

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Parts 405, 410, 411, 414, 418, 424, 484, and 486****[CMS-1429-P]****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:** Proposed rule.

**SUMMARY:** This proposed rule would refine the resource-based practice expense relative value units (RVUs) and make other changes to Medicare Part B payment policy. The proposed 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 proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. We solicit comments on these proposed policy changes.

This proposed rule also addresses the following provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA): coverage of an initial preventive physical examination; coverage of cardiovascular 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; clinical conditions for payment of covered items of durable medical equipment; and payment for diagnostic mammograms.

In addition, we discuss physicians' services associated with drug administration services and payment for set-up of portable x-ray equipment.

**DATES:** 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-P. 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-P,  
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 (410) 786-7197 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.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons

wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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).

Roberta 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).

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 all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1429-P 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, phone (410) 786-7197.

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This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The web 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 proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

ACC            American College of Cardiology

ACR            American College of Radiology

AMA            American Medical Association

APA            American Psychological Association

ASP	Average Sales Price
ATA	American Telemedicine Association
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
CAH	Critical Access Hospital
CF	Conversion factor
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
CNS	Clinical Nurse Specialist
CPT	[Physicians'] Current Procedural Terminology [4th Edition, 2002, copyrighted by the American Medical Association]
CPEP	Clinical Practice Expert Panel
CY	Calendar Year
E/M	Evaluation and management
ESRD	End-Stage Renal Disease
FMR	Fair market rental
FY	Fiscal Year
GAF	Geographic adjustment factor
GPCI	Geographic practice cost index
HCPCS	Healthcare Common Procedure Coding System
HHA	Home health agency

HHS	[Department of] Health and Human Services
HOCM	High osmolar contrast media
HPSA	Health Professional Shortage Area
HRSA	Health Resources and Services Administration
IDTFs	Independent Diagnostic Testing Facilities
IPPS	Inpatient prospective payment system
IOM	Internet Only Manual
ISO	Insurance Services Office
LOCM	Low osmolar contrast media
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
NP	Nurse Practitioner
OBRA	Omnibus Budget Reconciliation Act
OMB	Office of Management and Budget
OPPS	Outpatient prospective payment system
PA	Physician Assistant

PC	Professional component
PCF	Patient compensation fund
PEAC	Practice Expense Advisory Committee
PET	Positron Emission Tomography
PHSA	Public Health Services Act
PPS	Prospective payment system
PSA	Physician Scarcity Area
RN	Registered Nurse
RUC	[AMA's Specialty Society] Relative [Value] Update Committee
RUCA	Rural-Urban Commuting Area
RVU	Relative value unit
SCHIP	State Child Health Insurance Program
SGR	Sustainable growth rate
SLP	Speech language pathology
SMS	[AMA's] Socioeconomic Monitoring System
TC	Technical component
USPSTF	U.S. Preventive Services Task Force

## **I. Background**

### **A. Legislative History**

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), "Payment for Physicians' Services." The Act requires that payments under the fee schedule be

based on national uniform relative value units (RVUs) based on 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, the anesthesia conversion factor and 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 would be -4.5 percent; the initial estimate of the sustainable growth rate for CY 2004 was 7.4 percent; and the conversion factor for CY 2004 was \$35.1339.

Subsequent to the November 7, 2003 final rule, the Congress enacted the MMA (Pub. L. 108-17). 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 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.  
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.

## **II. Provisions of the Proposed Rule**

This proposed rule would affect the regulations set forth at Part 405, Federal Health Insurance for the Aged and Disabled; Part 410, Supplementary Medical Insurance (SMI) Benefits; Part 411, Exclusions from Medicare and Limitations on Medicare Payment; Part 414, Payment for Part B Medical and Other Health Services; Part 418, Hospice Care; Part 424, Conditions for Medicare Payment; Part 484, Home Health Services; and Part 486, Conditions for Coverage of Specialized Services Furnished by Suppliers.

A. Resource-Based Practice Expense Relative Value Units

[If you choose to comment on issues in this section, please include the caption "Practice Expense" at the beginning of your comments.]

