. At this time, future exception windows will be open only for pediatric facilities. The exceptions process is opened each time there is a legislative change in the composite payment rate or when we open the exception window. The fiscal intermediary will notify the ESRD pediatric facilities when a new exception window opens. However, it is our intent to open pediatric exception windows on an annual basis.

### 3. Home Dialysis Training Rates

Comment: One commenter asked if the training rate add-on to the composite rate would still be applied.

Response: Yes, the following rates will apply for self-dialysis or home dialysis training sessions:

- For intermittent peritoneal dialysis (IPD), continuous cycling peritoneal dialysis (CCPD) and hemodialysis training, the facility's case-mix adjusted payment excluding any approved exception rates will be

increased by \$20 per training session, furnished up to three times per week.

- For continuous ambulatory peritoneal dialysis (CAPD), the facility's case-mix adjusted payment excluding any approved exception rates will be increased by \$12 per training session, furnished up to three times per week.

Based on the example for John Smith in section L (Example of Payment Calculation Under the Case-Mix Adjusted Composite Rate System), the hemodialysis (IPD & CCPD) training rate would be his case-mix adjusted rate of \$170.80, increased by the training add-on of \$20 for a total training rate of \$190.80. For CAPD training, the training rate would be \$182.80 (\$170.80+\$12)

#### H. Implementation Date

Comment: We received a number of comments supporting our proposed delay in implementing the case-mix portion of the revised composite payment methodology. Many comments maintained that the proposed April 1, 2005 effective date was overly ambitious, and some suggested that a July 1, 2005 implementation date would be more realistic given the need for facility and fiscal intermediary training and education.

Response: The MMA requires that the basic case-mix adjusted composite payment rates be effective for services beginning January 1, 2005. Despite the statute's specificity, we pointed out in the proposed rule that all of the numerous systems, programming, and operational changes necessary to implement the case-mix adjusted payments cannot be completed in time for a January 1, 2005 implementation date.

As presented in the proposed rule, we considered two options that we believed effectively complied with the statute's January 1, 2005 implementation date. While we stated in the proposed rule that either of these options substantively complies with the January 1, 2005 implementation date requirement of the statute, we rejected both alternatives.

The likelihood of payment error, potential disruption of facility payments, and the cost of reprocessing bills militated against either option. We proposed instead an April 1, 2005 implementation date for the basic case-mix adjustments to the composite payment rates, including the budget neutrality reduction. This option avoids the need for reprocessing of bills and applies the budget neutrality adjustment applicable to the case-mix adjustments effective April 1, 2005. Although we agree with the comment that a

July 1, 2005 effective date would be ideal in light of the systems and operational changes required to implement the case-mix provisions, we believe that an April 1, 2005 effective date for the case-mix adjustments is feasible, and have decided not to revise that date. We have concluded based on our evaluation of ESRD claims processing systems that the April 1, 2005 implementation date is achievable. As we stated in the proposed rule, the 1.6 percent increase to the composite payment rates and drug add-on will be effective January 1, 2005.

I. Summary of Final Rule Implementing Changes to the ESRD Composite Payment Rate (Section 623 of MMA)

As set forth in this final rule, we will increase the ESRD composite payment rates by 1.6 percent effective January 1, 2005 in accordance with section 623(a) of the MMA. Also, the composite payment rates will be increased January 1, 2005 by 8.7 percent to reflect revisions to the drug pricing methodology for separately billable drugs, as discussed previously in this rule (Composite Rate Adjustments to Account for Changes in Pricing of Separately Billable Drugs and Biologicals). This section explains the development and computation of the revised drug add-on, which differs from the 11.3 percent amount described in the proposed rule, and our response to comments which advocated

separate add-on amounts for hospital-based and independent facilities

Despite the discretionary authority set forth in section 623(d)(1) of the MMA to replace the current outdated wage index used in the composite payment rates, we are taking no action to revise the wage index at the present time. A revised wage index will potentially significantly redistribute ESRD payments. We believe that further study is warranted before we revised the current index. Those assessments are presently underway.

We have also adopted a revised basic case-mix methodology for adjusting the composite payment rates based on a limited number of patient characteristics, as prescribed in section 623(d) of the MMA. The development and application of the revised case-mix adjusters were previously explained in the "Revised Patient Characteristic Adjustments" section of this final rule. The variables for which adjustments will be applied to each facility's composite payment rate include age, BSA, and low BMI. In response to comments, we eliminated gender in this final rule as a patient classification variable for purposes of case-mix adjustment, substituting BSA and a low BMI variable instead. We have also increased the number of age categories from three to five, and eliminated co-morbidities pending further study. Because height and weight are necessary to compute each patient's BSA and BMI, those

measurements, in centimeters and kilograms, respectively, will be required on the UB 92 for outpatient ESRD services furnished on and after January 1, 2005. This final rule also provides for a case-mix adjustment of 1.62 to a facility's composite payment rate for pediatric ESRD patients (that is, under age 18). The methodology used to develop the pediatric case-mix adjustment factor of 1.62 is described in the "Case-Mix Adjustment for Pediatrics Patients" section of this rule. Although the MMA requires that the basic case-mix adjusted composite payment rates be effective for services beginning January 1, 2005, the systems and operational changes necessary to implement them cannot be completed in time for a prospective January 1, 2005 effective date. The case-mix adjustments and the applicable budget neutrality adjustment of 0.9116 will be effective April 1, 2005.

#### Example of Payment Calculation Under the Case-Mix

##### Example 1

##### Adjusted Composite Rate System

The following example presents 2 patients dialyzing at Neighbor Dialysis, an independent ESRD facility located in Baltimore, MD.

#### Calculation of Basic Composite Rate for Neighbor Dialysis:

Wage adjusted composite rate for independent

facilities in Baltimore, MD

\$134.93

Wage adjusted composite rate increased by drug \$146.67

add-on adjustment \$134.93 x 1.087

Adjusted Facility Composite Rate after

Budget neutrality adjustment (\$146.67 x 0.9116) \$133.70

#### Patient #1

John Smith attains age 18 on April 10, 2005 and undergoes hemodialysis. John weighs 75.5 kg. and is 181.5 cm. in height. Because John Smith attains age 18 April 10, he is considered age 18 for the entire month of April, and would not be classified as a pediatric patient.

#### Calculation of case mix adjusted payment

The BSA and BMI for John Smith will be calculated by the PRICER program used to compute the composite payment for each patient based on the height and weight reported on the UB 92. However, the computations of the BSA and BMI for John Smith are shown below:

$$BSA = 0.007184 \times (\text{height})^{0.725} \times (\text{weight})^{0.425}$$

$$BSA = 0.007184 \times 181.5^{0.725} \times 75.5^{0.425}$$

$$BSA = 0.007184 \times 43.4196 \times 6.2824 = 1.960$$

$$BMI = \text{weight}/\text{height (m)}^2$$

John Smith is 181.5 cm. in height, which converts to 1.815 meters.

$$BMI = 75.5/1.815^2 = 22.919$$

The case mix adjustment factor for John Smith, an 18 year old whose BMI exceeds  $18.5 \text{ kg/m}^2$  and has a BSA of 1.960 is calculated as follows:

Age adjustment factor (age 18-44)

1.223

BMI adjustment factor ( $\text{BMI} \geq 18.5 \text{ kg/m}^2$ ) 1.000

BSA adjustment factor ( $1.037^{(1.960-1.84/0.1)}$ ) 1.0446

Case mix adjustment factor ( $1.223 \times 1.000 \times 1.0446$ ) 1.2775

Basic case mix adjusted composite payment ( $\$133.70 \times 1.2775$ ) \$170.80

#### Patient 2

Jane Doe is a 82 year old malnourished patient who undergoes hemodialysis. Jane is 158.0 cm. in height.

#### Calculation of case mix adjusted payment

The BSA and BMI for Jane Doe, which will be automatically computed by the PRICER program, are calculated as follows:

$$\text{BSA} = 0.007184 \times (\text{height})^{0.725} \times (\text{weight})^{0.425}$$

$$\text{BSA} = 0.007184 \times 158.0^{0.725} \times 31.25^{0.425}$$

$$\text{BSA} = 0.007184 \times 39.2669 \times 4.3183 = 1.2182$$

$$\text{BMI} = \text{weight}/\text{height(m)}^2$$

Jane Doe is 158 cm. in height, which converts to 1.580 meters.

$$\text{BMI} = 31.25/1.580^2 = 12.5180$$



The case mix adjustment factor for Jane Doe, an 82 year old whose BMI is less than  $18.5 \text{ kg/m}^2$  and has a BSA of 1.2182, is calculated as follows:

Age adjustment factor (age 80+)	1.174
BMI adjustment factor ( $\text{BMI} \leq 18.5 \text{ kg./m}^2$ )	1.112
BSA adjustment factor ( $1.037^{(1.2182-1.84/0.1)}$ )	0.7978
Case-mix adjustment factor ( $1.174 \times 1.112 \times 0.7978$ )	1.0415
Basic case mix adjusted composite payment ( $\$133.70 \times 1.0415$ )	\$139.24

#### Example 2

Linda Jones is age 16 and undergoes peritoneal dialysis at Community Hospital, a hospital-based facility in New York City. Linda weighs 35 kg and is 160.0 cm in height. The basic composite rate for Linda Jones is calculated as follows:

Wage adjusted composite rate for hospital-based facilities in New York, New York	\$146.35
Wage adjusted composite rate increased by drug Adjustment factor ( $\$146.35 \times 1.087$ )	\$159.08
Adjusted Facility Composite Rate after Budget neutrality adjustment ( $\$159.08 \times 0.9116$ )	\$145.02

Because Linda is a pediatric ESRD patient, the automatic pediatric adjustment factor of 1.62 applies. Neither the

age, BMI, nor BSA adjustments are applicable because Linda is less than age 18.

Pediatric adjusted composite rate ( $\$145.02 \times 1.62$ ) \$234.93

If Community Hospital were entitled to a composite rate exception, then the provider could elect to retain its exception rate in lieu of receiving the otherwise applicable pediatric payment rate of \$234.93.

#### Impact Analysis

Comment: One commenter observed that the budgetary impact on the Medicare program of proposed section 623 changes (impact table) generally indicates an "overall" neutral or modest reimbursement increase for all types of dialysis facilities (independent and rural, for profit and non-profit, urban and rural). This commenter requested data that indicate the number of dialysis facilities that are operating at a loss in the U.S., by corresponding facility characteristics shown in the impact table.

Response: The purpose of the impact table is to simulate what ESRD facilities will receive in payments under the MMA section 623 changes compared to what ESRD facilities would receive without any changes to the current composite payment rates. We do not have data to determine whether or not a facility may operate at a loss under MMA section 623.

J. Section 731—Coverage of Routine Costs for Category A Clinical Trials

Before the enactment of the MMA, Medicare did not cover services related to a noncovered Category A device. The MMA authorizes Medicare to cover the routine costs associated with certain Category A clinical trials for services furnished on or after January 1, 2005. For a trial to qualify for payment, it must meet certain criteria to ensure that the trial conforms to appropriate scientific and ethical standards. In addition, the MMA established additional criteria for trials initiated before January 1, 2010 to ensure that the devices involved in these trials are intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Seven commenters were in favor of this provision. Of them, four had additional comments. One commenter was against the provision.

Comment: One commenter stated that this provision would result in money being taken away from the pool of money for physician payments of non-experimental procedures.

Response: We considered this issue in determining the SGR for 2005. Since we have made a regulatory change to allow for coverage of routine costs associated with Category A clinical trials, we are required by statute to reflect any increased costs of this policy in the 2005 SGR.

At this time, we are estimating that the costs associated with coverage of routine costs of Category A clinical trials will increase Medicare spending for physicians' services by less than 0.1 percent. However, we are reviewing this issue and we will adjust our estimates once we have actual spending data for 2005.

Comment: One commenter specifically requested that we define routine costs.

Response: We discuss and define routine costs in section 310.1 of the Medicare National Coverage Determination Manual (pub 100.3). We will take this comment into consideration if we decide to revise section 310.1 in the future.

Comment: Two commenters recommended that we adopt a definition of "immediately life-threatening" that would allow contractors some level of flexibility when they apply this criteria to evaluate trials.

Response: We will consider the importance of some level of flexibility in defining "immediately life-threatening." Although we are not defining this term in our regulation, we intend to provide guidance through implementing instructions.

Comment: Another commenter suggested that contractors determine in advance if trials satisfy the immediately life threatening requirement.

Response: We are considering implementation requirements and will take this suggestion under advisement.

#### Result of Evaluation of Comments

We are finalizing the changes to §405.207 as proposed.

#### K. Section 629—Part B Deductible

Section 629 of the MMA provides for regular updates to the Medicare Part B deductible in consideration of inflationary changes in the nation's economy. Since 1991, the Medicare Part B deductible has been \$100 per year. The MMA stipulates that the Medicare Part B deductible will be \$110 for calendar year 2005, and, for a subsequent year, the deductible will be the previous year's deductible increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) of the Act, ending with that subsequent year (rounded to the nearest dollar). Section 1839(a)(1) of the Act requires the Secretary of Health and Human Services to calculate the monthly actuarial rate for Medicare enrollees age 65 and over.

We proposed to update §410.160(f), "Amount of the Part B annual deductible," to conform to the MMA and to

reflect that the Medicare Part B deductible is \$100 for calendar years 1991 through 2004.

Comment: Commenters stated that they understand that we are following the statute in implementing this provision, but encouraged us to educate Medicare beneficiaries regarding this change.

Response: We agree that it is important to educate beneficiaries about the deductible, as well as the other provisions of the MMA, such as the new screening benefits, and we will be using publications such as the "Medicare and You Handbook" for this purpose.

#### Result of Evaluation of Comments

We are finalizing the proposed changes to §410.160(f).

#### L. Section 512--Hospice Consultation

##### 1. Coverage of Hospice Consultation Services

As discussed in the proposed rule published August 5, 2004, effective January 1, 2005, section 512 of the MMA provides for payment to a hospice for specified services furnished by a physician who is either the medical director of, or an employee of, a hospice agency. Payment would be made on behalf of a beneficiary who is terminally ill (which is defined as having a prognosis of 6 months or less if the disease or illness runs its normal course), has not made a hospice election, and has not previously received

the pre-election hospice services specified in section 1812(a)(1)(5) of the Act as added by section 512 of the MMA. These services comprise an evaluation of an individual's need for pain and symptom management, counseling the individual regarding hospice and other care options, and may include advising the individual regarding advanced care planning.

We believe that most individuals will seek this type of service from their own physicians. Thus, we do not expect that the services of a hospice physician would be necessary for all individuals who elect hospice. However, a beneficiary, or his or her physician, may seek the expertise of a hospice medical director or physician employee of a hospice to assure that a beneficiary's end-of-life options for care and pain management are discussed and evaluated.

Currently, beneficiaries are able to receive this evaluation, pain management, counseling, and advice through other Medicare benefits. For example, physicians who determine the beneficiary's terminal diagnoses can provide for these E/M services as well as for pain and symptom management under the physician fee schedule. Beneficiaries may also obtain assistance with decisions pertaining to end-of life issues through discharge planning by social

workers, case managers, and other health care professionals. To the extent that beneficiaries have already received Medicare-covered evaluation and counseling for end-of-life care, the hospice evaluation and counseling would seem duplicative. We plan to monitor data regarding these services to assess whether Medicare is paying for duplicative services.

In the proposed rule, we proposed to cover the services described above for a terminally ill beneficiary when the services are requested by a beneficiary or the beneficiary's physician. The service would, in accordance with the statute, be available on a one-time basis to a beneficiary who has not elected or previously used the hospice benefit, but who might benefit from evaluation and counseling with a hospice physician regarding the beneficiary's decision-making process or to provide recommendations for pain and symptom management. The beneficiary or his or her physician decides to obtain this service from the hospice medical director or physician employee. Thus, the evaluation and counseling service may not be initiated by the hospice, that is, the entity receiving payment for the service.

The statute specifies that payment be made to the hospice when the physician providing the service is an



employee physician or medical director of a hospice. Therefore, other hospice personnel, such as nurse practitioners, nurses, or social workers, cannot furnish the service. The statute requires that the physician be employed by a hospice; therefore, the service cannot be furnished by a physician under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice. Moreover, if the beneficiary's physician is also the medical director or physician employee of a hospice, that physician already possesses the expertise necessary to furnish end-of-life evaluation, management, and counseling services and is providing these services to the beneficiary and receiving payment for these services under the physician fee schedule through the use of E/M codes.

In the event that the individual's physician initiates the request for services of the hospice medical director or physician, we indicated in the proposed rule that we would expect that appropriate documentation guidelines would be followed. The request or referral would be in writing, and the hospice medical director or employee physician would be expected to provide a written note on the patient's medical chart. The hospice employee physician providing these services would be required to maintain a written record of

this service. If the beneficiary initiates the services, we would expect that the hospice agency would maintain a written record of the service and that communication between the hospice medical director or physician and the beneficiary's physician would occur, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

We proposed to add new §418.205 and §418.304(d) to implement section 512 of the MMA.

Comment: Several commenters requested that this provision be extended to contracted physicians and nurse practitioners.

Response: Section 1812(a)(5) of the Act explicitly indicates that a physician employed by a hospice agency must provide the services under this provision. We recognize that contractual relationships are permitted by hospice agencies for medical director and physicians' services under the hospice benefit as described in section 1861(dd) of the Act. However, the plain language of section 1812(a)(5) provides only for employees of the hospice to furnish the service.

Section 1812(a)(5) of the Act also requires that this service be provided by a physician as defined in section 1861(r)(1) of the Act. While nurse practitioners may serve

as attending physicians for beneficiaries who have elected the hospice benefit, this provision does not permit non-physicians to provide this pre-hospice service.

Comment: We received several comments that supported this provision as beneficial for end-of-life care.

Response: We believe that this provision supports and supplements options available to beneficiaries as they make end-of life decisions when the individual's health care provider and community resources are not able to provide the expertise and information.

Comment: We received a comment suggesting that the certification of a terminal illness, with a 6-month prognosis if the disease runs its normal course, be eliminated and that this service should be available to any individual deemed to be terminal.

Response: Section 1812(a)(5) of the Act explicitly indicates that this one-time service is available to Medicare beneficiaries who are terminally ill and have not previously elected the hospice benefit. Section 1861(dd)(3)(A) of the Act defines the phrase "terminally ill" as denoting a medical prognosis that the individual's life expectancy is 6 months or less. Since section 1812(a)(5) of the Act specifies that the beneficiary must have a terminal illness, which includes the 6-month

prognosis, we have no authority to eliminate this definition.

Since the benefit is a pre-hospice one, we have not required that a certification be completed before this service is provided. Nonetheless, in the judgment of the individual's physician, the individual must be terminally ill, that is, having a 6-month or less life expectancy if the disease or illness runs its normal course.

## 2. Payment for Hospice Consultation Services

Section 512(b) of the MMA amends section 1814(i) of the Act and establishes payment for this service at an amount equal to an amount established for an office or other outpatient visit for E/M associated with presenting problems of moderate severity and requiring medical decision-making of low complexity under the physician fee schedule, other than the portion of such amount attributable to the practice expense component. No existing CPT or HCPCS code specifically represents these services. We proposed establishing a new HCPCS code, G0337 (proposed as G0xx4) Hospice--evaluation and counseling services, pre-election. The hospice would use this new HCPCS code to submit claims to the Regional Home Health Intermediary (RHHI) for payment for this service. Utilization of the code would allow us to provide payment

for the service, as well as enable us to monitor the frequency with which the code is used and assess its appropriate use. Payments by hospices to physicians or others in a position to refer patients for services furnished under this provision may implicate the Federal anti-kickback statute.

In accordance with the statute, we proposed that the payment amount for this service would be based on the work and malpractice expense RVUs for CPT code 99203 multiplied by the CF  $(1.34 \text{ Work RVU} + 0.10 \text{ Malpractice RVU}) * (\text{CF})$ . The CPT code for an office or outpatient visit for the E/M of a new patient represents a detailed history, detailed examination and medical decision making of low complexity. We believe that this E/M service is quite similar to the components of the new service provided by a medical director or physician employed by the hospice agency. Assuming that there are no changes in RVUs for CPT code 99203, and that the CY 2005 update to the physician fee schedule is the 1.5 percent specified in the MMA, the national payment amount for this service would be \$54.57 for this service  $(1.44 * \$37.8975)$ .

Comment: We received several comments indicating that CPT Code 99203, a mid-level office visit with a new patient, does not accurately reflect the complexity

associated with the hospice consultation. One commenter suggested using CPT code 99205. In addition, commenters stated that payment for this benefit should reflect the length and intensity of each consultation.

Response: Section 1814(i)(4) of the Act explicitly states that the payment for this service be equal to an amount established for an office or outpatient visit with presenting problems of moderate severity and requiring low complexity medical decision-making. We believe that CPT code 99203, rather than CPT code 99205, most closely conforms to the statutory language. However, in order to establish a payment rate that excludes the practice expense component and to ensure that we pay for the service only once, we established a G code.

Comment: We received one comment that indicated that existing consultation codes coupled with a place of service should be used.

Response: We appreciate the concern about introducing another code into a complex system of codes. While the title of the provision indicates that this is a consultative service, we believe that, unlike other consultations, beneficiaries are able to seek this service without a referral. Moreover, we need to be able to distinguish this service so that we can ensure that it is

furnished only once to an individual. In addition, existing E&M codes are billed by physicians. This provision is billed by the hospice agency and is not a result of reassignment of payment by a physician to a hospice agency. Finally, the G code will allow us to track utilization of this new benefit.

#### Result of Evaluation of Comments

We are adopting our proposed policy and revising the regulations at §418.205 and §418.304(d). We are also finalizing our proposal to pay for this service using a G code (G0337) Hospice--evaluation and counseling services, pre-election, with the payment based on the work and malpractice expense RVUs for CPT code 99203.

#### M. Section 302—Clinical Conditions for Coverage of Durable Medical Equipment (DME)

Section 1832(a)(1)(E) of the Act, as added by section 302(a)(2) of the MMA, requires the Secretary to establish clinical conditions of coverage standards for items of DME. The statute requires the Secretary to establish types or classes of covered items that require a face-to-face examination of the individual by a physician or specified practitioner. Due to the timeframe and the extensive number of public comments received, we will implement this

provision at a later date. We will address all public comments in a future Federal Register document.

N. Section 614—Payment for Certain Mammography Services

Medicare covers an annual screening mammogram for all beneficiaries who are women age 40 and older and one baseline mammogram for beneficiaries who are women age 35 through 39. Medicare also covers medically necessary diagnostic mammograms. Payment for screening mammography, regardless of setting, is paid under the physician fee schedule, but diagnostic mammography performed in the hospital outpatient department is currently paid under the hospital outpatient prospective payment system (OPPS).

As stated in the August 5, 2004 proposed rule, section 614 of the MMA amended section 1833(t)(1)(B)(iv) of the Act to exclude payment for screening and diagnostic mammograms from the OPPS. Beginning January 1, 2005, we will pay for diagnostic mammograms under the OPPS based on the payments established under the physician fee schedule. Thus, both diagnostic and screening mammography services provided in the OPPS setting will now be paid based on the physician fee schedule.

Comment: Commenters expressed support for this proposed change in payment and believe it will assist in ensuring that these services are available to women at risk for breast cancer.

Response: We agree that it is important to ensure access to these services. Additional discussion of the MMA



provision can also be found in the OPPS final rule, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2005 Payment Rates" currently under development.

O. Section 305—Payment for Inhalation Drugs

The August 5, 2004 proposed rule contained the ASP plus 6 percent payment amounts based on data received from manufacturers' ASP for the first quarter of 2004 for albuterol sulphate and ipratropium bromide. We indicated that such payment amounts were not the payment rates for 2005 and specified that Medicare payment rates for the first quarter of 2005 would be based on data submitted by manufacturers from the third quarter of 2004.

We proposed to establish a separate dispensing fee for inhalation drugs. We noted that Medicare currently pays a monthly dispensing fee of \$5 for each inhalation drug used in a nebulizer. We requested information about an appropriate dispensing fee amount.

We also proposed to make several changes related to billing for inhalation drugs. We proposed to allow a prescription for inhalation drugs written by a physician and filled by a pharmacy to be increased from 30-days to a 90-day period. We indicated that we had recently revised the guidelines regarding the time frame for delivery of refills of DMEPOS products to occur no sooner than

"approximately five days" prior to the end of usage for the current product. We emphasized the word "approximately" in this time frame. The change allows shipping of inhalation drug refills on "approximately" the 25<sup>th</sup> day of the month in the case of a 30-day supply and on "approximately" the 85<sup>th</sup> day in the case of a 90-day supply. We indicated our belief that such revision eliminates the need for suppliers to use overnight shipping of inhalation drugs and allows shipping of inhalation drugs by less expensive ground service.

We also clarified the ordering requirements for DMEPOS items, including drugs. Drugs, including, inhalation drugs, can be dispensed with a verbal physician order and without a written prescription. Although a written prescription must be obtained before submitting a claim, we reiterated that we allowed photocopied, electronic, or pen and ink prescriptions. We pointed out the recent revision to the Program Integrity Manual of acceptable proof of delivery requirements for DMEPOS items. Finally, we proposed to eliminate the requirement that pharmacies have a signed Assignment of Benefits (AOB) form from a beneficiary in order for Medicare to make a payment. Our proposal would eliminate a billing requirement for all

drugs, including inhalation drugs and other items where Medicare payment is only made on an assigned basis.

Comment: A number of commenters, particularly retail pharmacies, indicated that they are not able to obtain albuterol sulfate at the \$0.04 per milligram and ipratropium bromide at the \$0.30 per milligram rates specified in the proposed rule based on manufacturer submissions of data for the first quarter of 2004. A large company indicated that the ASPs stated in the proposed rule for albuterol sulfate and ipratropium bromide were extremely close to its own acquisition costs and inferred that the payment amount would be below smaller providers' purchase prices. A commenter questioned the suggestion in the proposed rule that because albuterol sulfate and ipratropium bromide are generic drugs with multiple manufacturers a pharmacy might be able to obtain them at a price below the average. The commenter suggested that this is highly speculative because we have not yet received the information from manufacturers to set the ASP for the first quarter of 2005.

Response: The ASP plus 6 percent prices for drugs in the proposed rule were calculated based on manufacturer submissions of data covering the first quarter of 2004. We indicated that such ASP plus 6 percent figures were not

actual payment rates for the first quarter of 2005. ASP data submitted by manufacturers for the second quarter of 2004 show some significant changes for inhalation drugs. The data show that the ASP plus 6 percent would be \$0.05 per milligram for albuterol sulfate, a 25 percent increase, and \$0.45 per milligram for ipratropium bromide, a 50 percent increase. We also note that in its recent study, "Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs" (GAO-05-72), the GAO found that acquisition costs of inhalation drugs varied widely. The GAO found that acquisition costs of albuterol sulfate ranged from \$0.04 to \$0.08 and ipratropium bromide ranged from \$0.23 to \$0.64. Based on the submission of manufacturer's average sales price data for the second quarter of 2004, Medicare's payment rates for ipratropium bromide and albuterol sulfate are within the acquisition cost range found by the GAO. The GAO also found that acquisition cost was not necessarily related to the size of the supplier.

Comment: One commenter suggested that we should consider delaying the implementation of cuts in Medicare reimbursement for inhalation drugs until 2006. The commenter suggested that a delay would ensure that

physicians and beneficiaries have a range of options available for managing respiratory diseases.

Response: We do not believe that we can delay the implementation of the ASP payment system until 2006 because the MMA provides for the implementation of the ASP payment system in 2005.

Comment: Commenters strongly supported our proposal to pay a separate dispensing fee for inhalation drugs, but we received varied comments on the scope of services appropriately included in a dispensing fee. Commenters indicated that an appropriate dispensing fee is necessary because the costs associated with dispensing these drugs typically exceed ASP plus six percent. Without adequate compensation, commenters argued that Medicare beneficiary access to inhalation drugs would be harmed. Commenters referenced an August 2004 report prepared for the American Association of Homecare (AAH) by a consultant that surveyed 109 homecare pharmacies between the end of May and the middle of July 2004. Commenters cited survey results from the report suggesting that 89 percent of suppliers would discontinue providing inhalation drugs to Medicare beneficiaries in the absence of adequate compensation. One commenter believes it is reasonable to expect that reducing Medicare payment for inhalation drugs will trigger an

increase in emergency room visits, doctor visits, and hospital admissions. Other commenters suggested a dispensing fee that is too low would result in a concentrated market, thereby adversely affecting beneficiary choice and access.

The AAH study indicated that in order to maintain 2004 levels of service to Medicare beneficiaries and provide an operating margin of 7 percent, Medicare would have to pay an additional payment of \$68.10 per service encounter. This figure includes an average of the costs reported as being incurred during the first quarter of 2004 for the pharmacies that responded to the AAH survey. The study defined a service encounter as each instance one or more billing codes were submitted to Medicare for payment. The study reported that the typical Medicare beneficiary has 8.8 service encounters each year, or one service encounter every 42 days. Most commenters who cited the AAH study supported a fee of \$68.10 per service encounter.

Commenters also cited another AAH report, dated September 2001 (and updated to 2003) from a different consultant, who surveyed a sample of 19 homecare pharmacies and found that drug acquisition costs accounted for 26 percent of costs incurred by homecare pharmacies. Facility, labor, delivery, patient care and education,

billing and collection costs and other direct costs were found to account for 46 percent; indirect costs such as management information systems, regulatory compliance programs, professional liability insurance and field and corporate administration was 25 percent; and bad debt was 3 percent. The study concluded that homecare pharmacies generated after-tax returns of 9.2 percent.

A retail pharmacy commented that a dispensing fee five to six times the current dispensing fee of \$5 is necessary to cover its costs. Another retail pharmacy indicated that a dispensing fee of \$25 would be an adequate dispensing fee, including the additional costs of processing Medicare claims and instructing the patient on using the drugs, and would be profitable for it.

A manufacturer urged CMS to conduct a study of the appropriate pharmacy activities and their costs in calculating a dispensing fee. The commenter believes such a study would yield a more accurate amount than data and information provided as part of comments to proposed rules does. One inhalation company indicated that the costs of rent, delivery and salary had recently increased by specific percentages. Several commenters opposed the inclusion in the dispensing fee of a transitional payment. Another commenter strongly urged establishing a dispensing

fee that include an appropriate transitional payment, given the significant payment reductions scheduled to begin in 2005.

On the scope of services, commenters indicated that various services involved with dispensing inhalation drugs to Medicare beneficiaries such as: (i) training beneficiaries and caregivers on proper use of drugs with nebulizers; (ii) establishing and revising a plan of care and coordinating care; (iii) providing in-home visits; (iv) providing 24-hours/7-days a week on-call personnel; (v) contacting physicians and beneficiaries regarding dispensing of inhalation drugs; (vi) providing follow-up contact with beneficiaries, including compliance monitoring and refill calls. Commenters indicated that they felt CMS has the authority to pay for costs associated with delivering inhalation drugs under the durable medical equipment (DME) benefit.

An association representing pharmacists recommended an expansion of Part B to include compensation for therapy management services furnished by pharmacists. An association representing respiratory therapists recommended a separate payment for beneficiary training by practitioners with documented evidence of education, clinical training and competency testing, such as



respiratory therapists. A company suggested that we establish a basic dispensing fee and separately reimbursable codes for those who provide additional services, reflecting the range of management services involved with inhalation drugs. Another association acknowledged that although limited peer reviewed studies exist on the role of homecare providers and the respiratory practitioners in furnishing care to COPD patients, significant anecdotal data and a consensus within the pulmonary medicine and respiratory therapy professional communities support the role and contribution of home respiratory care providers. Several commenters indicated that training a beneficiary on using a nebulizer should also be reimbursed. However, they pointed out that training can not be done by the physician or physician's staff because many physicians do not have a nebulizer on which to train the beneficiary and the Medicare payment is not sufficient to cover the physician's staff time.

Response: We appreciate the support for our proposal to establish a dispensing fee as well as the information about the levels and components of such a fee.

The October 12, 2004 GAO report is based on a survey of 12 companies representing 42 percent of the inhalation therapy market. The GAO found wide variation in suppliers'

monthly costs associated with dispensing inhalation drugs. In addition, the GAO found that large suppliers do not necessarily have lower costs and do not necessarily realize economies in costs associated with dispensing inhalation therapy drugs. The GAO indicated that the wide range is due in part to the range of services offered by suppliers and that some costs incurred by suppliers may not be necessary to dispense inhalation drugs, for example marketing, overnight shipping, and 24-hour hotlines for beneficiary questions. The GAO report indicates that the range of costs suppliers are incurring is a good starting point for a dispensing fee amount, but that the appropriate dispensing fee Medicare pays must take into account how excess payments affect the costs.

We note the extreme variation that the GAO found in the costs of dispensing nebulized drugs to Medicare beneficiaries: GAO found that per patient monthly costs of dispensing these medications ranged from a low of \$7 to a high of \$204 in 2003. Because it appears that the GAO survey and the 2004 AAH survey may have included different costs and services, further research is needed to understand these differences. In addition to the GAO and AAH studies, we note the wide range of comments indicating what services a dispensing fee should cover. We believe

that before a determination can be made as to an appropriate dispensing fee for inhalation drugs after 2005, we need to more fully understand the components of and the reasons behind the current variability in the costs of furnishing of these drugs and the services being provided. We intend to work with the AAH, others concerned with inhalation therapy and our partners in the Department of Health and Human Services to explore these issues more fully.

In the interim, for 2005, we are establishing a \$57 monthly fee and a \$80 90-day fee for furnishing inhalation drugs using data in the AAH study and the GAO report. We established the monthly fee based on the weighted average of the costs for new and established patients from the 2004 AAH study after excluding sales and marketing, bad debt, and an explicit profit margin. Because the AAH study did not establish a fee for the 90-day period, we applied the methodology used in the GAO report to the data in the AAH study to calculate the 2005 90-day fee. Accordingly, we assumed that direct costs associated with a monthly fee are similar to the direct costs associated with the 90-day fee and then we tripled the indirect costs. We intend to further examine the conversion of per encounter costs as

reported in the AAH study to comparable monthly and 90-day cost figures.

We note that although the AAH study contained costs related to services that may be of potential benefit to our beneficiaries, and many commenters indicated that we should provide payment for these and the other services described above, we are concerned that these services may be outside the scope of a dispensing fee. We are continuing to study these services and associated cost categories as the new payment systems are implemented and we gain experience with them. We intend to revisit this issue and proceed through notice and comment rulemaking in order to establish an appropriate dispensing fee for 2006.

Comment: A commenter suggested that the dispensing fee be established on a per dose basis. It was argued that this would provide Medicare with protection against pharmacies dispensing partial shipments or shipments more frequently than 30 or 90 days in order to increase the number of dispensing fees. We received comments in support of a need-based dispensing fee to accommodate additional drugs when beneficiaries suffer from disease flare-ups. We also received comments indicating that beneficiary's prescriptions change, often during the first month. Other commenters cited the AAH study, which calculated different

costs associated with dispensing inhalation drugs for new patients and established patient.

Response: The dispensing fee we are establishing covers all drugs shipped to a beneficiary during a month (or 90-day period) regardless of the number of times a supplier ships inhalation drugs to a beneficiary. If a supplier does not supply the prescription in full, it is the supplier's responsibility to fill and deliver the remainder of the prescription, but Medicare will not pay additional monthly dispensing fees. We will monitor the issue about partial shipments and potentially erroneous billing for multiple monthly dispensing fees. We also are concerned that a per-dose dispensing fee could provide an incentive to supply more drugs.

The 2005 fee is an average across all beneficiaries, new and established, and covers additional drugs shipped during a month if a beneficiary's prescription changes. We will study the issue further of different dispensing fees for new and established beneficiaries and the frequency that additional drugs are shipped for prescription changes.

Comment: A manufacturer recognized that compounded products can be covered under certain circumstances and that compounding could be included appropriately in a dispensing fee. Another manufacturer expressed concern

about including compounding in the activities that a dispensing fee covers. A suggestion was made that a HCPCS modifier be used for inhalation drugs that are compounded.

Response: The costs of compounding are included in the AAH study but are not separately identified in the direct cost line items. Because the 2005 fee is based on the AAH study, we need to avoid duplicate payment. With compounding bundled into the fee for 2005, we have concerns about paying separately for compounding in 2005.

Comment: A commenter recommended that we address compounding circumstances that might be inconsistent with FDA's policy prohibiting pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available and compounding that might be done without the necessary controls to ensure drug product sterility and potency.

Response: The fact that we consider compounding to be included in the 2005 fee to furnish inhalation drugs does not in any way support practices that are inconsistent with FDA guidelines.

Comment: The commenter also suggested that we consider creating a HCPCS modifier for drugs that a prescribing physician intends to be compounded but which a pharmacy dispenses separately in non-compounded form. The

commenter believes that such a modifier would help discourage pharmacies from leaving the responsibility for compounding to the beneficiary who would be combining the drugs in non-sterile, uncontrolled conditions.

Response: We understand the commenter's concerns and will study this issue.

Comment: We received comments suggesting that the actual savings attributable to MMA section 305 may be both higher and lower than the November 20, 2003 Congressional Budget Office (CBO) estimate for MMA section 305. One company suggested that the actual savings could be less than estimated by CBO because the ASP model potentially motivates drug manufacturers to increase drug costs, which will be directly passed on to the government. Other commenters cited two different estimates from the AAH report. Using one calculation, the commenters argued that a dispensing fee of \$68.10 per encounter would still enable Medicare to achieve savings of \$350 million per year or more than \$4 billion over 10 years. Using another calculation, the commenters argued that the savings would be \$7 billion over the 10-year budget-scoring window. The commenters indicated that the \$4 billion savings figure was comparable to the initial projections made by the Congressional Budget Office (CBO) in 2003 and the \$7

billion figure was in excess of the CBO estimated savings. Commenters cited these figures to argue that establishment of a per service encounter fee of \$68.10 would set the payment at the level originally envisioned by Congress. Another commenter suggested that a dispensing fee of \$0.85 per 2.5 mg dose for albuterol sulfate and \$0.97 per dose for a blended mix of other inhalation drugs including ipratropium bromide would be consistent with what they believe are the 17.7 percent savings assumed by CBO. One commenter indicated that CBO underestimated the savings from section 305.

Response: MMA specifically requires the use of the ASP methodology to establish more appropriate payment rates for drugs. MMA explicitly requires the establishment of a supplying fee for Part B covered oral drugs as determined to be appropriate by the Secretary. MMA also explicitly requires establishment of a furnishing fee for blood clotting factors. However, MMA does not specify a particular dispensing fee amount for inhalation drugs, nor does MMA specify a method to determine a dispensing fee for inhalation drugs. Accordingly, CMS used existing authority to propose in the NPRM that an appropriate dispensing fee be established. Because MMA did not require a specific method or amount for a dispensing fee for inhalation drugs,



we find the arguments unpersuasive that a dispensing fee of a particular amount was envisioned by Congress or consistent with Congressional intent as reflected in a CBO estimate.

Comment: We received comments that supported and opposed the use of 90-day prescriptions. One commenter supporting the proposed change indicated that most beneficiaries who receive nebulized medications suffer from chronic lung diseases and will require medication to manage their disease for prolonged periods. The commenter indicated that allowing a prescription for 90-days would reduce paperwork and redundant effort for beneficiaries, physicians and DME suppliers. A commenter indicated that there would be modest savings in dispensing, billing and shipping costs with allowance of a 90-day supply of refills. One company suggested savings of 12.5 percent, most notably in shipping. Commenters opposing 90-day prescriptions gave various reasons, including that beneficiaries may experience side effects and change prescriptions within the first month and a certain percent of beneficiaries die each month resulting in non-returnable product. In addition, some argued that pharmacy savings for a 90-day shipment would not be significant because shipping costs account for only an estimated 16 percent of

supplier's non-acquisition costs associated with providing inhalation drugs. Another company argued that a 90-day shipment would substantially increase provider's expenses for boxes and shipping. Some commenters agreed that certain chronic use medications should be provided in larger quantities, but urged caution due to the practices of some suppliers who automatically ship additional product without knowing whether the patient's current supply is exhausted. Some comments suggested that a 60-day supply might be more cost-effective in the long-term because there would be a reduced risk that large quantities of medications might be wasted. Another commenter suggested that the policy be defined to cover only drugs that are proven to be stable for at least 90 days following dispensing.

Response: As we indicated in the proposed rule, we believe that reasonableness should govern filling a monthly vs. 90-day prescription depending on the circumstances of the beneficiary. We agree with the commenter that the initial prescription for a new patient should be written for a 30-day period because of the potential for adverse reactions or changes in the treatment regimen. We would expect prescriptions for new patients to be for 30-day periods. In addition, we believe that it is reasonable for

physicians to write a 30-day prescription for those beneficiaries who they believe are less stable. Similarly, we believe that refill prescriptions for 90-day periods are reasonable, particularly for stable beneficiaries.

Although the Medicare program would achieve savings from the appropriate use of 30-day and 90-day prescriptions, we believe that given the comments it would be prudent for us to monitor the 90-day supply issue. Section 4.26.1, the Proof of Delivery Methods section of the Program Integrity Manual, instructs that suppliers of DMEPOS product refills contact the beneficiary prior to dispensing the refill to ensure that the refilled item is necessary and confirm any changes or modifications to the order. Suppliers who ship either a 30-day or 90-day supply of inhalation drugs without knowing the beneficiary's current supply is exhausted would be in violation of this policy. The 90-day period should not be of concern for inhalation drugs because most of these drugs are stable for at least 90-days and thus can be dispensed for such period. We would revisit this issue if additional inhalation drugs that are unstable after 90-days become available.

Because we received limited data on costs of furnishing a 90-day supply, it is more difficult to determine a 2005 fee for furnishing a 90-day supply of

inhalation drugs. However, given that this is an optional payment arrangement for beneficiaries whose course of treatment has stabilized to the point that the required dosage can be predicted with a reasonable degree of certainty over a 90-day period, we believe that it is important to establish a 90-day fee. As described earlier, we are establishing a 90-day fee for furnishing inhalation drugs by applying the methodology from the GAO report to the data in the AAH study. We assumed all of the direct costs associated with a monthly fee are similar to the direct costs associated with a 90-day fee and we tripled the indirect costs. We plan to study this issue further.