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 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 physician 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 workpool. 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 normally used in the calculation of the practice expense component of the physician fee schedule. By regulation (see 68 FR 63200), we provided that, beginning this year, supplemental survey data must be submitted by March 1 to be considered for use in computing practice expense RVUs for the following year. This allows us to publish our decisions regarding survey

data in the proposed rule and provides the opportunity for public comment on these results before implementation.

To continue to ensure the maximum opportunity for specialties to submit supplemental practice expense data, we extended until 2005 the period that we would accept survey data that meet the criteria set forth in the November 2000 final rule. We will no longer accept supplemental practice expense data after that point. 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 June 28, 2002 **Federal Register** (67 FR 43849), we proposed a technical change to the practice expense methodology that calculated the technical component as the difference between the global and professional component RVUs for services not included in the nonphysician work pool. In the December 31, 2002 final rule (67 FR 79979), we established a 1-year moratorium on the technical change for pathology services to allow CAP to do a survey of independent laboratories. Consistent with last year's rules, CAP submitted its supplemental survey by August 1, 2003 for use in determining the 2004 practice expense RVUs. Our contractor, The Lewin Group, evaluated the data and recommended that we accept the survey to

supplement the data on PE. However, because we changed the survey deadline to March 1, CAP requested that we delay incorporation of the survey data until this year's proposed rule. CAP also requested that we extend the moratorium on calculating the technical component as the difference between the global and professional component RVUs for pathology services for one additional year to allow us to evaluate in a proposed rule the combined effects of the use of the new survey data along with other proposed technical changes. In the November 7, 2003 final rule, in response to the CAP comment, we agreed to extend the moratorium by an additional year. In this proposed rule, we propose to incorporate the CAP survey data into the practice expense methodology and to end the moratorium on calculating the technical component as the difference between the global and professional component RVUs for pathology services. We propose 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	\$39.7	\$37.5	\$40.1	\$19.3	\$11.1	\$16.1	\$163.8

### 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 made recommendations to us regarding use of the data in a report on May 26, 2004. We have made The Lewin Group report available on the CMS web site at <http://www.cms.hhs.gov/physicians/pfs/>. The Lewin Group is recommending that we accept the data from ACC and ACR but indicated that the survey from ASTRO does not meet the precision criteria we have established for supplemental surveys. As a result, The Lewin Group is not recommending that we use the ASTRO survey results at this time. We agree with this recommendation and are proposing not using the ASTRO survey data at this time.

Many of the procedures that are performed by radiology, cardiology, and radiation oncology are affected by the nonphysician work pool calculations. We created the nonphysician work pool as an interim measure because of a concern that the top-down methodology was having a large adverse impact on payment for services that do not have physician work RVUs. As we stated in the December 31, 2002 final rule (67 FR 79979), we believe a relatively low

practice expense per hour explains the adverse impact on diagnostic and other services that would occur from eliminating the nonphysician work pool. The ACR, ACC, and ASTRO began undertaking surveys in 2003 following our analysis of options for eliminating the nonphysician work pool in the December 31, 2002 final rule. CMS' interest is in using the supplemental survey data to eliminate the nonphysician work pool and use a single methodology to establish payments for all physician fee schedule services.

We appreciate the efforts of these three specialties to undertake surveys and assist CMS in finding a permanent resolution of issues related to the nonphysician work pool. While the radiology survey data do meet the criteria we have established for use of supplemental surveys, the ACR has written to us asking 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. The ACC also requested that we use the supplemental survey for services that are in the cardiology pool. However, ACC also indicated if CMS determines that it would only be appropriate to use the survey data if cardiology services are removed from the nonphysician work pool or if the nonphysician work pool is eliminated, we

should delay using the data until the issues involved can be discussed further.