Comment: Many commenters acknowledged that most DMEPOS items, including drugs, can be dispensed based on verbal orders. Several commenters objected to the requirement that a written order from the physician still must be obtained before billing. They suggested that we revise policy so that a prescription could be both filled and billed based solely on a verbal order from a physician. They pointed out that the requirement that a pharmacy still obtain a written order for a prescription in order to be able to bill Medicare creates a significant administrative burden for a pharmacy because it often requires persistent follow-up with a physician. Another commenter suggested

that we consider accepting electronic transmissions of prescriptions, for example, e-scripts. Another commenter requested clarification of the rule for dispensing based on a verbal order for inhalation drugs and the proposed requirement that an order for an item of DMEPOS be signed and dated within 30 days of a face-to-face examination of a beneficiary.

Response: The policy that allows dispensing based on a verbal order but requires a written order for billing applies to all DMEPOS items. This policy balances fraud and abuse concerns with prompt dispensing of DMEPOS items to beneficiaries. Written orders from the physician can be faxed, photocopied, or provided via electronic or pen and ink forms. In accordance with current policy, pharmacies may accept electronic prescriptions from physicians.

Beneficiaries receiving inhalation drugs are having face-to-face exams routinely and generally do not need additional visits to re-order their drugs. A single face-to-face exam is generally sufficient for items ordered, that is, we would not require a separate face-to-face exam for the nebulizer and for the inhalation drugs. We assume that physicians would order them at the same time because they are used together.

Comment: One commenter supported the revision made earlier this year that provides flexibility regarding the timeframe for refilling Medicare prescriptions. The commenter noted that most third party plans allow pharmacies to refill prescriptions within five days of the end of usage for the previous prescription quantity dispensed. Another commenter recommended that the time frame for subsequent deliveries be expanded beyond five-days. The commenter indicated that they believe a five-day time frame is too short a period for ground service and would not eliminate the need for overnight shipping. This is based on the commenter's experience that beneficiaries do not respond to calls to confirm that they need additional supply until the beneficiary has only a few days' supply left.

Response: As we indicated in the proposed rule, the revised time frame for delivery of refills of DMEPOS products provides for refills to occur no sooner than "approximately five days prior to the end of the usage for the current product." In the proposed rule we emphasized the word "approximately". While we believe that normal ground service would allow delivery in five-days, if there were circumstances where ground service could not occur in five-days, the guideline would still be met if the shipment

occurs in six or seven days. As another commenter noted, the five-day standard is consistent with the time frame for shipping used by most third party plans. Given the consistency with private sector plans, because the requirement applies to all DMEPOS product refills, and because the standard is not a firm five-day limit, we do not believe that it is necessary to lengthen the standard. We will study further the ability of a supplier to contact beneficiaries for refills compared with its ability to provide beneficiary and caregiver training on a monthly basis.

Comment: One commenter indicated that the DMERCs have not consistently implemented the revised proof of delivery provisions but that they are engaged in dialogue with CMS and the DMERCs to clarify the requirements and standardize their interpretation across the four DMERCs. Other commenters suggested that the proof of delivery requirement be eliminated.

Response: We encourage dialogue to ensure consistent understanding and application of the proof of delivery requirements. The proof of delivery requirements have recently undergone an extensive review and revision and, based on the need to prevent fraud and abuse, we see a need to continue them.

Comment: Those commenters who addressed our proposed elimination of the Assignment of Benefits (AOB) form for items and services, including drugs, where assignment is required by statute, supported our proposed change. Commenters agreed that obtaining an AOB in each instance is redundant because the supplier is required by statute to accept the assignment. Some commenters suggested that a onetime AOB be obtained from the beneficiary that will be valid for every DMEPOS item he or she receives during the period of his or her medical necessity.

Response: We appreciate the support for our proposal. As discussed in section IV of this final rule, we are adopting our proposal to eliminate the requirement for AOB form for items and services, including drugs, where assignment is required by statute. We do not agree with the suggestion to allow for a one-time AOB form to cover items and services provided in the future because there could be fraud and abuse issues.

Comment: We received conflicting comments about the impact of the changes and clarifications relating to billing requirements on the costs of dispensing inhalation drugs.

Commenters differed on the impact of the revisions to the proof of delivery requirements that we pointed out in



the proposed rule that went into effect in early 2004. One company that currently uses automated systems indicated that the revision to the proof of delivery requirements would not generate savings for them. Commenters indicated that the DMERCs have not consistently implemented the changes, and that consequently there has not been significant administrative relief and subsequent savings.

We received conflicting comments about the impact of the revised time frame for shipping guidelines. While one commenter indicated that savings had already been achieved because the provision had already been implemented, another commenter indicated that the revision would have negligible effect because the commenter would not change its existing business practice of using overnight shipping.

One commenter said it had already adopted the provision of prescriptions being filled by verbal order, followed up by a written order for the claim submission and that these changes did not generate any additional savings for the commenter. Some suggested that the elimination of the AOB form for drugs would have limited savings because some suppliers currently obtain the AOB form at the same time that they obtain other forms that would be continued. Retail pharmacies agreed that elimination of the AOB form and verbal prescription order would reduce their paperwork. However, inhalation companies did not agree.

Response: We understand the commenters concerns and will study the impact of these billing changes on the different suppliers' costs as the new payment system is implemented.

Comment: Several commenters suggested that we review and consider changing several aspects of billing that might have cost-savings potential for suppliers of drugs. Several commenters indicated that Medicare's lack of on-line adjudication represented a significant cost and burden to them. One retail pharmacy commented that pharmacies face higher than normal rejection rate on claims because Medicare claims are not processed on-line, resulting in higher administrative costs. Others commented that pharmacies that dispense Medicare prescriptions must obtain documentation that is typically provided by the physician. For example, one company indicated that suppliers are held responsible for the appropriate medical necessity documentation in the patient's medical record but that the supplier has no control over physician records. Some suggested that we consider eliminating the requirement that a diagnosis code be required on the prescription. One pharmacy commented that pharmacies should not be expected to verify that the physician has in fact performed a face-to-face exam for the purpose of treating and evaluating the

patient's medical condition or whether the physician has created appropriate documents in his records. Rather, the pharmacy believes that this responsibility should be left to the physician, and the creation of a prescription should be all that is needed to verify that the physician has complied with all Medicare requirements. A commenter noted that Medicare requires that suppliers submit claims with the physician's Unique Physician Identification Number (UPIN) while most third party plans require the physician's DEA number and suggested that we consider adopting usage of the physician's DEA number instead of UPIN. A pharmacy commented that dispensing units are different than current National Council for Prescription Drug Programs (NCPDP) standards; Medicare reimburses products based on a per mg price while the NCPDP standard suggests reimbursement on a per ml price. The pharmacy indicated that this makes it more difficult for the pharmacy to calculate proper reimbursement for these Medicare claims. Other commenters suggested that the Medicare enrollment and reenrollment process for suppliers be significantly streamlined. A retail pharmacy indicated that Medicare requires pharmacy suppliers to submit extensive and often duplicative pharmacy-specific paperwork that is more voluminous than any other third party plan in which retail pharmacies

participate. One inhalation company suggested certain aspects of billing such as the requirement that the supplier query the physician and beneficiary to find out if the beneficiary had already received a same or similar item from another supplier. The company also identified what it claimed are several other labor-intensive, costly aspects of Medicare billing including electronic claims filing requirements; information system programming and testing; paperwork and new business procedures required to be compliant with HIPAA; Medicare and secondary insurance benefits verification and qualification; responding to significantly increased pre-payment audit activities; administering the Patient Financial Hardship Waiver prior to billing deductible and coinsurance amounts; billing and writing off beneficiary cost-sharing as bad debts; and differing DMERC policies concerning documentation needed to support home inhalation therapies.

Response: We thank the commenters for identifying these items. We plan to examine these aspects of billing. To the extent that there are different interpretations or applications of national policy by DMERCs, our goal is increased standardization.

Comment: A comment from a group focused on respiratory care indicated that there may be over

utilization of albuterol sulfate. The comment indicated that a large amount of scientific evidence concludes that high albuterol sulfate use is indicative of poor overall disease management. The commenter further indicated that Medicare's costs related to the use of albuterol sulfate may result from the fact that alternative drug treatment regimes are not adequately considered in the management of the patient's disease. The commenter urged us to examine the underlying causes of high utilization rates of albuterol sulfate.

Response: Our goal is to ensure that Medicare beneficiaries have access to the appropriate drugs to treat their diseases. We believe that the availability of discounts through the Medicare drug card and the implementation of the Part D drug benefit beginning in 2006 promote treatment decisions being made based on the best clinical evidence, rather than being influenced by differential coverage.

Comment: We received many comments addressing the issue of nebulizers versus metered dose inhalers (MDIs). Most commenters questioned whether a significant shift of Medicare beneficiaries to MDIs would occur when MDIs are covered in the Part D drug benefit beginning in 2006. We received many comments, studies and literature reviews on

nebulizers and MDIs. Some commenters identified the specific disadvantages of MDIs and holding chambers or spacers. Some commenters questioned the conclusion of the literature review mentioned in the proposed rule that nebulizers are not clinically superior in delivering inhalation drugs than MDIs and the commenters asserted that the two are not fully substitutes. Some commenters quantified the costs to beneficiaries of nebulizers and MDIs. One commenter pointed out that MDIs would increase in 2006 based on the ban of the propellant chlorofluorocarbon. Another commenter questioned the point in the proposed rule that MDIs are more portable than nebulizers since advances in nebulizer technology have included additional portability. The commenter noted that since Medicare covers only one standard nebulizer, many of their patients have purchased portable nebulizers on an out-of-pocket basis to use as a second device while outside of their home.

Response: A number of drugs are available to treat the persons with asthma or who develop COPD. These include drugs, often inhaled, that expand the bronchial tubes and allow the patient to breathe more freely. Depending on the needs of the individual patient, these medications can be delivered using nebulizers or MDIs. Although nebulizers

have long been covered under Medicare Part B, the MMA expanded access to MDIs beginning in 2006 through the new Medicare Part D drug benefit. While two meta-analyses cited by one commenter are consistent with the literature review mentioned in the proposed rule that found a lack of overall clinical superiority of MDIs over nebulizers, we recognize that even after coverage of MDIs begins in the Part D drug benefit in 2006, due to their particular circumstances, many beneficiaries will require the use of nebulizers and that nebulizers will continue to play an important role in inhalation therapy. Part B does not currently cover MDIs and we will gain experience with the costs of MDIs as the Part D drug benefit is implemented.

Comment: Comments were received from respiratory drug distributors and homecare providers addressing drugs that are supplied from the manufacturer in more than one form. One company suggested that since inhalation drugs are provided by the manufacturer in two forms, a premixed solution or as a powder (or other concentrate) that is diluted by the pharmacist, the ASP should be calculated separately for each of these two forms in order to reflect the different acquisition costs to the pharmacy for the different forms. The company suggested use of a modifier

for the J-code to distinguish between these two forms for reimbursement purposes.

Response: We disagree. Consistent with the statute, the ASP is calculated by the HCPCS codes rather than the NDC code. This allows flexibility in appropriate drug delivery.

Comment: We received letters from individual beneficiaries and their family members indicating that the beneficiary has tried MDIs unsuccessfully and that inhalation drugs administered through a nebulizer were a successful treatment. They asked us not to assume that everyone on a nebulizer could be switched to inhalers and asked that we allow inhalation medications administered through nebulizers to remain funded by Medicare.

Response: We recognize that nebulizers are required by many beneficiaries due to their particular health circumstances. We did not propose to eliminate Medicare funding for inhalation medications administered through nebulizers.

Comment: Several commenters questioned why there should be public funding for COPD treatments for persons who chose to smoke cigarettes. The commenters indicate that it may be too harsh a policy to cease all reimbursement for COPD treatments, but they suggested two



alternatives: (1) No individual who currently smokes should receive any Medicare benefit for the treatment of any respiratory condition, and (2) Any individual who historically smoked heavily and receives treatment for respiratory disorders should face an annual deductible equal to the cost of smoking a pack of cigarettes a day.

Response: As we indicated in the proposed rule, smoking has been linked to a large number of health problems and is the leading cause of cancer and pulmonary disease. The Department of Health and Human Services (HHS) has been actively encouraging Americans to quit smoking through its smoking cessation initiatives. Americans who quit smoking will enjoy longer, healthier lives and avoid diseases such as COPD. However, the Medicare law does not limit benefits to persons who do not currently smoke, nor does the Medicare law impose a deductible that is different for smokers and non-smokers. This regulation implements the law as it is currently written.

#### Result of Evaluation of Comments

In the proposed rule, we requested comments on the appropriate separate dispensing fee for inhalation drugs used in a nebulizer. In this final rule we are establishing 2005 fees of \$57.00 for furnishing a 30-day prescription and \$80.00 for furnishing a 90-day

prescription for inhalation drugs. This fee would be paid in addition to the Medicare payment amount for the drug.

As discussed in section IV, we are finalizing our proposal to eliminate the Assignment of Benefits (AOB) form for items and services, including drugs, where assignment is required by statute. We reiterate language in the recently updated guidelines for DMEPOS refills, emphasizing the word "approximately". This allows for refill prescriptions to be shipped by ground service on "approximately" the 25<sup>th</sup> or 85<sup>th</sup> day of the respective prescription period. In addition, we clarified the ordering requirements for DMEPOS items, including drugs, which can be dispensed with just a verbal physician order.

P. Section 706—Coverage of Religious Nonmedical Health  
Care Institution Services Furnished in the Home

1. Background

Section 706(a) of the MMA amended section 1821(a) of the Act by adding home health services to the list of services furnished to an individual by a religious nonmedical health care institution (RNHCI). Section 706(b) added section 1861(aaa) to the Act to expand the term "home health agency" (HHA) to include a RNHCI. However, this expansion is limited to RNHCI items (specified durable

medical equipment) and services furnished in the beneficiary's home when the items and services are comparable to those provided by a HHA that is not a RNHCI. Moreover, payment may not be in excess of \$700,000 per calendar year, and may not be made after December 31, 2006. Accordingly, we are implementing changes to the RNHCI regulation to include services furnished in the home that result from the enactment of the MMA and that are becoming effective January 1, 2005.

The new time-limited home health services benefit will be referred to as "home benefit" or "home services" throughout this rule. The RNHCI home benefit may only be provided to an eligible beneficiary who is confined to the home for health reasons and who has a condition that makes the beneficiary eligible to receive services under Medicare home health. Additionally, the beneficiary must have an effective RNHCI election and receive his or her home services from the RNHCI. The home benefit is not a substitute for hospice care. As in the original RNHCI benefit, Medicare will pay only for nonmedical services in the home, but not for those religious items or services provided by the RNHCI. Additionally, RNHCI home service patients who have a documented need for a specified DME

item can obtain that item with the applicable deductible and coinsurance.

## 2. Legislative History

In 1965, payments to Christian Science sanatoria (inpatient nonmedical care facilities for bedfast patients) were included in the initial provisions of Medicare under title XVIII of the Act. In 1996, in Children's Healthcare Is a Legal Duty, Inc. v. Vladeck, 938 F. Supp. 1466 (D. Minn. 1996) ("CHILD I"), a Federal district court held that some of the provisions pertaining to Christian Science sanatoria were unconstitutional on the grounds that they were sect specific, in violation of the Establishment Clause of the U.S. Constitution.

Section 4454 of the BBA amended section 1861(a)(1) of the Act, deleting Christian Science sanatoria from the Act and creating instead the RNHCI benefit to provide Medicare Part A and Medicaid access for all religious groups whose belief structure does not include medical intervention. We note that, in the Conference Report to the BBA (H.R. Conference Report, No. 105-217, at 768 (1997)), the Congress specified that the RNHCI provisions were a sect-neutral accommodation available to any person who is relying on a religious method of healing and for whom the acceptance of medical health services would be inconsistent

with his or her religious beliefs. Further, the Congressional conferees were convinced that the RNHCI provisions fully responded to and satisfied the constitutional concerns that had been addressed by the district court in CHILD I.

Besides adding the new RNHCI benefit, section 4454 of the BBA also added sections 1861(ss) and 1821 to the Act. Section 1861(ss) sets forth:

- The ten requirements that a provider must meet in order to be considered a RNHCI;
- Parameters for oversight and monitoring;
- Authority for Federal review of items and services provided for excessive or fraudulent claims; and
- Parameters for ownership/affiliations.

As in the past, the new provisions do not mention the use of a religious counselor or practitioner; we consider that to be the responsibility of the patient.

Section 1821 of the Act provides for conditions for coverage of RNHCI services including:

- The election, revocation, and limitations of the RNHCI benefit (section 1821(b));
- The monitoring and safeguarding against expenditures (section 1821(c)); and

- the sunset provisions for the RHNCI benefit (section 1821(d)).

Section 1821(a) of the Act, as amended by the MMA, provides for Part A payment for inpatient hospital services, post-hospital extended care services, or home health services furnished to a beneficiary in, or by, a RHNCI only when the beneficiary has:

- A valid election for the RHNCI benefit in effect; and
- A condition that would qualify for inpatient hospital, extended care services, or home health if the beneficiary were an inpatient or resident in a hospital or skilled nursing facility, or was a patient residing at home under the care of a HHA that was not a RHNCI.

The election of the RHNCI benefit becomes effective immediately after execution and remains in effect for a lifetime or until revoked. As described in section 1821(b) of the Act, the election is a written statement signed by the beneficiary or the beneficiary's legal representative which states that:

- The individual is conscientiously opposed to the acceptance of nonexcepted medical treatment;

- The individual's acceptance of that nonexcepted treatment would be inconsistent with the individual's sincere religious beliefs; and
- The individual's receipt of nonexcepted medical care constitutes a revocation of the election.

The RNHCI election may be revoked by voluntarily notifying the Secretary in writing of the revocation or the election may be revoked by simply receiving nonexcepted medical care for which payment is sought under Medicare. Once a RNHCI election is revoked twice, the next election may not take place until a date that is at least one year from the date of the most recent revocation. Any election thereafter does not become effective before a date that is at least five years after the date of the previous revocation. The receipt of excepted medical care does not result in a revocation of the election. As stated in §403.702 of the regulations, the following definitions apply—

- Excepted medical care or treatment for purposes of the RNHCI benefit is defined as medical care or treatment (including medical or other health care services) received involuntarily (for example, following an accident), or required by any level of government (for example, immunizations).

- Nonexcepted medical care or treatment refers to all medical care or treatment that is not defined as excepted medical care or treatment. The beneficiary always retains the right to receive medical care under Medicare based on his or her level of coverage (for example, Part A, Parts A and B). However, using nonexcepted care will result in the revocation of the RNHCI election.

On November 30, 1999, we published the RNHCI interim final rule with comment period in the **Federal Register** (64 FR 67028), effective on January 31, 2000. The final RNHCI regulations were published on November 28, 2003 (68 FR 66710). There are currently 16 RNHCIs in the United States: three in California; two each in Florida and Ohio; and one each in: Colorado, Illinois, Indiana, Massachusetts, New York, Texas, Virginia, Washington, and Wisconsin.

### 3. Summary of Section 706 of the MMA

Section 706 of the MMA amended the Act to extend Medicare coverage of RNHCI items and services to the RNHCI beneficiary's home when the items and services are comparable to those provided by a HHA that is not a RNHCI.

Specifically, section 706(a) of the MMA amended section 1821(a) of the Act by adding home health services



to the list of services furnished to an individual by a RNHCI. Section 706(b) of the MMA added section 1861(aaa) to the Act to expand the term "home health agency" to include a RNHCI as defined in section 1861(ss)(1) of the Act, but only for items and services that are ordinarily furnished by a RNHCI to individuals in their homes, and that are comparable to items and services furnished to individuals by a HHA that is not a RNHCI. Section 1861(aaa)(2)(A) of the Act states that, subject to section 1861(aaa)(2)(B), payment may be made for services provided by a RNHCI only to the extent and under the conditions, limitations, and requirements that are in regulations consistent with section 1821 of the Act. Section 1861(aaa)(2)(B) states that payment may not be made for RNHCI home services under section 1861(aaa)(2)(A) of the Act in excess of \$700,000 per calendar year, or after December 31, 2006.

This interim final rule amends the existing RNHCI regulations in Subpart G to implement section 706 of the MMA.

#### 4. Discussion

##### a. Implementation of Section 706 of the MMA

As stated above, section 706 of the MMA added section 1861(aaa)(1) to the Act to expand the term "home health

agency" to include a RNHCI, as defined in section 1861(ss)(1) of the Act, but only for items and services that are ordinarily furnished by that institution to individuals in their homes, and that are comparable to items and services furnished by a HHA that is not a RNHCI. This posed a number of implementation challenges as a RNHCI does not conform to the statutory definition or requirements of a HHA in section 1861(m) of the Act, which is based on a medical model. Some of these challenges result from the fact that--

- RNHCIs were established to accommodate those religious groups that do not believe in the use of physicians to direct or supervise health care; and
- RNHCI nursing does not correspond to the statutory or regulatory parameters established by Medicare for "skilled care" in the home setting.

In addition, the RNHCI payment methodology does not readily lend itself to payment to the RNHCI for items and services under the RNHCI home benefit. Therefore, in an effort to implement the intent of the amendment, we will generally use the definition and requirements for a RNHCI, rather than a HHA (with some exceptions), in order to extend RNHCI services into the home environment. However, in order to aid in determining comparability, we are also utilizing,

when appropriate, some of the home health requirements set forth in section 1861(m) of the Act.

The presence of physician orders and oversight is a keystone in the operational viability of a HHA and nonexistent in the RNHCI, where the religious practitioner (noncovered by Medicare) is the primary focal person in establishing the course for the religious method of healing. In addition, the RNHCI nurse further assists the patient in navigating the course established for the religious method of healing. To address the need for oversight for the RNHCI home benefit as with the current inpatient RNHCI benefit, we are implementing section 706 of the MMA by continuing to require that the RNHCI utilization review committee review the need for care (expanded now to include both admission to the home benefit and continued care in the home setting), and to oversee the utilization of items and services in the time-limited home benefit. The utilization review committee, however, cannot act in place of a physician in ordering items and services other than those designated specifically for the purpose of this time-limited RNHCI home benefit. A claim from any other individual or provider attempting to seek Medicare payment for non-designated RHNCI home benefit items and services without a physician order will be disallowed.

We also recognize that implementing section 706 is particularly challenging in light of the fact that no sophisticated physical treatments or procedures are provided in RNHCIs, while conventional medical care becomes more technical every year, making the care delivered by HHA personnel increasingly complex. The major challenge was determining comparability between home health services for HHAs defined in part 409 subpart E, and RNHCI services which are nonmedical in nature.

Medicare pays for supportive care or dependent services under the home health benefit only when under the orders and direction of a licensed physician if there is a medical need for skilled health care by a registered nurse, physical therapist, speech-language therapist, occupational therapist, or medical social worker. Under the Medicare home health benefit, when there is no longer a need for the "skilled" health care services, the supportive dependent services no longer qualify for payment. Based on section 1861(m) of the Act, we believe that Medicare home health care benefits are skilled-care oriented. These benefits were not designed to provide coverage for care related to help with activities of daily living unless the patient requires skilled nursing care or physical or speech therapy. The RNHCI nurse may be skilled in ministering to

a beneficiary's religious needs (not covered by Medicare), but does not have the training or nursing skill sets required of credentialed/licensed health care professionals (for example, a registered nurse). While the RNHCI nurse may provide supportive care, that care is focused primarily on religious healing and meeting basic beneficiary needs for assistance with activities of daily living (for example, bathing, toileting, dressing, ambulation), as part of creating an environment for religious healing. The care provided by a RNHCI nurse is not at the level of either a registered nurse or a licensed practical nurse. The physical care provided by a RNHCI nurse is at a level that could be considered as supportive, but is decidedly not skilled nursing care as that term is understood under the Medicare home health program.

In the search for comparability of services, we considered the requirements and functions of the home health aide contained in sections 1861(m) and 1891(a)(3)(A) of the Act and in the regulations at 42 CFR 484.36. We performed a parallel review of the activities and skills utilized by home health aides and RNHCI nurses to determine comparability at an operational level. We determined that both the RNHCI nurse and the home health aide perform the following basic tasks--

- Assisting with activities of daily living (ADLs) that include: ambulation, bed-to-chair transfer, and assisting with range of motion exercises; bathing, shampoo, nail care, and dressing; feeding and nutrition; and toileting;
- Performing light housekeeping, incident to visit; and
- Documenting the visit.

However, the home health aide is also responsible for--

- Care of catheters and drainage equipment;
- Checking oxygen and other respiratory equipment;
- Communicating with nurse or other skilled team members;\*
- Assisting with exercises as ordered by PT, OT or speech language therapist;
- Observation and reporting of existing medical conditions;\*
- Recognizing and responding to emergency situations (including CPR);
- Routine care of prosthetics and orthotics;
- Taking and reporting vital signs;\*
- Using basic infection control procedures;\* and
- Care of wound/stoma dressings.

The home health aide during a home visit will usually perform at least three of the four skills marked with an asterisk (\*) from the ten skills listed. The remaining areas of responsibility are carried out as indicated by the patient's needs and the patient's care plan.

In analyzing the outcomes of the home health aide/RNHCI nurse review, we found that both groups engaged in the comparable tasks of assisting with activities of daily living, performing light housekeeping (incident to visit), and documenting the visit. Therefore, we will pay for the performance of these tasks by a RNHCI nurse in the home under the home benefit established by section 706 of the MMA. However, in reviewing for comparability of these services, we also found that the Medicare requirements for a home health aide exceed the preparation and skills of the RNHCI nurse for furnishing physical care. The home health aide performs activities that support the patient's prescribed medical therapeutic regimen and contribute to the Outcome and Assessment Information Set (OASIS) data collection effort. Moreover, we assumed that a significant portion of each RNHCI nurse visit is focused on religious activity (noncovered by Medicare). However, in spite of the difference in skill levels and the incorporation of non-covered religious activity into a visit, Medicare

payment for the RNHCI home benefit is based on a fixed payment per visit, rather than on a total number of hours or number of caregivers involved. Unlike the home health benefit, the RNHCI benefit does not involve multiple levels of covered caregivers. Under the home health PPS only the low utilization payment adjustment (LUPA) rate provides for payment for individual home health visits. Due to the uniqueness of the RNHCI and RNHCI nurses in the Medicare program, we have developed a payment rate that is a percentage of the PPS LUPA rate for home health aide visits provided under the home health PPS, which we believe adequately represents the percentage of comparable tasks performed by the RNHCI nurse. Only a visit by a RNHCI nurse to a home is payable by Medicare. The cost for the religious portion of the visit continues to be the responsibility of the individual patient or the specific RNHCI.

Another challenge was posed by the provision of DME items for RNHCI patients in the home, since all DME is covered for Medicare payment only when ordered by a physician. That physician order may provide the RNHCI patient with the desired DME item, but will also revoke the patient's election for RNHCI care. We addressed the issue of DME by reviewing those items that are routinely found in



a RNHCI that are comparable to those used by a HHA that is not a RNHCI. This resulted in a list of DME items that one could normally buy or rent off the shelf from a community pharmacy or health care supply store. For purposes of this time-limited benefit, we are permitting the RNHCI nurse to order from this list of designated items under the oversight of the RNHCI utilization review committee. A listing of these items is provided in Table 15 below.

**TABLE 15:**

<b>DME with HCPCS Codes Available for the Home Benefit</b>	
<b>CANES</b>	
E0100	Cane, includes canes of all materials, adjustable or fixed, with tip
E0105	Cane, quad or three prong, includes canes of all materials, adjustable or fixed, with tip
<b>CRUTCHES</b>	
E0112	Crutches, underarm, wood, adjustable or fixed, pair, with pads, tips, and handgrips
E0113	Crutch, underarm, wood, adjustable or fixed, pair, with pad, tip, and handgrip
E0114	Crutches, underarm, other than wood, adjustable or fixed, pair, with pads, tips, and handgrips
E0116	Crutch, underarm, other than wood, adjustable or fixed, with pad, tip and handgrip
<b>WALKERS</b>	
E0130	Walker, rigid (pickup), adjustable or fixed height
E0135	Walker, folding (pickup), adjustable or fixed height
E0141	Walker, rigid, wheeled, adjustable or fixed height
E0143	Walker, folding, wheeled, adjustable or fixed height

<b>COMMODOES</b>	
E0163	Commode chair, stationary, with fixed arms
E0167	Pail or pan for use with commode chair
<b>WHEELCHAIRS</b>	
K0001	Standard wheelchair
<b>HOSPITAL BEDS and ACCESSORIES</b>	
E0250	Hospital bed, fixed height, with any type side rails, with mattress
E0255	Hospital bed, variable height, hi-lo, with any type side rails, with mattress
E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
E0275	Bed pan, standard, metal or plastic
E0276	Bed pan, fracture, metal or plastic
E0290	Hospital bed, fixed height, without side rails, with mattress
E0292	Hospital bed, variable height, hi-lo, without side rails, with mattress
E0325	Urinal; male, jug-type, any material
E0326	Urinal; female, jug-type, any material

We will provide the specifics for implementing the DME items and payment under this time-limited benefit in later Medicare program instructions.

Under section 1861(aaa)(2)(B) of the Act, payments for the RNHCI home benefit may not be made that exceed \$700,000 per calendar year, and not after December 31, 2006. Under the RNHCI home benefit, Medicare will pay only for

nonmedical health services in the home, as well as for those DME items included in Table 15 of this preamble. Medicare will not pay for religious items or services provided by the RNHCI. We have developed a special billing system for those RNHCI providers offering the home benefit to monitor expenditures on home services and items for purposes of staying within the statutory calendar year expenditure limit.

5. RNHCI Regulatory Provisions--RNHCI Medicare Benefits, Conditions of Participation, and Payment

As noted previously, to implement section 706 of the MMA, we reviewed the requirements for both HHAs and RNCIs to identify the most feasible approach. Accordingly, we have made the following changes to the RNHCI regulations:

a. Basis and Purpose of Religious Non-Medical Health Care Institutions Providing Home Services--§403.764

We added §403.764 to set forth the basis and purpose of the RNHCI home benefit. Specifically, we added subsection (a) to include a reference to section 1861(aaa) of the Act to the general RNHCI authority noted in §403.700 and a description of the provisions of section 1861(aaa). We also added subsection (b) to describe the home benefit, the statutory annual fiscal limitation, and the sunset provision.

b. Definitions and Terms--§403.702

We made no changes to the regulation.

c. Conditions for Coverage--§403.720

We made no changes to the regulation.

We wish to emphasize that the RNHCI home benefit is an option available to each RNHCI, and the facility is not required to offer this service to either gain or maintain RNHCI status.

The RNHCI home benefit is not to be confused with hospice care that may involve more frequent visits and can involve institutional services. If, for some reason, the RNHCI home-serviced patient requires more than what is provided under the RNHCI home benefit, RNHCI or other institutional services may be required.

d. Valid Election Requirements--§403.724

We made no changes to the regulation because no modification or clarification to this requirement is needed to implement the RNHCI home benefit. Section 1821(b) of the Act addresses the issues involved in beneficiary election of RNCHI services.

e. Conditions of Participation--§403.730 through §403.746

We have not changed the following conditions of participation, as they do not require any modification or clarification for implementing the RNHCI home benefit:

- Patient Rights (§403.730)
- Quality Assessment and Performance Improvement (§403.732)
- Administration (§403.738)
- Staffing (§403.740)

We have not changed the following conditions of participation, as they are specific to institutions and are not applicable to the implementation of the RNHCI home benefit:

- Food Services (§403.734)
- Discharge Planning (§403.736)
- Physical Environment (§403.742)
- Life Safety From Fire (§403.744)

The following condition of participation requires the addition of a new standard to reflect the additional responsibility necessary for implementing the RNHCI home benefit:

- Utilization Review (§403.746)

As explained previously, the utilization review committee will review the need for care and oversee the utilization of items and services for the RNHCI home benefit. Accordingly, §403.746 will be revised to reflect the additional responsibility necessary for implementing

the RNHCI home benefit. Specifically, \$403.746 will be modified to add a new subsection (c) to read as follows:

(c) Standard: Utilization review committee role in RNHCI home services. In addition to the requirements in (b), the utilization review committee is responsible for the admission and continued care review (at least every 30 days) of each patient in the RNHCI home services program. The utilization review committee is responsible for oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment (DME) items for beneficiaries in the program.

We again note that under the RNHCI home benefit, one of the tasks of the RNHCI nurse is to order from a selected group of DME items that meet the documented needs presented by a patient, if that need is presented by the patient. The utilization review committee will provide oversight for the DME orders and utilization of the items. The utilization review committee cannot act as a physician in ordering DME items other than those items designated specifically for the purpose of this time limited RNHCI benefit. A claim from any other individual or provider attempting to seek Medicare payment for non-designated

RNHCI home benefit DME items without a physician order will be disallowed.

In implementing section 706 of the MMA, we have also revised the regulations to add the following provisions:

a. Requirements for Coverage and Payment of RNHCI Home Services (§403.766)

The RNHCI home benefit is an option available to each RNHCI, but it is not a service that the facility must offer to gain or maintain RNHCI status. With the exception of limited DME items, we have determined that services that RNHCI nurses provide are generally covered for Medicare payment under the time limited RNHCI home benefit as these services (for example, assistance with ADLs, light housekeeping incident to the visit, and documentation of the visit), are comparable to the services of home health aides in HHAs that are not RNHCIIs.

To reflect the requirements of this limited benefit, we are adding a new section 403.766. Specifically, in §403.766(a), we are requiring the RNHCI provider to submit a notice of intent if it is interested in providing RNHCI home services. This will help us facilitate the implementation of the RNHCI home benefit by letting us focus our efforts on those providers interested in providing this new benefit. The RNHCI provider is also

responsible for providing RNHCI home services to eligible beneficiaries. We are imposing this requirement because we believe the RNHCI provider itself is responsible for providing the RNHCI home services, directly or under arrangement, to the eligible beneficiary. This means that the beneficiary cannot contract directly with a supplier or RNHCI nurse, but that the RNHCI provider itself is responsible for provision of the RNHCI home benefit services. This requirement conforms to the "under arrangement" requirement that home health agencies generally have to comply with to receive payment under the home health prospective payment system (see §409.100(a)(2)). Furthermore, because the RNHCI is not a supplier, we are explicitly requiring the RNHCI provider to make arrangements for suppliers to furnish the designated RNHCI home benefit DME items. Likewise, the RNHCI provider will have to arrange for the RNHCI nursing services. While the RNHCI regulations currently require the RNHCI provider to have a utilization review plan and committee in place, we believe it would be prudent in the RNHCI home benefit regulation to explicitly require the RNHCI home benefit provider to have a utilization review committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided



under the home benefit. Lastly, because the RNHCI home benefit does not supersede or otherwise replace the existing RNHCI benefit, the provider will continue to have to meet all the existing applicable RNHCI regulatory requirements in subpart G of part 403.

We will also define an "eligible beneficiary" for the RNHCI home benefit in §403.766(b). First, the beneficiary must elect to receive RNHCI services. Clearly, the RNHCI home benefit can only be provided to a beneficiary who has elected RNHCI services. Second, we believe that the purpose of providing a home benefit by a RNHCI provider was not to expand the basic eligibility criteria for receiving home health services. In fact, section 1821(a) of the Act, as amended by the MMA, now states that payment for RNHCI home services be made only if the individual has an election in effect and has a condition such that the individual would otherwise qualify for Medicare home health services. Specifically, this means that the individual must be confined to the home, as defined in section 1814(a) of the Aft and have a condition that would make him or her eligible to receive Medicare home health services. Third, much like the requirement that the RNHCI provider is responsible for providing RNHCI home services directly or under arrangement to the beneficiary, the beneficiary can

only receive RNHCI home services through the RNHCI. The purpose of this requirement is to provide Medicare payment for the RNHCI home benefit only to beneficiaries who receive these services through the RNHCI. This requirement is consistent with section 1821(a) of the Act, as amended, which provides Medicare payment for home services furnished an individual by a RNHCI. We note that under the home health benefit beneficiaries are responsible for the deductible and coinsurance for DME furnished as a home health services. We see no reason to modify that requirement for beneficiaries receiving RNHCI home services. As this is a new benefit for RNHCI beneficiaries, we wish to make it clear that they are responsible for deductible and coinsurance for the designated RNHCI home benefit DME items in the same manner as Medicare beneficiaries receiving DME under the home health benefit.

b. Excluded Services (§403.768)

Under the home health benefit, certain items and services are excluded under the benefit. The RNHCI home benefit will exclude the same items and services, which are:

- Drugs and biologicals;
- Transportation;

- Services that would not be covered as inpatient services;
- Housekeeping services;
- Services covered under the ESRD program;
- Prosthetic devices; and
- Medical social services provided to family members.

Accordingly, we are adding a new \$403.768 to reflect the services excluded under the RNHCI home benefit.

In addition, we note that the statute does not provide for the provision of the RNHCI home benefit in a home health agency that is not a RNHCI, and we will provide for this exclusion in the regulation. We wish to reiterate that items and services not provided by a RNHCI but instead provided by a supplier or RNHCI nurse not under arrangement with the RNHCI are not included under the RNHCI home benefit. The regulation will also note this exclusion.

c. Payment for RNHCI Home Services (\$403.770)

As discussed above, providing home services in the RNHCI environment incorporates many of the same components of the provision of home health aide services under the Medicare home health benefit. Because this is a new benefit not contemplated under the original RNHCI legislation, an appropriate payment methodology needed to

be developed. As explained previously, we believe that an appropriate proxy for the cost of providing RNHCI home services can be found in the low utilization payment amount for home health aide visits under the Medicare home health PPS. Generally, Medicare home health services are reimbursed a prospectively set payment amount for a 60-day episode of care, adjusted for case mix. This 60-day episode payment includes costs for non-routine medical supplies, as well as costs for the six major home health disciplines, including home health aide services. The home health episode payment rate does not include reimbursement for durable medical equipment, which is paid through a separate DME fee schedule. The home health PPS rates were required to be budget neutral to what would have been expended under the reasonable cost system. The 60-day episode rate is updated annually by some percentage of the home health market basket, as dictated by law, and is adjusted by the hospital wage index to account for geographic variations in labor costs.

Medicare home health services may also be paid on a visit basis if the home health episode has four or fewer visits. Medicare pays on the basis of a national per-visit amount by discipline, referred to as low utilization payment adjustment (LUPA), adjusted for case mix. As

mentioned previously, the LUPA rate for home health aide services is a very close approximation of the cost of providing home services in the RNHCI environment. However, due to the difference in skill levels and the incorporation of RNHCI religious activities that are not covered by Medicare, payment for the RNHCI home benefit is set at 80 percent of the per visit rate for a home health aide visit under the Medicare home health benefit.

The policies and rationale governing LUPA payments under the Medicare home health benefit are described in the July 3, 2000 HH PPS final rule (65 FR 41127). Generally, low utilization episodes are paid at a standardized average per visit amount, adjusted for geographic differences in wages, which will be the basis of calculating payment under the RNHCI home benefit program. These amounts are updated annually by the home health market basket percentage as dictated by statute and are being used for the RNHCI home benefit. For CY 2005, the Medicare HHA PPS rates were updated by the home health market basket minus 0.8 percent. The HHA PPS LUPA amount for CY 2005 is \$44.76 for a home health aide visit, as published in the **Federal Register** October 23, 2004 (69 FR 62124). Because we believe the intent is to provide comparable home health services to a beneficiary at home provided by a RNHCI, we believe it is

similarly necessary to develop a payment methodology to reflect the provision of these comparable services. As previously mentioned, we have determined that the LUPA payment, as calculated under the home health PPS and adjusted for geographic differences in wages is an appropriate payment methodology for the RNHCI home benefit. We further note that as the LUPA will be updated by the applicable market basket percentage under the home health PPS, we will also adopt the updated LUPA payment for CY 2006 as the basis of payment for the RNHCI home benefit in CY 2006. An update of the HHA payment rates is published annually in the **Federal Register**, with CY 2006 updated figures available in Fall 2005. As mentioned above, the beneficiary receiving the RNHCI home benefit will be responsible for deductible and coinsurance for the designated RNHCI home benefit DME items. The regulation will indicate that payment for DME as a RNHCI home item is made less the deductible and coinsurance amount.

In view of the small size and low volume of most RNHCIs, we will use a 30-day cycle for the submission of RNHCI home benefit claims. Unlike standard HHAs that use a 60-day cycle, the RNHCI will use a 30-day cycle for both payment request and as a minimum for continued care home benefit review by the utilization review committee.

Specific instructions on the processing of RNHCI home benefit payments will be issued in separate Medicare instructions.

**Example of LUPA Payment Adapted for RNHCI Home Benefit**

**Payment:**

A RNHCI in Baltimore, Maryland is providing the RNHCI home benefit to a patient with a RNHCI election. The RNHCI has provided 12 visits within a 30-day cycle. The RNHCI would determine the payment for the home benefit visits as follows:

**TABLE 16:**

**Computation of Wage Index Adjusted Low Utilization Payment  
for the RNHCI Home Benefit**

	Final wage standardized and budget neutral per- visit payment amount per 30 days for 2005
1. Home Health Aide Visit (2005).....	\$ 44.76
2. RNHCI Nurse Visit .....(0.80 * \$ 44.76)	35.81
3. Calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit.....(0.76775 * \$.35.81)	27.49
4. Apply wage index factor for Baltimore, MD.....(0.9907 * \$ 27.49)	27.23
5. Calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit..... (0.23225 * \$ 35.81)	8.32
6. Subtotal—Low Utilization Payment Adjustment (LUPA) wage for 1 RNHCI nurse visit.....(\$ 27.49 + \$ 8.32)	\$ 35.55
7. Total - Calculate total Low Utilization Payment Adjustment (LUPA) for 12 RNHCI nurse visits provided during the 30-day episode ... ..(12 * \$ 35.55)	\$ 426.60

Note: The same “labor”/“non-labor” portions applied in the home health PPS will be used calculating the RNHCI LUPA payments.

Step 1. Take the home health aide visit base rate for the involved year from the home health PPS update published.

Step 2. To calculate the RNHCI nurse visit base rate, multiply the home health aide visit base rate (\$ 44.76) by the allowed percentage for a RNHCI nurse visit (0.80 percent) = (\$ 35.81).

Step 3. To calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the labor portion of 0.76775 by the RNHCI nurse visit rate from Step 2 (\$ 35.81) = (\$ 27.49).

Step 4. Apply the wage index for the involved Metropolitan Statistical Area (MSA)



from the home health PPS payment update published annually each November in the **Federal Register** (Baltimore, MD = 0.9907) multiplied by the labor portion of the RNHCI nurse visit from Step 3 (\$ 27.49) = (\$27.23).

Step 5. To calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the non-labor portion of 0.23225 by the RNHCI nurse visit rate from Step 2 (\$ 35.81) = (\$ 8.32).

Step 6. To calculate the LUPA rate for 1 RNHCI nurse visit, add the products from Step 4 (\$27.49) and Step 5 (\$ 8.32) = (\$ 35.55).

Step 7. To calculate the LUPA payment for RNHCI nurse visits to one beneficiary in a 30-day period, multiple the product of Step 6 (\$ 35.55) by the number of visits (12) = (\$ 426.60).

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#### **IV. Other Issues**

##### A. Provisions Related to Therapy Services

##### 1. Outpatient Therapy Services Performed "Incident To" Physicians' Services

Section 1862(a)(20) of the Act permits payment for therapy services furnished incident to a physician's professional services only if the practitioner meets the standards and conditions that would apply to the therapy services if they were furnished by a therapist, with the exception of any licensing requirement. We proposed to amend the regulations at §410.26, §410.59, §410.60, and §410.62 to reflect the statutory prohibition on payment for "therapy" services of individuals who do not meet the existing qualification and training standards for therapists (with the exception of licensure) as these standards are set out in §484.4.

As discussed in the August 5, 2004 proposed rule, section 1862(a)(20) of the Act refers only to PT, OT, and SLP services and not to any other type of therapy or service. This section applies to covered services of the type described in sections 1861(p), 1861(g) and 1861(ll) of the Act; it does not, for example, apply to therapy provided by qualified clinical psychologists. This section also does not apply to services that are not covered either as therapy or as E/M services provided incident to a physician or NPP, such as recreational therapy, relaxation therapy, athletic training, exercise physiology, kinesiology, or massage therapy services.

In the following discussion, the phrase "therapy services" means only PT, OT, and SLP. Also, "therapist" means only a physical therapist, occupational therapist, and speech-language pathologist.

Section 1861(s)(2)(K) of the Act permits certain NPPs, specifically PAs, NPs, and CNSs, to function as physicians for the purposes of furnishing therapy services which they are legally authorized to perform by the State in which the services are performed. Therefore, in our responses to comments in the following discussion, the statements concerning therapy services that apply to physicians also apply to PAs, NPs, and CNSs.

We received many comments on this proposal from professionals and associations for audiologists, speech-language pathologists, physical therapists, occupational therapists, long term care facilities, kinesiotherapists, massage therapists, athletic trainers, nurses, and physicians such as physiatrists, neurologists, podiatrists, chiropractors, osteopaths, medical groups, and family practitioners.

The proposal describes covered Medicare services and is not intended to affect the policies of other insurers who may cover services that Medicare does not, for example, therapy services performed by massage therapists or athletic trainers.

Comment: Several associations believe that this proposal is based on an incorrect interpretation of the intent of section 1862(a)(20) of the Act. Some claim that the proposed clarification is prohibited by the statute. They note the lack of any elaboration upon the Congress' intent in the Conference Report accompanying section 4541(b) of the BBA, but suggest the provision was based on a 1994 OIG report, "Physical Therapy in Physicians' Offices" (OEI-02-90-00590, March 1994). In the view of some commenters, the intended effect of section 1862(a)(20) of the Act was to apply to incident to therapy services the

standards and conditions related to treatment plans, the need for goals, and the requirement that therapy is to be restorative. This position is based on the fact that these standards were the focus of the 1994 OIG report. The commenters point out that the report did not compare therapist services to services furnished by nontherapists in a physician's office, but it only compared the services billed by therapists to those billed by physicians.

Commenters argued that the plain meaning of section 1862(a)(20) of the Act indicates that incident to services are not necessarily furnished by therapists. They point to the parenthetical exclusion of licensure requirements in the statutory language as evidence that the Congress did not intend to apply the personnel requirements applicable to therapists in private practice to incident to therapy services. Some commenters believe this exclusion was intended to preserve the right of physicians to supervise auxiliary personnel that were not licensed as therapists. They suggest that we are creating a de facto licensure requirement.

Comments from the two members of the Congress who introduced the act that resulted in section 1862(a)(20) of the Act support the proposed rule, stating that the proposed clarification meets the intent of the law when it was passed by the Congress in 1997. These commenters confirm that the legislation was based in part on the 1994 OIG report and the

intent was to establish "a consistent standard for the delivery for PT services to ensure quality patient care." Two additional comments were received from the Congress in support of the proposal.

Response: Our interpretation is based on the plain language of the law: no payment may be made for incident to therapy services "that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) . . . "

The second sentence of section 1861(p) of the Act reads as follows:

"The term 'outpatient physical therapy services' also includes PT services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary."

It is evident then, that the standards and conditions referenced in section 1862(a)(20) of the Act encompass qualifications of the individual providing the therapy. Consequently, we disagree with those commenters who suggest that it was not the intent of section 1862(a)(20) of the Act to apply the personnel qualifications of the second sentence of section 1861(p) of the Act to therapy provided incident to a physician's service. We believe our interpretation of the law is further supported by the comment received from the Congress members who sponsored the original bill that became section 1862(a)(20) of the Act.

According to the proposed requirements, a person who is trained in therapy, but has not completed the further requirements of therapy licensure, may provide services incident to a physician's services. These individuals are not therapists, since they are not licensed, but they are qualified personnel who may, under direct supervision, provide therapy services incident to a physician.

A physician may utilize supervised unlicensed staff and may bill for a covered therapy service incident to the physician's service if it is provided according to Medicare policies, including coverage and incident to policies.

Comment: Commenters also note that qualifications at §484.4 are in the home health agency section of the regulations, while the second sentence of section 1861(p)

of the Act (referenced by section 1862(a)(20) of the Act) does not apply to therapy provided in home health agencies.

Response: The statute specifies therapy services provided incident to a physician must meet the standards and conditions that would apply to a therapist, except licensure. For the history of the qualifications for the private practice setting, please see the discussion in this rule as described below in section IV.A.2, "Qualification Standards and Supervision Requirements in Therapy Private Practice Settings." We proposed to apply to all settings the qualifications in §484.4 because they are standards that currently apply to therapists in provider settings. It is our intent to make therapist qualifications consistent in all settings (unless otherwise required by statute). Therefore, unless a person meets the standards in §484.4, except licensure, their services may not be billed as therapy services incident to a physician's service, regardless of any other training, other licensure or certification or other experience they may have. For example, the services of chiropractors or athletic trainers who do not meet the requirements in §484.4 except licensure, cannot be billed as therapy services incident to a physician's service.

Comment: Several associations indicated that we are changing our interpretation of the statute. They assumed any instruction relevant to the law was made in 1998 through Transmittal 1606. That transmittal provided guidance for therapy services, but did not address the qualification of the people who furnish therapy incident to physician services. It was also suggested that we delay implementation to allow further study and comment from interested parties. The AMA urged us to withdraw proposed changes and reissue a later proposal after consulting with all affected physician and other health professional organizations.

Also, the commenters note that the Administrative Procedure Act (APA) requires that we characterize this as a change rather than a clarification.

Response: In the past, we did not discuss the plain language of the law because we did not believe it needed extensive clarification. However, it has become clear to us that contractors have varied in their policies.

Some contractors created local policies that paid only for services provided by licensed therapists in all settings including incident to a physician's service. Others had no policies that assured the qualifications of personnel



furnishing services billed as therapy services incident to a physician.

Study of the utilization of therapy services, internal discussions with contractors and medical review of claims for the purpose of error rate analysis all suggested that the services being performed in the offices of physicians did not consistently meet the standards and conditions we applied to therapy services in private practice or in provider settings. Problems associated with an imprecise definition of therapy services were discussed at length in Section 4.1 of the "Study and Report on Outpatient Therapy Utilization" (the DynCorp utilization study) found at [www.cms.hhs.gov/medlearn/therapy](http://www.cms.hhs.gov/medlearn/therapy). Review of medical records following this report reinforced the personnel qualification problem.

In Pub. 100-04, the Medicare Claims Processing Manual at chapter 5, section 20, there is a list of codes that represent services that are always therapy services (available online at [http://www.cms.hhs.gov/manuals/104\\_claims/clm104c05.pdf](http://www.cms.hhs.gov/manuals/104_claims/clm104c05.pdf)). Whenever these codes are billed, they must have a modifier that identifies the type of therapy (PT, OT, or SLP) and the services provided must meet the standards and conditions that apply to outpatient therapy services. In

the medical review of therapy claims, there were frequent observations of "always therapy" services performed by persons other than therapists, which were billed inappropriately as therapy.

Since the qualifications of therapists and therapy services continued to be problematic, we chose to raise the subject of therapist qualifications last year. Last year's comments made it clear that there is widespread use of nontherapists, particularly athletic trainers, in the offices of physicians and those services are being billed as therapy services. The volume of similar comments this year made it evident to us that the clarification was needed.

We characterize this statement as a clarification because it merely restates the law. Moreover, we announced our clarification in the proposed rule, and it has been subject to comment in last year's proposed rule and again this year. So, assuming that it did change policy, its promulgation meets the requirements of the APA.

In addition, we note that we continue to pay only for covered services whether they are therapy or other services. Coverage rules in the Program Integrity Manual, chapter 13.5.1, require, for example, that the service be safe, effective, in accordance with accepted standards of medical practice, and furnished by qualified personnel.

We recognize there has been inconsistent application of this statutory requirement. Therefore, in order to allow sufficient time for physicians to adjust their practices, and to avoid disrupting ongoing therapy in affected practices, we will delay implementation until manual instructions are published. We anticipate publication of manual instructions on or after March 1, 2005.

Comment: Many commenters offered the opinion that restricting payment for therapy services to those performed by therapists would reduce access and quality of care and increase costs. They noted that it is more convenient for therapy to be available in a physician's office than at another site. Also, there was concern that therapists may not work in rural areas, especially because there is a shortage of qualified therapists.

Response: The statute requires that those who provide therapy services meet therapy standards. It provides an exception for licensure in an incident to setting, but it does not provide an exception for rural areas. Since recent changes allow physical and occupational therapists that are enrolled in Medicare to work for physicians, there is no legal impediment to physicians being able to provide therapy services in their offices without the use of

nontherapists. The Department of Labor Bulletin 2572, titled "Occupational Projections and Training Data 2004-05 Edition", suggests no shortage of therapists.

Nor do we find evidence to suggest the quality of care will be decreased by the use of personnel trained in therapy services as opposed to those trained in other disciplines. The cost of therapy services to Medicare will not be changed by the use of appropriately trained personnel.

Comment: Many comments from physical therapists and PT associations agreed in principle with consistently defining the qualifications for therapists in all settings. They point out that, although the statute allows unlicensed people to provide therapy services incident to the services of a physician, the purpose of licensure is to assure that services are safely and effectively furnished by professionals who have demonstrated the necessary knowledge and skills. The statute permits the use of therapists who have not met licensing requirements and those whose licenses were revoked due to malpractice or fraud. The supervision requirement that the physician be present somewhere in the suite, but not in line of sight, is insufficient to assure the safety and quality of service provided by unlicensed staff.

Response: Although the law permits unlicensed individuals to provide services incident to the services of a physician, we believe physicians will be motivated to screen employees to weed out sanctioned or incompetent people who have training in therapy since physicians would be liable for the actions of an incompetent employee. We require direct supervision of the employee by the physician as a minimum standard, but a physician will provide whatever guidance and supervision is required to assure the safety, effectiveness and quality of the service.

Comment: Many comments were received from individuals such as athletic trainers, kinesiotherapists, massage therapists and chiropractors describing their training as equal or superior to therapists' and suggesting that they provide care similar to therapists.

Response: The statute allows Medicare to pay only for PT, OT and SLP services. Comments from therapists and nontherapists agreed that their training and licensure is unique to their professions, and they are separately trained and licensed for those unique professions. It is clear that many nontherapist health care practitioners are well-trained professionals dedicated to the provision of quality treatment for their patients. However, their

training is not in PT, OT, or SLP, but in the other disciplines for which they are licensed or accredited.

Comment: A number of physicians and associations for physicians wrote to tell us that they believe it is their right and within their authority to decide who can provide effective therapy services in their offices.

Response: The statute requires Medicare to pay only for services that meet the standards and conditions, except licensure, that apply to therapists. It is the right and responsibility of a physician to recommend services for patients that in the physician's judgment are needed and effective. Medicare, however, need not pay for all services that a physician recommends. We are required to pay for services that are covered in the statute and to deny payment for services that are not covered, even if the physician considers those services necessary and effective.

Comment: Some physicians wrote to tell us they are currently billing Medicare for therapy services when athletic trainers perform services in their offices. Several commenters asked what services may be billed to Medicare when provided by auxiliary staff who are qualified as athletic trainers, or who have certification in fields other than therapy.

Response: While some carriers may have paid claims for incident to therapy services furnished by individuals without therapy training, we have never had a policy that permits athletic trainers or any other staff who do not have training in PT to provide services that are billed as PT services. Carrier payment for a service is not conclusive evidence that the service was appropriately rendered. Billing with a code that does not accurately represent the service provided is inappropriate. If identified by carrier medical review, these claims must be denied, and further development of the claim may be indicated to determine if there was intent to bill improperly.

Medicare defines PT, OT and SLP as services that require the skills of a physical therapist, occupational therapist or speech-language pathologist. Therapy codes are priced based on the salaries and expenses of therapists and we expect that therapy claims are made for services of therapists (or, for incident to services by someone with their training, except for licensure).

When a service is not a covered service, it is inappropriate to bill Medicare for that service as a service incident to a physician, or as an E/M service. For example, if a service is appropriately described as

acupuncture or athletic training or massage therapy, Medicare will not pay for that service because it is not covered.

A physician may not bill Medicare for a service that is on the list of "always therapy" services (see Pub. 100-04, the Medicare Benefit Policy Manual, chapter 5, section 20) if the service was done by staff that is not qualified to provide a skilled therapy service, because that is not a covered therapy service. The "always therapy" codes always require a modifier to describe whether the service was PT, OT or SLP.

There are covered services that other staff, such as athletic trainers, may perform with other training, however, these are not therapy services. Other codes on the therapy list are "sometimes therapy" services and require modifiers only when they are therapy services rather than physician services. For example, a physician may apply a surface neurostimulator (CPT 64550) as an isolated service, outside of a therapy plan of care and appropriately bill the code without a therapy modifier. That service is not a therapy service. If that physician supervises auxiliary personnel in the provision of that same nontherapy service, the auxiliary personnel does not have to be qualified as a therapist because the service rendered is not therapy. In any case, when Medicare is billed for a service, the person providing the service must be qualified to provide the



service, as determined by the contractor in accordance with coverage requirements in Pub. 100-08, the Medicare Program Integrity Manual, chapter 13.5.1. However, if a therapist provides the service under any circumstance, or if either the physician or qualified personnel provides the service as part of a therapy plan of care, it is a therapy service and it requires a modifier. In cases where there is doubt, the contractor will determine whether the service is therapy or is not therapy.

Further information about services that may be completed by non-therapists will be available in implementing instructions.

Comment: The American Chiropractic Association commented that doctors of chiropractic are authorized to perform PT services in all but two States, Michigan and Washington. They request that we note that fact in our commentary and in the regulation. They note that Doctors of Chiropractic are included in the definition of "physician" and they propose language in addition to that in §484.4 to define the qualifications of chiropractors, in order to recognize the State-authorized practice privileges of Doctors of Chiropractic.

Response: Chiropractors may bill services to Medicare as physicians, but only for the purposes of providing manipulation of the spine for the correction of a subluxation, which is a chiropractor service, and not a therapy service. For these manipulation services,

chiropractors may directly supervise employees who provide incident to services. However, as Medicare physicians, chiropractors are not authorized to order therapy services or to perform any other services. To qualify to provide therapy services incident to a physician, chiropractors must meet all of the criteria set forth at §484.4 except licensure.

Comment: Several associations and some individuals commented that we are creating a monopoly for therapists to provide therapy services and unnecessarily restricting other professions from providing therapy services.

Response: We are bound by the statutory authority given to us in section 1832 of the Act to pay only for services for which there are benefits enumerated in the statute. PT, OT and SLP have benefits in section 1861 of the Act. Therefore, Medicare pays only for those services.

Comment: Several commenters noted that some NPPs, specifically PAs, NPs, and CNSs, may perform therapy services billable under Medicare as therapy services if their State scope of practice allows. The commenters question whether those NPPs may also perform therapy services incident to a physician or NPP.

Response: Medicare does not impose therapy training requirements on physicians whose State scope of practice allows them to perform therapy services. Section 1861(s)(2)(K) of the Act permits PAs, NPs, and CNSs, to

furnish services which would be physicians' services, that is, to function as physicians for purposes of furnishing services, including therapy services, which they are legally authorized to perform by the State in which the services are performed. Therefore, this final rule has been modified to reflect that in States that authorize physicians, PAs, NPs, and CNSs to provide one or more of the therapy services (PT, OT, or SLP services), those NPPs may provide the services incident to the services of a physician or NPP under the same conditions as physicians, that is, without meeting the training requirements applicable to therapists.

#### Results of Evaluation of Comments

To the extent that this policy is different from current manual text, we proposed this rule and received comments. We are finalizing the proposal in this final rule with the changes noted above in accordance with the APA. We will implement this regulation through manual guidance on or after March 1, 2005.

#### 2. Qualification Standards and Supervision Requirements in Therapy Private Practice Settings

Sections 1861(g) and (p) of the Act include services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed

by the Secretary if the services meet the necessary conditions for health and safety. These services include those furnished in the therapist's office or the individual's home. By regulation, we have defined therapists under this provision as physical or occupational therapists in private practice (PTPPs and OTPPs).

Under Medicare Part B, outpatient therapy services, including physical and occupational therapy services, are generally covered when reasonable and necessary and when provided by physical and occupational therapists meeting the qualifications set forth at §484.4. Services provided by qualified therapy assistants, including physical therapist assistants (PTAs) and occupational therapy assistants (OTAs), may also be covered by Medicare when furnished under the level of supervision by the therapist that is required for the setting in which the services are provided (institutions and private practice therapist offices). For PTPPs and OTPPs, the regulations now specify only that the PT or OT meet State licensure or certification standards; the regulations and do not currently refer to the professional qualification requirements at §484.4.

Since 1999, when therapy services are provided by PTAs and OTAs in the private practice of a PT or OT, the

services must be personally supervised by the PTPP or OTPP. In response to a requirement to report to the Congress on State standards for supervision of PTAs, we contracted with the Urban Institute. The Urban Institute found that no State has the strict, full-time personal supervision requirement, for any setting, that Medicare places on PTAs in PTPPs. (The report examined only PTAs, who are more heavily regulated by the States than OTAs).

To provide a consistent therapy assistant supervision policy, we proposed to revise the regulations at §410.59 and §410.60 to require direct supervision of PTAs and OTAs when PTs or OTs provide therapy services in private practice. We also specifically solicited comments regarding the proposed PTA supervision policy, and whether or not it would have implications for the quality of services provided, or for Medicare spending, either through increased capacity to provide these services, or, in the event that the Congress again extends the moratorium on the implementation of the limits on Medicare reimbursement for therapy services imposed by the BBA of 1997.

In addition, as discussed in the August 5, 2004 proposed rule, the current OTPP or PTPP regulations at §410.59(c) and §410.60(c) do not reference qualification requirements for therapy assistants or other staff working

for PTs and OTs in private practices. In order to create consistent requirements for therapists and for therapy assistants, we proposed to restore the qualifications by adding the cross-reference to the qualifications at §484.4 for privately practicing therapists and their therapy assistants at §410.59 and §410.60.

Comment: Commenters representing therapy organizations, as well as individual providers, were supportive of our proposal to revise the regulations at §410.59 and §410.60 to require direct, rather than personal, supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice. (We use the 3 supervision levels defined at §410.32, personal, direct, and general, to describe the supervision requirements for various Medicare services and settings.)

Many commenters also stated that this is consistent with the Medicare requirements in other provider settings, such as hospitals, HHAs and rehabilitation agencies and is also consistent with the Medicare requirements for therapists in private practice that were in place prior to 1999. Commenters also believe that this will assist in ensuring access to therapy services and in protecting patient privacy.

Response: Requiring direct supervision of therapy assistants in PT and OT private practice settings is consistent with the supervision requirements that PTs and OTs in independent practice were required to meet, prior to 1999, at §410.59(c) and §410.60(c). This direct supervision requirement in PT and OT private practices requiring the therapist to be on site or "in the office suite" differs from our therapy assistant supervision requirements in institutional settings (for example, outpatient hospital departments, HHAs, and rehabilitation agencies). In those settings, PTs and OTs may provide general supervision of therapy assistants without being on-site.

We agree that changing the level of supervision of therapy assistants from personal to direct will help to improve access to medically necessary services.

Comment: A few commenters stated they believe permitting general supervision, rather than direct, is more consistent with State therapy supervision requirements. While State requirements vary, this variation may be due to the fact that PTAs are not licensed in some States. Other commenters stated that therapy assistants are qualified to provide services without having therapists in-the-room to provide personal supervision.

Response: A review of State practice acts revealed that Medicare's personal in-the-room supervision requirement for therapy assistants in PT and OT private practices was more stringent than any State supervision requirement for any setting. The Urban Institute report also found that most States permit a supervision level similar to our general supervision requirement for institutional settings. However, we believe that services delivered by therapy assistants in private practices require a higher level of therapist supervision than those provided in institutional settings where stringent standards for Medicare participation are enforced through State survey and certification programs, rather than the simplified carrier enrollment process for the PT or OT private practice offices.

Comment: One commenter stated that only licensed therapists should be allowed to provide and bill for therapy and another commenter demanded that therapy services only be reimbursed when provided by a therapist, not any other professional, including nurses, PAs, or chiropractors, and not by therapy assistants. They suggested that without this requirement there would be program abuses.



Response: We concur with the therapy associations and the overwhelming majority of commenters that therapy assistants are qualified by their training and education to provide services without the personal in-the-room supervision in the private practice setting. This does not mean, however, that therapy assistants may bill for the services they provide. Under the law, only PTs and OTs in private practice may bill Medicare for the therapy services provided by PTAs and OTAs. These therapists enroll in the Medicare program and receive a provider identification number (PIN) in order to file claims for the therapy services provided as a PTPP or OTTP. Institutional therapy providers bill Medicare on behalf of the PTs, OTs, and speech language pathologists who provide therapy services in these settings.

Other professionals, including nurses, athletic trainers, and chiropractors do not meet the statutory requirements for therapists in section 1861(p) of the Act and as implemented at §484.4. We proposed to amend the regulations at §410.59 and §410.60 to specify that only individuals meeting the qualification standards and training consistent with §484.4 may bill and receive Medicare payment for therapy services. In addition, a State license or certification in PT or OT will continue to

be required for therapist providing services as PTPPs or OTPPs.

When PAs, NPs, or CNSs are authorized by their State practice acts to provide physical or occupational therapy services, and these NPPs are acting within their capacity to provide physician services under section 1861(s) (2) (K) of the Act, their services are considered therapy services.

Comment: One commenter stated that allowing lesser trained individuals such as therapist assistants to provide services if a therapist supervises, but prohibiting physicians from delegating performance of these services to doctors of chiropractic inappropriately gives therapists more authority than physicians.

Response: Medicare law recognizes chiropractors as physicians, but only for the limited purpose of providing manipulation of the spine for the correction of a subluxation. In order to qualify as a PT or OT for Medicare purposes, chiropractors would need to meet all of the criteria set forth at §484.4.

Comment: In response to our request for information on the impact of this proposed change on the quality of services and Medicare spending, several individuals stated that the proposed change would not affect the way therapists practice, since they are fully accountable for

services provided under their direction and, therefore, the change would not diminish the quality of services.

Furthermore, commenters believe the change would also allow the appropriate and efficient utilization of therapist assistants because the in-the-room supervision unnecessarily drives up the cost of health care without providing additional consumer protection.

The American Physical Therapy Association (APTA) anticipates there will be little, if any, increase in spending as a result of this policy and believes that any increases would be due to improving access to medically necessary outpatient therapy services provided by qualified practitioners. For spending implications, the APTA believes it is highly unlikely that physical therapists would significantly alter their staffing patterns and thereby increase spending as a result of this change in policy. The majority of States have laws that establish limits on the number of PTAs that a PT can supervise (referred to as "supervision ratios"). For example, a large number of States have a supervision ratio of one PT to two PTAs. There are also a limited number of PTAs whom PTs could supervise, and APTA does not anticipate substantial growth in the number of PTAs in the foreseeable

future. To the contrary, the number of PTA education programs is declining.

Furthermore, services of PTs in private practice comprise a relatively small percentage of services billed under the Medicare program. Therefore, the overall financial impact of any change in the supervision requirement in this setting would be minimal.

Response: We appreciate the information provided by the commenters. Other opportunities already exist for therapists to provide services under Medicare in rehabilitation agencies and CORFs where the therapy assistant supervision level is general. Therapists opting to utilize therapy assistants might be more likely to own a rehabilitation facility where the physical or occupational therapy assistant supervision level is general, rather than a private practice office where the therapist is required to be on-site to supervise services of the therapy assistant. The Urban Institute Report confirmed the limited number of therapy assistants available to be hired and found that workforce and distribution percentages of PTs and PTAs parallel each other, with nearly 25 percent of PTAs employed by PTPPs. We believe that the State supervision requirements and the limited number of PTAs are likely to limit the financial implications of this change.

We plan to monitor this area to determine whether volume changes occur and, if so, in what settings they occur.

Comment: Commenters supported our proposal to revise §410.59 and §410.60 to cross-reference the qualifications at §484.4 for privately practicing therapists and their therapy assistants.

Response: We appreciate the numerous letters of support for this proposal, including the national and State-level therapy organizations, other professional organizations, and many therapists and therapy assistants.

#### Result of Evaluation of Comments

We will finalize the proposed revisions to §410.59 and §410.60 to require direct supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice and also to cross-reference the qualifications at §484.4 for privately practicing therapists and their therapy assistants.

### 3. Other Technical Revisions

We proposed technical corrections to §410.62 to refer consistently to SLP (currently the terms "speech pathology" and "speech-language pathology" are used interchangeably) and proposed revisions to §410.62(a)(2)(iii) to appropriately reference §410.61 (the current reference is to §410.63).

We also proposed removing subpart D, Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists, from part 486. Our November 1998 rule (63 FR 58868) discussed replacing this subpart with a simplified carrier enrollment process for physical or occupational therapists in private practice; however, the conforming regulatory change to remove subpart D was never made.

In addition, we proposed a technical change at §484.4 to correct the title "physical therapy assistant" to "physical therapist assistant" and proposed amending §410.59(e) and §410.60(e) to include a reference to the 2-year moratorium on the therapy caps established by section 624 of the MMA.

Comment: Commenters representing therapy specialty organizations supported these changes.

Response: We will finalize these changes as proposed.

Result of Evaluation of Comments

We are finalizing the changes as proposed.

B. Low Osmolar Contrast Media

High osmolar and low osmolar contrast media (LOCM) are used to enhance the images produced by various types of diagnostic radiological procedures. When the Medicare physician fee schedule was established, findings of studies of patients

receiving both types of contrast media had been published, and the ACR had adopted criteria for the use of LOCM. At that time, we determined that the older, less expensive high osmolar contrast media (HOCM) could be used safely in a large percentage of the Medicare population. However, we also decided that separate payment for LOCM may be made for patients with certain medical characteristics. We adopted the ACR criteria, with some modification, as the basis for a policy that separate payments are made for the use of LOCM in radiological procedures for patients meeting certain criteria. These criteria were established at \$414.38. Under these conditions, we pay for LOCM, utilizing HCPCS codes A4644 through A4646.

In the August 5, 2004 rule, we proposed to revise the regulations at \$414.38 to eliminate the restrictive criteria for the payment of LOCM. This proposal would make Medicare payment for LOCM consistent across settings since, under the OPPS, there is no longer a payment difference between LOCM and other contrast materials.

We also proposed that, effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent in accordance with the standard methodology for drug pricing established by the MMA. However, because the technical portions of radiology services are currently valued in the nonphysician work pool and the CPEP inputs for these services are not used in

calculating payment, we also indicated we would continue to reduce payment for LOCM by eight percent to avoid any duplicate payment for contrast media.

Comment: Commenters representing radiology, interventional radiology, and imaging contrast manufacturers were supportive of this proposed change; however, our payment methodology of ASP plus six percent minus eight percent was questioned. Two commenters also believe that the implementation date for the application of ASP methodology should be changed from January 1, 2005. One requested an effective date of April 1, 2005 and the other requested an effective date of January 1, 2006.

Response: We appreciate the commenters' support for this change. We stated in the proposed rule that effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent. However, there is an October 30, 2004 deadline for submission of the ASP data used for the January 1, 2005 payment, and this date occurred prior to our finalizing the proposed payment methodology for LOCM. Therefore, the ASP payment methodology for LOCM will be made effective April 1, 2005. Manufacturers of LOCM will be required to submit their fourth quarter 2004 (4Q04) ASP information to us on or before January 30, 2005. Subsequent data must be submitted



within 30 days after the end of each calendar quarter. The 4Q04 data will be used to determine the April 1, 2005 ASP plus six percent payment limits. Further information on the specific format of the data submission and the address to which the information can be sent is found on the CMS ASP website, specifically at <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

Our policy to reduce payment for LOCM by 8 percent stems from the fact that the technical component RVUs for these procedures took into account the use of (and expenses for) HOCM in the (see the November 25, 1991 final rule (56 FR 59502)). However, since that time, the price differential between HOCM and LOCM has declined. In addition, upon further review, we are not able to determine accurately the degree of duplicate payment that might occur when both the imaging procedure and LOCM are billed. Therefore, we are not applying the eight percent reduction to the LOCM payment as proposed. The payment for LOCM will be consistent with the payment rate for the majority of drugs administered by physicians.

Comment: One contrast agent industry association suggested that we issue additional codes for the reporting of contrast media.

Response: For 2005, we are continuing to use the current three HCPCS codes in the reporting of low osmolar contrast agents. However, we are exploring the possibility of additional codes to accurately capture the cost differences among all contrast agents as well as the differing clinical uses, concentration, and dose administrations. We welcome input from the medical community and the manufacturers of contrast media on this issue.

Comment: A commenter suggested that we use a model to capture volume and concentration variances of LOCM. In this model, ASP would be calculated as  $ASP = \text{Total Sales} / \text{Total Volume}$ .

Response: This suggested methodology does not take into account the weighted average for each national drug code (NDC) within a HCPCS code that must be used to derive an appropriate ASP code price.

#### Result of Evaluation of Comments

We are revising the regulations at §414.38 to eliminate the criteria for the payment of LOCM. In addition, effective April 1, 2005, payment for LOCM will be made on the basis of the ASP plus six percent.

C. Payments For Physicians and Practitioners Managing Patients on Dialysis

1. ESRD-Related Services Provided to Patients in Observation Settings

In response to comments received on billing procedures for physicians and practitioners managing patients on dialysis when the dialysis patient is hospitalized during the month, we stated in the November 7, 2003 **Federal Register** (68 FR 63220) that ESRD-related visits furnished to patients in observation status would not be counted as visits under the MCP but would be paid separately. Prior to this, long-standing Medicare policy had included ESRD-related visits furnished in the observation setting within the MCP. However, upon further review of this issue, in the proposed rule published August 5, 2004, we proposed a revision to this policy and stated that ESRD-related visits provided to patients by the MCP physician in an observation setting would be counted as visits for purposes of billing the MCP codes.

Comment: Several commenters expressed support for allowing ESRD-related visits provided to patients by the MCP physician in the observation setting to be counted for purposes of billing the MCP codes. However, Kidney Care Partners (KCP) and the Renal Physicians Association (RPA)

requested clarification as to how a physician or practitioner who is not part of the MCP practice team should bill for visits furnished in the hospital observation setting. The RPA suggested that a hemodialysis procedure with single physician evaluation as described by CPT code 90935 be used.

Response: Physicians or practitioners who are not part of the MCP practice team but who furnish a visit to an ESRD beneficiary in the observation setting can bill the appropriate observation codes that accurately describe the service (CPT codes 99217 through 99220). A hemodialysis procedure with single physician visit as described by CPT code 90935 will only be used when the beneficiary is an inpatient or for outpatient dialysis services for a non-ESRD patient.

## 2. Payment for Outpatient ESRD-Related Services For Partial Month Scenarios

Since changing our payments for physicians and practitioners managing patients on dialysis, we have received a number of comments from the nephrology community requesting guidance on billing for outpatient ESRD-related services provided to transient patients and in partial month scenarios (for example, when the patient is hospitalized during the month or receives a kidney

transplant). To address this issue, we proposed to change the description of the G codes for ESRD-related home dialysis services, less than full month, as identified by G0324 through G0327. The new descriptor would include other partial month scenarios, in addition to patients dialyzing at home. The proposed descriptors for G0324 through G0327 are as follows:

- G0324, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients under two years of age;
- G0325, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between two and eleven years of age;
- G0326, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day, for patients between twelve and nineteen years of age.
- G0327, End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day, for patients twenty years of age and over.

In the August 5, 2004 proposed rule, we stated that these G codes would provide a consistent way to bill for

outpatient ESRD-related services provided under the following circumstances:

- Transient patients - Patients traveling away from home (less than full month);
- Home Dialysis Patients (less than full month);
- Partial month where there were one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had received a kidney transplant.

However, we noted that this proposed change to the descriptions of G0324 through G0327 was intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the MCP and that use of the codes would be limited to the circumstances listed above. Physicians who have an on-going formal agreement with the MCP physician to provide cursory visits during the month (for example "rounding physicians") could not use the per diem codes.

#### Clarification on Billing for Transient Patients

In the August 5, 2004 proposed rule, we stated that, for transient patients who are away from their home dialysis site and at another site for fewer than 30 consecutive days, the revised per diem G codes (G0324 through G0327) would be billed by the physician or practitioner responsible for the

transient patient's ESRD-related care. Only the physician or practitioner responsible for the traveling ESRD patient's care would be permitted to bill for ESRD-related services using the per diem G codes (G0324 through G0327).

If the transient patient is under the care of a physician or practitioner other than his or her regular MCP physician for a complete month, the physician or practitioner responsible for the transient patient's ESRD-related care would not be able to bill using the per diem codes. We also solicited comments on when a patient will be considered transient.

Comment: Several commenters, including the ASN, KCP, and the RPA, supported our proposed change to the description of HCPCS codes G0324-G0327 (per diem codes). The KCP believed that this change would provide a consistent billing method when the patient is transient, furnished home dialysis (less than full month), and for other partial month scenarios when the patient is hospitalized, has a transplant or when the patient expires. Additionally, several commenters praised us for our willingness to work with the renal community to address the multitude of issues surrounding the way physicians and practitioners are paid for managing patients on dialysis.

However, the RPA and KCP suggested that, in addition to the situations described in the proposed rule, the per

diem codes as described by G0324 through G0327 should be used to bill whenever one or more visits occurred during the month regardless of whether the complete monthly assessment was furnished.

Response: As explained in the proposed rule, we believe the per diem codes will only be used for unusual circumstances where the ongoing management of an ESRD patient would not be paid through the MCP. As discussed earlier, we proposed to allow the per diem codes only in specific circumstances. However, after further review of this issue, we believe that it would also be appropriate to use the per diem codes when the beneficiary's MCP practitioner changes permanently during the month. For example, the ESRD beneficiary moves from one State to another and a new MCP physician or practitioner has the ongoing responsibility for the E/M of the patient's ESRD-related care who is not part of the same group practice as an employee of the previous MCP physician. We addressed this issue in a recent instruction published on September 17, 2004 (CR 3414 "Payment for Outpatient ESRD-Related Services", Transmittal 300). For more information on this instruction please visit our website at <http://www.cms.hhs.gov/manuals/> and select 2004 transmittals under the program transmittals link.



However, we will not permit the use of per diem codes (HCPCS codes G0324 through G0327) for all instances when the MCP physician or practitioner furnishes at least one visit during the month without regard to the status of a complete monthly assessment of the patient. We are concerned that permitting the per diem codes to be used in this manner may undermine the MCP. For example, the ESRD MCP includes various physician and practitioner services such as the establishment of a dialyzing cycle, outpatient E/M of the dialysis visit(s), telephone calls, patient management as well as clinically appropriate physician or practitioner visit(s) during the month. At least one of the visits must include a clinical examination of the vascular access site furnished face-to-face by a physician, CNS, NP or PA. When a practitioner bills for the MCP, the medical record must document that all of these services are furnished. By using the per diem codes in the manner suggested by the commenter, it would not be necessary for the practitioner to provide a complete monthly assessment of the ESRD beneficiary to receive payment for the ongoing management of patients on dialysis.

Comment: With regard to the ESRD-related services for home dialysis patients, less than full month, one healthcare corporation believes that the proposed coding changes continue to penalize nephrologists for prescribing home therapy because a per diem (pro-rated) payment is made

when a hospitalization occurs. The commenter believes that this policy results in an inequity as compared to a physician providing 2-3 visits per month for center-based dialysis patients. Additionally, the commenter argues that the pro-rated methodology used for home dialysis patients (partial month) is inconsistent with how we pay the MCP physician for patients undergoing dialysis treatments in a dialysis facility.

The commenter believes that we should increase the payment for ESRD-related services for home dialysis patients to a level that is at least as high as the ESRD-related services (for full month) with 4 or more visits per month. The commenter contends that raising the payment amount for home-based dialysis patients would result in revenue opportunities similar to those available in the center-based scenario and would provide a greater incentive for home dialysis treatment.

Response: We do not agree with the commenter's statement that an inconsistency exists in the way we pay the MCP physician for managing a home dialysis patient (less than full month) and center dialysis patient (less than full month).

Our proposed change to the description of HCPCS codes G0324 through G0327 would apply to dialysis patients who

receive dialysis in a dialysis center or other facility during the month as well as to home dialysis patients. For example, if a center dialysis patient is hospitalized during the month, has a transplant, or expires before a complete assessment is furnished (including a face-to-face examination of the vascular access site), the MCP physician would use the per diem rate to bill for ESRD-related care. When either a home dialysis patient or a patient who receives dialysis in a dialysis facility is hospitalized, the MCP physician or practitioner may bill for inpatient hemodialysis visits as appropriate (for example CPT codes 90935 and 90937).

Additionally, we believe the current payment level for physicians managing patients on home dialysis for a full month already provides an incentive for an increased use of home dialysis. For instance, payment for the monthly management of home dialysis patients is made at the same rate as the MCP with 2 to 3 visits. However, a monthly visit is not required as a condition of payment for physicians and practitioners managing home dialysis patients. Essentially, a physician or practitioner managing ESRD patients who receive dialysis in a dialysis facility would be required to furnish 2 to 3 face-to-face visits in order to receive the same level of payment as he

or she would have received for managing a home dialysis patient. We do not believe it would be appropriate to pay physicians managing home dialysis patients at the highest MCP amount when no visits are required as a condition of payment.

#### Definition of a 'Transient Patient'

Comment: The RPA and KCP believe that it would be more appropriate to refer to these patients as "visiting patients". The RPA suggested that a "visiting patient" be defined as a "patient receiving dialysis or renal-related care whose care is temporarily supervised (for less than one month's time) by a physician who is not a member of the practice that usually charges under the MCP or G codes".

Response: We believe the term "transient patients" better describes a beneficiary who is away from his or her home dialysis site for less than a full month.

#### General Comments on our Changes in Payments For Physicians and Practitioners Managing Patients on Dialysis

Comment: One commenter requested clarification as to how ESRD-related visits furnished to beneficiaries residing in a skilled nursing facility (SNF) adjacent to a hospital should be handled. The commenter explained that his SNF patients with ESRD usually receive dialysis treatments in an independent dialysis facility connected to a hospital's

SNF. However, in cases when the patient is "too ill" to be transported to the independent dialysis facility, the dialysis treatment occurs in the inpatient dialysis treatment area (but the patient is not admitted to the hospital as an inpatient). The commenter noted that ESRD-related visits may be furnished while the patient is dialyzing or at the SNF when the patient is not dialyzing.

Response: Although we have not issued specific instructions on this issue, we believe that ESRD-related visits furnished to SNF residents are similar to other ongoing management services under the MCP. As such, ESRD-related visits furnished to patients residing in a SNF will be counted for purposes of billing the MCP codes. However, if the beneficiary is admitted to the hospital as an inpatient, the appropriate inpatient visit code will be used, for example, CPT code 90935.

Comment: With regard to our revisions to the MCP (as published in the CY 2004 final rule), the American Association of Kidney Patients (AAKP) questioned if we have any current data on or future plans to study whether access to nephrologists or the quality of medical care for ESRD patients has been improved or impaired. Additionally, AAKP questioned whether we have any plans to develop additional

proposals (beyond the telehealth proposal) to address access needs in rural and other underserved areas.

Response: In evaluating the MCP, we will be looking for trends in hospitalization rates and resource utilization for ESRD patients. Moreover, we understand the challenges nephrologists face in visiting all patients on dialysis. To that end, we believe that our policy to allow clinical nurse specialists, nurse practitioners and physician assistants to furnish visits under the MCP, along with our addition of specific ESRD-related services to the list of Medicare telehealth services, will help ameliorate access issues.

Comment: The RPA and the ASN continued to express concerns with the changes made in the CY 2004 final rule to the way physicians are paid for managing patients on dialysis. The RPA strongly believes that many of the underlying principles of the new HCPCS codes for managing ESRD patients need to be changed. The RPA cited the impact on rural providers, the lack of gradation in payment amounts between furnishing 2 and furnishing 3 visits per month, and the premise that more visits will equate to better quality of care as major shortcomings of the new ESRD MCP.

The RPA and ASN emphasized their belief that more physician and practitioner visits per month does not correlate to efforts to improve the quality of care for ESRD patients. RPA contends that a stratified MCP system based on the number of monthly physician and practitioner visits is unnecessarily complicated and believes that the vast majority of nephrologists provided appropriate ESRD-related care under the previous MCP. To that end, the RPA urged us to implement a simpler system based on a minimum number of patient visits and a new documentation requirement for the services provided under the MCP.

Response: We appreciate the commenters' suggestions and will consider these comments as we continue to refine how we pay for physicians and practitioners managing patients on dialysis.

#### Results of Evaluation of Comments

ESRD-related visits provided to patients by the MCP physician or practitioner in an observation setting will be counted as visits for purposes of billing the MCP codes.