At this time, we are not proposing to eliminate the nonphysician work pool or to remove selected radiology and cardiology codes from it. Since our interest is in using supplemental data in conjunction with pricing all services under the top-down methodology, we agree with the request from ACR to delay use of its supplemental survey until issues related to the nonphysician work pool can be addressed. Furthermore, we believe the high practice expense per hour for cardiology from the supplemental survey results from the inclusion of practices that do very high cost office-based cardiology services. Because the RVUs for these office-based cardiology services are currently determined using the nonphysician work pool methodology, we believe the ACC supplemental survey data should only be used in conjunction with removing cardiology services from the nonphysician work pool. For this reason, we are also delaying use of the ACC survey data as we continue to analyze elimination of the nonphysician work pool in conjunction with using supplemental survey data. As we complete our analysis, we look forward to working with the medical community to find a permanent resolution of this issue.

b. Practice Expense Advisory Committee (PEAC)Recommendations on CPEP inputs for 2005

Since 1999, 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) for existing CPT codes. As we did last year, we are including our proposals regarding the PEAC recommendations in the proposed rule, to enable specialty groups to assess the impact of the proposed changes on their services and to make comments on them before the final rule.

These PEAC recommendations are the result of meetings held in March and August 2003 and January and March 2004, and account for over 2,200 codes from many specialties. (A list of these codes can be found in Addendum C.)

The PEAC held its last meeting in March 2004, and these are the last recommendations we will be receiving from the committee. The AMA established the PEAC to assist the RUC in refining the direct input data used in calculating the practice expense RVUs for established codes. Since its inception, the PEAC has provided recommendations on over 7,600 codes, which leaves only a few hundred physician fee schedule codes that we believe are still unrefined. The PEAC has also recommended

standard times for many clinical staff activities and has established several supply and equipment packages that can be applied across wide ranges of codes. This has helped us ensure that the CPEP inputs have been assigned equitably across procedures performed by different specialties. The work of the PEAC has, therefore, contributed greatly to the refinement of the practice expense inputs, and we appreciate the 5 years of hard work by the specialty societies and the AMA that helped make the PEAC so successful. Future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, will be handled by the RUC. We anticipate the RUC will formulate the specific process at a future meeting, possibly as soon as October 2004. If possible, additional information on this process will be included in the final fee schedule rule.

We have reviewed the PEAC-submitted recommendations and propose to adopt nearly all of them. We have worked with the PEAC staff to correct any typographical errors and to make certain that the recommendations are in line with previously accepted standards. In addition, in order to prevent rank order anomalies, we 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 are proposing 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 are proposing to eliminate the discharge 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 are proposing to delete any extra clinical staff time for post-visit phone calls because that time is already included in the time allotted for the visits.

The complete PEAC recommendations and the revised practice expense database can be found on our web site. (See the "Supplementary Information" section of this proposed rule for directions on accessing our website.)

We disagree with the PEAC recommendation for clinical labor time for CPT 99183, Hyperbaric oxygen (HBO) therapy. During last year's rulemaking, we assigned, on an interim basis, 135 minutes of total clinical labor. The PEAC however, recommended 42 minutes of total clinical labor time, which allows for 20 minutes for the HBO chamber treatment (intra) time. We believe that 90 minutes is a more appropriate estimation of the clinical staff time actually needed for the intra time because, according to

our data, a typical HBO treatment session billed under the outpatient prospective payment system is 90 minutes and the clinical staff is in constant attendance. Therefore, we are proposing a total clinical labor time of 112 minutes for this service.

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 subsequent to receipt of the PEAC recommendations, we learned this is incorrect, since an injected form of methacholine chloride is not currently available. For CPT 91011, esophageal motility study, we are proposing to include edrophonium, 1 ml, as the drug typically used in this procedure. For CPT 91052, gastric analysis study, we were unable to identify the single drug that is most typically used with this procedure. We have added the edrophonium to the list of supplies where we need information from the specialty in order to price appropriately (see Table 3). We are also requesting that commenters, particularly the specialty organizations, provide us with information on the drug that is most typically used for CPT 91052, including drug dosage and

price, so that it can be included in the practice expense database.