Moreover, we will change the description of the G codes for ESRD-related home dialysis services, less than full month, as identified by G0324 through G0327. The new descriptor will include other partial month scenarios, in

addition to patients dialyzing at home. The descriptors for G0324 through G0327 will be as follows:

- G0324: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients under two years of age.
- G0325: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between two and eleven years of age.
- G0326: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients between twelve and nineteen years of age.
- G0327: End stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients twenty years of age and over.

The revised per diem ESRD-related services G codes will be used for outpatient ESRD-related services provided in the following scenarios:

- Transient patients - Patients traveling away from home (less than full month);
- Home dialysis patients (less than full month);
- Partial month where one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was



furnished, dialysis stopped due to death, or the patient had a transplant.

- Patients who have a permanent change in their MCP physician during the month.

D. Technical Revision--§411.404

In §411.404, Medicare noncoverage of all obesity-related services is used as an example. Since we are currently revising this coverage policy, we proposed to omit this example.

Commenters were supportive of this proposed change and we are finalizing it as proposed.

E. Diagnostic Psychological Tests

All diagnostic tests covered under section 1861(s) (3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b) (2) (iii) states an exception to these physician supervision requirements for clinical psychologists and independently practicing psychologists (who are not clinical psychologists) which allows them to personally perform diagnostic psychological testing services without physician supervision. However, diagnostic psychological tests performed by anyone other than a clinical psychologist or an independently practicing psychologist must be provided under the general supervision of a physician as defined in section

1861(r) of the Act. Accordingly, clinical psychologists and independently practicing psychologists have not been permitted to supervise others in the administration of diagnostic psychological tests.

As discussed in the August 5, 2004 proposed rule, we were asked to re-evaluate our regulations regarding clinical psychologists' supervision of diagnostic psychological tests, and additional information concerning provision of these services was also supplied. Based upon our review of this issue, we determined that clinical psychologists possess knowledge sufficient to direct test selection and interpret test data. Therefore, we proposed to change the requirements at §410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance of diagnostic psychological and neuropsychological testing services.

Comment: Two specialty societies representing psychologists and many individual commenters were in support of the change. One major association representing psychiatrists and a few individual commenters opposed the proposal. According to the association, expanding the supervision requirements will not lessen the burden on physicians and healthcare facilities within rural areas. In addition, this association asked that we provide data

showing that the change to the supervision requirements will reduce the burden on physicians and health care facilities, and that access will be improved in rural areas.

Response: We appreciate the positive comments in support of this proposal.

In response to the request for evidence that this change will reduce burden and improve access, we would first note that our primary reason for proposing this change was that we believe clinical psychologists possess the core knowledge to sufficiently supervise the administration of these tests. By enabling them to do so, this change will allow greater flexibility in their practices.

With regard to improved access in rural areas, we noted previously in this rule that we recognize mental health HPSAs for incentive payments for psychiatrists. Accordingly, we believe that the expansion of the supervision requirements will help improve access in these areas.

#### Result of Evaluation of Comments

As proposed, we are revising §410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance

of diagnostic psychological and neuropsychological testing services.

F. Care Plan Oversight

Care Plan Oversight (CPO) refers to the supervision of patients receiving Medicare-covered home health or hospice services requiring complex multidisciplinary care modalities, including regular development and review of plans of care. In the August 5, 2004 rule, we proposed to revise §414.39 to clarify that NPPs can perform home health CPO; however, they cannot certify a patient for home health services and sign the plan of care. We also proposed the conditions under which NPP services may be billed for CPO and explained that the proposed conditions are meant to ensure that the NPP has seen and examined the patient and that the appropriate and established relationship exists between the physician who certifies the patient for home health services and the NPP who will provide the home health CPO.

Comment: Several commenters support the proposed revision and conditions of coverage. They support the integrated practice arrangements required by proposed §414.39(c)(2)(iii). They believe the proposed conditions ensure appropriate, ongoing supervision of both the patient's condition and the NPP.

Response: We appreciate the commenters' support for this proposal.

Comment: We received a comment from an association representing home care physicians requesting that we include PAs in the clarification because PAs increasingly play the same role as NPs in home health care and bill under the same house call codes.

Response: We agree with the commenter that we include PAs in the clarification. The definition of NPPs in proposed §414.39(a) includes NPs, CNSs, and PAs. However, we also note that PAs cannot bill directly for their own services.

Comment: We received a comment requesting that we clearly state the definition of the appropriate relationship between the physician and the NPP. The commenter requested that we cross-reference applicable State standards because the meaning of collaboration varies across States and some States require employment relationships. Also, the commenter recommended that we require a written agreement regarding the responsibilities for managing care when the NP or PA is not from the same organization as the physician who has certified the skilled home care services.

Response: We agree that State laws or regulations governing collaborative relationships, where applicable, would be useful in this regard. In the absence of State

laws or regulations, NPs and CNSs will be required to document their scope of practice and indicate the relationships they have with physicians to handle issues outside their scope of practice. If the NPP is a PA, the physician signing the plan of care also must be the physician who provides general supervision of PA services for the practice.

Comment: We received a comment requesting that this clarification be made retroactive to at least FY 2000 to allow denied claims to be resubmitted. The commenter stated that many claims for CPO services by NPs were denied over the past several years, despite CMS and legislative intent to have these claims reimbursed.

Response: We clarified in the November 1, 2000 final rule (65 FR 65407) that CPO services of NPPs, practicing within the scope of State law applicable to their services, could be paid under Medicare. However, our policy has also been that the physician who bills for CPO must be the same physician who signs the plan of care.

Appeal rights are available for these claims for CPO services provided by NPPs in HHAs if the appeal is requested within 120 days of the date of the claim denial. If appeal rights have expired, the physician or supplier may request a reopening for any reason within 12 months of

the date of the notice of initial determination. After the 12-month period, but within 4 years from the date of the initial determination, a reopening may be requested for good cause. The decision on whether to reopen a claim at the request of the physician or supplier is at the discretion of the Medicare contractor.

Comment: We received comments noting that this clarification does not allow NPs, CNSs, or PAs to certify a patient for home health care services or to sign the plan of care. The commenters noted that certification by NPPs is not currently permitted under the statute. One of the commenters recommended that we revise the rules on certification and recertification to allow NPs, CNSs, or PAs to perform them.

Response: The commenters are correct that the statute (sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) requires a physician to certify a patient for home health care services or to sign the plan of care. Therefore, the issue of whether to allow NPs, CNSs, or PAs to certify a patient for home health care services or to sign the plan of care is not within the purview of this rule.

Result of Evaluations of Comments

We are adopting the proposed changes to §414.39 that clarify that NPPs can provide care plan oversight for beneficiaries who receive home health services.

G. Assignment of Medicare Claims--Payment to the Supplier

The current regulation requires the beneficiary (or the person authorized to request payment on the beneficiary's behalf) to assign a claim to the supplier for an assignment to be effective. However, over time, the Act was amended in various sections to require that Medicare payment for certain services would only be made on an assigned basis regardless of whether or not the beneficiary actually assigns the claim to the supplier. In these instances, the current requirement in §424.55(a), which specifies that the beneficiary assign the claim to the supplier, is now unnecessary. Therefore, we proposed to create an exception to the general rule in §424.55(a). New §424.55(c) would eliminate the requirement that beneficiaries assign claims to suppliers in situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier.

Comment: The ACLA supports the proposal and agrees that this new exception to the requirement for beneficiaries to assign benefits in situations where



benefits can, by statute, only be paid on an assigned basis will reduce the paperwork burden on beneficiaries and suppliers.

Response: We agree that the proposed regulation will reduce the paperwork burden on beneficiaries and suppliers and we are finalizing the revisions as proposed.

#### Result of Evaluation of Comments

We are finalizing §424.55(c) as proposed.

#### H. Additional Issues Raised by Commenters

Comment: Two specialty societies representing plastic surgeons and podiatrists, as well as the RUC, recommended that the global period for CPT 15342, Application of bilaminate skin substitute/neodermis; 25 sq cm, be changed from a 10-day global period to a 0-day global period. The commenters stated that the plastic surgeons generally perform this procedure on more severely injured patient, such as burn patients, who are often seen in the inpatient setting. The podiatrists, on the other hand, typically treat patients with diabetic foot ulcers in the outpatient setting. Therefore, the commenters contend that though the work required to perform the procedure is the same for both specialties, the post-surgical work and time are not and the change in the global period would allow both scenarios to be paid appropriately.

Response: We understand that this code can represent differing scenarios. However, while podiatrists perform approximately 45 percent of the procedures and general surgeons 17 percent, plastic surgeons perform only 7 percent. In addition, only 9 percent are performed in the inpatient hospital setting. Our general approach and the one adopted by the RUC for valuing all services is to base our review on the typical patient. In this case, the podiatric scenario would clearly dominate and applying a 10-day global period to capture the post-procedure office visit appears appropriate. However, we would be willing to discuss this issue further with the specialties involved and with the RUC.

Comment: The American Society of Anesthesiologists (ASA) provided comments asking that we consider revising the current teaching regulations to place teaching anesthesiologists' reimbursements on par with the teaching of resident physicians in surgery and other high-risk specialties. Also, that we redefine the HCPCS claims service modifier "AA" to include both the personal administration of the anesthesia by the physician and teaching up to two resident physicians concurrently. In its comments, the ASA stated that it believes we possess the authority under the terms of section 1871 of the

Medicare statute to make the requested change in its teaching reimbursement rules, effective January 1, 2005, as follows: the agency can treat the rule as a logical outgrowth of a prior proposal; it can issue a final rule with comment period as part of the 2005 physician payment final rule; or, it can promptly issue a free-standing rule proposing the change and allow for public comment and subsequent effectiveness along with the 2005 physician payment rule. The American Association of Nurse Anesthetists (AANA) asked that, if we review proposed revisions to the teaching anesthesiologist rules, that we carefully consider how these revisions might impact teaching Certified Registered Nurse Anesthetists (CRNAs). The AANA commented that our rules should not favor one type of provider over another.

Response: Surgical services are paid differently than anesthesia services. For example, surgical codes usually have global periods and payment includes the payment for the surgical procedure and postoperative visits during the global period. Anesthesia services include the preanesthesia examination and evaluation, the anesthesia service associated with the surgical service, and immediate postanesthesia care. Currently, the teaching physician's presence during the key or critical period criteria applies

to both the services of the teaching surgeon and the teaching anesthesiologist. The key or critical services are different for the service of each specialty.

We plan to explore these issues further prior to deciding whether to include this change in the proposed rule for 2006.

Comment: We received comments from a manufacturer, many providers and individuals requesting that new HCPCS codes be created for a specific laser surgery treatment for benign prostatic hyperplasia. Commenters stated that current CPT codes used for billing this service under the physician fee schedule are not specific to the unique technology involved with this laser surgery treatment and result in underpayment when this technology is used. They noted that under the hospital OPPS, this treatment was assigned to a new technology code.

We also received requests from other individuals for new G codes and payment for other specific services, and for certain HCPCS codes that currently are paid only under OPPS.

Response: We do not believe that it is necessary to create new HCPCS codes for these services. Commenters that believe the existing CPT codes do not reflect their technology or services, may contact the AMA's CPT Editorial Panel to review these matters, particularly since the CPT

Editorial Panel has a new coding classification specifically for new and emerging technologies.

There will be situations where codes are used under OPPOS but not recognized under the physician fee schedule (PFS) because of the different payment methodologies.

Comment: A specialty society urged us to discontinue use of the HCPCS codes for positron emission tomography (PET) procedures and to instruct physicians to use the available CPT codes. They also urged us to adopt RUC recommendations for new PET codes rather than carrier price these services. The commenter stated they would like to meet to discuss these new codes and PET/computed tomography (CT) technology.

Response: We will continue to use HCPCS codes and carrier price these services at this time. We will be examining the overall issue of Medicare coding, payment, and coverage of PET services and would be happy to meet with the specialty society to discuss this issue.

#### General Issues

We also received comments on issues and concerns that were beyond the scope of the proposed rule. These include: the need for quality standards for diagnostic imaging; concerns about outreach and access; requests for revisions to current policy; and, concerns about the accuracy of code

descriptors. While we will try to ensure these comments are provided to appropriate CMS components, commenters should also feel free to contact the appropriate CMS components about their concerns. To the extent that these comments involved valuation of services under the physician fee schedule, we are also soliciting comments on services for which the physician work may be misvalued. See section VI for additional information on this process.

**V. Refinement of Relative Value Units for Calendar Year 2005 and Response to Public Comments on Interim Relative Value Units for 2004**

[If you choose to comment on issues in this section, please include the caption "Interim Work Relative Value Units" at the beginning of your comments.]

A. Summary of Issues Discussed Related to the Adjustment of Relative Value Units

Section V.B. and V.C. of this final rule describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new and revised CPT codes. Changes to codes on the physician fee schedule reflected in Addendum B are effective for services furnished beginning January 1, 2005.

B. Process for Establishing Work Relative Value Units for the 2004 Physician Fee Schedule

Our November 7, 2003 final rule (69 FR 1084) contained the work RVUs for Medicare payment for existing procedure codes under the physician fee schedule and interim RVUs for new and revised codes beginning January 1, 2004. We considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. (Note that the November rule was subsequently revised on January 7, 2004 to reflect revisions to procedure codes required by the MMA.) In this section, we summarize the refinements to the interim work RVUs published in the November 7, 2003 rule and our establishment of the work RVUs for new and revised codes for the 2005 physician fee schedule.

### C. Work Relative Value Unit Refinements of Interim

#### Relative Value Units

#### 1. Methodology (Includes Table titled "Work Relative Value Unit Refinements of the 2003 Interim and Related Relative Value Units")

Although the RVUs in the January 2004 final rule were used to calculate 2004 payment amounts, we considered the RVUs for the new or revised codes to be interim. We accepted comments for a period of 60 days. We received substantive comments on approximately 12 CPT codes with interim work RVUs.

To evaluate these comments we used a process similar to the process used since 1997. (See the October 31, 1997 final rule (62 FR 59084) for the discussion of refinement of CPT codes with interim work RVUs.) We convened a multispecialty panel of physicians to assist us in the review of the comments. The comments that we did not submit to panel review are discussed at the end of this section, as well as those that were reviewed by the panel. We invited representatives from the organizations from which we received substantive comments to attend a panel for discussion of the code on which they had commented. The panel was moderated by our medical staff, and consisted of the following voting members:

- One or two clinicians representing the commenting organization.
- One primary care clinician nominated by the American College of Physicians and American Society of Internal Medicine.
- Four carrier medical directors.
- Four clinicians with practices in related specialties who were expected to have knowledge of the service under review.



The panel discussed the work involved in the procedure under review in comparison to the work associated with other services under the physician fee schedule. We assembled a set of 300 reference services and asked the panel members to compare the clinical aspects of the work of the service a commenter believed was incorrectly valued to one or more of the reference services. In compiling the set, we attempted to include: (1) services that are commonly performed whose work RVUs are not controversial; (2) services that span the entire spectrum from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. The intent of the panel process was to capture each participant's independent judgment based on the discussion and his or her clinical experience. Following the discussion, each participant rated the work for the procedure. Ratings were individual and confidential, and there was no attempt to achieve consensus among the panel members.

We then analyzed the ratings based on a presumption that the interim RVUs were correct. To overcome this presumption, the inaccuracy of the interim RVUs had to be apparent to the broad range of physicians participating in each panel.

Ratings of work were analyzed for consistency among the groups represented on each panel. In addition, we used statistical tests to determine whether there was enough agreement among the groups of the panel and whether the agreed-upon RVUs were significantly different from the interim RVUs published in Addendum C of the final rule. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group and looked for agreement among the remaining groups as the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the 1993 physician fee schedule. The statistical tests were described in detail in the November 25, 1992 final rule (57 FR 55938).

Our decision to convene multispecialty panels of physicians and to apply the statistical tests described above was based on our need to balance the interests of those who commented on the work RVUs against the redistributive effects that would occur in other specialties.

We also received comments on RVUs that were interim for 2004, but for which we did not submit the RVUs to the

panel for review for a variety of reasons. These comments and our decisions on those RVUs commented upon are discussed in further detail below.

Table 17 below lists those interim codes reviewed under the refinement panel process described in this section. This table includes the following information:

- CPT Code. This is the CPT code for a service.
- Description. This is an abbreviated version of the narrative description of the code.
- 2004 Work RVU. The work RVUs that appeared in the January 2004 rule are shown for each reviewed code.
- Requested Work RVU. This column identifies the work RVUs requested by commenters.
- 2005 Work RVU. This column contains the final RVUs for physician work.

**TABLE 17:**

Codes Reviewed Under the Refinement Panel Process

CPT code*	Mod	Descriptor	2004 work RVU	Requested work RVU	2005 work RVU
43752		Nasal/orogastric w/stent	0.68	0.82	0.81
63103		Remove vertebral body add-on	3.90	5.00	4.82

\*All CPT codes and descriptions copyright 2004 American Medical Association. All rights reserved and applicable FARS/DFARS clauses apply.

## 2. Interim 2004 Codes

**CPT code 43752** Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report).

The RUC recommended a work RVU of 0.82 for this service based on a comparison of this procedure to CPT code 44500, Introduction of long gastrointestinal tube. While we agreed that CPT code 43752 is similar in work intensity to CPT code 44500, we believed the intra-service time is more appropriately valued at the 25<sup>th</sup> percentile (15 minutes of intra-service time vs. 20 minutes of intra-service time). This reduced the total time associated with CPT code 43752 from 30 minutes to 25 minutes. We applied the ratio of the RUC recommended value of 0.82 work RVU over 30 minutes to the revised intra-service time of 25 minutes and assigned 0.68 interim work RVUs for CPT code 43752.

Comment: Commenters disagreed with our decision not to accept the RUC recommended WRVU of 0.82 and with our rejection of the survey time, particularly since this service involves both tube placement and imaging. Based on these comments, we referred this code to the multispecialty validation panel for review.

Response: As a result of the statistical analysis of the 2004 multispecialty validation panel ratings, we have assigned 0.81 work RVUs to CPT code 43752.

CPT code 63103 Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (for example, for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure).

The RUC recommended a work RVU of 5.00 for this service based on a comparison of this procedure to CPT code 63088, the add-on code for the vertebral corpectomy, thoracic lumbar approach. We stated that it was unclear from the clinical vignettes supplied by the specialty society whether the additional corpectomy would more commonly involve the lumbar or the thoracic region of the spine. There is a significant difference in work intensity associated with the resection of an additional corpus in the thoracic region as opposed to the lumbar region. For this reason we applied the ratio of the reference service (CPT code 63088) to its primary service (CPT code 63087) to CPT code 63101 (primary service associated with CPT 63103) to assign 3.90 interim work RVUs for CPT code 63103.

Comment: Commenters requested that we withdraw the arbitrary reduction of the work RVU for CPT code 63103 stating that the unique aspects of the lateral extracavitary approach make the location in the lumbar and thoracic spine less relevant than the actual exposure of an additional level itself. The commenters stated that in contrast to anterior thoracic or lumbar approaches for vertebral corpectomy, the lateral extracavitary approach requires an unrelated and significantly greater muscle dissection of spinal/paraspinal tissues, as well as an additional rib, transverse process, and pedicle removal with isolation and division of another pair of segmental vessels. Based on these comments, we referred this code to the multispecialty validation panel for review.

Response: As a result of the statistical analysis of the 2004 multispecialty validation panel ratings, we have assigned 4.82 work RVUs to CPT code 63103.

CPT codes 38207 Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage, 38208 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, 38209 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing 38210 Transplant preparation of hematopoietic progenitor

cells; specific cell depletion within harvest, T-cell depletion, 38211 Transplant preparation of hematopoietic progenitor cells; tumor cell depletion, 38212 Transplant preparation of hematopoietic progenitor cells; red blood cell removal, 38213 Transplant preparation of hematopoietic progenitor cells; platelet depletion, 38214 Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion, 38215 Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer

These codes were new for CY 2003 but we did not receive the final RUC recommendations in time for inclusion in the final rule. In the December 31, 2002 rule we discussed the interim RUC recommendations and our concerns for removing these codes from the laboratory fee schedule, and paying them instead on the physician fee schedule (67 FR 80007). We received the final RUC recommendations in May 2003 and in the November 7, 2003 final rule we stated we were maintaining a status indicator "I" for these services making them not valid for payment under the physician fee schedule. (Note: In the December 31, 2002 rule, as part of the discussion about these CPT codes, we discussed the creation of HCPCS codes G0265, Cryopreservation, freezing and storage of cells for

therapeutic use, each cell line; G0266 Thawing and expansion of frozen cells for therapeutic use, each aliquot; and G0267, Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (for example, T-cells, metastatic carcinoma). We stated that these HCPCS codes are paid under the laboratory fee schedule.)

Comment: We received comments regarding these codes in response to the 2002 and 2003 final rules. Commenters expressed concern, which was shared by the RUC about the CMS decision pertaining to these CPT codes. They stated that CMS was invited to conduct site visits to observe and have a better understanding of these services. They believe such visits would provide additional information on these services and allow for a more informed decision about their placement on the physician fee schedule.

Response: CPT codes 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214 and 38215 reflect services that are typically provided by laboratory personnel who require general oversight and supervision by a laboratory physician, analogous to a physician providing oversight in a blood banking facility. Based on site visits, we continue to believe that these services are not typically provided by a physician. We recognize that variability



pertaining to the clinical and laboratory management of patients does exist and that in some bone marrow transplant centers these laboratory services are closely supervised and managed by physicians. These centers, however, do not reflect the typical practice pattern for the majority of bone marrow transplant centers. Therefore, we will continue to allow use of HCPCS codes G0265 Cryopreservation, freezing and storage of cells for therapeutic use, each cell line and G0266 Thawing and expansion of frozen cells for therapeutic use, each aliquot to report these services, and G0267 Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (for example, T-cells, metastatic carcinoma). These services are currently on the laboratory fee schedule. We welcome additional comments to help us better determine whether to place CPT codes 38207 through 38215 on either the physician or laboratory fee schedule.

Note: We identified the services provided within transplant centers as clinical services typically provided by a physician in conjunction with the following codes: CPT codes 38205- Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic, CPT 38206- Blood-derived hematopoietic progenitor cell harvesting for transplantation, per

collection; autologous, CPT codes 38240- Bone Marrow or bone derived peripheral stem cell transplantation; allogenic, CPT code 38241- Bone Marrow or bone derived peripheral stem cell transplantation; autologous, and CPT code 38242- Bone Marrow or bone derived peripheral stem cell transplantation; allogeneic lymphocyte donor infusions. We believe the physician work RVUs assigned by the RUC to these codes (CPT code 38205- 1.50, CPT code 38206- 1.50, CPT code 38240- 2.24 RVUs, CPT code 38241- 2.24 RVUs, and CPT code 38242- 1.71 RVUs) appropriately reflect the physician work intensity for each of these services and reaffirm our prior decision announced in 2002. CPT code 38204- Management of recipient hematopoietic progenitor cell donor search and cell acquisition was valued at 2.00 RVUs by the RUC in 2002. We believe there may be physician work when providing this service. However, information obtained during our site visits revealed that the bulk of the service was provided by the transplant coordinator, who worked closely with the physician. It is unclear at this point what the appropriate value will be for the physician who provides this service. We welcome comments on this issue.

CPT code 76514 Ophthalmic ultrasound, echography, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness).

We accepted the RUC recommendation of 0.17 work RVUs.

Comments: The American Academy of Ophthalmology commented that the assigned work RVU does not accurately reflect the value intended by the RUC or CPT; the value should be doubled. The Academy stated that the problem arose when the RUC recommended to CPT that the descriptor should be changed from unilateral to unilateral or bilateral. The commenter suggested that either the descriptor be changed to reflect only the unilateral, which will take a while to accomplish, or that we increase valuation to correctly reflect valuation by RUC.

Response: Because we have no data that indicates whether the unilateral or bilateral procedure is more typical, we are not changing the RVUs at this time. We would suggest that the Academy contact the CPT Editorial Panel if a change to the descriptor would be helpful to the specialty.

Establishment of Interim Work Relative Value Units for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System Codes (HCPCS) for 2005 (Includes Table titled

"American Medical Association Specialty Relative Value  
Update Committee and Health Care Professionals Advisory  
Committee Recommendations and CMS's Decisions for New and  
Revised 2005 CPT Codes")

One aspect of establishing RVUs for 2005 was to assign interim work RVUs for all new and revised CPT codes. As described in our November 25, 1992 notice on the 1993 physician fee schedule (57 FR 55983) and in section III.B. of the November 22, 1996 final rule (61 FR 59505 through 59506), we established a process, based on recommendations received from the AMA's RUC, for establishing interim work RVUs for new and revised codes.

This year we received work RVU recommendations for 149 new and revised CPT codes from the RUC. Our staff and medical officers reviewed the RUC recommendations by comparing them to our reference set or to other comparable services for which work RVUs had previously been established. We also considered the relationships among the new and revised codes for which we received RUC recommendations and agreed with the majority of the relative relationships reflected in the RUC values. In some instances, although we agreed with the relationships, we nonetheless revised the work RVUs to achieve work neutrality within families of codes. That is, the work

RVUs have been adjusted so that the sum of the new or revised work RVUs (weighted by projected frequency of use) for a family will be the same as the sum of the current work RVUs (weighted by projected frequency of use) for the family of codes. We reviewed all the RUC recommendations and accepted approximately 99 percent of the RUC recommended values. For approximately 1 percent of the recommendations, we agreed with the relativity established by the RUC, but needed to adjust work RVUs to retain budget neutrality.

We received four recommendations from the HCPAC. We agreed with two of these recommendations and disagreed with two of them.

Table 18, titled "AMA RUC and HCPAC Recommendations and CMS Decisions for New and Revised 2005 CPT Codes," lists the new or revised CPT codes, and their associated work RVUs, that will be interim in 2005. This table includes the following information:

- A "#" identifies a new code for 2005.
- CPT code. This is the CPT code for a service.
- Modifier. A "26" in this column indicates that the work RVUs are for the professional component of the code.

- Description. This is an abbreviated version of the narrative description of the code.
- RUC recommendations. This column identifies the work RVUs recommended by the RUC.
- HCPAC recommendations. This column identifies the work RVUs recommended by the HCPAC.
- CMS decision. This column indicates whether we agreed or we disagreed with the RUC recommendation. Codes for which we did not accept the RUC recommendation are discussed in greater detail following this table. An "(a)" indicates that no RUC recommendation was provided.
- 2005 Work RVUs. This column establishes the interim 2005 work RVUs for physician work.

**TABLE 18: AMA RUC and HCPAC Recommendations and CMS Decisions for New and Revised 2005 CPT Codes**

*CPT CODE	Mod	Description	RUC recommendation	HCPAC recommendation	CMS Decision	2004 work RVU
#11004		Debride genitalia & perineum	10.31	-----	Agree	10.31
#11005		Debride abdom wall	13.75	-----	Agree	13.75
#11006		Debride genit/per/abdom wall	12.61	-----	Agree	12.61
#11008		Remove mesh from abd wall	5.00	-----	Agree	5.00
#19296		Place po breast cath for rad	3.63	-----	Agree	3.63
#19297		Place breast cath for rad	1.72	-----	Agree	1.72
#19298		Place breast rad tube/caths	6.00	-----	Agree	6.00
#27412		Autochondrocyte implant knee	23.23	-----	Agree	23.23
#27415		Osteochondral knee allograft	18.49	-----	Agree	18.49
#29866		Autgrft implnt, knee w/scope	13.88	-----	Agree	13.88
#29867		Allgrft implnt, knee w/scope	17.00	-----	Agree	17.00
#29868		Meniscal trnspl, knee w/scpe	23.59	-----	Agree	23.59

#31545	Remove vc lesion w/scope	6.30	-----	Agree	6.30
#31546	Remove vc lesion scope/graft	9.73	-----	Agree	9.73
#31620	Endobronchial us add-on	1.40	-----	Agree	1.40
31630	Bronchoscopy dilate/fx repr	3.81	-----	Agree	3.81
31631	Bronchoscopy, dilate w/stent	4.36	-----	Agree	4.36
#31636	Bronchoscopy, bronch stents	4.30	-----	Agree	4.30
#31637	Bronchoscopy, stent add-on	1.58	-----	Agree	1.58
#31638	Bronchoscopy, revise stent	4.88	-----	Agree	4.88
#32019	Insert pleural catheter	4.17	-----	Agree	4.17
#32855	Prepare donor lung, single	(a)	-----	(a)	Carrier
#32856	Prepare donor lung, double	(a)	-----	(a)	Carrier
#33933	Prepare donor heart/lung	(a)	-----	(a)	Carrier
#33944	Prepare donor heart	(a)	-----	(a)	Carrier
#34803	Endovas aaa repr w/3-p part	24.00	-----	Agree	24.00
#36475	Endovenous Rf, 1st Vein	6.72	-----	Agree	6.72
#36476	Endovenous rf, vein add-on	3.38	-----	Agree	3.38
#36478	Endovenous Laser, 1st Vein	6.72	-----	Agree	6.72
#36479	Endovenous laser vein addon	3.38	-----	Agree	3.38
#36818	Av fuse, uppr arm, cephalic	11.52	-----	Agree	11.52
36819	Av fuse, uppr arm, basilic	13.98	-----	Agree	13.98
37205	Transcath iv stent, percut	8.27	-----	Agree	8.27
37206	Transcath iv stent/perc addl	4.12	-----	Agree	4.12
#37215	Transcath stent, cca w/eps	18.71	-----	Agree	18.71
#37216	Transcath stent, cca w/o eps	17.98	-----	Agree	17.98
#43257	Uppr gi scope w/thrml txmnt	5.50	-----	Agree	5.50
#43644	Lap gastric bypass/roux-en-y	27.83	-----	Agree	27.83
#43645	Lap gastr bypass incl smll i	29.96	-----	Agree	29.96
#43845	Gastroplasty duodenal switch	Carrier	-----	Agree	Carrier
#44137	Remove intestinal allograft	Carrier	-----	Agree	Carrier
#44715	Prepare donor intestine	(a)	-----	(a)	Carrier
#44720	Prep donor intestine/venous	5.00	-----	Agree	5.00
#44721	Prep donor intestine/artery	7.00	-----	Agree	7.00
#45391	Colonoscopy w/endoscope us	5.09	-----	Agree	5.09
#45392	Colonoscopy w/endoscopic fnb	6.54	-----	Agree	6.54
#46947	Hemorrhoidopexy by stapling	5.20	-----	Agree	5.20
47140	Partial removal, donor liver	54.92	-----	Agree	54.92
47141	Partial removal, donor liver	67.40	-----	Agree	67.40
47142	Partial removal, donor liver	74.89	-----	Agree	74.89
#47143	Prep donor liver, whole	(a)	-----	(a)	Carrier
#47144	Prep donor liver, 3-segment	(a)	-----	(a)	Carrier
#47145	Prep donor liver, lobe split	(a)	-----	(a)	Carrier
#47146	Prep donor liver/venous	6.00	-----	Agree	6.00
#47147	Prep donor liver/arterial	7.00	-----	Agree	7.00
#48551	Prep donor pancreas	(a)	-----	(a)	Carrier
#48552	Prep donor pancreas/venous	4.30	-----	Agree	4.30
#50323	Prep cadaver renal allograft	(a)	-----	(a)	Carrier
#50325	Prep donor renal graft	(a)	-----	(a)	Carrier

#50327	Prep renal graft/venous	4.00	-----	Agree	4.00
#50328	Prep renal graft/arterial	3.50	-----	Agree	3.50
#50329	Prep renal graft/ureteral	3.34	-----	Agree	3.34
50360	Transplantation of kidney	31.48	-----	Agree	31.48
50365	Transplantation of kidney	36.75	-----	Agree	36.75
#50391	Instll rx agnt into rnal tub	1.96	-----	Agree	1.96
50547	Laparo removal donor kidney	25.46	-----	Agree	25.46
#57267	Insert mesh/pelvic flr addon	4.88	-----	Agree	4.88
57282	Colpopexy, extraperitoneal	8.85	-----	Disagree	6.86
#57283	Colpopexy, intraperitoneal	14.00	-----	Disagree	10.84
#58356	Endometrial cryoablation	Carrier	-----	Agree	Carrier
#58565	Hysteroscopy, sterilization	7.02	-----	Agree	7.02
#58956	Bso, omentectomy w/tah	20.78	-----	Agree	20.78
#63050	Cervical laminoplasty	20.75	-----	Agree	20.75
#63051	C-laminoplasty w/graft/plate	24.25	-----	Agree	24.25
#63295	Repair of laminectomy defect	5.25	-----	Agree	5.25
66710	Ciliary transsleral therapy	4.77	-----	Agree	4.77
#66711	Ciliary endoscopic ablation	6.60	-----	Agree	6.60
75960	Transcath iv stent rs&i	0.82	-----	Agree	0.82
76075	Dxa bone density, axial	0.30	-----	Agree	0.30
76076	Dxa bone density/peripheral	0.22	-----	Agree	0.22
#76077	Dxa bone density/v-fracture	0.17	-----	Agree	0.17
#76510	Ophth us, b & quant a	1.55	-----	Agree	1.55
76511	Ophth us, quant a only	0.94	-----	Agree	0.94
76512	Ophth us, b w/non-quant a	0.94	-----	Agree	0.94
76513	Echo exam of eye, water bath	0.66	-----	Agree	0.66
76514	Echo exam of eye, thickness	0.17	-----	Agree	0.17
#76820	Umbilical artery echo	0.50	-----	Agree	0.50
#76821	Middle cerebral artery echo	0.70	-----	Agree	0.70
76827	Echo exam of fetal heart	0.58	-----	Agree	0.58
76828	Echo exam of fetal heart	0.56	-----	Agree	0.56
77750	Infuse radioactive materials	4.90	-----	Agree	4.90
#78811	Tumor imaging (pet), limited	1.54	-----	Agree	1.54
#78812	Tumor image (pet)/skul-thigh	1.93	-----	Agree	1.93
#78813	Tumor image (pet) full body	2.00	-----	Agree	2.00
#78814	Tumor image pet/ct, limited	2.20	-----	Agree	2.20
#78815	Tumorimage pet/ct skul-thigh	2.44	-----	Agree	2.44
#78816	Tumor image pet/ct full body	2.50	-----	Agree	2.50
#79005	Nuclear rx, oral admin	1.80	-----	Agree	1.80
#79101	Nuclear rx, iv admin	1.96	-----	Agree	1.96
79200	Nuclear rx, intracav admin	1.99	-----	Agree	1.99
79300	Nuclr rx, interstit colloid	1.60	-----	Agree	1.60
79440	Nuclear rx, intra-articular	1.99	-----	Agree	1.99
#79445	Nuclear rx, intra-arterial	2.40	-----	Agree	2.40
79999	Nuclear medicine therapy	Carrier	-----	Agree	Carrier
84165	Protein e-phoresis, serum	0.37	-----	Agree	0.37
#84166	Protein e-phoresis/urine/csf	0.37	-----	Agree	0.37



86334	Immunofix e-phoresis, serum	0.37	-----	Agree	0.37
#86335	Immunifx e-phorsis/urine/csf	0.37	-----	Agree	0.37
#88184	Flowcytometry/ tc, 1 marker	0.00	-----	Agree	0.00
#88185	Flowcytometry/tc, add-on	0.00	-----	Agree	0.00
#88187	Flowcytometry/read, 2-8	1.36	-----	Agree	1.36
#88188	Flowcytometry/read, 9-15	1.69	-----	Agree	1.69
#88189	Flowcytometry/read, 16 & >	2.23	-----	Agree	2.23
#88360	Tumor immunohistochem/manual	1.10	-----	Agree	1.10
88361	Tumor immunohistochem/comput	1.18	-----	Agree	1.18
88365	Insitu hybridization (fish)	1.20	-----	Agree	1.20
#88367	Insitu hybridization, auto	1.30	-----	Agree	1.30
#88368	Insitu hybridization, manual	1.40	-----	Agree	1.40
#90465	Immune admin 1 inj, < 8 yrs	0.17	-----	Agree	0.17
#90466	Immune admin addl inj, < 8 y	0.15	-----	Agree	0.15
#90467	Immune admin o or n, < 8 yrs	0.17	-----	Agree	0.17
#90468	Immune admin o/n, addl < 8 y	0.15	-----	Agree	0.15
90471	Immunization admin	0.17	-----	Agree	0.17
90472	Immunization admin, each add	0.15	-----	Agree	0.15
#91034	Gastroesophageal reflux test	0.97	-----	Agree	0.97
#91035	G-esoph reflx tst w/electrod	1.59	-----	Agree	1.59
#91037	Esoph impeded function test	0.97	-----	Agree	0.97
#91038	Esoph Imped Funct Test > 1h	1.10	-----	Agree	1.10
#91040	Esoph balloon distension tst	0.97	-----	Agree	0.97
#91120	Rectal sensation test	0.97	-----	Agree	0.97
93741	Analyze ht pace device sngl	0.80	-----	Agree	0.80
93742	Analyze ht pace device sngl	0.91	-----	Agree	0.91
#93745	Set-up cardiovert-defibrill	(a)	-----	(a)	Carrier
#93890	Tcd, vasoreactivity study	1.00	-----	Agree	1.00
#93892	Tcd, emboli detect w/o inj	1.15	-----	Agree	1.15
#93893	Tcd, emboli detect w/inj	1.15	-----	Agree	1.15
#94452	Hast w/report	0.31	-----	Agree	0.31
#94453	Hast w/oxygen titrate	0.40	-----	Agree	0.40
#95928	C motor evoked, uppr limbs	1.50	-----	Agree	1.50
#95929	C motor evoked, lwr limbs	1.50	-----	Agree	1.50
95971	Analyze neurostim, simple	0.78	-----	Agree	0.78
95972	Analyze neurostim, complex	1.50	-----	Agree	1.50
95973	Analyze neurostim, complex	0.92	-----	Agree	0.92
#95978	Analyze neurostim brain/1h	3.50	-----	Agree	3.50
#95979	Analyz neurostim brain addon	1.64	-----	Agree	1.64
#97597	Active wound care/20 cm or <	-----	0.58	Agree	0.58
#97598	Active wound care > 20 cm	-----	0.80	Agree	0.80
#97605	Neg press wound tx, < 50 cm	-----	0.55	Disagree	0.00
#97606	Neg press wound tx, > 50 cm	-----	0.60	Disagree	0.00

(a) No Final RUC recommendation provided

# New CPT codes

\* All CPT codes copyright 2005 American Medical Association

Table 19, which is titled "AMA RUC ANESTHESIA RECOMMENDATIONS AND CMS DECISIONS FOR NEW AND REVISED 2005 CPT CODES", lists the new or revised CPT codes for anesthesia and their base units that will be interim in 2005. This table includes the following information:

- CPT code. This is the CPT code for a service.
- Description. This is an abbreviated version of the narrative description of the code.
- RUC recommendations. This column identifies the base units recommended by the RUC.
- CMS decision. This column indicates whether we agreed or we disagreed with the RUC recommendation. Codes for which we did not accept the RUC recommendation are discussed in greater detail following this table.
- 2005 Base Units. This column establishes the 2005 base units for these services.

**TABLE 19:**  
**AMA RUC ANESTHESIA RECOMMENDATIONS AND CMS DECISIONS**  
**FOR NEW AND REVISED CPT CODES**

*CPT CODE	Description	RUC recom- mendation	CMS Decision	2005 Base Units
#0056 1	Anesth, heart surg < age 1	25.00	Agree	25.00

\*All CPT codes copyright 2005 American Medical Association.

# New CPT code.

Discussion of Codes for Which There Were No RUCRecommendations or for Which the RUC Recommendations Were  
Not Accepted

The following is a summary of our rationale for not accepting particular RUC work RVU or base unit recommendations. It is arranged by type of service in CPT order. Additionally, we discuss those CPT codes for which we received no RUC recommendations for physician work RVUs. This summary refers only to work RVUs or base units.

New and Revised Codes for 2005

CPT code 97605 Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters and CPT code 97606 Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

The RUC HCPAC review board recommended 0.55 work RVUs for CPT code 97605 and 0.60 work RVUs for CPT code 97606, which we did not accept. We disagree with their

recommendation that these services contain physician work and will not assign work RVUs. Further, when the negative pressure wound therapy service does not encompass selective debridement, we consider this service to represent a dressing change and will not make separate payment. When the negative pressure wound therapy service includes the need for selective debridement, we consider the services represented by CPT codes 97605 and 97606 to be bundled into CPT codes 97597 or 97598, the new debridement codes, which will be appropriately billed. We are assigning a status indicator of "B" to these two new CPT codes (97605 and 97606), meaning that we will not make separate payment for these services.

CPT code 57282, Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus) and CPT code 57283 Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy).

The CPT Editorial Panel revised an existing code (57282) and created a new code (57283) to describe vaginal extra and intraperitoneal colpopexies. The RUC recommended maintaining the current work RVUs of 8.85 for 57282 and recommended 14.00 work RVUs for 57283. Previously, both the extra-peritoneal approach and intra-peritoneal approach were billed under CPT code 57282. Effective

January 1, 2005, CPT code 57282 will be used to report colpopexy, vaginal; extra-peritoneal approach, while CPT code 57283 will be used to report colpopexy vaginal; intra-peritoneal approach. Although we agree with the relativity established by the RUC, we believe that the work RVUs for CPT code 57282 should have been adjusted to reflect that the intra-peritoneal approach is now being reported using CPT code 57283. In order to retain work neutrality between these two services, we adjusted the work RVUs using the utilization crosswalks provided by the specialty survey to account for the work that was previously associated with performing these procedures when only one code existed. This results in work RVUs of 6.86 for CPT code 57282 and 10.84 work RVUs for CPT code 57283.

We have not received the final recommendations from the RUC on these services and carriers will price these services in 2005.

CPT Code 32855 Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral; CPT Code 32856 Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from

surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral; CPT Code 33933 Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation; CPT Code 33944 Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation; CPT Code 44715 Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein; CPT Code 47143 Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe spilt; CPT Code 47144 Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal

of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (that is, left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII)); CPT Code 47145 Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (that is, left lobe (segments II, III, and IV) and right lobe (segments I and V through VIII)); CPT Code 48551 Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery, CPT Code 50323 Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland,

and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary; CPT Code 50325 Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary; and CPT Code 93745 Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problem or events.

Establishment of Interim Practice Expense RVUs for New and Revised Physician's Current Procedural Terminology (CPT) Codes and New Healthcare Common Procedure Coding System (HCPCS) Codes for 2005.