In last year's final rule, we indicated that we would not go forward with the 2003 PEAC recommendations on eight E/M codes for nursing home services, CPT codes 99301 through 99316 and on two E/M codes for home visits, CPT codes 99348 and 99350, to allow the PEAC to reconsider the clinical staff time for these codes based on the specific input from the representatives of the nursing home and home visit specialties. This year's PEAC recommendations for the E/M nursing home services included the views of the long-term care physicians and represent an overall decrease in clinical labor inputs for these codes. However, the home care physicians subsequently withdrew these codes from further PEAC consideration, which leaves the 2003 PEAC recommendation for these services unchanged. Therefore, we are proposing to adopt the direct practice expense input recommendations from the March 2003 PEAC meeting for CPT codes 99348 and 99350.

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 considered the useful life of the equipment in establishing an equipment cost per minute of use. This was discussed in our proposed rule published June 18, 1997 (62 FR 33164). The primary source of this information was the "Estimated Useful Lives of Depreciable Hospital Assets" (1993 edition) from the American Hospital Association (AHA).

We proposed updates and revisions to the clinical staff salary data and supply inputs and finalized these in the rules published November 1, 2001 (66 FR 55255) and November 7, 2003 (68 FR 63196), respectively. We also indicated that, in future rulemaking, we would be proposing updates to the equipment inputs that are used in the CPEP database.

We contracted with a consultant to assist us in obtaining the current price for each equipment item in our CPEP database. The consultant has been able to determine the current prices for most of the equipment inputs and, to ensure that accurate information was obtained, has submitted documentation from vendor catalogs or websites for nearly 600 equipment items.

Our contractor also 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 are proposing 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 because there does not appear to be a standard configuration for such a room across the nuclear medicine codes.

Although individual equipment items valued under \$500 are not included in the equipment database, we do include instrument packs or surgical trays that are maintained, stored, and used as a unit, where the aggregate cost of individual items equals or exceeds \$500. We have adopted the PEAC recommendation based on consensus among

specialties to establish two generic instrument packages rather than list a myriad of different packages for each specialty. The basic instrument pack, assigned a value of \$500, includes instrument aggregate costs ranging from \$500 to \$1,499. The medium pack was assigned \$1,500, for instrument packages priced at or above \$1,500. We are proposing to replace all surgical packs and trays in the practice expense database with the appropriate standardized packs described above.

Our consultant worked closely with the specialty societies to obtain accurate information to identify equipment and applicable prices. The useful life for each equipment item has also been reviewed and updated as necessary. This update is primarily based on the AHA's "Estimated Useful Lives of Depreciable Hospital Assets" (1998 edition) by direct association with a listed item in the publication or by crosswalking from a reasonably similar item. We understand that AHA will publish updated guidelines this summer, and we plan to reflect any updates in our final rule.

Addendum D lists the proposed new prices for equipment items, instrument packs, and rooms/lanes, as well as new descriptions when needed. A more detailed spreadsheet can be found on our website,

<http://www.cms.hhs.gov/physicians/pfs>. This spreadsheet contains additional information regarding the sources used to price each equipment item.

Additionally, there are specific equipment items for which a source has not yet been identified or for which pricing information has not yet been found and documented. These are included in Table 2 below. In this table, we have identified the equipment code (if assigned), the existing description for the equipment item and current price, the procedures or specialties associated with the item, as well as the proposed new description and standardized life for the equipment's use, where this could be identified. We have also identified equipment for deletion from the database, such as equipment items less than \$500 and items that have become obsolete. We are requesting that commenters, particularly the relevant specialty groups, provide us with the needed pricing information, including appropriate documentation. Whenever possible, commenters should provide multiple sources of documentation so that a typical price can be determined. If we are not able to obtain any verified pricing information for an item, we may eliminate it from the database.

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

<b>Code</b>	<b>2005 Description</b>	<b>Price</b>	<b>Primary specialties associated with item</b>	<b>*CPT code(s) associated with item</b>	<b>Status of item</b>
	Ambulatory blood pressure monitor	3,000.00	cardiology	93784, 93786, 93788	See Note A
	biofeedback equipment		psychology	90875	See Note A
	CAD processor unit (mammography)	210,000.00	radiology	76082, 76083, 76085	See Note A (Need system components)
E53005	camera system, cardiac, nuclear	675,000.00	anesthesia, IM, cardiology	78414	See Note A
E53026	collimator, cardiofocal set	29,990.00	radiology	78206, 78607, 78647, 78803, 78807	See Note A
E71013	computer and VDT and software	9,000.00	ophthalmology, optometry	92060, 92065	See Notes A and C
	computer software, MR/PET/CT fusion	60,000.00	radiation oncology	77301	See Note A
E51022	computer system, record and verify	60,000.00	radiation oncology	77418	See Note A
E51050	computer workstation, 3D teletherapy treatment planning	221,500.00	radiation oncology	77300, 77305, 77310, 77315, 77321, 77331	See Note A
	computer workstation, MRA post processing		radiology	71555, 72159, 72198, 73225, 73725, 74185	See Note A
	computer, server		radiation oncology	77301	See Note A (Need system components)
	cortical bipolar-biphasic stimulating equipment		neurosurgery, neurology	95961, 95962	See Note A
	CPAP/BiPAP remote clinical unit		pulmonary disease, neurology	95811	See Note A
	cryo-thermal unit		anesthesia	64620	See Notes A and C

E53034	densitometry unit, whole body, DPA	65,000.00	radiology	78351	See Notes A and C
E53032	densitometry unit, whole body, SPA	22,500.00	radiology	78350	See Notes A and C
E53036	Detector (Probe)	14,000.00	radiology, cardiology	78455	See Notes A and C
	dialysis access flow monitor	10,000.00	nephrology	90940	See Note A
	diathermy, microwave		anesthesia, GP, podiatry	97020	See Notes A and C
	DNA image analyzer (ACIS)	200,000.00	lab, pathology	88358, 88361	See Note A
	drill, ophthalmology		ophthalmology	65125	See Note A
E55035	ECG signal averaging system	8,250.00	cardiology, IM	93278	See Note A
	EEG monitor, digital, portable		neurology	95953	See Note A
E54008	EEG recorder, ambulatory	6,940.00	neurology	95950	See Note A
E54009	EEG review station, ambulatory	44,950.00	neurology	95950	See Note A
	electroconvulsive therapy machine		psychiatry	90870	See Note A
	electromagnetic therapy machine	25,000.00	physical therapy	G0329	See Note A
E54012	EMG botox	1,500.00	critical care, pulmonary, ophthalmology	92265	See Note A
E52002	fetal monitor <u>software</u>	35,000.00	ob-gyn, radiology	76818, 76819	See Note A
	film alternator (motorized film viewbox)	27,500.00	radiology	329 codes	See Note B
	generator, constant current	950.00	neurology, NP	95923	See Note A
E51072	HDR Afterload System, Nucletron - Oldelft	375,000.00	radiation oncology	77781-84	See Note A
	hyperbaric chamber	125,000.00	FP, IM, EM	99183	See Note A
	hyperthermia system, ultrasound, external	360,000.00	radiation oncology	77600	See Note A

	hyperthermia system, ultrasound, intracavitary	250,000.00	radiation oncology	77620	See Note A
	hysteroscopy ablation system	19,500.00	ob-gyn	58563	See Note A
E13652	image analyzer (CAS system)	92,000.00	pathology, neurology	88355, 88356	See Note A
	IMRT physics tools	55,485.00	radiation oncology	77301, 77418	See Note A
E91008	IVAC Injection Automatic Pump	2,500.00	radiology	78206, 78607, 78647, 78803, 78807	See Note A
	mammography reporting software		radiology	76090, 76091, 76092	See Note A
E12002	neurobehavioral status instrument-average	717.00	psychology, IM	96115, 96117	See Note A
	orthovoltage radiotherapy system	140,000.00	radiation oncology	77401	See Note A
	OSHA ventilated hood	5,000.00	radiation oncology	77334	See Note B
E91011	plasma pheresis machine w/UV light source	37,900.00	radiology, dermatology	36481, 36510, 36522	See Note A
E55013	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
	pulse oxymetry recording software (prolonged monitoring)	3,660.00	pulmonary disease, IM	94762	See Note A
	radiation treatment vault	550,670.00	radiation oncology	774XX	See Note B
	radiation virtual simulation system		radiation oncology	77280, 77285, 77290, 77402-16	See Note A
	remote monitoring service (neurodiagnostics)	9,500.00	neurology	95955	See Note A
E54010	review master	23,500.00	pulmonary disease, neurology	95805, 95807-11, 95816, 95822, 95955-56	See Note A
E51004	room, basic radiology	150,000.00	radiology	103 codes	See Note A