We have developed a process for establishing interim practice expense RVUs for new and revised codes that is similar to that used for work RVUs. Under this process, the RUC recommends the practice expense direct inputs (the staff time, supplies and equipment) associated with each new code. We then review the recommendations in a manner similar to our evaluation of the recommended work RVUs.



The RUC recommendations on the practice expense inputs for the new and revised 2005 codes were submitted to us as interim recommendations.

We have accepted, in the interim, the practice expense recommendations submitted by the RUC for the codes listed in the table titled "AMA RUC and HCPAC RVU Recommendations and CMS Decisions for New and Revised 2005 CPT Codes." However, we will be reviewing the supplies, including the DNA probes, for the new and revised in situ hybridization codes (CPT 88365, 88367 and 88368) to ensure that the practice expense database accurately reflects the supplies associated with these services.

#### Other Issues

Comment: The RUC requested that we modify the definition of the "preservice" portion for the 0-, 10- and 90-day global periods to state, "The preservice period includes the physicians' services following the visit at which the decision for surgery is finalized until the time of the operative procedure." The current definition of the preservice time for the 0 and 10-day global periods includes the preservice work occurring on the day of surgery, while the 90-day global period includes the preservice work occurring the day before surgery.

Response: We are reluctant to revise the definition of preservice until there is further review of the issue.

Though the suggested change in preservice definition for physician work would correspond to the change made in the definition for practice expense purposes, that revision was made at the beginning of the practice expense refinement. It is not clear to us how the relativity would be maintained between existing codes valued under the current definition and new codes valued using an expanded definition of preservice work. In addition, among different procedures, there is most likely much variation in the time period between the decision to perform surgery and the time of the operative procedure. The absence of a specific timeframe could result in an inconsistent application of the definition. However, we would look forward to further discussion with the RUC concerning this issue.

Comment: Solid compensator-based intensity modulated radiation therapy (IMRT) is one of the IMRT technologies currently paid using the radiation therapy CPT code 77418, Intensity modulated treatment delivery. For 2005, CPT created a Category III tracking code 0073T, Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensatory convergent beam modulated fields, per

treatment session. CPT instructions for CPT code 77418 now specifically exclude this technology.

Physicians performing compensator-based IMRT expressed concern that we generally carrier price tracking codes and that carriers often will not pay for them, considering services reported with a tracking code to be experimental. One commenter requested that, in order to allow payment for solid compensator-based IMRT under the physician fee schedule, we assign RVUs to the new CPT tracking code 0073T.

Response: As noted by the commenters, we generally do not nationally price tracking codes, which are most often used to report new or experimental services. Rather, we designate them as carrier priced until there is sufficient volume and information to develop appropriate RVUs. However, solid compensator based IMRT is an established technology that is currently paid both under the physician fee schedule and in the hospital outpatient department. We are concerned that having this service be reported using a carrier-priced tracking code could have an adverse effect on access to this technology. Therefore, we are assigning interim RVUs to this tracking code. For payment under the physician fee schedule, we will crosswalk the practice expense and malpractice RVUs assigned to CPT code 77418 to

the Category III tracking code 0073T. (Note that this is a technical component only service and there are no associated physician work RVUs.)

Comment: For 2005, CPT has eliminated CPT code 79900, Provision of Therapeutic Radiopharmaceuticals. We received comments from several organizations and individuals concerning elimination of this CPT code. Commenters requested we either grant a grace period for the CPT code or reinstate the HCPCS code Q3001, Radioelements for brachytherapy, any type, each, so that payment can be made under the physician fee schedule.

Response: We are reinstating HCPCS code Q3001 under the physician fee schedule. This service will be carrier priced.

Note that there have been new HCPCS drug administration codes for physicians' services established for CY 2005. Please see section III.E.2 for specific information related to these new HCPCS codes.

## **VI. Five-Year Refinement of Relative Value Units**

[If you choose to comment on issues in this section, please include the caption "Five Year Refinement of Work Relative Value Units for Calendar Year 2004" at the beginning of your comments.]

### A. Background

The work RVUs were originally developed by a research team at the Harvard School of Public Health in a cooperative agreement with us. Harvard established the work RVUs for almost all fee schedule codes. The RVUs for anesthesia services were based on relative values from the American Society of Anesthesiology. The original RVUs for radiology codes were based on the American College of Radiology relative value scale. The work RVUs reflect the physician's effort in providing a service by accounting for: the physician's time; the technical difficulty of the procedure; the average severity of illness among patients receiving the procedure; and the degree of physical and mental effort required of the physician to perform the procedure.

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less than every 5-years. We initiated the first 5-year review in 1994 and refinements went into effect beginning in 1997. The second 5-year review began in 1999 and refinements went into effect beginning in 2002. It is now time to begin the third 5-year review of the physician work RVUs with the resulting changes being effective beginning in 2007.

As part of the final rule published December 8, 1994 (59 FR 63453), we solicited public comment on all work RVUs

for approximately 7,000 CPT and HCPCS codes. The scope of the 5-year review was limited to work values, since at that time, the statute required practice expense and malpractice RVUs be calculated based on 1991 allowed charges and practice expense and malpractice expense shares for the specialties performing the services. Also, the December 8, 1994 final rule outlined the proposed process for refinement of the work RVUs and provided a suggested format for submission of comments.

We indicated that we were particularly interested in receiving comments on physicians' services for which medical practice had changed since the Harvard surveys were performed, but for which there were no code changes and, therefore, no reconsideration of whether the work RVUs were still accurate. As a result of the December 8, 1994 final rule, we received more than 500 comments on approximately 1,100 codes. Subsequent to review of the comments by our medical staff, comments on approximately 700 codes were forwarded to the AMA's Specialty Society RUC for review. An additional 300 codes identified by our staff as potentially misvalued were also forwarded to the RUC. A process similar to that used for the annual physician fee schedule update was used for evaluating the proposed changes to the work RVUs and a notice discussing these

proposed changes was published in the May 3, 1996 **Federal Register** (61 FR 19992). As outlined in this notice, we proposed to increase the work RVUs for 28 percent of the codes; we proposed to maintain the work RVUs for 61 percent of the codes and we proposed to decrease the work RVUs for 11 percent of the codes. (Our proposed work RVUs agreed with the RUC recommendations for 93 percent of the codes.) In response to the May 3, 1996 proposed notice, we received more than 2,900 comments on approximately 133 codes plus all anesthesia services. In order to address these comments, we convened multi-specialty panels of physicians. A detailed discussion of this process, as well as the results of the 5-year review were included in the final rule with comment period published November 22, 1996 (61 FR 59490).

We initiated the second 5-year review by soliciting comments on potentially misvalued work RVUs for all services in the CY 2000 physician fee schedule in the November 2, 1999, final rule (64 FR 59427). We indicated that the scope of the second 5-year review would be restricted to work RVUs, since resource-based malpractice RVUs had only just been implemented in CY 2000, and we were in the middle of transitioning to a fully resource-based system for practice expense RVUs.

In our July 17, 2000 proposed rule (66 FR 31028), we explained the process used to conduct the second 5-year review of work, beginning with the solicitation of comments on services that were potentially misvalued, in our November 2, 1999 final rule with comment period.

We received comments from approximately 30 specialty groups, organizations, and individuals involving over 900 procedure codes. After review by our medical staff, we shared all of the comments we received concerning potentially misvalued services with the RUC.

The RUC submitted work RVU recommendations for all of the codes we forwarded with the exception of the anesthesia codes and conscious sedation codes. We analyzed all of the RUC recommendations and evaluated both the recommended work RVUs and the rationale for the recommendations. If we had concerns about the application of a particular methodology, but thought the recommended work RVUs were reasonable, we verified that the recommended work RVUs were appropriate by using alternative methodologies. We announced our proposed decisions on the revised work RVUs in the proposed notice published June 8, 2001 (66 FR 31028).

Overall, we proposed to accept 92 percent of RUC recommended work RVUs (RVUs or 792 services). Of the RUC recommendations we disagreed with, we proposed to increase



the work RVUs for 37 services and decrease the work RVUs for 22 services. We did not accept the RUC recommendations of an increase for 6 services that were previously reviewed by a multi-specialty physician panel in 2000. The Health Care Professional Advisory Committee (HCPAC), an advisory committee to the RUC representing non-physician health professionals, also reviewed a total of 12 services as part of the 5-year review. For 5 of the services reviewed, the HCPAC did not offer a recommendation. Of the remaining 7 services, we proposed to accept the HCPAC recommendations.

Comments received on the June 8, 2001 proposed notice generally supported our proposed changes. In addition, we received more than 125 comments on approximately 39 specific codes plus all the anesthesia services. The majority of these comments addressed the gastrointestinal endoscopy codes and anesthesia services. As with the first 5-year review we convened a multi-specialty panel of physicians to assist us in the review of the comments. For additional information about this process, the comments received, and the results of the second 5-year review, see the final rule with comment period published November 2, 2001 (66 FR 55285).

#### B. Scope of the 5-Year Refinement

As with the second 5-year review, we are soliciting comments only on the work RVUs that may be inappropriately valued. The malpractice RVUs were implemented in CY 2000 and revisions to these RVUs are addressed as part of this final rule.

We are not including the practice expense RVUs as part of this refinement. The PEAC, an advisory committee of the RUC, has been providing us with recommendations for refining the direct practice expense inputs (clinical staff, supplies, and equipment) used in calculating the practice expense RVUs for established codes. As discussed in the August 5, 2004 proposed rule, the PEAC held its last meeting March 2004 and future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC. As we determine the process that will be used to refine the remaining codes, we will also be considering how to address future review of practice expense RVUs. We would also welcome comments on how this might be addressed. However, to the extent that there are changes in physician time or in the number or level of post procedure visits as a result of the 5-year review of work, there would be a potential impact on the practice expense inputs, and we would revise the inputs accordingly.

### C. Refinement of Work Relative Value Units

During the first and second 5-year reviews, we relied on public commenters to identify services that were potentially misvalued.

For the third 5-year review, we are again requesting comments on potentially misvalued work RVUS for all services in the CY 2005 physician fee schedule. However, we recognize that this process generally elicits comments focusing on undervalued codes. Therefore, in addition to the codes submitted by commenters, we will also identify codes (especially high-volume codes across specialties) that:

- Are valued as being performed in the inpatient setting, but that are now predominantly performed on an outpatient basis; and
- Were not reviewed by the RUC, (that is, Harvard RVUs are still being used, or there is no information).

Public comments must include the appropriate CPT code (for example, CPT code 90918) and the suggested RVUs (for example, 11.00 RVUs), and evidence that the current work RVU is misvalued. Failure to provide this information may result in our inability to evaluate the comments adequately. We will consider all comments on all work RVUs

in the development of a proposed rule that we intend to publish in 2006. In that rule, we will propose the revisions to work RVUs that we believe are needed. We will then review and analyze the comments received in response to our proposed revisions and publish our decisions in the 2006 final rule.

In addition to internal review and analysis, we propose to share comments we receive on all work RVUs with the RUC, which currently makes recommendations to us on the assignment of RVUs to new and revised CPT codes. This process was used during the last 5-year review, and we believe that it was beneficial. The RUC's perspective will be helpful because of its experience in recommending RVUs for new and revised CPT codes since we implemented the physician fee schedule. Furthermore, the RUC, by virtue of its multispecialty membership and consultation with approximately 65 specialty societies, involves the medical community in the refinement process.

#### D. Nature and Format of Comments on Work Relative Value Units

While all written public comments are welcomed, based on our past experience we have found it particularly beneficial if the comments include certain information: the CPT code or codes recommended for review, a clinical

description of the service(s), the current work RVUs and the suggested work RVUs. Because our initial assumption will be that each code is currently appropriately valued, the commenter may also include some rationale to support the need for review. For example, one approach would be to compare the physician work of each nominated code to the work involved in an analogous service that has higher or lower work RVUs. In other situations, the commenter could demonstrate that there is a rank order anomaly within a family of codes. Another reason for reviewing the physician work involved in a service could be that the physician time or intensity required by the procedure has changed since it was last reviewed, perhaps because of a change in technology or in patient characteristics.

The RUC has also developed more detailed "Compelling Evidence Standards" which are used by the RUC as part of their process to determine if a recommendation to change the work RVUs is warranted for a given code. We are including these standards below solely for informational purposes so that commenters are aware what kind of information will be needed to make a successful argument to the RUC for changing work RVUs.

#### RUC Compelling Evidence Standards

The RUC operates with the initial presumption that the current values assigned to the codes under review are correct. This presumption can be challenged by a society or other organization presenting a compelling argument that the existing values are no longer rational or appropriate for the codes in question. The argument for a change must be substantial and meet the RUC's compelling evidence standards. This argument must be provided in the comment letter to us, and then later to the RUC in writing on the Summary of Recommendation form. The following guidelines may be used to develop a "compelling argument" that the published relative value for a service is inappropriately valued:

- Documentation in the peer-reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following:
  - + Technique
  - + Knowledge and technology
  - + Patient population
  - + Site-of-service
  - + Length of hospital stay
  - + Physician time
- An anomalous relationship between the code being

valued and other codes. For example, if code A describes a service that requires more work than codes B, C, and D, but is nevertheless valued lower. The specialty would need to assemble evidence on service time, technical skill, patient severity, complexity, length of stay and other factors for the code being considered and the codes to which it is compared. These reference services may be both inter- and intra-specialty.

- Evidence that technology has changed physician work that is, diffusion of technology).
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, as documented, such as:
  - + A misleading vignette, survey or flawed crosswalk assumptions in a previous evaluation;
  - + A flawed mechanism or methodology used in the previous valuation, for example, evidence that no pediatricians were consulted in assigning pediatric values; and

- + A previous survey was conducted by one specialty to obtain a value, but in actuality that service is currently provided primarily by physicians from a different specialty according to utilization data.

We emphasize, however, as we reiterated for the last 5-year review, that we retain the responsibility for analyzing the comments on the suggested work RVU revisions, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether to revise RVUs. We are not delegating this responsibility to the RUC or any other organization.

## **VII. Update to the Codes for Physician Self-Referral Prohibition**

[If you choose to comment on issues in this section, please include the caption "Physician Self-Referral Designated Health Services" at the beginning of your comments.]

### **A. Background**

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to a health care entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception



applies. The following services are DHS, as specified in section 1877 of the Act and in regulations at §411.351:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

In §411.351, the entire scope of the first four of these DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS publications. The updated Code List appears as an addendum to the physician fee schedule final rule and is available on our web site at <http://cms.hhs.gov/medlearn/refphys.asp>. We also include in the Code List those items and services that

may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§411.351(g)).
- Preventive screening tests, immunizations or vaccines (§411.351(h)).

The Code List was updated in the physician fee schedule final rule published in the **Federal Register** on November 7, 2003 (68 FR 63196). It was subsequently corrected in a notice that was published in the **Federal Register** on March 26, 2004 (69 FR 15729). We also published the Phase II physician self-referral interim final rule with comment period on March 26, 2004 in the **Federal Register** (69 FR 16054), which made several additional changes to the Code List, effective July 26, 2004.

The updated all-inclusive Code List effective January 1, 2005 is presented in Addendum L of this final rule.

#### B. Response to Comments

We received two public comments relating to the Code List published in the November 7, 2003 physician fee schedule final rule. One commenter supported the exclusion of interventional radiology services from the definition of

radiology and certain other imaging services, as reflected on the Code List. The other commenter raised a concern over the exclusion of nuclear medicine services as a DHS.

Additionally, the proposed physician fee schedule rule that was published on August 5, 2004 in the Federal Register (69 FR 47488) generated one comment relating to the Code List. That comment and our response also are provided below. We note that we will address in a separate **Federal Register** document those public comments relating to the Code List that were received in response to the Phase II physician self-referral final rule published on March 26, 2004.

Comment: One commenter requested that we include nuclear medicine services as DHS. The commenter is concerned that physicians may engage in lucrative financial relationships associated with nuclear medicine studies such as PET scans.

Response: We are mindful of the issue raised by the commenter, and we continue to consider the application of section 1877 of the Act to nuclear medicine procedures. However, we note that the purpose of this update is merely to conform the Code List to the most recent publications of HCPCS and CPT codes. Substantive changes to DHS definitions, such as that advocated by the commenter, are beyond the scope of this rulemaking.

Comment: One commenter asked us to clarify that the Code List does not define all DHS and that we indicate where providers can obtain more information on the remaining categories. Additionally, the commenter suggested that we define all DHS in the Code List and that the definitions be included in the quarterly updated Microsoft Excel spreadsheet of RVU values, global periods and supervision levels for Medicare covered services posted on our web site.

Response: We believe that most readers are aware that the Code List does not define every DHS category. Nevertheless, we will add a footnote to the Code List indicating that §411.351 defines those DHS categories not reflected on the Code List.

The comment advocating that we define all DHS by CPT or HCPCS code on the Code List would require a substantive change to existing DHS definitions and is therefore beyond the scope of this rulemaking. We will explore the possibility of identifying certain DHS in the National Physician Fee Schedule Relative Value File (<http://www.cms.hhs.gov/providers/pufdownload/rvudown.asp>).

#### C. Revisions Effective for 2005

Tables 20 and 21, in this section, identify the additions and deletions, respectively, to the comprehensive

Code List included in the Phase II physician self-referral interim final rule published March 26, 2004. Tables 20 and 21 also identify the additions and deletions to the lists of codes used to identify the items and services that may qualify for the exceptions in §411.355(g) (regarding EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in §411.355(h) (regarding preventive screening tests, immunizations and vaccines).

We will consider comments for the codes listed in Tables 20 and 21 below, if we receive them by the date specified in the "DATES" section of this final rule. We will not consider any comment that advocates a substantive change to any of the DHS defined in §411.351.

**TABLE 20: ADDITIONS TO THE PHYSICIAN SELF-REFERRAL**

**HCPCS/CPT<sup>1</sup> CODES**

CLINICAL LABORATORY SERVICES

0064T Spectroscop eval expired gas

0085T Breath test heart reject

0087T Sperm eval hyaluronan

36415 Routine venipuncture

PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE  
PATHOLOGY SERVICES

97597 Active wound care/20cm or <

97598 Active wound care > 20cm  
97605 Neg press wound tx, < 50 cm  
97606 Neg press wound tx, > 50 cm  
G0329 Electromagntic tx for ulcers

## RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES

76077 Dxa bone density/v-fracture  
76510 Ophth us, b & quant a  
76820 Umbilical artery echo  
76821 Middle cerebral artery echo  
93890 Tcd, vasoreactivity study  
93892 Tcd, emboli detect w/o inj  
0067T Ct colonography;dx  
Q0092 Set up port xray equipment

## RADIATION THERAPY SERVICES AND SUPPLIES

19296 Place po breast cath for rad  
19297 Place breast cath for rad  
19298 Place breast rad tube/caths  
57155 Insert uteri tandems/ovoids  
58346 Insert Heyman uteri capsule  
0073T Delivery, comp imrt  
0082T Stereotactic rad delivery  
0083T Stereotactic rad tx mngmt

## DRUGS USED BY PATIENTS UNDERGOING DIALYSIS

[no additions]

## PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES

- 80061      Lipid panel [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]
- 82465      Assay, bld/serum cholesterol [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]
- 82947      Assay, glucose, blood quant [only when billed with ICD-9-CM code V77.1]
- 82950      Glucose test [only when billed with ICD-9-CM code V77.1]
- 82951      Glucose tolerance test (GTT) [only when billed with ICD-9-CM code V77.1]
- 83718      Assay of lipoprotein [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]
- 84478      Assay of triglycerides [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V.81.2]
- 90656      Flu vaccine no preserv 3 & >

<sup>1</sup>CPT codes and descriptions only are copyright 2004 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

**TABLE 21: DELETIONS TO THE PHYSICIAN SELF-REFERRAL  
HCPCS/CPT<sup>1</sup> CODES**

CLINICAL LABORATORY SERVICES

G0001 Drawing blood for specimen

PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE  
PATHOLOGY SERVICES

97601 Wound(s) care, selective

RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES

[no deletions]

RADIATION THERAPY SERVICES AND SUPPLIES

50559 Renal endoscopy/radiotracer

DRUGS USED BY PATIENTS UNDERGOING DIALYSIS

[no deletions]

PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES

[no deletions]

<sup>1</sup>CPT codes and descriptions only are copyright 2004 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

The additions specified in Table 20 generally reflect new CPT and HCPCS codes that become effective January 1, 2005 or that became effective since our last update. It also reflects the addition of codes that will be recognized by Medicare for payment purposes effective January 1, 2005.



Additionally, we are adding HCPCS code Q0092 to the category of radiology and certain other imaging services since it may be billed in conjunction with the provision of portable x-ray services and had been inadvertently omitted.

We are also adding two existing brachytherapy codes (CPT 57155 and 58346) to the category of radiation therapy services and supplies. As noted in the March 26, 2004 Phase II physician self-referral interim final rule (69 FR at 16104-16105), brachytherapy is a DHS. We inadvertently omitted these codes when compiling the Code List.

Table 20 also reflects the addition of a flu vaccine code (CPT 90656), CV screening blood tests (CPT 80061, 82465, 83718 and 84478) and diabetes screening tests (CPT 82947, 82950 and 82951) to the list that identifies preventive screening tests, immunizations and vaccines that may qualify for the exception described in §411.355(h) for such items and services. The physician self-referral prohibition will not apply to these services if the conditions set forth in §411.355(h) are satisfied. We note that CPT codes 80061, 82465, 83718, 84478, 82947, 82950, and 82951 are eligible for the exception at §411.355(h) only when billed with the appropriate screening diagnosis codes specified on the Code List for each test.

Table 21 reflects the deletions necessary to conform the Code List to the most recent publications of CPT and HCPCS codes.

#### **VIII. Physician Fee Schedule Update for Calendar Year 2005**

##### **A. Physician Fee Schedule Update**

The physician fee schedule update is determined using a formula specified by statute. Under section 1848(d)(4) of the Act, the update is equal to the product of 1 plus the percentage increase in the MEI (divided by 100) and 1 plus the update adjustment factor (UAF). For CY 2005, the MEI is equal to 3.1 percent (1.031). The UAF is -7.0 percent (0.930). Section 1848(d)(4)(F) of the Act requires an additional 0.8 percent (1.008) increase to the update for 2005. The product of the MEI (1.031), the UAF (0.930), and the statutory adjustment factor (1.008) equals the CY 2005 update of -3.3 percent (0.967). However, section 601 of the MMA amended section 1848(d) of the Act to specify that the update to the single CF for 2005 cannot be less than 1.5 percent. Because the statutory formula will yield an update of -3.3 percent, consistent with section 601 of the MMA, we are establishing a 2005 physician fee schedule update of 1.5 percent.

Our calculations of all of the above figures are explained below.

B. The Percentage Change in the Medicare Economic Index  
Medicare Economic Index (MEI)

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has 2000 base year weights, is comprised of two broad categories: physician's own time and physician's practice expense.

The physician's own time component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: wages and salaries, and fringe benefits.

The physician's practice expense category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician's practice expense component also includes the following categories of nonlabor inputs: office expense, medical materials and supplies, professional liability insurance, medical equipment, professional car, and other expenses. The

components are adjusted to reflect productivity growth in physicians' offices by the 10-year moving average of multifactor productivity in the private nonfarm business sector. The Table 22 below presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 2005 update. For calendar year 2005, the increase in the MEI is 3.1 percent, which includes a 0.9 percent change in the 10-year moving average of multifactor productivity. This result is the result of a 3.0 percent increase in Physician's Own Time and a 5.2 percent increase in Physician's Practice Expense. Within the Physician's Practice Expense, the largest increase occurred in Professional Liability Insurance, which increased 23.9 percent.

**TABLE 22:**

<b>INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005<sup>1</sup></b>		
Cost Categories and Price Measures	CY 2000 Weights <sup>2</sup>	CY 2005 Percent Changes
Medicare Economic Index Total, productivity adjusted	n/a	3.1
Productivity: 10-year moving average of multifactor productivity, private nonfarm business sector*	n/a	0.9
Medicare Economic Index Total, without productivity adjustment	100.000	4.0
1. Physician's Own Time <sup>3</sup>	52.466	3.0
a. Wages and Salaries: Average Hourly Earnings, private nonfarm	42.730	2.1
b. Fringe Benefits: Employment Cost Index, benefits, private nonfarm	9.735	6.8
2. Physician's Practice Expense <sup>3</sup>	47.534	5.2
a. Nonphysician Employee Compensation	18.653	3.8
1. Wages and Salaries: Employment Cost Index, wages and salaries, weighted by occupation	13.808	3.0

INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005 <sup>1</sup>		
2. Fringe Benefits: Employment Cost Index, fringe benefits, white collar	4.845	6.1
b. Office Expense: Consumer Price Index for Urban Areas (CPI-U), housing	12.209	2.3
c. Drugs and Medical Materials and Supplies	4.319	4.0
1. Medical Materials and Supplies: Producer Price Index (PPI), surgical appliances and supplies/CPI-U, medical equipment and supplies (equally weighted)	2.011	2.0
2. Pharmaceuticals: Producer Price Index (PPI ethical prescription drugs)	2.308	5.6
d. Professional Liability Insurance: Professional liability insurance premiums <sup>4</sup>	3.865	23.9
e. Medical Equipment: PPI, medical instruments and equipment	2.055	1.9
f. Other Expenses	6.433	1.4

<b>INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005<sup>1</sup></b>	
<p>* As of September 22, 2004, Bureau of Labor Statistics had not released the estimates of nonfarm multifactor productivity growth for 2002. Therefore, we used the most recently available information (thru CY 2001) to develop the productivity adjustment for the CY 2005 update. This produces a productivity adjustment that is equivalent to the one used in the CY 2004 update.</p>	
1	<p>The rates of historical change are estimated for the 12-month period ending June 30, 2004, which is the period used for computing the CY 2005 update. The price proxy values are based upon the latest available Bureau of Labor Statistics data as of September 22, 2004.</p>
2	<p>The weights shown for the MEI components are the 2000 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2000. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2000 weight. The sum of these products (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.</p>
3	<p>The measures of productivity, average hourly earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics website- <a href="http://stats.bls.gov">http://stats.bls.gov</a>.</p>

<b>INCREASE IN THE MEDICARE ECONOMIC INDEX UPDATE FOR CALENDAR YEAR 2005<sup>1</sup></b>	
4	Derived from data collected from several major insurers (the latest available historical percent change data are for the period ending second quarter of 2004).
n/a	Productivity is factored into the MEI categories as an adjustment to the price variables; therefore, no explicit weight exists for productivity in the MEI.



C. The Update Adjustment Factor

Section 1848(d) of the Act provides that the physician fee schedule update is equal to the product of the MEI and a UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as "allowed expenditures") equal. Allowed expenditures are equal to actual expenditures in a base period updated each year by the sustainable growth rate (SGR). The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

1. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with 2001 is equal to the sum of the following--

- Prior Year Adjustment Component. An amount determined by--
  - + Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;

- + Dividing that difference by the amount of the actual expenditures for those services for that year; and
- + Multiplying that quotient by 0.75.
- Cumulative Adjustment Component. An amount determined by--
  - + Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;
  - + Dividing that difference by actual expenditures for those services for the prior year as increased by the sustainable growth rate for the year for which the update adjustment factor is to be determined; and
  - + Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. Section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (2005 in this case), the current CY (2004) and the preceding CY (2003) are to be determined on the basis

of the best data available as of September 1 of the current year. Allowed expenditures are initially estimated and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the final revision to 2003 allowed expenditures in this final rule). Once the SGR and allowed expenditures for a year have been revised twice, they are final.

Table 23 shows annual and cumulative allowed expenditures for physicians' services from April 1, 1996 through the end of the current CY, including the transition period to a CY system that occurred in 1999. Also shown is the SGR corresponding with each period. The calculation of the SGR is discussed in detail below.

**TABLE 23:**

Period	Annual Allowed Expenditures (\$ in billions)	Annual Actual Expenditures (\$ in billions)	Cumulative Allowed Expenditures (\$ in billions)	Cumulative Actual Expenditures (\$ in billions)	FY/CY SGR
4/1/96-3/31/97	\$48.9	\$48.9	\$48.9	\$48.9	N/A
4/1/97-3/31/98	50.5	49.4	99.4	98.4	FY 1998=3.2%
4/1/98-3/31/99	52.6	50.5	152.0	148.9	FY 1999=4.2%
1/1/99-3/31/99	13.3	13.1	( <sup>1</sup> )	148.9	FY 1999=4.2%
4/1/99-12/31/99	42.1	39.5	( <sup>2</sup> )	188.4	FY 2000=6.9%
1/1/99-12/31/99	55.3	52.6	194.1	188.4	FY 1999/2000 <sup>(3)</sup>
1/1/00-12/31/00	59.4	58.1	253.4	246.5	CY 2000=7.3%
1/1/01-12/31/01	62.0	66.3	315.5	312.9	CY 2001=4.5%
1/1/02-12/31/02	67.2	71.0	382.6	383.8	CY 2002=8.3%
1/1/03-12/31/03	72.1	76.8	454.6	460.6	CY 2003=7.3%
1/1/04-12/31/04	77.1	84.9	531.8	545.5	CY 2004=7.0%

1/1/05-12/31/05	80.4	N/A	612.2	N/A	CY 2005=4.3%
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(<sup>1</sup>) Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.

(<sup>2</sup>) Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

(<sup>3</sup>) Allowed expenditures in the first year (April 1, 1996--March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our website under the Medicare Office of the Actuary's (OACT) publications at the following address: <http://www.cms.hhs.gov/statistics/actuary/>. We expect to update the website with the most current information later this month.



Consistent with section 1848(d)(4)(E) of the Act, Table 23 includes our final revision of allowed expenditures for 2003, a recalculation of allowed expenditures for 2004, and our initial estimate of allowed expenditures for 2005. To determine the update adjustment factor for 2005, the statute requires that we use allowed and actual expenditures from April 1, 1996 through December 31, 2004 and the 2005 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making further revisions to the 2004 and 2005 SGRs and 2004 and 2005 allowed expenditures. Because we have incomplete actual expenditure data for 2004, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the update adjustment factor for future years.

We are using figures from Table 23 in the statutory formula illustrated below:

$$UAF = \frac{\text{Target}_{04} - \text{Actual}_{04}}{\text{Actual}_{04}} \times .75 + \frac{\text{Target}_{4/96-12/04} - \text{Actual}_{4/96-12/04}}{\text{Actual}_{04} \times SGR_{05}} \times .33$$

UAF = Update Adjustment Factor

Target<sub>04</sub> = Allowed Expenditures for 2004 or \$77.1 billion

Actual<sub>04</sub> = Estimated Actual Expenditures for 2004 = \$84.9 billion

Target  $_{4/96-12/04}$  = Allowed Expenditures from 4/1/1996 -  
12/31/2004 = \$531.8 billion

Actual  $_{4/96-12/04}$  = Estimated Actual Expenditures from 4/1/1996  
- 12/31/2003 = \$545.5 billion

SGR<sub>05</sub> = 4.3 percent (1.043)

$$\frac{\$77.1 - \$84.9}{\$84.9} \times .75 + \frac{\$531.8 - \$545.5}{\$84.9 \times 1.043} \times .33 = -0.120$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than -0.070 or greater than 0.03. Since -0.120 is less than -0.070, the UAF for 2005 will be -0.070.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1 to -0.070 makes the update adjustment factor equal to 0.930.

C. IX. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

A. Medicare Sustainable Growth Rate

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in



actual expenditures exceeds the SGR. Rather, the physician fee schedule update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with 2001) is equal to the product of the following four factors:

- (1) The estimated change in fees for physicians' services.
- (2) The estimated change in the average number of Medicare fee-for-service beneficiaries.
- (3) The estimated projected growth in real GDP per capita.
- (4) The estimated change in expenditures due to changes in law or regulations.

In general, section 1848(f)(3) of the Act requires us to publish SGRs for 3 different time periods, no later than November 1 of each year, using the best data available as of September 1 of each year. Under section 1848(f)(3)(C)(i) of the Act, the SGR is estimated and subsequently revised twice (beginning with the FY and CY 2000 SGRs) based on later data. (There were also

provisions in the Act to adjust the FY 1998 and FY 1999 SGRs. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule, we are making our preliminary estimate of the 2005 SGR, a revision to the 2004 SGR, and our final revision to the 2003 SGR.

B. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute indicates that "the term "physicians' services" includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee." We published a definition of physicians' services for use in the SGR in the **Federal Register** (66 FR 55316) on November 1, 2001. We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. For purposes of determining allowed expenditures, actual expenditures, and

SGRs through December 31, 2002, we have specified that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified):

- Physicians' services.
- Services and supplies furnished incident to physicians' services.
- Outpatient PT services and outpatient OT services.
- Antigens prepared by, or under the direct supervision of, a physician.
- Services of PAs, certified registered nurse anesthetists, CNMs, clinical psychologists, clinical social workers, NPs, and CNSs.
- Screening tests for prostate cancer, colorectal cancer, and glaucoma.
- Screening mammography, screening pap smears, and screening pelvic exams.
- Diabetes outpatient self-management training services.
- Medical nutrition therapy services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).

- X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
- Bone mass measurements.

Sections 611 through 613 of the MMA, respectively, modified section 1861(s) of the Act to add Medicare coverage for an initial preventive exam, CV screening blood tests, and diabetes screening tests. We believe that these services are commonly performed or furnished by a physician or in a physician's office and are including them in the definition of physicians' services for purposes of the SGR.

Comment: We received a number of comments requesting that we use our administrative authority to remove drugs from the SGR. According to one of these comments, drugs are not physicians' services and should never have been included in the SGR. One of these comments indicated that the SGR "is a seriously flawed formula that will continue to require frequent Congressional intervention to avoid payment cuts . . ." According to this comment, "the Administration should reduce the price tag and help pave the way for an appropriate long-term solution by removing drugs from the SGR pool." We also received a number of comments suggesting that we use our administrative

authority to adjust the SGR for changes in spending associated with national coverage determinations (NCDs).

Response: We remain concerned about forecasts of reductions in physician fees and will carefully consider the issues raised by the comments when we make changes to the physician fee schedule for 2006. We believe that the physician payment system should be structured to control costs and achieve predictable and stable changes to Medicare's rates while being equitable to physicians. We note that administrative changes affecting the SGR would have significant long-term cost implications but will not have an impact on the update for 2006 or the subsequent few years. Therefore, without a statutory change, there will still be a reduction in physicians' fee schedule rates for 2006 and subsequent years. Towards those goals, we have already taken several actions that will improve Medicare's physician payment system:

- Using multifactor productivity in place of labor productivity in the MEI beginning in 2003. This change increased the physician fee schedule update by 0.7 percentage points for 2003 and was estimated to increase Medicare spending by \$14.5 billion over 10 years.
- Increasing the weight of malpractice costs in the MEI from 3.2 to 3.9 percent, a 21 percent increase beginning in 2004.

- Incorporating an increase in malpractice premiums of 16.9 percent into the 2004 MEI and 23.9 percent into the 2005 MEI. The increased weight for malpractice in the MEI makes the index a more accurate representation of inflation in physician office costs.

#### C. Preliminary Estimate of the SGR for 2005

Our preliminary estimate of the 2005 SGR is 4.3 percent. We first estimated the 2005 SGR in March and made the estimate available to the Medicare Payment Advisory Commission and on our website. Table 24 shows that March 2004 and our current estimates of the factors included in the 2005 SGR.

**TABLE 24:**

Statutory Factors	March Estimate	Current Estimate
Fees	2.6 percent (1.026)	1.3 percent (1.013)
Enrollment	-0.2 percent (0.998)	-0.3 percent (0.997)
Real Per Capita GDP	2.2 percent (1.022)	2.2 percent (1.022)
Law and Regulation	0.0 percent (1.000)	1.0 percent (1.010)
Total	4.6 percent (1.046)	4.3 percent (1.043)

(Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is,  $1.013 \times 0.997 \times 1.022 \times 1.010 = 1.37$ ). A more detailed explanation of each figure is provided below in section H.1.

D. Revised Sustainable Growth Rate for 2004

Our current estimate of the 2004 SGR is 7.0 percent. Table 25 shows our preliminary estimate of the 2004 SGR that was published in the **Federal Register** on November 7, 2003 (68 FR 63249) and our current estimate.

**TABLE 25:**

Statutory Factors	November 7, 2003 Estimate	Current Estimate
Fees	2.7 percent (1.027)	1.4 percent (1.014)
Enrollment	1.7 percent (1.017)	1.7 percent (1.017)
Real Per Capita GDP	2.8 percent (1.028)	2.2 percent (1.022)
Law and Regulation	0.0 percent (1.000)	1.5 percent (1.015)
Total	7.4 percent (1.074)	7.0 percent (1.070)

A more detailed explanation of each figure is provided below in section H.2.

E. Final Sustainable Growth Rate for 2003

The SGR for 2003 is 7.3 percent. Table 26 shows our preliminary estimate of the SGR published in the **Federal Register** on December 31, 2002 (67 FR 80027), our revised estimate published in the **Federal Register** on November 7, 2003 (67 FR 63249) and the final figures determined using the latest available data.

**TABLE 26:**

Statutory Factors	12/31/02 Estimate	11/7/03 Estimate	Final
Fees	2.9 percent (1.029)	2.8 percent (1.028)	2.8 percent (1.028)
Enrollment	1.2 percent (1.012)	2.4 percent (1.024)	2.3 percent (1.023)
Real Per Capita GDP	3.3 percent (1.033)	1.4 percent (1.014)	2.0 percent (1.020)
Law and Reg	0.0 percent (1.000)	0.0 percent (1.000)	0.0 percent (1.000)
Total	7.6 percent (1.076)	6.7 percent (1.067)	7.3 percent (1.073)

A more detailed explanation of each figure is provided below in section H.2.

F. Calculation of 2005, 2004, and 2003 Sustainable Growth Rates

1. Detail on the 2005 SGR

All of the figures used to determine the 2005 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent physician fee schedule updates.

**Factor 1--Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2005**

This factor is calculated as a weighted average of the 2005 fee increases for the different types of services



included in the definition of physicians' services for the SGR. Medical and other health services paid using the physician fee schedule are estimated to account for approximately 83.9 percent of total allowed charges included in the SGR in 2005 and are updated using the MEI. The MEI for 2005 is 3.1 percent. Diagnostic laboratory tests are estimated to represent approximately 7.1 percent of Medicare allowed charges included in the SGR for 2005. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI-U). However, section 629 of the MMA specifies that diagnostic laboratory services will receive an update of 0.0 percent from 2004 through 2008.

Drugs are estimated to represent 9.0 percent of Medicare allowed charges included in the SGR in 2005. As indicated earlier in this final rule, sections 303 and 304 of the MMA require Medicare to pay for most drugs at 106 percent of ASP beginning January 1, 2005. We estimated a weighted average change in fees for drugs included in the SGR using the ASP plus 6 percent pricing methodology of - 14.7 percent for 2005. Table 27 shows the weighted average of the MEI, laboratory and drug price changes for 2005.

**TABLE 27:**

	Weight	Update
Physician	0.839	3.1

Laboratory	0.071	0.0
Drugs	0.090	-14.7
Weighted Average	1.000	1.3

We estimate that the weighted-average increase in fees for physicians' services in 2005 under the SGR (before applying any legislative adjustments) will be 1.3 percent.

**Factor 2--The Percentage Change in the Average Number of Part B Enrollees from 2004 to 2005**

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from 2004 to 2005. Services provided to Medicare+Choice (M+C) plan enrollees are outside the scope of the SGR and are excluded from this estimate. OACT estimates that the average number of Medicare Part B fee-for-service enrollees will decrease by 0.3 percent from 2004 to 2005. Table 28 illustrates how this figure was determined.

**TABLE 28:**

	2004	2005
Overall	39.041 million	39.547 million
Medicare+Choice	4.671 million	5.275 million
Net	34.370 million	34.272 million
Percent Increase		-0.3 percent

An important factor affecting fee-for-service enrollment is beneficiary enrollment in M+C plans. Because it is difficult to estimate the size of the M+C enrollee population before the start of a calendar year, at this time we do not know how actual enrollment in M+C plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for 2005 becomes known.

**Factor 3--Estimated Real Gross Domestic Product Per Capita Growth in 2005**

We estimate that the growth in real per capita GDP from 2004 to 2005 will be 2.2 percent. Our past experience indicates that there have also been large changes in estimates of real per capita GDP growth made before the year begins and the actual change in GDP computed after the year is complete. Thus, it is likely that this figure will change as actual information on economic performance becomes available to us in 2005.

**Factor 4--Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in CY 2005 Compared With CY 2004**

There are a number of statutory provisions that will affect the 2005 SGR. As indicated above, sections 303 and 304 of the MMA changed Medicare payment for drugs. These provisions also changed Medicare payments for the administration of drugs. Section 303(a)(1) amended section 1848(c)(2) of the Act to require the Secretary to make a number of changes that increased Medicare payment for drug administration beginning January 1, 2004. These changes permanently increased Medicare payments for drug administration by a weighted average of 110 percent. Section 303(a)(4) of the MMA required an additional transitional adjustment (temporary increase) to Medicare's payment for drug administration of 32 percent for 2004 and 3 percent for 2005. The change in the transitional adjustment of 32 percent for 2004 to 3 percent for 2005 would reduce Medicare payments for drug administration between 2004 and 2005. However, some of this reduction will be lessened because we are also adopting changes to the codes and payment amounts for drug administration based on recommendations from the AMA's CPT Editorial Panel and Relative Value Update Committee (RUC), under the authority of section 1848(c)(2)(J) of the Act. We are further increasing physician fee schedule payments by paying separately for injections provided on the same day as another physician fee schedule service. We are further increasing physician fee schedule payments by paying separately for injections provided on the same day as

another physician fee schedule service. We estimate that changes to our policy on injections and the changes to our drug administration payments taken together will increase physician spending by 0.2 percent.

We are also adjusting the SGR to account for OACT's assumptions about predicted physician behavior in response to the payment reductions. OACT assumes that reduced fees are likely to be met by a combination of an increase in volume and a shift in the mix or intensity of services furnished to Medicare beneficiaries so as to offset 30 percent of the payment reduction that would otherwise occur. Because OACT assumes that physicians will offset some of the loss in payments that will occur from changes in Medicare payments for drugs (as described earlier) and drug administration and the change in payment can be attributed to a change in law, we are increasing the SGR by 0.4 percent for this factor. (Discussion may change based on recent decisions.)

There are several other statutory provisions that are estimated to increase Medicare spending for physicians' services under the SGR. Section 413(a) of the MMA establishes a 5 percent increase in the physician fee schedule payment for services provided in physician scarcity areas. Section 413(b) improves the procedures for paying the 10 percent physician fee schedule bonus payment for services provided in health professional shortage areas. We

estimate that the provisions of section 413 will increase Medicare physician fee schedule payments by 0.1 percent.

Sections 611 through 613 of the MMA, respectively, provide Medicare coverage for an initial preventive physical examination, CV and diabetes screening tests. We estimate that new Medicare coverage for these preventive services will increase spending for physicians' services under the SGR by 0.3 percent. Taken together, we estimate that all of the statutory provisions for 2005 will increase Medicare spending for physicians' services by 0.5 percent.

Comment: We received comments concerned that we will underestimate the costs associated with the initial preventive physical examination. These comments suggested that we should account for "both spending due to use of the new or expanded benefit, as well as additional services triggered by implementation of the new benefit." We received other comments concerned that we will underestimate the cost of CV and diabetes screening tests because we will use the national coverage determination (NCD) process to decide if any additional tests may be eligible for coverage. The commenters have this concern because we do not adjust the SGR for NCDs.

Response: Our estimates of the costs of the initial preventive physical exam and the CV and diabetes screening tests account for utilization of other Medicare services (preventive and nonpreventive) that may result from coverage of the new preventive services. We also note that our

current estimates of the initial preventive examination and CV and diabetes screening tests are based only on our projections without any data on actual use of the benefits. The statute requires us to revise our current estimate of the 2005 SGR no later than November 1, 2005 and to make a final revision to our estimate no later than November 1, 2006. At the time we make the final revision to the 2005 SGR, we will have complete data on use of the new preventive services that will enable us to more accurately reflect these costs in the SGR.

With respect to the comments about use of the NCD process to establish additional CV and diabetes screening tests that will be eligible for Medicare coverage, the regulation lists the common types of tests that are currently used to screen patients for these conditions. Our adjustment to the SGR will cover all of the costs associated with these new Medicare covered screening tests. However, if we use the NCD process to cover additional tests, we will consider this issue further.

## 2. Detail on the 2004 SGR

A more detailed discussion of our revised estimates of the four elements of the 2004 SGR follows.

### **Factor 1--Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for 2004**

This factor was calculated as a weighted average of the 2004 fee increases that apply for the different types

of services included in the definition of physicians' services for the SGR.

We estimate that services paid using the physician fee schedule account for approximately 83.7 percent of total allowed charges included in the SGR in 2004. These services were updated using the 2004 MEI of 2.9 percent. We estimate that diagnostic laboratory tests represent approximately 7.1 percent of total allowed charges included in the SGR in 2004. Medicare payments for these tests are updated by the CPI-U. However, section 629 of the MMA specifies that diagnostic laboratory services will receive an update of 0.0 percent from 2004 through 2008. We estimate that drugs represent 9.2 percent of Medicare allowed charges included in the SGR in 2004. Historically, Medicare paid for drugs under section 1842(o) of the Act at 95 percent of average wholesale price (AWP). However, with some exceptions, sections 303 and 304 of the MMA generally require Medicare to pay for drugs at 85 percent of the AWP determined as of April 1, 2003 or a specified percentage of AWP based on studies by the Government Accountability Office and the Office of the Inspector General in 2004. (We implemented section 303 and 304 of the MMA in an interim final rule published in the **Federal Register** on January 7, 2004 (see 69 FR 1086). Taking sections 303 and



304 of the MMA into account, we estimate a weighted average change in fees for drugs included in the SGR of -11.7 percent for 2004. Table 29 shows the weighted average of the MEI, laboratory and drug price changes for 2004.

**TABLE 29:**

	Weight	Update
Physician	0.837	2.9
Laboratory	0.071	0.0
Drugs	0.092	-11.7
Weighted Average	1.000	1.4

After taking into account the elements described in Table 29, we estimate that the weighted-average increase in fees for physicians' services in 2004 under the SGR (before applying any legislative adjustments) will be 1.4 percent. Our November 7, 2003 estimate of this factor was 2.7 percent. The reduction from 2.7 percent to our current estimate of 1.4 percent is primarily due to application of the drug pricing changes required by sections 303 and 304 of the MMA.

**Factor 2--The Percentage Change in the Average Number of Part B Enrollees from 2003 to 2004**

OACT estimates that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in M+C plans) increased by 1.7 percent in 2004. Table 30 illustrates how we determined this figure.

**TABLE 30:**

	2003	2004
Overall	38.465 million	39.041 million
Medicare+Choice	4.655 million	4.671 million
Net	33.810 million	34.370 million
Percent Increase		1.7 percent

OACT's estimate of the 1.7 percent change in the number of fee-for-service enrollees, net of M+C enrollment for 2004 compared to 2003, is the same as our original estimate published in the November 7, 2003 final rule (68 FR 63250). While our current projection based on data from 8 months of 2004 is the same as our original estimate when we had no data, it is still possible that our final estimate of this figure will be different once we have complete information on 2004 fee-for-service enrollment.

**Factor 3--Estimated Real Gross Domestic Product Per Capita Growth in 2004**

We estimate that the growth in real per capita GDP will be 2.2 percent for 2004. Our past experience indicates that there have also been large differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is likely that this figure will change further as complete actual information on 2004 economic performance becomes available to us in 2005.

**Factor 4--Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in 2004 Compared With 2003**

There are four statutory provisions that are increasing 2004 Medicare spending relative to 2003. Section 412 of the MMA established a floor of 1.0 on adjustments to the physician work relative value unit for the geographic practice cost index (GPCI) for the years 2004 through 2006. Section 602 of the MMA increases the GPICs for work, practice expense, and malpractice in Alaska to 1.67. Because these provisions increase the work GPICs that are below 1.0 to 1.0 and, for services in Alaska, we estimate that sections 412 and 602 of the MMA are increasing 2004 Medicare spending included in the SGR by 0.6 percent. Sections 303 and 304 of the MMA increased Medicare's payments for drug administration in 2004. It further exempted the increases in payment from the budget neutrality provisions of section 1848(c)(2) of the Act. We estimate the section 303 and 304 provisions will increase spending for physicians' services by 0.8 percent in 2004. Taken together, we estimate that statutory provisions are increasing 2004 spending for physicians' services by 1.5 percent (after accounting for rounding).

3. Detail on the 2003 SGR

A more detailed discussion of our revised estimates of the four elements of the 2003 SGR follows.

**Factor 1--Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for 2003**

This factor was calculated as a weighted average of the 2003 fee increases that apply for the different types of services included in the definition of physicians' services for the SGR.

Services paid using the physician fee schedule accounted for approximately 83.0 percent of total Medicare allowed charges included in the SGR for 2003 and are updated using the MEI. The MEI for 2003 was 3.0 percent. Diagnostic laboratory tests represent approximately 7.2 percent of total Medicare allowed charges included in the SGR and are updated by the CPI-U. The CPI-U applied to payments for laboratory services for 2003 was 1.1 percent. Drugs represented approximately 9.8 percent of total Medicare allowed charges included in the SGR for 2003. According to section 1842(o) of the Act, Medicare pays for drugs based on 95 percent of AWP. Using wholesale pricing information and Medicare utilization for drugs included in the SGR, we estimate a weighted average fee increase for drugs of 1.9 percent for 2003. Table 31 shows the weighted

average of the MEI, laboratory, and drug price increases for 2003.

**TABLE 31:**

	Weight	Update
Physician	0.830	3.0
Laboratory	0.072	1.1
Drugs	0.098	1.9
Weighted Average	1.000	2.8

After taking into account the elements described in Table 31, we estimate that the weighted-average increase in fees for physicians' services in 2003 under the SGR (before applying any legislative adjustments) was 2.8 percent.

**Factor 2--The Percentage Change in the Average Number of Part B Enrollees from 2002 to 2003**

We estimate the increase in the number of fee-for-service enrollees (excluding beneficiaries enrolled in M+C plans) from 2002 to 2003 was 2.3 percent. Our calculation of this factor is based on complete data from 2003.

Table 32 illustrates the calculation of this factor.

**TABLE 32:**

	2002	2003
Overall	38.049 million	38.465 million
Medicare+Choice	5.005 million	4.655 million
Net	33.044 million	33.810 million
Percent Increase		2.3 percent

**Factor 3--Estimated Real Gross Domestic Product Per Capita Growth in 2003**

We estimate that the growth in real per capita GDP was 2.0 percent in 2003. This figure is a final one based on complete data for 2003.

**Factor 4--Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in 2003 Compared With 2002**

There are no statutory or regulatory changes that affect Medicare expenditures for services included in the SGR in 2003.

**X. Anesthesia and Physician Fee Schedule Conversion**

**Factors (CF) for Calendar Year 2005**

The 2005 physician fee schedule CF will be \$37.8975. The 2005 national average anesthesia conversion factor is \$17.7594.

Physician Fee Schedule Conversion Factor

Under section 1848(d)(1)(A) of the Act, the physician fee schedule CF is equal to the CF for the previous year multiplied by the update determined under section 1848(d)(4) of the Act. Using this formula would result in a 3.3 percent reduction to the physician fee schedule CF for 2005. However, section 601 of the MMA amended section 1848(d) of the Act to specify that the update to the single CF for 2004 and 2005 will not be less than 1.5 percent. Because the statutory formula will yield a 3.3 percent

reduction to the 2005 physician fee schedule CF and the amendments to the statute indicate that the update for 2005 cannot be less than 1.5 percent, we are increasing the physician fee schedule conversion factor by 1.5 percent.

We illustrate the calculation for the 2005 physician fee schedule CF in Table 33 below.

**TABLE 33:**

2004 Conversion Factor	\$37.3374
2005 Update	1.5 percent (1.015)
2005 Conversion Factor	\$37.8975

- Anesthesia Fee Schedule Conversion Factor

Anesthesia services do not have RVUs like other physician fee schedule services. Therefore, we account for any necessary RVU adjustments through an adjustment to the anesthesia fee schedule CF. The only adjustment we are applying to the anesthesia fee schedule CF for 2005 is the physician fee schedule update. We used the following figures to determine the anesthesia fee schedule CF (see Table 34).

**TABLE 34:**

2004 Anesthesia Conversion Factor	\$17.4969
2005 Update	1.5 percent (1.0150)
2005 Anesthesia Conversion Factor	\$17.7594





**XI. Telehealth Originating Site Facility Fee Payment****Amount Update**

Section 1834(m) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001 through December 31 2002, at \$20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2005 is 3.1 percent.

Therefore, for CY 2005, the payment amount for HCPCS code "Q3014, telehealth originating site facility fee" is 80 percent of the lesser of the actual charge or \$21.86. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in table 35.

**TABLE 35:**

<b>Facility Fee</b>	<b>MEI Increase</b>	<b>Period</b>
\$20.00	N/A	10/01/2001 – 12/31/2002
\$20.60	3.0%	01/01/2003 – 12/31/2003
\$21.20	2.9%	01/01/2004 – 12/31/2004
\$21.86	3.1%	01/01/2005 – 12/31/2005

**XII. Provisions of the Final Rule**

The provisions of this final rule restate the provisions of the August 2004 proposed rule, except as noted elsewhere in the preamble.

**XIII. Waiver of Proposed Rulemaking**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that providing a notice and comment procedure with regard to the RNHCI home benefit would be contrary to the public interest. The RNHCI home benefit provisions were added by the Congress to get a RNHCI benefit to those beneficiaries who are confined to the home. We believe that the Congress intended to provide the benefit to the homebound RNHCI beneficiaries as means of providing a similar home option as is offered to the

general Medicare population. However, this expanded benefit is, by statute, a time limited benefit. Any delay in implementation could prevent beneficiaries from utilizing this expanded benefit at all or could seriously impinge on the amount of time they can use the benefit. Therefore, we find good cause to waive notice and comment procedures as contrary to the public interest with regard to the RNHCI home benefit. We are, however, providing a 60-day period for public comment.

**XIV. Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

**\$403.766 Requirements for Coverage/Payment of Home Services**

In summary, \$403.766 states the RNHCI provider must submit a written letter of intent to us if they choose to participate in offering the home service benefit.

The burden associated with this requirement is the time and effort of the RNHCI provider to prepare and submit a letter of intention. It is estimated that this two-sentence letter should take no longer than 15 minutes to prepare and submit. There are currently 16 RNHCI providers and, if all elected to participate, it would result in a one-time burden of 4 hours.

We have submitted a copy of this final rule with comment to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

§410.16 Initial preventive physical examination:

Conditions for limitations on coverage

In summary, §410.16 requires the furnishing of education, counseling and referral services as part of an initial preventive physical examination, a written plan for obtaining the appropriate screening and other preventive services which are also covered as separate Medicare B Part services.

The burden associated with this requirement is the time required of the physician or practitioner to provide beneficiaries with education, counseling, and referral services and to develop and provide a written plan for obtaining screening and other preventive services.

While these requirements are subject to the PRA; we believe the burden associated with these requirements to be usual and customary business practice; therefore, the burden for this collection requirement is exempt under 5 CFR 1320.3(b) (2) & (3).

§411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

In summary, §411.404 requires that written notice must be given to a beneficiary, or someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

Although this section is subject to the PRA, the burden associated with this requirement is currently captured and accounted for in two currently approved information collections under OMB numbers 0938-0566 and 0938-0781.

§418.205 Special requirements for hospice pre-election evaluations and counseling services.

In summary, §418.205 states that written documentation is required and must be maintained for referral requests and services furnished.

While these information collection requirements are subject to the PRA, the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services

Office of Strategic Operations and Regulatory Affairs,  
Attn: Melissa Musotto (CMS-1429-FC)

Room C5-13-28, 7500 Security Boulevard,  
Baltimore, MD 21244-1850;

and

Office of Information and Regulatory Affairs,

Office of Management and Budget,  
Room 10235, New Executive Office Building,  
Washington, DC 20503,

Attn: Christopher Martin, CMS Desk Officer  
(CMS-1429-P), [Christopher.Martin@omb.eop.gov](mailto:Christopher.Martin@omb.eop.gov) FAX  
(202) 395-6974.

#### **XV. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and,

when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

#### **XVI. Regulatory Impact Analysis**

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub.L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub.L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for final rules with economically significant effects (that is, a final rule that would have an annual effect on the economy of \$100 million or more in any 1 year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities).



As indicated in more detail below, we expect that the physician fee schedule provisions included in this final rule will redistribute more than \$100 million in 1 year. We also anticipate that the combined effect of several provisions of the MMA implemented in this final rule will increase spending by more than \$100 million. Other MMA provisions implemented in this final rule are expected to reduce spending by more than \$100 million. We are considering this final rule to be economically significant because its provisions are expected to result in an increase, decrease or aggregate redistribution of Medicare spending that will exceed \$100 million. Therefore, this final rule is a major rule and we have prepared a regulatory impact analysis.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this final rule would have minimal impact on small hospitals located in rural areas. Of 517 hospital-based ESRD facilities located in rural areas, only 40 are affiliated with hospitals with fewer than 100 beds.

For purposes of the RFA, physicians, nonphysician practitioners, and suppliers are considered small businesses if they generate revenues of \$6 million or less. Approximately 95 percent of physicians are considered to be small entities. There are about 875,000 physicians, other practitioners and medical suppliers that receive Medicare payment under the physician fee schedule. There are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. As noted previously in this final rule and described further below, we are implementing significant changes to the payments for drugs.) The 20,000 physicians that receive payments for

drugs are generally concentrated in the specialties of oncology, urology, rheumatology and infectious disease. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent in urology.

For purposes of the RFA, approximately 98 percent of suppliers of durable medical equipment (DME) and prosthetic devices are considered small businesses according to the Small Business Administration's (SBA) size standards. We estimate that 106,000 entities bill Medicare for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) each year. Total annual estimated Medicare revenues for DME suppliers exceed approximately \$4.0 billion. Of this amount, approximately \$1.6 billion are for DME drugs. These suppliers will be affected by the payment changes being made in this final rule for drugs.

In addition, most ESRD facilities are considered small entities, either based on nonprofit status, or by having revenues of \$29 million or less in any year. We consider a substantial number of entities to be affected if the rule is estimated to impact more than 5 percent of the total number of small entities. Based on our analysis of the 785 nonprofit ESRD facilities considered small entities in accordance with the above definitions, we estimate that the combined impact of the changes to payment for renal

dialysis services included in this rule would have a 1.6 percent increase in payments relative to current composite rate payments.

The analysis and discussion provided in this section, as well as elsewhere in this final rule, complies with the RFA requirements. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. Medicare beneficiaries are considered to be part of the private sector for this purpose. The net impact of the provisions of this rule, including those related to the MMA, are estimated to result in a savings to beneficiaries of nearly \$485 million for FY 2005. However, we note that this savings figure compares FY 2005 beneficiary costs occurring as a result of provisions of this final rule to FY 2005 estimated beneficiary costs in the absence of final rule implementation (that is, the savings figure compare beneficiary costs with implementation of the ASP drug payment provisions to continuing the AWP drug payment methodology). The specific effects of the provisions being implemented in this final rule are explained in greater detail below.

We have examined this final rule in accordance with Executive Order 13132 and have determined that this regulation would not have any significant impact on the rights, roles, or responsibilities of State, local, or tribal governments.

We have prepared the following analysis, which, together with the information provided in the rest of this preamble, meets all assessment requirements. It explains the rationale for and purposes of the rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we use to minimize the burden on small entities. As indicated elsewhere in this final rule, we are refining resource-based practice expense RVUs and making a variety of other changes to our regulations, payments, or payment policy to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. We are also implementing several changes resulting from the MMA, including changes to Medicare payment rates for outpatient drugs, changes to the payment for renal dialysis services, creating new preventive health care benefits and creating incentive payment program improvements for physician scarcity.

We are providing information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

A. Resource-Based Practice Expense and Malpractice  
Relative Value Units

Under section 1848(c)(2) of the Act, adjustments to RVUs may not cause the amount of expenditures to differ by more than \$20 million from the amount of expenditures that would have resulted without such adjustments. We are implementing several changes that would result in a change in expenditures that would exceed \$20 million if we made no offsetting adjustments to either the conversion factor or RVUs.

With respect to practice expense RVUs, our policy has been to meet the budget-neutrality requirements in the statute by incorporating a rescaling adjustment in the practice expense methodologies. That is, we estimate the aggregate number of practice expense RVUs that will be paid under current and revised policy in CY 2005. We apply a uniform adjustment factor to make the aggregate number of revised practice expense RVUs equal the number estimated

that would be paid under current policy. While we are continuing to apply this policy for general changes in coding and RVUs, we are increasing aggregate physician fee schedule payments to account for the higher payments for drug administration. These increases in payment are being made under the authority of section 1848(c)(2)(J) of the Act that exempts the changes in payments for drug administration from the budget neutrality requirements of section 1848(c)(2)(B)(iv) of the Act.

Table 36 shows the specialty level impact on payment of the practice expense and malpractice RVU changes being implemented for CY 2005. Our estimates of changes in Medicare revenues for physician fee schedule services compare payment rates for 2005 with payment rates for 2004 using 2003 Medicare utilization for both years. We are using 2003 Medicare claims processed and paid through June 30, 2004, that we estimate are 98.5 percent complete, and have adjusted the figures to reflect a full year of data. Thus, because we are using a single year of utilization, the estimated changes in revenues reflect payment changes only between 2004 and 2005. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown

here. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the physician fee schedule. For instance, independent laboratories receive approximately 80 percent of their Medicare revenues from clinical laboratory services that are not paid under the physician fee schedule. The table shows only the payment impact on physician fee schedule services.

The column labeled "NPRM Impacts" shows the effect of the changes in payment attributable to practice expense and malpractice RVUs from the proposed rule. (See 69 FR 47556 through 47559 for a complete description of the payment changes shown in this column). We have also made some additional changes to the practice expense and malpractice RVUs since the proposed rule in response to comments and additional information that became available to us during the comment period. The additional changes in payment based on further refinements of the practice expense RVUs



generally have no specialty level impact. The 1 percent increase in payment for vascular surgery shown in the practice expense refinements column is attributed to substitution of a vascular ultrasound room for a general ultrasound room in the equipment resources for CPT code 93880. Similarly, the increase in practice expense RVUs for diagnostic testing facilities is also attributable to the increase in payment for 93880 and 93925 due to the substitution of a vascular ultrasound room for a general ultrasound room in the equipment resources.

The column labeled "Additional Malpractice RVU Refinements" show the additional impact of changes in the malpractice expense RVUs since the proposed rule on total payment for physician fee schedule services. As explained earlier, we are making several changes to malpractice RVUs that will change the impacts we illustrated in the proposed rule. We are removing assistants-at-surgery from the Medicare utilization that goes into determining the malpractice RVUs. Relative to the proposed rule, this change will increase total payments to neurosurgeons by nearly 1 percent. We also increased the ISO risk classification for the all physician crosswalk used for podiatry increasing their payments by 1 percent relative to the proposed rule. Several specialty groups, including

dermatology commented that the major surgery risk factor should not be used for the dermatology codes. Relative to the proposed rule, payments to dermatologists will decrease by approximately 1 percent as a result of this change. The changes also increase payment to the specialty of allergy/immunology by nearly 1 percent relative to the proposed rule. This increase occurs because we are setting a minimum value of 0.01 malpractice RVUs. In the proposed rule, we did show malpractice RVUs in Addendum B if the rounded RVU equaled 0.0.

The column labeled "Immunizations/Injections" shows the impact of making separate payment for injections provided on the same day as another physician fee schedule service and the increase in payment for immunizations. These changes generally benefit those specialties that provide injections and immunizations in their offices. The provision is estimated to increase payment by 2 percent to family practice and by 1 percent to general practice, geriatrics, internal medicine and pediatrics. The column labeled "Total" shows the combined percentage change in payments resulting from the practice expense and malpractice RVU changes including those that were described in the proposed rule and the additional changes we are making in this final rule.

As explained in the proposed rule, the practice expense refinements will reduce payments to audiologists by approximately 4 percent. Virtually all of the reduction in payment is due to the refinement of procedure code 92547. We accepted the PEAC recommendation to reduce the clinical staff time of the audiologist involved in this service from 71 minutes to 1 minute. The refinement of clinical staff and equipment resulted in a reduction from 1.15 to 0.08 practice expense RVUs producing the 4 percent reduction in payments shown in table 37. However, this impact assumes no change in how frequently these services are performed. While we received comments suggesting that the code was valued based on only one occurrence of the service, the commenter asserted that it is typically performed more than once per day. Currently, CPT allows it only to be billed once per day. If CPT were to change its policy and the service was billed more frequently, the impact shown in table 37 would be less than shown here.

In the proposed rule, we estimated that payments to vascular surgeons would increase by 3 percent as a result of the repricing of medical equipment used in performing noninvasive vascular diagnostic tests. As indicated above, the total increase in payments including the additional refinements we made to equipment will make the total

increase in payment from RVU changes equal to 4 percent. We originally estimated that payments to interventional radiology would increase by 2 percent due practice expense refinements and the establishment of nonfacility pricing for procedure codes 35470 to 35476. Due to additional practice expense RVU refinements, we are now estimating that the total increase in payments will be 3 percent. We are estimating slightly less than a 3.5 percent increase in payment to oral and maxillofacial surgeons from the refinement of medical supplies for procedure codes 21210 and 21215. The estimated impact for this specialty is slightly less than we were estimating for the proposed rule. As we indicated in the proposed rule, the 1 percent decrease in payment to nurse practitioners and geriatricians is attributed to the refinement of the nonfacility practice expense RVUs for nursing facility visits (procedure codes 99301 through 99316). These impacts are unchanged from the proposed rule.

As we indicated in the proposed rule, the increases for pathology and independent laboratories result from use of a practice expense survey provided by the College of American Pathology (CAP). The increases in the final rule are similar to the figures we estimated for the proposed rule. We further note that independent laboratories receive

approximately 20 percent of their total Medicare revenues from physician fee schedule services. The remaining 80 percent of their Medicare revenues are from clinical diagnostic laboratory services that will be unchanged by use of the CAP survey data. Thus, total Medicare revenues to independent laboratories as a result of using the CAP survey will increase by slightly more than 1 percent (or 20 percent of the 6 percent increase in physician fee schedule revenues). There will be little or no impact on all other specialties from use of the CAP survey.

**TABLE 36:**  
Impact of Practice Expense and Malpractice RVU Changes  
on Total Medicare Allowed Charges  
by Physician, Practitioner and Supplier Subcategory

Specialty	Medicare Allowed Charges (\$ in Millions)	NPRM Impacts	Additional Practice Expense Refinements	Additional Malpractice RVU Refinements	Injections Immunizations	Total
Physicians:						
ALLERGY/IMMUNOLOGY	\$ 161	-2%	0%	1%	0%	-1%
ANESTHESIOLOGY	\$ 1,422	0%	0%	0%	0%	0%
CARDIAC SURGERY	\$ 359	0%	0%	1%	0%	1%
CARDIOLOGY	\$ 6,579	0%	0%	0%	0%	0%
COLON AND RECTAL SURGERY	\$ 110	1%	0%	0%	0%	1%
CRITICAL CARE	\$ 130	0%	0%	0%	0%	0%
DERMATOLOGY	\$ 1,864	1%	0%	-1%	0%	0%
EMERGENCY MEDICINE	\$ 1,687	0%	0%	0%	0%	0%
ENDOCRINOLOGY	\$ 279	0%	0%	0%	0%	0%
FAMILY PRACTICE	\$ 4,456	0%	0%	0%	2%	1%
GASTROENTEROLOGY	\$ 1,634	0%	0%	0%	0%	0%
GENERAL PRACTICE	\$ 1,003	0%	0%	0%	1%	1%
GENERAL SURGERY	\$ 2,264	1%	0%	0%	0%	1%
GERIATRICS	\$ 116	-1%	0%	0%	1%	0%
HAND SURGERY	\$ 57	0%	0%	0%	0%	0%
INTERNAL MEDICINE	\$ 8,784	0%	0%	0%	1%	1%
INTERVENTIONAL RADIOLOGY	\$ 191	2%	1%	0%	0%	3%
NEPHROLOGY	\$ 747	1%	0%	0%	0%	1%

NEUROLOGY	\$	1,197	0%	0%	0%	0%	0%
NEUROSURGERY	\$	492	-1%	0%	1%	0%	0%
NUCLEAR MEDICINE	\$	85	0%	0%	0%	0%	0%
OPHTHALMOLOGY	\$	4,566	-1%	0%	0%	0%	-1%
ORTHOPEDIC SURGERY	\$	2,903	0%	0%	0%	0%	0%
OTOLARNGOLOGY	\$	814	0%	0%	0%	0%	0%
PATHOLOGY	\$	846	2%	0%	0%	0%	2%
PEDIATRICS	\$	60	-1%	0%	0%	1%	0%
PHYSICAL MEDICINE	\$	680	0%	0%	0%	0%	0%
PLASTIC SURGERY	\$	283	1%	0%	0%	0%	0%
PSYCHIATRY	\$	1,109	0%	0%	0%	0%	0%
PULMONARY DISEASE	\$	1,446	0%	0%	0%	0%	0%
RADIATION ONCOLOGY	\$	1,163	0%	0%	0%	0%	0%
RADIOLOGY	\$	4,693	0%	0%	0%	0%	0%
THORACIC SURGERY	\$	464	0%	0%	0%	0%	1%
VASCULAR SURGERY	\$	487	3%	1%	0%	0%	4%
Practitioners:							
AUDIOLOGIST	\$	28	-4%	0%	0%	0%	-4%
CHIROPRACTOR	\$	658	-1%	0%	0%	0%	-1%
CLINICAL PSYCHOLOGIST	\$	494	0%	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	\$	317	0%	0%	0%	0%	0%
NURSE ANESTHETIST	\$	485	0%	0%	0%	0%	0%
NURSE PRACTITIONER	\$	556	-1%	0%	0%	0%	-1%
OPTOMETRY	\$	666	0%	0%	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	\$	36	4%	0%	0%	0%	4%
PHYSICAL/OCCUPATIONAL THERAPY	\$	998	-2%	0%	0%	0%	-2%
PHYSICIAN ASSISTANT	\$	414	0%	0%	0%	0%	0%
PODIATRY	\$	1,392	-1%	0%	1%	0%	1%
Suppliers:							
DIAGNOSTIC TESTING FACILITY	\$	879	1%	1%	0%	0%	2%

INDEPENDENT LABORATORY	\$	452	6%	0%	0%	0%	6%
PORTABLE X-RAY SUPPLIER	\$	92	0%	0%	0%	0%	0%
Other:							
ALL OTHER	\$	93	2%	0%	0%	0%	1%
ALL PHYSICIAN FEE SCHEDULE	\$	65,803	0%	0%	0%	0%	0%



As discussed in section II.C of this rule, we are making changes to the malpractice RVUs based on more current malpractice premium data. As anticipated from past revisions to the malpractice RVUs, use of more current malpractice premium data results in minimal impacts on the specialty level payments. The table below shows the impact on total physician fee schedule revenues from the changes to the malpractice RVUs, the additional changes resulting from this final rule and the total impact. See Table 37, "Impact of Malpractice RVU Changes Proposed Rule and Final Rule", for a breakdown of the impacts of these revisions on individual specialties. As described above, policies we are adopting in this final rule will increase payments for allergy, neurosurgery and podiatry and decrease payments for dermatology relative to the proposed rule. These changes will also slightly increase payments to cardiac surgery, orthopedic surgery, thoracic surgery and result in a smaller increase in payment for vascular surgery.

**Table 37:**  
Impact Malpractice RVU Changes  
Proposed Rule and Final Rule

Medicare Allowed Charges	NPRM	Change due to	% Change in Total Payment from MP RVU

Specialty	(\$ in Millions)		Impacts	Final Rule	Changes
Physicians:					
ALLERGY/IMMUNOLOGY	\$	161	-0.9%	0.8%	-0.1%
ANESTHESIOLOGY	\$	1,422	0.0%	0.0%	0.1%
CARDIAC SURGERY	\$	359	-0.1%	0.5%	0.4%
CARDIOLOGY	\$	6,579	0.0%	-0.2%	-0.1%
COLON AND RECTAL SURGERY	\$	110	0.6%	0.1%	0.7%
CRITICAL CARE	\$	130	0.5%	-0.2%	0.3%
DERMATOLOGY	\$	1,864	0.7%	-0.9%	-0.2%
EMERGENCY MEDICINE	\$	1,687	0.0%	0.0%	0.0%
ENDOCRINOLOGY	\$	279	0.1%	-0.1%	0.0%
FAMILY PRACTICE	\$	4,456	0.0%	-0.1%	-0.1%
GASTROENTEROLOGY	\$	1,634	0.5%	0.1%	0.6%
GENERAL PRACTICE	\$	1,003	0.0%	-0.1%	-0.1%
GENERAL SURGERY	\$	2,264	0.5%	0.1%	0.6%
GERIATRICS	\$	116	0.3%	-0.2%	0.1%
HAND SURGERY	\$	57	-0.1%	0.1%	0.0%
HEMATOLOGY/ONCOLOGY	\$	1,747	0.0%	-0.1%	0.0%
INFECTIOUS DISEASE	\$	401	0.4%	-0.3%	0.1%
INTERNAL MEDICINE	\$	8,784	0.1%	-0.1%	0.0%
INTERVENTIONAL RADIOLOGY	\$	191	0.0%	0.0%	-0.1%
NEPHROLOGY	\$	747	0.1%	-0.1%	0.0%
NEUROLOGY	\$	1,197	0.2%	-0.1%	0.2%
NEUROSURGERY	\$	492	-0.6%	0.9%	0.3%
NUCLEAR MEDICINE	\$	85	-0.1%	0.0%	-0.1%
OBSTETRICS/GYNECOLOGY	\$	582	0.1%	0.0%	0.1%
OPHTHALMOLOGY	\$	4,566	0.0%	0.0%	0.0%
ORTHOPEDIC SURGERY	\$	2,903	-0.4%	0.4%	0.0%
OTOLARNGOLOGY	\$	814	-0.1%	0.0%	-0.1%
PATHOLOGY	\$	846	0.2%	0.0%	0.2%
PEDIATRICS	\$	60	-0.1%	0.0%	0.0%
PHYSICAL MEDICINE	\$	680	0.2%	-0.1%	0.1%
PLASTIC SURGERY	\$	283	0.6%	-0.5%	0.2%
PSYCHIATRY	\$	1,109	0.3%	-0.3%	0.0%
PULMONARY DISEASE	\$	1,446	0.3%	-0.2%	0.1%
RADIATION ONCOLOGY	\$	1,163	0.0%	0.0%	0.0%
RADIOLOGY	\$	4,693	-0.3%	0.0%	-0.3%
RHEUMATOLOGY	\$	412	-0.1%	0.0%	-0.1%
THORACIC SURGERY	\$	464	0.0%	0.4%	0.4%
UROLOGY	\$	1,695	0.0%	0.0%	-0.1%
VASCULAR SURGERY	\$	487	0.1%	0.2%	0.3%
Practitioners:					
AUDIOLOGIST	\$	28	-0.1%	0.1%	0.0%
CHIROPRACTOR	\$	658	-0.2%	0.0%	-0.2%
CLINICAL PSYCHOLOGIST	\$	494	-0.1%	0.0%	-0.1%
CLINICAL SOCIAL WORKER	\$	317	0.0%	0.0%	0.0%

NURSE ANESTHETIST	\$	485	0.0%	0.0%	0.0%
NURSE PRACTITIONER	\$	556	0.2%	-0.2%	0.1%
OPTOMETRY	\$	666	0.2%	-0.1%	0.1%
ORAL/MAXILLOFACIAL SURGERY	\$	36	0.6%	0.0%	0.6%
PHYSICAL/OCCUPATIONAL THERAPY	\$	998	-1.3%	-0.1%	-1.4%
PHYSICIAN ASSISTANT	\$	414	-0.1%	0.1%	0.1%
PODIATRY	\$	1,392	-0.4%	1.1%	0.7%

## Suppliers:

DIAGNOSTIC TESTING FACILITY	\$	879	0.0%	0.0%	0.0%
INDEPENDENT LABORATORY	\$	452	0.2%	0.0%	0.2%
PORTABLE X-RAY SUPPLIER	\$	92	-0.1%	0.0%	-0.1%

## Other:

ALL OTHER	\$	93	0.0%	0.0%	0.0%
ALL PHYSICIAN FEE SCHEDULE	\$	65,803	0.0%	0.0%	0.0%

Section 1848(d) and (f) of the Act requires the Secretary to set the physician fee schedule update under the sustainable growth rate (SGR) system. For 2004 and 2005, the statute requires the update to be no less than 1.5 percent. Using the statutory formula in section 1848(d)(4) will produce an update of less than 1.5 percent for 2005. Therefore, the physician fee schedule update for 2005 will be 1.5 percent. We have included a complete discussion of our methodology for calculating the SGR and physician fee schedule update in another section of this final rule. Table 38 below shows the estimated change in average payments by specialty resulting from changes to the practice expense and malpractice RVUs and the 2005 physician fee schedule update. (Please note that the table does not include the specialties of Hematology/Oncology,

Urology, Rheumatology, Obstetrics/Gynecology and Infectious Disease. There are unique issues related to drug administration that will further affect these specialties that are presented in detail below).

**Table 38:**

Impact of Practice Expense and Malpractice RVU Changes  
and Physician Fee Schedule Update on Total Medicare Allowed Charges  
by Physician, Practitioner and Supplier Subcategory

Specialty	Medicare Allowed Charges (\$ in Millions)	Practice Expense & Malpractice RVU Changes	Physician Fee Schedule Update	Total
Physicians:				
ALLERGY/IMMUNOLOGY	\$ 161	-1%	1.5%	1%
ANESTHESIOLOGY	\$ 1,422	0%	1.5%	2%
CARDIAC SURGERY	\$ 359	1%	1.5%	2%
CARDIOLOGY	\$ 6,579	0%	1.5%	2%
COLON AND RECTAL SURGERY	\$ 110	1%	1.5%	2%
CRITICAL CARE	\$ 130	0%	1.5%	2%
DERMATOLOGY	\$ 1,864	0%	1.5%	2%
EMERGENCY MEDICINE	\$ 1,687	0%	1.5%	2%
ENDOCRINOLOGY	\$ 279	0%	1.5%	2%
FAMILY PRACTICE	\$ 4,456	1%	1.5%	3%
GASTROENTEROLOGY	\$ 1,634	0%	1.5%	2%
GENERAL PRACTICE	\$ 1,003	1%	1.5%	2%
GENERAL SURGERY	\$ 2,264	1%	1.5%	2%
GERIATRICS	\$ 116	0%	1.5%	1%
HAND SURGERY	\$ 57	0%	1.5%	2%
INTERNAL MEDICINE	\$ 8,784	1%	1.5%	2%
INTERVENTIONAL RADIOLOGY	\$ 191	3%	1.5%	4%
NEPHROLOGY	\$ 747	1%	1.5%	2%
NEUROLOGY	\$ 1,197	0%	1.5%	2%
NEUROSURGERY	\$ 492	0%	1.5%	2%
NUCLEAR MEDICINE	\$ 85	0%	1.5%	2%
OPHTHALMOLOGY	\$ 4,566	-1%	1.5%	0%
ORTHOPEDIC SURGERY	\$ 2,903	0%	1.5%	1%
OTOLARNGOLOGY	\$ 814	0%	1.5%	2%
PATHOLOGY	\$ 846	2%	1.5%	4%

PEDIATRICS	\$	60	0%	1.5%	2%
PHYSICAL MEDICINE	\$	680	0%	1.5%	1%
PLASTIC SURGERY	\$	283	0%	1.5%	2%
PSYCHIATRY	\$	1,109	0%	1.5%	1%
PULMONARY DISEASE	\$	1,446	0%	1.5%	2%
RADIATION ONCOLOGY	\$	1,163	0%	1.5%	1%
RADIOLOGY	\$	4,693	0%	1.5%	2%
THORACIC SURGERY	\$	464	1%	1.5%	2%
VASCULAR SURGERY	\$	487	4%	1.5%	6%

## Practitioners:

AUDIOLOGIST	\$	28	-4%	1.5%	-2%
CHIROPRACTOR	\$	658	-1%	1.5%	1%
CLINICAL PSYCHOLOGIST	\$	494	0%	1.5%	1%
CLINICAL SOCIAL WORKER	\$	317	0%	1.5%	1%
NURSE ANESTHETIST	\$	485	0%	1.5%	2%
NURSE PRACTITIONER	\$	556	-1%	1.5%	0%
OPTOMETRY	\$	666	0%	1.5%	1%
ORAL/MAXILLOFACIAL SURGERY	\$	36	4%	1.5%	5%
PHYSICAL/OCCUPATIONAL THERAPY	\$	998	-2%	1.5%	-1%
PHYSICIAN ASSISTANT	\$	414	0%	1.5%	1%
PODIATRY	\$	1,392	1%	1.5%	2%

## Suppliers:

DIAGNOSTIC TESTING FACILITY	\$	879	2%	1.5%	3%
INDEPENDENT LABORATORY	\$	452	6%	1.5%	8%
PORTABLE X-RAY SUPPLIER	\$	92	0%	1.5%	1%

## Other:

ALL OTHER	\$	93	1%	1.5%	3%
ALL PHYSICIAN FEE SCHEDULE	\$	65,803	0%	1.5%	2%

Table 39 shows the impact on payments for selected high-volume procedures of all of the changes previously discussed. We selected these procedures because they are the most commonly provided procedures by a broad spectrum of physician specialties, or they are of particular interest to the physician community (for example, the initial preventive physical exam and EKG, codes G0344, G0366, G0367 and G0368). We note that the table below shows Medicare payment for the administration of an influenza vaccine, G0008, increasing from \$8.21 to \$18.57, or 126 percent. As explained earlier, we are establishing the same RVUs for the administration of a vaccine and an injection. For 2005 only, we will pay 3 percent more for the injection (\$19.13) because of the transitional adjustment required by section 303. After 2005, the payment for the administration of a vaccine and an injection will be the same. This table shows the combined impact of the change in the practice expense and malpractice RVUs and the estimated physician fee schedule update on total payment for the procedure. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility practice expense RVUs refer to §414.22(b)(5)(i). The table shows the estimated change in

payment rates based on provisions of this final rule and the estimated physician fee schedule update.

**Table 39:**  
Impact of Final Rule and Physician Fee Schedule Update  
on Medicare Payment for Selected Procedures

CODE	MOD	DESCRIPTION	Non-Facility			Facility		
			Old	New	% Change	Old	New	% Change
11721		Debride nail, 6 or more	\$ 38.08	\$ 38.66	2%	\$ 29.87	\$ 29.94	0%
17000		Destroy benign/premalignant lesion	\$ 60.49	\$ 61.39	1%	\$ 35.84	\$ 45.10	26%
27130		Total hip arthroplasty	N/A	N/A	N/A	\$1,370.28	\$1,383.26	1%
27244		Treat thigh fracture	N/A	N/A	N/A	\$1,115.27	\$1,128.97	1%
27447		Total knee arthroplasty	N/A	N/A	N/A	\$1,475.95	\$1,493.16	1%
33533		CABG, arterial, single	N/A	N/A	N/A	\$1,882.18	\$1,905.49	1%
35301		Rechanneling of artery	N/A	N/A	N/A	\$1,114.89	\$1,122.52	1%
43239		Upper GI endoscopy, biopsy	\$321.85	\$333.88	4%	\$ 159.43	\$ 162.58	2%
66821		After cataract laser surgery	\$240.83	\$248.23	3%	\$ 237.09	\$ 230.42	-3%
66984		Cataract surg w/iol, 1 stage	N/A	N/A	N/A	\$ 684.39	\$ 684.05	0%
67210		Treatment of retinal lesion	\$577.98	\$599.54	4%	\$ 560.81	\$ 573.39	2%
71010	26	Chest x-ray	\$ 9.33	\$ 9.47	2%	\$ 9.33	\$ 9.47	2%
76091	26	Mammogram, both breasts	\$ 44.80	\$ 45.10	1%	\$ 44.80	\$ 45.10	1%
76091		Mammogram, both breasts	\$ 96.33	\$ 97.40	1%	N/A	N/A	N/A
76092	26	Mammogram, screening	\$ 36.22	\$ 36.38	0%	\$ 36.22	\$ 36.38	0%
76092		Mammogram, screening	\$ 84.76	\$ 85.65	1%	N/A	N/A	N/A
77427		Radiation tx management, x5	\$169.14	\$172.05	2%	\$ 169.14	\$ 172.05	2%
78465	26	Heart image (3d), multiple	\$ 76.17	\$ 77.31	1%	\$ 76.17	\$ 77.31	1%
88305	26	Tissue exam by pathologist	\$ 41.44	\$ 42.07	2%	\$ 41.44	\$ 42.07	2%
90801		Psy dx interview	\$150.84	\$153.48	2%	\$ 142.26	\$ 144.39	1%
90862		Medication management	\$ 51.15	\$ 52.30	2%	\$ 48.17	\$ 49.27	2%
90935		Hemodialysis, one evaluation	N/A	N/A	N/A	\$ 72.06	\$ 73.14	1%
92012		Eye exam established patient	\$ 63.47	\$ 65.18	3%	\$ 36.22	\$ 37.14	3%
92014		Eye exam & treatment	\$ 93.34	\$ 96.26	3%	\$ 58.99	\$ 60.64	3%
92980		Insert intracoronary stent	N/A	N/A	N/A	\$ 812.09	\$ 830.33	2%
93000		Electrocardiogram, complete	\$ 26.51	\$ 27.29	3%	N/A	N/A	N/A
93010		Electrocardiogram report	\$ 8.96	\$ 9.10	2%	\$ 8.96	\$ 9.10	2%
93015		Cardiovascular stress test	\$106.78	\$108.39	2%	N/A	N/A	N/A
93307	26	Echo exam of heart	\$ 49.29	\$ 49.27	0%	\$ 49.29	\$ 49.27	0%
93510	26	Left heart catheterization	\$252.77	\$257.32	2%	\$ 252.77	\$ 257.32	2%
98941		Chiropractic manipulation	\$ 36.22	\$ 36.76	1%	\$ 31.74	\$ 31.83	0%
99203		Office/outpatient visit, new	\$ 95.96	\$ 97.02	1%	\$ 71.69	\$ 72.38	1%
99213		Office/outpatient visit, established	\$ 52.65	\$ 52.68	0%	\$ 35.47	\$ 35.62	0%
99214		Office/outpatient visit, established	\$ 82.14	\$ 82.62	1%	\$ 57.87	\$ 59.12	2%

99222	Initial hospital care	N/A	N/A	N/A	\$ 111.27	\$ 112.93	1%
99223	Initial hospital care	N/A	N/A	N/A	\$ 154.95	\$ 157.27	1%
99232	Subsequent hospital care	N/A	N/A	N/A	\$ 54.89	\$ 56.09	2%
99233	Subsequent hospital care	N/A	N/A	N/A	\$ 78.04	\$ 79.58	2%
99236	Observ/hosp same date	N/A	N/A	N/A	\$ 226.26	\$ 223.60	-1%
99239	Hospital discharge day	N/A	N/A	N/A	\$ 95.21	\$ 96.64	2%
99243	Office consultation	\$120.60	\$122.79	2%	\$ 92.22	\$ 93.99	2%
99244	Office consultation	\$170.63	\$172.81	1%	\$ 136.65	\$ 138.70	2%
99253	Initial inpatient consult	N/A	N/A	N/A	\$ 97.45	\$ 98.91	1%
99254	Initial inpatient consult	N/A	N/A	N/A	\$ 140.39	\$ 142.12	1%
99261	Follow-up inpatient consult	N/A	N/A	N/A	\$ 22.40	\$ 22.36	0%
99262	Follow-up inpatient consult	N/A	N/A	N/A	\$ 44.80	\$ 45.48	2%
99263	Follow-up inpatient consult	N/A	N/A	N/A	\$ 66.09	\$ 67.46	2%
99283	Emergency dept visit	N/A	N/A	N/A	\$ 61.61	\$ 62.15	1%
99284	Emergency dept visit	N/A	N/A	N/A	\$ 95.58	\$ 97.02	2%
99291	Critical care, first hour	\$242.69	\$256.57	6%	\$ 203.12	\$ 207.68	2%
99292	Critical care, add'l 30 min	\$107.91	\$114.07	6%	\$ 101.56	\$ 104.22	3%
99302	Nursing facility care	\$ 97.82	\$ 87.92	-10%	\$ 82.52	\$ 87.92	7%
99303	Nursing facility care	\$120.97	\$108.39	-10%	\$ 102.68	\$ 108.39	6%
99312	Nursing fac care, subseq	\$ 63.10	\$ 56.85	-10%	\$ 51.53	\$ 56.85	10%
99313	Nursing fac care, subseq	\$ 86.25	\$ 79.96	-7%	\$ 72.43	\$ 79.96	10%
99348	Home visit, est patient	\$ 75.42	\$ 72.01	-5%	N/A	\$ 68.22	N/A
99350	Home visit, est patient	\$169.89	\$165.23	-3%	N/A	\$ 160.31	N/A
G0008	Admin influenza virus vac	\$ 8.21	\$ 18.57	126%	N/A	N/A	N/A
G0317	ESRD relsvc 4+/mo;20+yr	\$303.18	\$307.73	2%	\$ 303.18	\$ 307.73	2%
G0344	Initial preventive exam	N/A	\$ 97.40	N/A	N/A	\$ 72.76	N/A
G0366	EKG for initial prevent exam	N/A	\$ 27.29	N/A	N/A	N/A	N/A
G0367	EKG tracing for initial prev	N/A	\$ 17.81	N/A	N/A	N/A	N/A
G0368	EKG interpret & report preve	N/A	\$ 9.10	N/A	N/A	\$ 9.10	N/A

Section 303(a)(1) of the MMA amended section 1848(c)(2) of the Act to require increased work and practice expense RVUs for drug administration services. Section 303(a)(4) of the MMA required an additional temporary increase in payment to specific drug administration services of 32 percent for 2004 and 3 percent for 2005. Table 41 shows the payment amounts for selected high-volume drug administration CPT codes from 2002 to 2006 including the



effect of the transition adjustment of 32 percent required for 2004 and 3 percent for 2005. Because we may also pay an additional \$130 per encounter under the national demonstration project in 2005, we are also including the effect of this additional payment where applicable. Table 42 that follows table 41 shows the payment amount for 2004 and 2005 without the additional transition adjustment required by the MMA and national demonstration payment amount. By showing the payment amounts without the transition and demonstration, we can isolate the permanent change in the payment amounts that is occurring as a result of the MMA, the CPT/RUC review and the physician fee schedule update. The amounts shown in the table include the effect of the 1.5 percent update for 2004 and 2005. As described above, the CPT and RUC have recommended changes to the coding and payment for drug administration services. The CPT/RUC review was undertaken at our request under the authority of section 1848(c)(2)(J) of the Act that requires the Secretary to promptly evaluate existing drug administration codes using existing processes. While this review was completed expeditiously, CPT did not have sufficient time to adopt the coding recommendations into the 2005 version of CPT. For this reason, we are

establishing new G-codes for 2005 that correspond with the new CPT codes that will become active in 2006.

Tables 41 and 42 show the payment amounts for the most frequently performed drug administration services from 2002 to 2004 under the CPT codes and payment for the comparable service in 2005 using the G code. For instance, a therapeutic injection was previously billed under the CPT code 90782. This same service will now be billed using HCPCS code G0351. As a result of the RUC review, our acceptance of their recommendations for refinements to the practice expense inputs, our policy of pooling the utilization for the injection with vaccine administration, and the required reduction in the transitional adjustment, payment for this service will be reduced from \$24.64 in 2004 to \$19.13 in 2005. However, the 2004 transition adjustment largely accounts for the decline. If the transitional adjustment of 32 percent for 2004 and 3 percent for 2005 were not applied, payment for the injection would be virtually the same in 2005 as in 2004, a decline of \$0.10 from \$18.67 to \$18.57. This table shows the permanent large increase in payment for this code from 2002 to 2005. The payment for a therapeutic injection increased from \$3.98 in 2002 to \$19.13 in 2005, a 381

percent increase (or \$18.57 if the transitional adjustment were not applied, a 367 percent increase).

CPT is also recommending separate codes for the administration of hormonal anti-neoplastic subcutaneous/intramuscular (SC/IM) injections from other anti-neoplastic injections. Under the current CPT codes, all anti-neoplastics administered SC/IM are billed using CPT code 96400. HCPCS code G0356 will be used for the administration of hormonal anti-neoplastic injections. CPT code 96400 is currently paid \$64.07. Its comparable code for 2005 (G0356) will be paid \$36.69 or a reduction of 43 percent. Without the transition, payment for the code would have been reduced from \$48.54 to \$35.62 or 27 percent between 2004 and 2005. However, payment for this code increased from \$5.07 to \$35.62 (without the transition) between 2002 and 2005 or by 603 percent.

There is currently one CPT code for anti-neoplastic drugs administered by intravenous (IV) push (96408). In 2004, physicians are receiving \$154.76 for CPT code 96408. Payment in 2005 for G0351 (the comparable code) will be \$125.69. In addition, Medicare may also pay an additional \$130.00 per encounter under the demonstration increasing the total payment to \$255.69 or an increase of 65 percent between 2004 and 2005. Without the transitional

adjustments or the demonstration, payment for this service would have increased from \$117.24 in 2004 to \$122.03 in 2003 or by 4 percent. From 2002 to 2005, payment will have increased from \$35.11 to \$122.03 (without the transition), or a 248 percent increase.

CPT will be creating new codes that distinguish between the first and subsequent administration of a drug by IV push to the same patient on the same day. The RUC is recommending fewer inputs for the subsequent administration of a drug by IV push than the initial drug. We are creating code G0358 for each subsequent drug administered by IV push for 2005. Before the enactment of the MMA, Medicare allowed CPT code 96408 to be paid only once per patient per day. However, as a result of the MMA, we changed our policy and allowed physicians to bill and be paid for more than one administration of a chemotherapy drug by IV push to the same patient on a single day (see 69 FR 1094-1095). Thus, because separate codes do not currently exist for the multiple administrations of chemotherapy drugs by IV push on a single day, physicians currently are paid at the rate for 96408 (or \$154.76) for each subsequent administration. Using the CPT's and RUC recommendations, we will pay \$72.99 for subsequent drugs administered by IV push using HCPCS code G0358. While the

payment is less in 2005 and 2004, payment remains higher in 2005 than in 2003 and prior years when Medicare provided no payment for the subsequent administration of a drug by IV push.

We are creating HCPCS codes G0359 and G0360 for the initial and subsequent hour respectively of chemotherapy drugs administered by IV infusion. As described in the drug administration section, CPT has changed its definition of chemotherapy to include infusion of substances such as monoclonal antibody agents or other biologic response modifiers in addition to anti-neoplastic drugs. Thus, services previously billed under the CPT code 90780 (initial hour) and 90781 (each additional hour) that meet this new definition of chemotherapy will now be billed under CPT code G0359 (initial hour) and G0360 (each additional hour). Payment for the infusion of substances such as monoclonal antibody agents or other biologic response modifiers paid under CPT code 90780 will be increasing from \$117.79 in 2004 to \$177.61 in 2005 using HCPCS code G0359, a 51 percent increase. Without including the transition adjustment, payment for these services will have increased by 93 percent from \$89.24 in 2004 to \$172.43 in 2005 or by 325 percent from the 2002 rate of \$40.54. Payment for the subsequent hour infusion under CPT code

90781 will increase from \$33.02 in 2004 to \$40.21 in 2005 under HCPCS code G0360 or by 22 percent. Without including the transition adjustment, payment for the subsequent hour infusion will have increased 56 percent from \$25.02 in 2004 to \$39.03 in 2005 or 93 percent from its 2002 rate of \$20.27.

Anti-neoplastic agents that were previously billed under CPT code 96410 (initial hour) and 96412 (each additional hour) will also be billed under codes G0359 and G0360. We have listed codes G0359 and G0360 twice to reflect that Medicare payment for each respective code is paid under two different CPT codes for services rendered prior to January 1, 2005. Payment for the initial hour of an anti-neoplastic agent administered by infusion under CPT code 96410 will be going from \$217.35 in 2004 to \$177.61 in 2005. Including the \$130.00 per encounter demonstration payment in this amount brings the total payment to \$307.61, an increase of 65 percent. Without including the transition adjustment, payment for these services will have increased by 5 percent from \$164.66 in 2004 to \$172.43 in 2005 or by 209 percent from the 2002 rate of \$55.75. Payment for the subsequent hour infusion under CPT code 96412 will decrease from \$48.30 in 2004 to \$40.21 in 2005 under HCPCS code G0360 or by 17 percent. Without including

the transition adjustment, payment for the subsequent hour infusion will have increased 7 percent from \$36.59 in 2004 to \$39.03 in 2005. Payment for the subsequent hour infusion of an anti-neoplastic agent has been reduced by 6 percent from its 2002 rate of \$41.63. The reduction in payment is occurring because resource-based pricing replaced the use of charge-based RVUs when the services were removed from the nonphysician work pool in 2004.

The CPT is also recommending a new code for the initial hour of a subsequent chemotherapy drug administered by infusion. The new code would recognize that there are higher resources associated with the first hour of infusion of a subsequent drug than there are in the subsequent hour of the initial drug. Under current CPT coding, the first hour of a subsequent drug administered by IV infusion is paid under CPT code 96412. In 2004, Medicare pays \$48.30 for this service. In 2005, we will pay \$86.66 or 79 percent more for HCPCS code G0362 that will be used for the initial hour of a subsequent drug administered by IV infusion. Without including the transition adjustment, payment for this service will have increased 130 percent from \$36.59 in 2004 to \$84.13 in 2005 or 102 percent from the 2002 rate of \$41.63.

The volume-weighted average permanent increase in payment among all drug administration services is approximately 117 percent from 2003 to 2005 including the effect of the CPT/RUC recommendations but excluding the effect of the transition adjustment. Including the effect of the transition (but not the demonstration payment) makes the volume-weighted increase in payment for these codes more than 120 percent from 2003 to 2005.



**Table 40:**  
Impact of Final Rule and Physician Fee Schedule Update  
on Medicare Payment for Selected Drug Administration Services  
Including the Effect of the 32 and 3% Transition Adjustments and Demonstration Project

Old Code	New Code	Description	2002 Payment	2003 Payment	2004 Payment with Transition	2005 Payment with Transition	2005 Demo Payment*	2005 w/Transition and Demo	% Change 04 to 05
90782	G0351	Therapeutic/diagnostic injec	\$ 3.98	\$ 4.41	\$ 24.64	\$ 19.13	N/A	\$ 19.13	-22%
96400	G0356	Hormonal anti-neoplastic	\$ 5.07	\$ 37.52	\$ 64.07	\$ 36.69	N/A	\$ 36.69	-43%
96408	G0357	IV push single/initial subst	\$ 35.11	\$ 37.52	\$ 154.76	\$ 125.69	\$130.00	\$ 255.69	65%
N/A	G0358	IV push each additional drug	N/A	N/A	\$ 154.76	\$ 72.99	N/A	\$ 72.99	-53%
96410	G0359	Chemotherapy IV one hr initi	\$ 55.75	\$ 59.22	\$ 217.35	\$ 177.61	\$130.00	\$ 307.61	42%
90780	G0359	Chemotherapy IV one hr initi	\$ 40.54	\$ 42.67	\$ 117.79	\$ 177.61	N/A	\$ 177.61	51%
96412	G0360	Each additional hr 1-8 hrs	\$ 41.63	\$ 44.14	\$ 48.30	\$ 40.21	N/A	\$ 40.21	-17%
90781	G0360	Each additional hr 1-8 hrs	\$ 20.27	\$ 21.70	\$ 33.02	\$ 40.21	N/A	\$ 40.21	22%
96412	G0362	Each add sequential infusion	\$ 41.63	\$ 44.14	\$ 48.30	\$ 86.66	N/A	\$ 86.66	79%

- The demonstration payments will only be made once per day per patient with a diagnosis of cancer. Thus, we are only showing them as an additional payment to an initial drug administration service when an anti-neoplastic agent is administered.

**Table 41:**

Impact of Proposed Rule and Physician Fee Schedule Update  
on Medicare Payment for Selected Drug Administration Services  
Excluding the Effect of the 32 and 3% Transition Adjustments and Demonstration Project

Old Code	New Code	Description	2002 Payment	2003 Payment	2004 Payment without Transition	2005 Payment without Transition
90782	G0351	Therapeutic/diagnostic injec	\$ 3.98	\$ 4.41	\$ 18.67	\$ 18.57
96400	G0356	Hormonal anti-neoplastic	\$ 5.07	\$ 37.52	\$ 48.54	\$ 35.62
96408	G0357	IV push single/initial subst	\$ 35.11	\$ 37.52	\$ 117.24	\$ 122.03
N/A	G0358	IV push each additional drug	N/A	N/A	\$ 117.24	\$ 70.87
96410	G0359	Chemotherapy IV one hr initi	\$ 55.75	\$ 59.22	\$ 164.66	\$ 172.43
90780	G0359	Chemotherapy IV one hr initi	\$ 40.54	\$ 42.67	\$ 89.24	\$ 172.43
96412	G0360	Each additional hr 1-8 hrs	\$ 41.63	\$ 44.14	\$ 36.59	\$ 39.03
90781	G0360	Each additional hr 1-8 hrs	\$ 20.27	\$ 21.70	\$ 25.02	\$ 39.03
96412	G0362	Each add sequential infusion	\$ 41.63	\$ 44.14	\$ 36.59	\$ 84.13

Table 42 below shows the impact of physician fee schedule changes for selected specialties that receive a significant portion of their total Medicare revenues from drugs. Table 43 that follows table 42 shows the combined impact of the physician fee schedule and drug payment changes on total Medicare revenues. Our estimates of changes in Medicare revenues for drugs and physician fee schedule services compare payment rates for 2005 with payment rates for 2004 using 2003 Medicare utilization for both years. For physician fee schedule services, we mapped the 2003 Medicare utilization to the code set in use for 2005 based on assumptions about how the new drug administration codes will be billed. These assumptions are based on our consultations with the American Society of Clinical Oncology and other physician specialty societies that participated in the CPT's Drug Administration workgroup. We are using 2003 Medicare claims processed and paid through June 30, 2004 that we estimate are 98.5 percent complete and have adjusted the figures to reflect a full year of data. Thus, because we are using a single year of utilization, the estimated changes in revenues reflect payment changes only between 2004 and 2005. To the extent that there are year-to-year changes in the volume and mix of drugs and physician fee schedule services provided by

physicians, the actual impact on total Medicare revenues will be different than those shown here.

The column labeled "NPRM Impacts" shows the impact of the practice expense and malpractice RVU changes described earlier. The refinements of the practice expense RVUs and 5-year review of malpractice will have little or no impact on physician fee schedule payments for the 5 specialties shown. The column labeled "Coding and RVU Changes" shows the impact of our adoption of the CPT/RUC recommended revisions to the codes and payment amount for drug administration services. We estimate that the changes from the CPT/RUC process will increase physician fee schedule payments for oncologists by 5 percent. This impact is generally attributable to higher permanent increases in payment for the administration of drugs by IV push (G0357), infusion (G0359 and G0360) and the ability to be paid at a higher rate for the initial hour of infusion of a subsequent drug administered. We estimate that the changes from the CPT/RUC process will increase payments to rheumatologists by 4 percent. This impact is due to the change in the definition of the chemotherapy that will allow rheumatologists to bill substances such as monoclonal antibody agents or other biologic response modifiers using the chemotherapy administration codes. The CPT/RUC changes

will have little or no specialty level impact on other specialties that administer drugs.

The next column shows the effect of the drug administration transition on Medicare physician fee schedule revenues for the specialties shown. As explained earlier, section 303(a)(4) requires that the transition adjustment percentage be reduced from 32 percent in 2004 to 3 percent in 2005. The change to the transition payment percentage will reduce payments for the specialties that provide drug administration services. The reduction has a larger impact on oncologists than the other physician specialties shown because drug administration services represent a larger proportion of their physician fee schedule revenues.

The column labeled "Additional Payments for Injections" shows the effect of paying for injections (as well as non-chemotherapy drugs administered by IV push) provided on the same day as other physician fee schedule services. We estimate that this policy change will increase payment an estimated 3 percent for oncologists and 1 percent for other specialties. This policy change will also modestly increase payment to other specialties that provide injections (primarily family practitioners and internists) and has been incorporated into the earlier impact tables.

The next column shows the impact of the 1.5 percent physician fee schedule update. The column labeled "One-Year Demonstration Project" shows the impact of our plan to establish a national demonstration project that will pay oncologists \$130 for providing specific services to their patients and reporting patient quality data. If oncologists participate in this demonstration project and provide the required services and requested information, we estimate that their payments will increase by 15 percent. Taken together, we estimate that the coding and RVU changes, the change to the transition amount for drug administration, the additional payments for injections, the physician fee schedule update and the national demonstration project will increase physician fee schedule payments to oncologists by 10 percent. The combined impact of these factors (other than the national demonstration project) will increase physician fee schedule payments by 1 percent urologists, 5 percent for rheumatologists, 1 percent for obstetrics/gynecologists and 0 percent for infectious disease.

Table 43 shows the combined impact of changes we are making to Medicare drug and physician fee schedule payments for the same specialties shown in table 42. The payment impacts for drugs are based on the 2<sup>nd</sup> quarter ASP

submissions from drug manufacturer's and reflect  $\frac{3}{4}$  of an annualized increase in drug prices between the 2<sup>nd</sup> quarter of 2004 and the 1st quarter of 2005 of 3.39 percent or 2.54 percent. The drug payment impacts are based on ASP prices for drugs accounting for approximately 94 percent of Medicare's total drug payments. Of Medicare's total payments for drugs, at least 4 percent are paid under "not otherwise classified (NOC)" codes (i.e. J3490 and J0999). Thus, we based our impacts on ASP prices for drugs accounting for approximately 98 percent of Medicare revenues that are not in the NOC category.

The column labeled "% of Total Medicare Revenues from Fee Schedule" shows the proportion of total Medicare revenues received from physician fee schedule services. The following column shows the physician fee schedule payment impact. All of the payment impacts are the same as those shown in Table 43. The following column shows the proportion of total Medicare revenues received from drugs, while the next column shows the payment impact from adoption of the ASP drug payment methodology. The next 3 columns show combined Medicare revenues from all sources and the combined Medicare payment impact from the earlier described changes being adopted for 2005.

Our estimates of changes in Medicare revenues for both

drugs and drug administration services compare payment rates for 2005 with payment rates for 2004 using the same utilization in both years. We used 2003 utilization for these comparative impacts since they are the latest data available. Thus, the estimated changes in revenues reflect purely price changes between 2004 and 2005. We note that these impacts and percentages represent averages for each specialty or supplier. The percentages and impacts for any individual physician are dependent on the mix of drugs and physician fee schedule services they provide to Medicare beneficiaries. For this analysis, we are also supplementing the data showing the change in revenues with volume growth based on historical trends.

As indicated in Table 43, physician fee schedule services account for approximately 28 percent of oncology's 2004 Medicare revenues. The changes we are adopting in this final rule are estimated to increase Medicare payments for physician fee schedule services by 10 percent from 2004 to 2005. We estimate that approximately 69 percent of total 2004 Medicare revenues for oncologists are attributed to drugs and the adoption of the ASP pricing methodology will reduce these revenues by 13 percent. We based our analysis on drugs accounting for approximately 92 percent of total oncology drug revenues (and 99 percent of oncology



drug revenues not paid under NOC codes). The actual impact on oncologists' total Medicare revenues will be different from these estimated impacts to the extent that utilization of drugs and drug administration services does increase. In recent years, increasing utilization, for example, drug spending growth in excess of 20 percent per year, has occurred. The weighted average of the drug and physician fee schedule changes assuming no change in utilization would decrease Medicare revenues to oncology by 6 percent. However, if the volume of drugs and physician fee schedule services increased at historical rates, total Medicare revenues for oncologists are estimated to increase by 4 percent between 2004 and 2005, excluding the demonstration project. If we include the demonstration project, Medicare revenues to oncologists are estimated to increase by 8 percent between 2004 and 2005. We note that our actuaries' estimates of section 303 with the drug prices and policy changes in this final rule match earlier estimates of the FY 2005 and 10-year savings figures.

We estimate that urology receives approximately 57 percent of their 2004 total revenues from physician fee schedule services and 35 percent from drugs. We estimate that physician fee schedule revenues for urologists will increase by approximately 1 percent from 2004 to 2005.

Based on ASP prices for drugs accounting for 100 percent of urologists' drug revenues, we estimate a 40 percent reduction assuming no growth in the volume of services provided. In this scenario, combined Medicare payments to urologists would decline approximately 14 percent. However, if the volume of physician fee schedule services and drugs were to grow at historical rates, we estimate that Medicare revenues to urologists would decline by 8 percent.

We estimate that physician fee schedule revenues account for approximately 49 percent of rheumatology's total revenues. Drugs account for approximately 44 percent rheumatology's total revenues. Physician fee schedule revenues are estimated to increase 5 percent for rheumatology and revenues from drugs are estimated to decline by 8 percent. Assuming no growth in utilization, the combined reduction in rheumatologists' revenues would be 1 percent. If the volume of drugs and physician fee schedule services grew at historical rates, rheumatologists' revenues from Medicare would increase by 9 percent.

We estimate that physician fee schedule revenues account for approximately 87 percent of total revenues for obstetrics/gynecology. These revenues are anticipated to

increase by 1 percent. Drug revenues represent 13 percent of total Medicare revenues for obstetrics/gynecology and are estimated to decline by 21 percent. Assuming no growth in utilization, we estimated that obstetrics/gynecology's combined Medicare revenues would decline by 2 percent. Using the historical projected rates of growth for the volume of drugs and physician fee schedule services would make the estimated change in revenues equal an increase of 4 percent.

We estimate that physician fee schedule revenues account for approximately 94 percent of total revenues for infectious disease physicians. These payments are not estimated to change. The remainder of Medicare revenues for infectious disease physicians can be attributed to drugs. These payments are expected to decline by 25 percent. The weighted average change in infectious disease revenues from the changes we are adopting in this final rule is -2 percent assuming no growth in the volume of drugs and physician fee schedule services. If future growth in the volume of drugs and physician fee schedule services were to grow at historical rates, revenues to infectious disease physicians would increase would increase 7 percent.

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**Table 42:**  
Impact of Drug and Physician Fee Schedule Payment Changes  
on Total Medicare Allowed Charges  
for Selected Specialties

Specialty	Physician Fee Schedule							
	Medicare Allowed Charges (\$ in Millions)	NPRM Impacts	Coding and RVU Changes	Drug Administration Transition	Additional Payments for Injections	Physician Fee Schedule Update	One-Year Demonstration Project	Total
HEMATOLOGY/ONCOLOGY	\$ 1,747	0%	5%	-12%	3%	1.5%	15%	10%
UROLOGY	\$ 1,695	0%	0%	-1%	0%	1.5%	N/A	1%
RHEUMATOLOGY	\$ 582	0%	4%	-2%	1%	1.5%	N/A	5%
OBSTETRICS/GYNECOLOGY	\$ 412	0%	0%	-1%	0%	1.5%	N/A	1%
INFECTIOUS DISEASE	\$ 401	0%	0%	-1%	0%	1.5%	N/A	0%

**Table 43:**  
**Combined Payment Impact**  
**Drug and Physician Fee Schedule Payment Changes**  
**for Selected Specialties**

Specialty	Physician Fee Schedule		Drugs		All Revenues		
	% of Total Medicare Revenues from Fee Schedule	% Change Medicare Physician Fee Schedule Revenues	% of Total Medicare Revenues from Drugs	% Change Medicare Drug Revenues	Combined Medicare Revenues All Sources (\$ in Millions)	Combined % Change All Medicare Revenues Constant Utilization	Combined % Change All Medicare Revenues** w/Utilization Growth
HEMATOLOGY/ONCOLOGY	28%	10%	69%	-13%	\$ 6,346	-6%	8%
UROLOGY	57%	1%	35%	-40%	\$ 2,967	-14%	-8%
RHEUMATOLOGY	49%	5%	44%	-8%	\$ 844	-1%	16%
OBSTETRICS/GYNECOLOGY	87%	1%	13%	-21%	\$ 667	-2%	5%
INFECTIOUS DISEASE	94%	0%	6%	-25%	\$ 428	-2%	7%

\*\* Note: We estimate that Medicare payments to oncologists would increase by 8% between 2004 and 2005 if growth in the volume of drugs and physician fee schedule services were to continue growing at historical rates and the effect of the demonstration project was included. Revenue projections including price and volume changes for the other specialties are shown as well.

## B. Geographic Practice Cost Indices

As discussed in section II.B, in this rule, we are proposing changes to the work and practice expense GPCIs based on new census data. The resulting geographic redistributions would not result in an overall increase in the current geographic adjustment indices by more than 3.5 percent or a decrease by more than 1.6 percent for any given locality in 2005. These geographic redistributions would not result in an overall increase in the current geographic adjustment indices by more than 7 percent or a decrease by more than 3.5 percent for any given locality in 2006. Addenda F and G illustrate the locality specific overall impact of this proposal. The GAF, as displayed in Addenda F and G is a weighted composite index of the individual revisions to the work, practice expense, and malpractice expense GPCIs, respectively. The malpractice GPCI was updated as part of the November 7, 2003 final rule, and the MMA provisions were addressed in the final rule published on January 7, 2004.

## C. Coding Issues

### 1. Additions to the List of Medicare Telehealth Services

In section II.D, we are adding end stage renal disease (ESRD) services, as represented by HCPCS codes G0308,

G0309, G0311, G0312, G0314, G0315, G0317, G03178 to the list of telehealth services. We believe that this change will have little effect on Medicare expenditures.

## 2. National Pricing of G0238/G0239 (Respiratory Therapy Service Codes)

As discussed earlier in the preamble, we are using the nonphysician workpool to value two respiratory therapy service codes (G0238 and G0239) that are currently carrier priced. We believe that this change will eliminate the uncertainty surrounding payment of these codes when performed in comprehensive outpatient rehabilitation facilities that are paid under the physician fee schedule through fiscal intermediaries. We do not anticipate that nationally pricing these services will have a significant impact on Medicare expenditures.

## 3. New HCPCS Code for Bone Marrow Aspiration

We are implementing a new HCPCS add-on code, G0367 for instances when a bone marrow aspiration and a bone marrow biopsy are performed on the same day through a single incision. While this coding change will allow for a small additional payment for the second procedure performed through a single incision on the same day, we anticipate that the costs will be insignificant.

## 4. New HCPCS Code for Venous Mapping

As stated earlier in the preamble, we are implementing a new HCPCS code G0365, for mapping of vessels for hemodialysis access. Payment for this code will be crosswalked by CPT code 93990, Doppler Flow Testing. We anticipate that the costs of this change will be minor and may result in improved care to Medicare beneficiaries and less long-term costs to Medicare.

D. MMA Provisions

1. Section 611-Preventive Physical Examination

As discussed earlier in this preamble, the MMA authorizes coverage of an initial preventive physical examination effective January 1, 2005, subject to certain eligibility and other limitations. This new benefit will result in an increase in Medicare expenditures for new payments made to physicians and other practitioners who provide these examinations and for any medically necessary follow-up tests, counseling, or treatment that may be required as a result of the coverage of these examinations. The impact of this provision is shown in the following table.



**TABLE 44:**  
Medicare Cost Estimates for MMA Provision 611  
(in millions)

MMA provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 611	\$40	\$40	\$40	\$40	\$40

## 2. Section 613—Diabetes Screening

Section 613 of the MMA adds subsection (yy) to section 1861 of the Social Security Act and mandates coverage of diabetes screening tests, effective on or after January 1, 2005. We expect that this change in coverage for certain beneficiaries will result in an increase in Medicare payments. These payments will be made to physicians' office laboratories and other laboratory suppliers who perform these tests as a result of the increased frequency of coverage of these tests. The impact of this provision is shown in Table 45 that follows.

## 3. Section 612—Cardiovascular Screening

Section 612 of the MMA provides for Medicare coverage for cholesterol and other lipid or triglyceride levels of cardiovascular screening blood tests for the early detection of abnormalities associated with an elevated risk for such diseases effective on or after January 1, 2005.

We estimate that this change in coverage for certain beneficiaries will result in an increase in Medicare payments. These payments will be made to physician office laboratories and other laboratory suppliers who perform these tests as a result of the increased frequency of coverage of these tests. Increased Medicare program expenditures for this provision are shown in Table 45 below.

**TABLE 45:**

Medicare Cost Estimates for MMA Provisions 612 and 613  
(in millions)

MMA Provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 612 Cholesterol and Blood Lipid	50	80	90	90	100
Sec. 613 Diabetes Screening	20	40	50	60	80

#### 4. Section 413—Incentive Payment for Physician Scarcity

##### a. Physician Scarcity Areas

Section 413(a) of the MMA provides a new 5-percent incentive payment to physicians who furnish services in physician scarcity areas. The MMA provides for paying primary care physicians furnishing services in a primary care scarcity area, and specialty physicians furnishing services in a specialist care scarcity county, an additional amount equal to 5 percent of the amount paid for their professional services under the fee schedule from

January 1, 2005 to December 31, 2007. We estimate that this new incentive payment for physicians' services will result in an increase in Medicare payments that are shown in Table 46.

b. Improvement to Medicare HPSA Incentive Payment Program

Section 413(b) of the MMA amended section 1833(m) of the Act to mandate that we automate payment of the 10 percent HPSA incentive payment to eligible physicians. Since the inception of the HPSA incentive payment program, physicians have been required to determine their eligibility and correctly code their Medicare claims using modifiers. We estimate that this change to the HPSA incentive payment program to provide for automation of payment will result in an increase in Medicare payments because many eligible physicians are not applying for bonuses due to the burden of verifying eligibility. The impact of this provision is shown in Table 46.

**TABLE 46:**  
Medicare Cost Estimates for MMA Provisions  
(in millions)

MMA Provision	FY05	FY06	FY07	FY08	FY09
Sec. 413(a) Physician Scarcity Areas	30	50	50	20	-
Sec. 413(b) Improvement to HPSA	20	30	30	30	30

5. Sections 303–304–Payment for Covered Outpatient Drugs and Biologicals and Section 305–Payment for Inhalation Drugs

Sections 303 and 304 of the MMA make changes to Medicare payment for covered outpatient drugs and biologicals and changes to the administration of those drugs. Section 305 makes changes to payment for inhalation drugs. We implemented provisions of sections 303 through 305 changing payments in 2004 for drugs and their administration in the January 7, 2004 **Federal Register** (69 FR 1084). In this final rule, we are making further changes to Medicare's payment for drugs and drug administration for 2005 required by sections 303 through 305 of the MMA. As indicated earlier in this final rule, we are revising the codes and payments for drug administration based on recommendations of the CPT Editorial Board and the Relative Value Update Committee. Consistent with section 1848(c)(2)(J) of the Act (as

amended by section 303(a) of the MMA), the increase in payment resulting from this review are exempt from the budget neutrality requirements that apply to changes in RVUs. We are further increasing payments to physicians that treat patients with cancer who participate in a national demonstration project. In addition, we are also paying a supplying fee of \$50 per month for the first month and \$24 for each subsequent month for Medicare Part B oral drug prescriptions. We are also proposing to pay a furnishing fee of \$0.14 per unit of clotting factor and a dispensing fee of \$57 per month for inhalation drugs. Taking all of these provisions into account, we estimate Medicare savings for section 303-305 as follows:

**TABLE 47:**

Medicare Cost (Savings)  
Estimates for MMA Provision 303-305  
(in millions)

Provision	FY05	FY06	FY07	FY08	FY09
303-305	(730)	(1,300)	(1,650)	(1,820)	(1,990)

#### 6. Section 952—Reassignment

The reassignment provisions discussed in section III.F is currently estimated to have no significant impact on Medicare expenditures.

#### 7. Section 623—Payment for Renal Dialysis Services

##### a. Effects on the Medicare Program (Budgetary Effect)

Because the basic case mix adjusted composite payment rate and the revised payment for ESRD drugs must be budget neutral in accordance with section 623(d)(1) of the MMA, except for the statutorily required 1.6 percent increase set forth in section 623(a), we estimate that there would be no budgetary impact for the Medicare program beyond this increase. The impact of this provision (net of beneficiary liability) is shown in the following table:

**TABLE 48:**

Medicare Cost Estimates for MMA Provision 623  
(in millions)

Provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Section 623	\$40	\$50	\$50	\$60	\$60

b. Impact on ESRD Providers

To understand the impact of the changes affecting payments to ESRD facilities that result from enactment of the MMA on different categories of ESRD facilities, it is necessary to compare estimated payments under the current payment system (current payments) to estimated payments under the revisions to the composite rate payment system as set forth in this final rule (MMA payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and MMA payments contain similar inputs. Therefore, we simulated

MMA payments only for those ESRD facilities for which we are able to calculate both current payment and MMA payment.

Due to data limitations, we are unable estimate current and MMA payments for 461 facilities that bill for ESRD drugs. ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from HCRIS. We also used the June 2004 update of CY 2003 Standard Analytical File (SAF) claims as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. As we stated in the proposed rule, this final rule impact on providers uses updated OSCAR, cost report and claims data.





**Table 49:**  
Impact of MMA Section 623  
Payments to Hospital Based and Independent ESRD Facilities  
(Includes Drug and Composite Rate Payments)

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

	<b>Number Of facilities</b>	<b>Number of Dialysis Treatments (in millions)</b>	<b>Effect of Changes In Drug Payments 1/</b>	<b>Effect of 1.6% Composite rate Update on Total Payments 2/</b>	<b>Effect of Case Mix 3/</b>	<b>Overall Effect 4/</b>
All	3,907	31.0	0.0	1.0	0.0	1.0
Independent	3,390	27.5	-0.6	1.0	0.0	0.4
Hospital Based	517	3.5	5.2	1.1	0.3	6.6
Size						
Small <5000 treatment per year	1,274	3.9	0.2	1.0	0.5	1.5
Medium 5000-10000 treatments per yr	1,586	11.5	-0.3	1.0	0.1	0.7
Large > 10000 treatments per year	1,047	15.6	0.2	1.0	-0.2	1.0
Type of Ownership						
For-profit	2,782	22.6	-0.7	1.0	-0.2	0.1
Not-for-profit	785	5.8	3.0	1.1	0.4	4.3
Other	340	2.6	0.5	1.0	0.6	1.8
Urban	2,903	25.0	0.0	1.0	-0.1	0.9
Rural	1,004	6.0	-0.1	1.0	0.4	1.1
Region						
New England	128	1.1	0.8	1.0	-0.3	1.7
Middle Atlantic	498	4.3	0.5	1.0	-0.5	1.2

East North Central	570	4.6	0.3	1.0	1.0	1.9
West North Central	270	1.7	1.0	1.0	1.3	2.9
South Atlantic	920	7.2	-0.9	0.9	0.5	0.3
East South Central	317	2.3	-0.9	0.9	1.2	0.7
West South Central	530	4.3	-0.9	1.0	-0.3	-0.1
Mountain	204	1.3	2.4	1.0	-0.7	3.0
Pacific	442	3.8	0.8	1.0	-1.7	0.8
Puerto Rico	28	0.4	0.7	1.0	-4.1	-0.9

1/ This column shows the effect of the changes in drug payments to ESRD providers. These include changes in payment for separately billable drugs and the 8.7% drug add-on.

2/ This column shows the effect of the 1.6% update to the composite rate on total payments to ESRD providers. Note that ESRD providers receive an average of 39% of their total revenues from separately billable drugs which results in an average net increase of 1.0%.

3/ This column shows impact of case-mix adjustments only.

4/ This column shows the overall effect of payments to ESRD facilities with and without the application of MMA Section 623. The MMA provisions include the 1.6% increase, the 8.7% drug add-on, and the case-mix adjustments times treatments plus MMA payment for separately billable drugs. The current payment to ESRD facilities includes the current composite rate times treatments plus current drug payments for separately billable drugs.

Table 49 shows the impact of MMA Section 623 on hospital based and independent facilities. We have included both composite rate payments as well as payments for separately billable drugs and biologicals because both are effected by section 623 of the MMA. The first column of Table 49 identifies the type of ESRD provider, the second column indicates the number of ESRD facilities for each type, and the third column indicates the number of dialysis treatments.

The fourth column shows the effect of the changes in drug payments to ESRD providers. The overall effect of changes in drug payments is budget-neutral as required by MMA. The drug add-on adjustment is designed to result in the same aggregate amount of expenditures as would have been made without the statutory policy change.

Current payments for drugs represent 2005 Medicare reimbursement using 95 percent of AWP prices for the top ten drugs. Medicare spending for drugs other than EPO is estimated using 2004 AWP prices updated by a 3 percent inflation factor times actual drug utilization from 2003 claims. EPO is priced \$10 per 1000 units (EPO units are estimated using payments because the units field on bills represents the number of EPO administrations rather than the number EPO units). Medicare spending under the MMA is

2003 average acquisition cost for the top ten drugs updated to 2005 figures (using the PPI for prescriptions drugs) times actual drug utilization from 2003 claims. These inflation factors were 4.81 percent and 3.72 percent for 2004 and 2005, respectively.

Payment for drugs under MMA also includes the 8.7 percent drug add-on to the composite rate. This amount is computed by multiplying the composite rate for each provider (with the 1.6 percent increase) times dialysis treatments from 2003 claims. Column 4 is computed by comparing spending under MMA provisions for drugs including the 8.7 percent drug add-on amount to spending under current payments for drugs. In order to make column 4 comparable with rest of Table 49, current composite rate payments to ESRD facilities were included in both current and MMA spending calculations.

Column 5 shows the effect of the 1.6 percent increase to the composite rate on total payments to ESRD providers. While all ESRD providers will get a 1.6 percent increase to their composite rate, this table shows the net effect of this increase on ESRD providers' total Medicare revenues (both drug and composite rate payments combined), and therefore does not show a 1.6 percent increase.

On average, ESRD providers receive an average of 39 percent of their total revenues from separately billable drugs and 61 percent of their total revenues from composite rate payment. Since the 1.6 percent increase is applied to the 61 percent portion of their total Medicare revenues, the 1.6 percent composite rate increase is also arithmetically equal to a 1.0 percent increase in ESRD providers' total Medicare revenues. Column 5 is computed by combining MMA payment for drugs (including the 8.7 percent drug add-on amount) with: (1) current composite rate times dialysis treatments from 2003 claims or (2) composite rate with 1.6 percent increase times dialysis treatments from 2003 claims. The difference between these two combinations is the net effect of the 1.6 percent increase on total payments to ESRD providers. In order to isolate the effect of the 1.6 percent increase, the computation in Column 5 assumes that drug payments to ESRD providers remain constant.

Column 6 shows the impact of the case-mix adjustments as described earlier in this preamble of this final rule. Because MMA requires this adjustment to be budget-neutral in the aggregate, there is no overall impact on ESRD providers as a whole. While the case-mix adjustment will have an impact within the various provider types, Column 6

shows that the effect between provider groupings is minimal. Column 6 is computed as the difference between payments to ESRD providers with the case-mix adjustments compared to payments to providers without the case-mix adjustments. As described earlier in this preamble, we developed a case-mix budget neutrality factor to meet the MMA requirement that payment be budget-neutral with respect to aggregate payments. Therefore, there is no change for ESRD providers in the aggregate. We note that when applying the case-mix adjustments, we did so at the facility level.

Column 7 shows the overall effect of all changes in drug and composite rate payments to ESRD providers. The overall effect of payments to ESRD facilities is measured as the difference between payment with and without application of MMA section 623 as described in this final rule and current payment. MMA payment is computed by multiplying the composite rate for each provider (with both 1.6 percent increase and the 8.7 percent add-on) times dialysis treatments from 2003 claims times the appropriate case-mix adjustment by provider. In addition, MMA payment includes payments for separately billable drugs under the revised pricing methodology as described in this preamble. Current payment is the current composite rate for each

provider times dialysis treatments from 2003 claims plus current drug payments for separately billable drugs.

The overall impact to ESRD providers in aggregate is 1.0 percent. Among the three separately shown effects, the effect of changes in drug payments has the most variation among provider type and contributes most to the overall effect. Separately billable ESRD drugs are paid differently to hospital-based and independent ESRD providers. As discussed earlier in this preamble, we are using a single drug add-on to the composite rates for both hospital based and independent facilities. The 6.6 percent increase in payments to hospital-based providers is largely due to the single drug add-on to the composite rate.

#### 8. Section 731—Coverage of Routine Costs for Category A Clinical Trials

The coverage of routine costs associated with certain Category A clinical trials as discussed in MMA section 731(b) will have no significant impact on Medicare expenditures.

#### 9. Section 629—Part B Deductible

As explained earlier in the preamble, section 629 of the MMA provides for annual updates to the Medicare Part B deductible. The MMA stipulates that the Medicare Part B deductible will be \$110 for calendar year 2005, and, for subsequent years, the deductible will be the previous year's deductible increased by the annual percentage increase in the monthly actuarial rate under section

1839(a)(1) of the Act, ending with that subsequent year (rounded to the nearest dollar). We note that while this MMA provision results in a savings to the Medicare program, it also increases beneficiary costs by an equal amount and was implemented in a **Federal Register** notice published on September 9, 2004 (69 FR 54674).

**TABLE 50:**

Estimated Medicare Savings for MMA Provision 629  
(in millions)

MMA provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 629	110	290	440	590	770

#### 10. Section 512—Hospice Consultation Service

As explained in section III.K of this preamble, effective January 1, 2005, section 512 of the MMA provides for payment to be made to a hospice for specified services furnished by a physician who is either the medical director of, or an employee of, a hospice agency. We estimate that this MMA provision will increase Medicare expenditures by \$10 million per year beginning in 2005.

#### 11. Section 706 Coverage of Religious Nonmedical Health Care Institution (RNHCI) Services Furnished in the Home

We anticipate that the time limited RNHCI home benefit will either meet or fall short of the annual \$700,000 per calendar year statutory spending limit and therefore will not have a significant financial impact on the Medicare program.



## E. Other Issues

### 1. Outpatient Therapy Services Performed "Incident To" Physicians' Services

As discussed in section IV.A, we are amending the regulations to include the statutory requirement that only individuals meeting the existing qualification and training standards for therapists (with the exception of licensure) consistent with §484.4 qualify to provide therapy services incident to physicians' services. We believe that while this will have little impact on Medicare expenditures, it will assist in ensuring the quality of services provided to beneficiaries.

### 2. Supervision Requirements for Therapy Assistants in Private Practice

As discussed earlier in section IV.A, we are revising the regulations at §410.59 and §410.60 to replace a requirement to provide personal supervision and instead require direct supervision of physical therapist assistants and occupational therapy assistants when therapy services are provided by physical therapists or occupational therapists in private practice. This policy change will provide beneficiaries access to medically necessary therapy services, under a physician-certified plan of care. We believe that this change could result in a 5 percent

increase in therapy billing in therapy private practice settings with an estimated cost of \$9 million for FY 2005. Projected costs for FY 2006 are \$17 million while each subsequent year would only increase by \$1 million each year, assuming the therapy caps are applied.

### 3. Low Osmolar Contrast Media

As discussed earlier in the preamble, we are revising the regulations at §414.38 to eliminate the restrictive criteria for the payment of LOCM. This regulation will make payment for LOCM consistent across Medicare payment systems. Shown in the following table are estimates of program costs due to the removal of the restrictive criteria for administering LOCM, assuming increased utilization and removal of the 8 percent reduction. Without current ASP data, we could not include the additional impact of the change in payment for LOCM to ASP plus 6 percent, effective April 1, 2005. Contrast-enhanced procedures that most commonly use LOCM, the typical ranges of LOCM amounts used by modality, and the cost ranges for LOCM in the marketplace were considered in valuing the additional program costs.

<b>TABLE 51:</b>					
Regulatory Provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
LOCM	20	30	30	30	30

#### 4. Payments for Physicians and Practitioners Managing Patients on Dialysis

We believe that the proposals with respect to ESRD-related services furnished to patients in observation settings and payment for outpatient ESRD-related services for partial month scenarios discussed earlier in section xx provide clarification of current policy surrounding these issues. We do not believe these proposals will have a significant impact on Medicare expenditures.

#### 5. Supervision of Clinical Psychological Testing

We are changing the supervision requirements regarding who can supervise diagnostic psychological testing services. As previously discussed, having ancillary staff supervised by clinical psychologists will enable these practitioners with a higher level of expertise to oversee psychological testing and potentially relieve burdens on physicians and healthcare facilities.

Additionally, in rural areas, we anticipate that permitting psychologists to supervise diagnostic psychological testing services will reduce delays in

testing, diagnosis, and treatment that could result from the unavailability of physicians to supervise the tests. We believe that this revision to the supervision requirements will have little impact on Medicare expenditures.

#### 6. Care Plan Oversight

As discussed earlier in the preamble, we are revising §414.39 to clarify that NPPs can perform home health care plan oversight even though they cannot certify a patient for home health services and sign the plan of care. We do not expect that this change will have an impact on Medicare expenditures, since it is primarily a clarification in policy.

#### 7. Assignment of Medicare Claims

The changes with respect to assignment of Medicare claims are currently estimated to have no significant impact on Medicare expenditures. However, as stated earlier in this preamble at section IV.G, we believe the changes will reduce the paperwork burden on beneficiaries and suppliers.

#### F. Alternatives Considered

This final rule contains a range of policies, including proposals related to specific MMA provisions. The preamble provides descriptions of the statutory

provisions that are addressed, identifies those policies when discretion has been exercised and presents rationale for our decisions and, when possible, alternatives that were considered.

G. Impact on Beneficiaries

There are a number of changes made in this rule that would have an effect on beneficiaries. In general, we believe these changes will improve beneficiary access to services that are currently covered or will expand the Medicare benefit package to include new services. As explained in more detail below, the MMA or regulatory provisions may increase beneficiary liability in some cases. Any changes in aggregate beneficiary liability from a particular provision will be a function of the coinsurance (20 percent if applicable for the particular provision after the beneficiary has met the deductible) and the effect of the aggregate cost (savings) of the provision on the calculation of the Medicare Part B premium rate (generally 25 percent of the provision's cost or savings).

The MMA provisions that expand Medicare benefits include: section 611, adding an initial preventive physical exam for newly eligible Medicare beneficiaries; section 612 providing coverage of cardiovascular screening blood tests; and section 613, providing coverage for diabetes screening

tests for Medicare beneficiaries at risk for diabetes. While the initial preventive physical examination for newly eligible Medicare beneficiaries is subject to deductible and coinsurance, we believe Medicare beneficiaries will continue to benefit from expanded coverage for this service. We believe many beneficiaries have supplemental insurance coverage or Medicaid that pays the Medicare deductible on their behalf and there will be no immediate additional out-of-pocket cost. Further, even if a beneficiary pays nearly all of the costs of this new benefit, the preventive office visit will substitute for another service a beneficiary may need to meet the annual deductible and the beneficiary will receive more covered benefits at little additional cost. There are no out-of-pocket costs to the beneficiary for the cardiovascular screening blood tests and diabetes screening tests.

Other proposals in this rule related to the MMA will also impact beneficiary liability, with the most significant related to indexing of the part B deductible (section 629 of the MMA) and the drug administration payment changes (sections 303 and 305 of the MMA). MMA provisions that improve administration of the 10 percent HPSA bonus and provide an additional 5 percent bonus payment to physicians in Medicare scarcity areas will have

no impact on beneficiary liability because the bonus payments are applied to the amount Medicare pays the physician net of beneficiary liability. These provisions will also improve access for Medicare beneficiaries by increasing payments to physicians in areas that traditionally have had a low ratio of physicians to population.

We are summarizing the impact of all of the changes we are adopting in this rule in table 52. We note that Medicare savings estimates are relative to projected expenditures that would occur if the provisions of the MMA and this final regulation were not implemented. Thus, the savings figures are reductions in beneficiary liability relative to the amounts they otherwise would have paid. The figures do not necessarily mean that we are estimating that beneficiaries will have lower out-of-pocket costs in 2005 than 2004.

**TABLE 52:**  
Estimated Medicare Beneficiary  
Impact of MMA Provisions Being Implemented  
In this Final Rule  
(in millions)

Provision	FY 05	FY06	FY07	FY08	FY09
Sections 303-305	-\$570	-\$930	-\$1,090	-\$1,200	-\$1,320
Section 611	20	20	20	20	20
Section 612	13	20	23	23	25
Section 613	5	10	13	15	20
Section 413(a)	8	13	13	5	-
Section 413(b)	5	8	8	8	8

Section 623	20	25	25	30	30
Section 629	110				
Section 512	5	5	5	5	5
LOCM	10	15	15	15	15
Physical Therapy	0	10	10	10	10

The implementation of MMA provisions related to drugs and drug administration will reduce Medicare beneficiary liability for Medicare covered services even after including the additional increases in payment for drug administration and establishing a supplying fee for immunosuppressive drugs, a furnishing fee for the clotting factor and a dispensing fee for immunosuppressive drugs. We do not believe that the drug and drug administration payment changes required by the MMA are intended to lessen beneficiary access to care. As indicated earlier, the changes we are making to Medicare payments for the administration of drugs are permanently increasing them by a weighted average of more than 117 percent between 2003 and 2005 and they are being increased by an additional 3 percent for 2005 only. While payments for drugs are being reduced between 2004 and 2005, the statute requires Medicare to pay for them at 6 percent more than their average sales price or the price they are purchased at in the market after taking into account rebates and discounts. Nevertheless, we acknowledge that there is a concern among physicians and others that the large changes in Medicare's



payments may affect their ability or willingness to continue making drugs and related services available. CMS' Office of Research Demonstrations and Information is analyzing Medicare utilization for drugs and drug administration beginning in 2002 and plans to continue to analyze the data for shifts or changes in utilization patterns as the information becomes available to us. To date, we have no evidence that beneficiaries are having any problems with access to drugs. While we do not believe the payment changes for drugs and drug administration will result in access problems, we plan to continue studying this issue. We also note that the MMA requires the Medicare Payment Advisory Commission (MedPAC) to study related issues. Specifically, section 303(a)(5) of the MMA requires MedPAC to study items and services furnished by oncologists and drug administration services furnished by other specialists.

We are also undertaking several changes using our administrative authority that will affect Medicare beneficiaries. Our proposal to remove restrictions that limit Medicare payment for use of low osmolar contrast material to specific indications would update Medicare's payment policy to be consistent with the standard practice

of medicine and will improve the quality of care for beneficiaries.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects**42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

**PART 403—SPECIAL PROGRAMS AND PROJECTS**

**Subpart G—Religious Nonmedical Health Care Institutions -  
Benefits, Conditions of Participation, and Payment**

1. The authority citation for part 403 continues to read as follows:

**Authority:** 42 U.S.C. 1359b-3 and secs 1102 and 1871 of the Social Security act (42 U.S.C. 1302 and 1395hh).

2. Section 403.746 is amended by adding a new paragraph (c) to read as follows:

**§403.746 Condition of participation: Utilization review.**

\* \* \* \* \*

(c) Standard: Utilization review committee role in RNHCI home services. In addition to the requirements in paragraphs (a) and (b) of the section, the utilization review committee is responsible for:

(1) The admission, and at least every 30 days, the continued care review of each patient in the RHNCI home services program.

(2) Oversight and monitoring of the home services program, including the purchase and utilization of

designated durable medical equipment items for beneficiaries in the program.

3. In subpart G, §403.764 through §403.770 are added to read as follows:

**§403.764 Basis and purpose of religious nonmedical health care institutions providing home service.**

(a) Basis. This subpart implements sections 1821, 1861, 1861(e), 1861(m), 1861(y), 1861(ss) and 1861(aaa), 1869 and 1878 of the Act regarding Medicare payment for items and services provided in the home setting furnished to eligible beneficiaries by religious nonmedical health care institutions (RNHCIs).

(b) Purpose. The home benefit provides for limited durable medical equipment (DME) items and RNHCI services in the home setting that are fiscally limited to \$700,000 per calendar year, with an expiration date of December 31, 2006, or the date on which the 2006 spending limit is reached.

**§403.766 Requirements for coverage and payment of RNHCI home services.**

(a) Medicare Part B pays for RNHCI home services if the RNHCI provider foes the following:

(1) Submit a notice of intent to CMS to exercise the option of providing home service.

(2) Provide RNHCI services to eligible beneficiaries,

(3) Arrange with suppliers to furnish appropriate DME items as required to meet documented eligible beneficiary needs.

(4) Arrange for RNHCI nurse home visits to eligible beneficiaries.

(5) Have a utilization committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided under the home benefit.

(6) Meet all applicable requirements set forth in subpart G of this part.

(b) To be an eligible beneficiary to RNHCI home services the beneficiary must:

- (1) Have an effective election in place.
- (2) Be confined to the home, as specified in §409.42(a) of this chapter.
- (3) Have a condition that makes him or her eligible to receive services covered under Medicare home health.
- (4) Receive home services and DME items from a RNHCI.
- (5) Be responsible for deductible and coinsurance for DME, as specified in §409.50 of this chapter.

**§403.768 Excluded services.**

In addition to items and services excluded in §409.49 of this chapter, items and services are also excluded if they are provided by:

(a) A HHA that is not a RNHCI.

(b) A supplier who is not providing RNHCI designated items under arrangement with a RNHCI.

(c) A nurse who is not providing RNHCI home nursing services under arrangement with a RNHCI.

**§403.770 Payments for home services.**

(a) The RNHCI nursing visits are paid at the modified low utilization payment adjusted (LUPA) rate used under the home health prospective payment system at \$484.230 of this chapter.

(b) Appropriate DME items are paid as priced by Medicare, minus the deductible and coinsurance liability of the beneficiary.

**PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

4. The authority citation for part 405 continues to read as follows:

**Authority:** Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).



5. Section 405.207 is amended by revising paragraph (b) to read as follows:

**§405.207 Services related to a noncovered device.**

\* \* \* \* \*

(b) When payment is made. Medicare payment may be made for--

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care services related to experimental/investigational (Category A) devices as defined in §405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination process; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

(3) Routine care services related to a non-experimental/investigational (Category B) device defined in §405.201(b) that is furnished in conjunction with an FDA-approved clinical trial.

6. Section 405.517 is amended by adding a new paragraph (a)(3) to read as follows:

**§405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.**

(a) Applicability. \* \* \*

(3) Payment for drugs and biologicals on or after January 1, 2005. Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart K of this chapter.

\* \* \* \* \*

**PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

7. The authority citation for part 410 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

8. Section 410.1(a) is amended by adding a new paragraph (a)(6) to read as follows:

**§410.1 Basis and scope.**

(a) \* \* \*

(6) Section 1842(o)— Payment for drugs and biologicals not paid on a cost or prospective payment basis.

\* \* \* \* \*

9. Section 410.10 is amended by adding new paragraph (y) to read as follows:

**§410.10 Medical and other health services: Included services.**

\* \* \* \* \*

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

10. Section 410.16 is added to read as follows:

**§410.16 Initial preventive physical examination:  
Conditions for and limitations on coverage.**

(a) Definitions. As used in this section, the following definitions apply:

Eligible beneficiary means an individual who receives his or her initial preventive physical examination within 6 months after the effective date of his or her first Medicare Part B coverage period, but only if that first Part B coverage period begins on or after January 1, 2005.

Initial preventive physical examination means all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner with the goal of health promotion and disease detection:

(1) Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in this section.

(2) Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.

(3) Review of the beneficiary's functional ability, and level of safety as those terms are defined in this section, as described in paragraph (4) of this definition, based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified nonphysician practitioner may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(4) An examination to include measurement of the beneficiary's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.

(5) Performance and interpretation of an electrocardiogram.

(6) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(7) Education, counseling, and referral, including a brief written plan such as a checklist provided to the beneficiary for obtaining the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in section 1861(s)(10), section 1861(jj), section 1861(nn), section 1861(oo), section 1861(pp), section 1861(qq)(1), section 1861(rr), section 1861(uu), section 1861(vv), section 1861(xx)(1), and section 1861(yy) of the Act.

Medical history is defined to include, at a minimum, the following:

(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

(2) Current medications and supplements, including calcium and vitamins.

(3) Family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk.

A physician for purposes of this section means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

A qualified nonphysician practitioner for purposes of this section means a physician assistant, nurse practitioner, or clinical nurse specialist (as authorized under section 1861(s)(2)(K)(i) and section 1861(s)(2)(K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §410.74, §410.75, and §410.76).

Review of the beneficiary's functional ability and level of safety must include, at a minimum, a review of the following areas:

- (1) Hearing impairment.
- (2) Activities of daily living.
- (3) Falls risk.
- (4) Home safety.

Social history is defined to include, at a minimum, the following:

- (1) History of alcohol, tobacco, and illicit drug use.
- (2) Diet.
- (3) Physical activities.

(b) Condition for coverage of an initial preventive physical examination. Medicare Part B pays for an initial

preventive physical examination provided to an eligible beneficiary, as described in this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in this section.

(c) Limitations on coverage of initial preventive physical examinations. Payment may not be made for an initial preventive physical preventive examination that is performed for an individual who is not an eligible beneficiary as described in this section.

11. A new §410.17 is added to read as follows:

**§410.17 Cardiovascular disease screening tests.**

(a) Definition. For purposes of this subpart, the following definition apply:

Cardiovascular screening blood test means:

(1) A lipid panel consisting of a total cholesterol, HDL cholesterol, and triglyceride. The test is performed after a 12-hour fasting period.

(2) Other blood tests, previously recommended by the U.S. Preventive Services Task Force (USPSTF), as determined by the Secretary through a national coverage determination process.

(3) Other non-invasive tests, for indications that have a blood test recommended by the USPSTF, as determined

by the Secretary through a national coverage determination process.

(b) General conditions of coverage. Medicare Part B covers cardiovascular disease screening tests when ordered by the physician who is treating the beneficiary (see §410.32(a)) for the purpose of early detection of cardiovascular disease in individuals without apparent signs or symptoms of cardiovascular disease.

(c) Limitation on coverage of cardiovascular screening tests. Payment may be made for cardiovascular screening tests performed for an asymptomatic individual only if the individual has not had the screening tests paid for by Medicare during the preceding 59 months following the month in which the last cardiovascular screening tests were performed.

12. A new §410.18 is added to read as follows:

**§410.18 Diabetes screening tests.**

(a) Definitions. For purposes of this section, the following definitions apply:

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two



different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Pre-diabetes means a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100--125 mg/dL, or a 2-hour post-glucose challenge of 140--199 mg/dL. The term pre-diabetes includes the following conditions:

- (1) Impaired fasting glucose.
- (2) Impaired glucose tolerance.

(b) General conditions of coverage. Medicare Part B covers diabetes screening tests after a referral from a physician or qualified nonphysician practitioner to an individual at risk for diabetes for the purpose of early detection of diabetes.

(c) Types of tests covered. The following tests are covered if all other conditions of this subpart are met:

- (1) Fasting blood glucose test.
- (2) Post-glucose challenges including, but not limited to, an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, a 2-hour post glucose challenge test alone.
- (3) Other tests as determined by the Secretary through a national coverage determination.

(d) Amount of testing covered. Medicare covers the following for individuals:

(1) Diagnosed with pre-diabetes, two screening tests per calendar year.

(2) Previously tested who were not diagnosed with pre-diabetes, or who were never tested before, one screening test per year.

(e) Eligible risk factors. Individuals with the following risk factors are eligible to receive the benefit:

(1) Hypertension.

(2) Dyslipidemia.

(3) Obesity, defined as a body mass index greater than or equal to 30 kg/m<sup>2</sup>.

(4) Prior identification of impaired fasting glucose or glucose intolerance.

(5) Any two of the following characteristics:

(i) Overweight, defined as body mass index greater than 25, but less than 30 kg/m<sup>2</sup>.

(ii) A family history of diabetes.

(iii) 65 years of age or older.

(iv) A history of gestational diabetes mellitus or delivery of a baby weighing more than 9 pounds.

13. Section 410.26 is amended by revising paragraph (c) to read as follows:

**§410.26 Services and supplies incident to a physician's professional services: Conditions.**

\* \* \* \* \*

(c) Limitations. (1) Drugs and biologicals are also subject to the limitations specified in §410.29.

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in §410.59(a)(3)(iii), §410.60(a)(3)(iii), and §410.62(a)(3)(ii).

14. Section 410.32 is amended by revising paragraph (b)(2)(iii) to read as follows:

**§410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(iii) Diagnostic psychological testing services when—

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or a clinical psychologist.

\* \* \* \* \*

15. Section 410.59 is amended by--

A. Revising paragraph (a) introductory text and paragraph (a) (3) (ii) .

B. Adding new paragraph (a) (3) (iii) .

C. Revising paragraph (b) heading.

C. Revising paragraph (c) (2) .

D. Adding new paragraph (e) (1) (iii) .

The additions and revisions read as follows:

**§410.59 Outpatient occupational therapy services:**

**Conditions.**

(a) Basic rule. Except as specified in paragraph (a) (3) (iii) of this section, Medicare Part B pays for outpatient occupational therapy services only if they are furnished by an individual meeting the qualifications in §484.4 of this chapter for an occupational therapist or by an appropriately supervised occupational therapy assistant but only under the following conditions: \* \* \*

(3) \* \* \*

(ii) By, or under the direct supervision of, an occupational therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform

occupational therapy services within the scope of State law. When an occupational therapy service is provided incident to the service of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to occupational therapy and occupational therapists, except that a license to practice occupational therapy in the State is not required.

(b) Conditions for coverage of outpatient therapy services furnished to certain inpatients of a hospital or a CAH or SNF.   \*   \*   \*

\*   \*   \*   \*   \*

(c) Special provisions for services furnished by occupational therapists in private practice.   \*   \*   \*

(2) Supervision of occupational therapy services.

Occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services.

\* \* \* \* \*

(e) Annual limitation on incurred expenses.

(1) \* \* \*

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

\* \* \* \* \*

16. Section 410.60 is amended by--

- A. Revising paragraph (a) introductory text.
- B. Revising paragraph (a) (3) (ii).
- C. Adding new paragraph (a) (3) (iii).
- D. Revising paragraph (b) heading.
- E. Revising paragraph (c) (2).
- F. Adding new paragraph (e) (1) (iii).

The additions and revisions read as follows

**§410.60 Outpatient physical therapy services: Conditions.**

(a) Basic rule. Except as specified in paragraph (a) (3) (iii) of this section, Medicare Part B pays for outpatient physical therapy services only if they are furnished by an individual meeting the qualifications in §484.4 of this chapter for a physical therapist or by an appropriately supervised physical therapist assistant but only under the following conditions:

\* \* \* \* \*

(3) \* \* \*

(ii) By, or under the direct supervision of a physical therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law. When a physical therapy service is provided incident to the service of a physician, physician's assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.

(b) Condition for coverage of outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.      \*      \*      \*

(c) Special provisions for services furnished by physical therapists in private practice.      \*      \*      \*

(2) Supervision of physical therapy services.  
Physical therapy services are performed by, or under the direct supervision of, a physical therapist in private

practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services.

\* \* \* \*

(e) Annual limitation on incurred expenses.

(1) \* \* \*

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

\* \* \* \*

17. Section 410.62 is amended by—

A. Revising paragraph (a) introductory text and (a) (2) (i), (a) (2) (iii) and (a) (3).

B. Revising paragraphs (b) and (c).

The revisions read as follows:

**§410.62 Outpatient speech-language pathology services:**  
**Conditions and exclusions.**

(a) Basic rule. Except as specified in paragraph (a) (3) (ii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets the qualifications for a speech-language pathologist in §484.4 of this chapter and only under the following conditions: \* \* \*

(2) \* \* \*



(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech-language pathologist who provides the services to the particular individual;

(ii) \* \* \*

(iii) Meets the requirements of §410.61.

(3) They are furnished--

(i) By a provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform speech-language pathology services under State law. When a speech-language pathology service is provided incident to the services of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to speech-language pathology and speech-language pathologists, except that a license to practice speech-language pathology services in the State is not required.

(b) Condition for coverage of outpatient speech-language pathology services to certain inpatients of a hospital, CAH, or SNF. Medicare Part B pays for outpatient speech-language pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires the services but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) Excluded services. No service is included as an outpatient speech-language pathology service if it is not included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

\* \* \* \* \*

18. Section 410.63 is amended by--

- A. Revising paragraph (b) heading.
- B. Adding a new paragraph (c).

The revision and addition reads as follows:

**§410.63 Hepatitis B vaccine and blood clotting factors:**  
**Conditions.**

(b) Blood clotting factors: Conditions. \* \* \*

(c) Blood clotting factors: Furnishing Fee.

(1) Effective January 1, 2005, a furnishing fee of \$0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through

another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay.

(2) The furnishing fee for blood clotting factors furnished in 2006 or a subsequent year is be equal to the furnishing fee paid the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

19. Section 410.78 is amended by --

A. Revising paragraph (a) (4) .

B. Revising paragraph (b) introductory text.

The revisions read as follows:

**§410.78 Telehealth services.**

(a) Definitions \* \* \*

(4) Originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) General rule. Medicare Part B pays for office and other outpatient visits, professional consultation,

psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management and end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site) furnished by an interactive telecommunications system if the following conditions are met:

\* \* \* \* \*

20. Section 410.160 is amended by revising paragraph (f) to read as follows:

**§410.160 Part B annual deductible.**

\* \* \* \* \*

(f) Amount of the Part B annual deductible. (1)

Beginning with expenses for services furnished during calendar year 2006, and for all succeeding years, the annual deductible is the previous year's deductible plus the annual percentage increase in the monthly actuarial rate for Medicare enrollees age 65 and over, rounded to the nearest dollar.

(2) For 2005, the deductible is \$110.

(3) From 1991 through 2004, the deductible was \$100.

(4) From 1982 through 1990, the deductible was \$75.

(5) From 1973 through 1981, the deductible was \$60.

(6) From 1966 through 1972, the deductible was \$50.

\* \* \* \* \*

**PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON  
MEDICARE PAYMENT**

21. The authority citation for part 411 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

22. Section 411.15 is amended by—

- A. Revising paragraph (a)(1).
- B. Adding paragraph (k)(11).

The revision and addition read as follows:

**§411.15 Particular services excluded from coverage.**

\* \* \* \* \*

(a) \* \* \*

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, or initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(11) of this section.

\* \* \* \* \*

(k) \* \* \*

(11) In the case of initial preventive physical examinations, with the goal of health promotion and disease prevention, subject to the conditions and limitations specified in §410.16 of this chapter.

\* \* \* \* \*

23. Section 411.404 is amended by revising paragraph (b) to read as follows:

**§411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.**

\* \* \* \* \*

(b) Written notice. (1) Written notice is given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

(2) A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion.

(3) After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition.

\* \* \* \* \*

**PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES.**

24. The authority citation for part 414 continues to read as follows:

**Authority:** Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

**§414.38 [Removed]**

25. Section 414.38 is removed.

26. Section 414.39 is amended by--

A. Revising paragraph (a).

B. Adding paragraph (c).

The revision and addition read as follows:

**§414.39 Special rules for payment of care plan oversight.**

(a) General. Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

\* \* \* \* \*

(c) Special rules for payment of care plan oversight provided by nonphysician practitioners for beneficiaries who receive HHA services covered by Medicare.

(1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either:

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a consultant whose participation is limited to a single medical condition rather than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.



27. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

**§414.65 Payment for telehealth services.**

(a) \* \* \*

(1) The Medicare payment amount for office or other outpatient visits, consultation, individual psychotherapy, psychiatric diagnostic interview examination, pharmacologic management and end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site) furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

\* \* \* \* \*

28. Section 414.66 is added subpart B to read as follows:

**§414.66 Incentive payments for physician scarcity areas.**

(a) Definition. As used in this section, the following definitions apply

Physician scarcity area is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

Primary care physician is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

29. Section 414.67 is added to subpart B read as follows:

**§414.67 Incentive payments for Health Professional Shortage Areas.**

(a) Physicians' services furnished to a beneficiary in a geographic-based Health Professional Shortage Area (HPSA) are eligible for a 10 percent incentive payment above the

amount paid for their professional services under the physician fee schedule.

(b) Physicians furnishing services in a geographic-based primary medical care HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(c) Psychiatrists furnishing services in a mental health HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule. (The only physicians eligible to receive the 10 percent incentive payment in mental health HPSAs that do not overlap with primary care HPSAs are psychiatrists.)

30. Part 414 is amended by adding a new subpart K to read as follows:

**Subpart K - Payment for Drugs and Biologicals in 2005**

Sec.

414.900 Basis.

414.902 Definitions.

414.904 Basis of Payment.

**Subpart K - Payment for Drugs and Biologicals in 2005**

**§414.900 Basis.**

(a) This subpart implements section 1842(o) of the Act by specifying the methodology for determining the

payment allowance limit for drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza

(ii) Pneumococcal and hepatitis vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

#### **§414.902 Definitions.**

As used in this subpart, unless the context indicates otherwise—

Drug means both drugs and biologicals.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c) (6) (C) of the Act.

Single source drug means a drug described by section 1847A(c) (6) (D) of the Act.

Unit is defined as in part 414, subpart J of this chapter.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c) (6) (B) of the Act.

**§414.904 Basis of payment.**

(a) Method of payment. Payment for a drug for calendar year 2005 is based on the lesser of -

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(b) Multiple source drugs. (1) Average sales prices. The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) Calculation of the average sales price. The average sales price is determined by--

(i) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(c) Single source drugs. (1) Average sales price. The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) Calculation of the average sales price. The average sales price is determined by computing --

(i) The sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(d) Limitations on the average sales price. (1) Wholesale acquisition cost for a single source drug. The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) Payment limit for a drug furnished to an end-stage renal disease patient. (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(3) Widely available market price and average manufacturer price. If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2005, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

(e) Exceptions to the average sales price. (1)

Vaccines. The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) Infusion drugs furnished through a covered item of durable medical equipment. The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2005.

(3) Blood and blood products. In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) Payment limit in a case where the average sales price during the first quarter of sales is unavailable. In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale



acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

31. Part 414 is amended by adding a new subpart L to read as follows:

**Subpart L-Supplying and Dispensing Fees**

Sec.

414.1000 Purpose.

414.1001 Basis of Payment.

**§414.1000 Purpose.**

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

**§414.1001 Basis of payment.**

(a) A supplying fee of \$24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) A supplying fee of \$50 is paid to a pharmacy for the initial supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J) of the Act provided to a patient during the first month following a transplant.

(c) During 2005, a dispensing fee of \$57 is paid to a supplier for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) During 2005, a dispensing fee of \$80 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

#### **PART 418—HOSPICE CARE**

32. The authority citation for part 418 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

33. Section 418.205 is added to subpart F to read as follows:

**§418.205 Special requirements for hospice pre-election evaluation and counseling services.**

(a) Definition. As used in this section the following definition applies.

Terminal illness has the same meaning as defined in §418.3.

(b) General. Effective January 1, 2005, payment for hospice pre-election evaluation and counseling services as specified in §418.304(d) may be made to a hospice on behalf of a Medicare beneficiary if the requirements of this section are met.

(1) The beneficiary. The beneficiary:

(i) Has been diagnosed as having a terminal illness as defined in §418.3.

(ii) Has not made a hospice election.

(iii) Has not previously received hospice pre-election evaluation and consultation services specified under this section.

(2) Services provided. The hospice pre-election services include an evaluation of an individual's need for pain and symptom management and counseling regarding hospice and other care options. In addition, the services

may include advising the individual regarding advanced care planning.

(3) Provision of pre-election hospice services.

(i) The services must be furnished by a physician.

(ii) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(iii) The services cannot be furnished by hospice personnel other than employed physicians, such as but not limited to nurse practitioners, nurses, or social workers, physicians under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice.

(iv) If the beneficiary's attending physician is also the medical director or a physician employee of the hospice, the attending physician may not provide nor may the hospice bill for this service because that physician already possesses the expertise necessary to furnish end-of-life evaluation and management, and counseling services.

(4) Documentation. (i) If the individual's physician initiates the request for services of the hospice medical director or physician, appropriate documentation is required.

(ii) The request or referral must be in writing, and the hospice medical director or physician employee is expected to provide a written note on the patient's medical record.

(iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

34. Section 418.304 is amended by adding paragraph (d) to read as follows.

**§418.304 Payment for physician services.**

\* \* \*

(d) Payment for hospice pre-election evaluation and counseling services. The intermediary makes payment to the hospice for the services established in §418.205. Payment for this service is set at an amount established under the physician fee schedule, for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring

medical decision-making of low complexity other than the portion of the amount attributable to the practice expense component. Payment for this pre-election service does not count towards the hospice cap amount.

**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

35. The authority citation for part 424 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

36. Section 424.55 is amended by adding new paragraph (c) to read as follows:

**§424.55 Payment to the supplier.**

\* \* \* \* \*

(c) Exception. In situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

37. Section 424.71 is amended as follows:

A. The definition of "Health care delivery system or system" is removed.

B. The definition of the term "Entity" is added in alphabetical order.

The addition reads as follows:

**§424.71 Definitions.**

\* \* \* \* \*

Entity means a person, group, or facility that is enrolled in the Medicare program.

\* \* \* \* \*

38. Section 424.80 is amended by—

A. Revising paragraph (a).

B. Revising paragraph (b) (2).

C. Removing paragraph (b) (3).

D. Redesignating paragraphs (b) (4) through (6) as paragraphs (b) (3) through (5), respectively.

E. Revising paragraph (c).

F. Adding a new paragraph (d).

The revisions and addition read as follows:

**§424.80 Prohibition of reassignment of claims by suppliers.**

(a) Basic prohibition. Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement. Nothing in this section alters a

party's obligations under the anti-kickback statute (section 1128B(b) of the Act), the physician self-referral prohibition (section 1877 of the Act), the rules regarding physician billing for purchased diagnostic tests (§414.50 of this chapter), the rules regarding payment for services and supplies incident to a physician's professional services (§410.26 of this chapter), or other laws, rules, and regulations.

(b) \* \* \*

(1) \* \* \*

(2) Payment to an entity under a contractual arrangement. Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section.

\* \* \* \* \*

(c) Rules applicable to an employer or entity. An employer or entity that may receive payment under paragraph (b)(1) or (b)(2) of this section is considered the supplier of those services for purposes of subparts C, D, and E of this part, subject to the provisions of paragraph (d) of this section.

(d) Reassignment to an entity under a contractual arrangement: Conditions and limitations. (1) Liability of



the parties. An entity enrolled in the Medicare program that receives payment under a contractual arrangement under paragraph (b)(2) of this section and the supplier that otherwise receives payment are jointly and severally responsible for any Medicare overpayment to that entity.

(2) Access to records. The supplier furnishing the service has unrestricted access to claims submitted by an entity for services provided by that supplier.

#### **PART 484-HOME HEALTH SERVICES**

39. The authority citation for part 484 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

#### **§484.4 [Amended]**

40. In §484.4 in the definition of physical therapy assistant the term "physical therapy assistant" is removed and the term "physical therapist assistant" is added in its place wherever it appears.

**PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES  
FURNISHED BY SUPPLIERS**

41. The authority citation for part 486 continues to read as follows:

**Authority:** Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart D [Removed and Reserved]**

42. Part 486 subpart D, consisting of §486.150 through §486.163, is removed and reserved.

(Catalog of Federal Domestic Assistance Program No. 93.774,  
Medicare--Supplementary Medical Insurance Program)

Dated: \_\_\_\_\_

\_\_\_\_\_  
**Mark B. McClellan,**  
Administrator,  
Centers for Medicare &  
Medicaid Services.

Dated: \_\_\_\_\_

\_\_\_\_\_  
**Tommy G. Thompson,**  
Secretary

**BILLING CODE 4120-01-P**

**Note:** These addenda will not appear in the Code of Federal Regulations.

**Addendum A -- Explanation and Use of Addenda B**

The addenda on the following pages provide various data pertaining to the Medicare fee schedule for physicians' services furnished in 2005. Addendum B contains the RVUs for work, non-facility practice expense, facility practice expense, and malpractice expense, and other information for all services included in the physician fee schedule.

In previous years, we have listed many services in Addendum B that are not paid under the physician fee schedule. To avoid publishing as many pages of codes for these services, we are not including clinical laboratory codes and most alphanumeric codes (Healthcare Common Procedure Coding System (HCPCS) codes not included in CPT) in Addendum B.

**Addendum B--2005 Relative Value Units and Related**

**Information Used in Determining Medicare Payments for 2005**

This addendum contains the following information for each CPT code and alphanumeric HCPCS code, except for alphanumeric codes beginning with B (enteral and parenteral therapy), E (durable medical equipment), K (temporary codes

for nonphysicians' services or items), or L (orthotics), and codes for anesthesiology.

1. CPT/HCPCS code. This is the CPT or alphanumeric HCPCS number for the service. Alphanumeric HCPCS codes are included at the end of this addendum.

2. Modifier. A modifier is shown if there is a technical component (modifier TC) and a professional component (PC) (modifier -26) for the service. If there is a PC and a TC for the service, Addendum B contains three entries for the code: one for the global values (both professional and technical); one for modifier -26 (PC); and one for modifier TC. The global service is not designated by a modifier, and physicians must bill using the code without a modifier if the physician furnishes both the PC and the TC of the service.

Modifier -53 is shown for a discontinued procedure. There will be RVUs for the code (CPT code 45378) with this modifier.

3. Status indicator. This indicator shows whether the CPT/HCPCS code is included in the physician fee schedule and whether it is separately payable if the service is covered.

A = Active code. These codes are separately payable under the fee schedule if covered. There will be RVUs for

codes with this status. The presence of an "A" indicator does not mean that Medicare has made a national decision regarding the coverage of the service. Carriers remain responsible for coverage decisions in the absence of a national Medicare policy.

B = Bundled code. Payment for covered services is always bundled into payment for other services not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are incident. (An example is a telephone call from a hospital nurse regarding care of a patient.)

C = Carrier-priced code. Carriers will establish RVUs and payment amounts for these services, generally on a case-by-case basis following review of documentation, such as an operative report.

E = Excluded from physician fee schedule by regulation. These codes are for items or services that we chose to exclude from the physician fee schedule payment by regulation. No RVUs are shown, and no payment may be made under the physician fee schedule for these codes. Payment for them, if they are covered, continues under reasonable charge or other payment procedures.

I = Not valid for Medicare purposes. Medicare uses another code for the reporting of, and the payment for these services. (Code **NOT** subject to a 90-day grace period.)

N = Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment.

P = Bundled or excluded code. There are no RVUs for these services. No separate payment should be made for them under the physician fee schedule.

- If the item or service is covered as incident to a physician's service and is furnished on the same day as a physician's service, payment for it is bundled into the payment for the physician's service to which it is incident (an example is an elastic bandage furnished by a physician incident to a physician's service).
- If the item or service is covered as other than incident to a physician's service, it is excluded from the physician fee schedule (for example, colostomy supplies) and is paid under the other payment provisions of the Act.

R = Restricted coverage. Special coverage instructions apply. If the service is covered and no RVUs are shown, it is carrier-priced.

T = Injections. There are RVUs for these services, but they are only paid if there are no other services payable under the physician fee schedule billed on the same date by the same provider. If any other services payable under the physician fee schedule are billed on the same date by the same provider, these services are bundled into the service(s) for which payment is made.

X = Exclusion by law. These codes represent an item or service that is not within the definition of "physicians' services" for physician fee schedule payment purposes. No RVUs are shown for these codes, and no payment may be made under the physician fee schedule. (Examples are ambulance services and clinical diagnostic laboratory services.)

4. Description of code. This is an abbreviated version of the narrative description of the code.

5. Physician work RVUs. These are the RVUs for the physician work for this service in 2005. Codes that are not used for Medicare payment are identified with a "+."



6. Facility practice expense RVUs. These are the fully implemented resource-based practice expense RVUs for facility settings.

7. Non-facility practice expense RVUs. These are the fully implemented resource-based practice expense RVUs for non-facility settings.

8. Malpractice expense RVUs. These are the RVUs for the malpractice expense for the service for 2005.

9. Facility total. This is the sum of the work, fully implemented facility practice expense, and malpractice expense RVUs.

10. Non-facility total. This is the sum of the work, fully implemented non-facility practice expense, and malpractice expense RVUs.

11. Global period. This indicator shows the number of days in the global period for the code (0, 10, or 90 days). An explanation of the alpha codes follows:

MMM = The code describes a service furnished in uncomplicated maternity cases including antepartum care, delivery, and postpartum care. The usual global surgical concept does not apply. See the 1999 Physicians' Current Procedural Terminology for specific definitions.

XXX = The global concept does not apply.

YYY = The global period is to be set by the carrier (for example, unlisted surgery codes).

ZZZ = Code related to another service that is always included in the global period of the other service. (Note: Physician work and practice expense are associated with intra-service time and in some instances the post-service time.)