E51016	room, mammography	130,000.00	radiology	19030, 19290-91, 19295, 76086-92, 76096	See Note A
E51005	room, radiographic-fluoroscopic	475,000.00		123 codes	See Note A
	source, 10 Ci Ir 192	22,000.00	radiation oncology	77781-84	See Note A
	strontium-90 applicator	8,599.00	radiation oncology	77789	See Note A
	table, cystoscopy		urology	52204-24, 52265-75, 52310-17, 52327-32	See Note A
E52001	ultrasound color doppler, transducers and vaginal probe	155,000.00	ob-gyn	59070, 59074, 76818- 19	See Note A
E52007	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
	vacuum cart		anesthesia	64620	See Notes A and C
E13635	video camera	1,000.00	radiation oncology	77418	See Note A
	water chiller (radiation treatment)	28,000.00	radiation oncology	77402-16	See Note B
E51076	well counter		radiology	78160-72, 78282	See Note A

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Notes:

- A. Additional information required. Need detailed description (including system components as specified), source, and current pricing information.
- B. Proposed deletion as indirect expense.
- C. Item may no longer be available.

In addition to reviewing and updating the cost information for equipment items in the database, our contractor also recommended the following revisions to provide uniformity and consistency in the CPEP equipment database. All of the following recommendations are noted in Addendum D:

Assignment of equipment categories. In the original CPEP data, a number was assigned to each item of equipment. The contractor has recommended that each equipment item also be assigned a "category" to allow for easier identification and sorting of items. We agree and are proposing that equipment be assigned to one of the following six categories: documentation, laboratory, scopes, radiology, furniture, rooms-lanes, and other equipment.

These categories could also be used to establish a new numbering system for equipment that would more clearly identify them for practice expense purposes. We would assign a letter to each category and use this in conjunction with a number (000 through 999) to identify each item of equipment. This would enable specialty groups to identify more easily whether an item of equipment has already been included in the practice expense database and would help avoid duplication of references to the same item

of equipment under different descriptions. If we proceed in the final rule with this proposed method for categorizing equipment, we will assign new identifying numbers to each equipment input item and these will be available on our website.

Consolidation/standardization of item descriptions.

When items appear to be duplicative, we are proposing to combine the items. 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 propose to merge these two line items and reflect both prices in the price of the LEEP system. All proposed changes are specifically referenced in Addendum D.

We welcome any comments on the proposed pricing and all other proposed revisions. To help us evaluate the information provided, comments should include documentation from more than one source, where available, such as information from a vendor catalog or website or from a current invoice.

d. Miscellaneous Practice Expense Issues

i. Pricing for Seldinger Needle

We received comments from a specialty organization on our November 7, 2003 rule stating that the \$72.90 price

assigned to the Seldinger needle, which is used in certain radiological procedures, is too high. The organization estimated that the cost is actually closer to \$7.00; however, documentation was not provided to support this price estimate. Our contractor was able to confirm pricing information from two sources, including a price of \$3.50 from a hospital supplier and a price of \$6.85 from a cardiology supplier. Based on this pricing variability, we are proposing to average the two prices of this supply item to reflect a cost of \$5.175. If a commenter disagrees with this proposed 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.

ii. Hysteroscopic Endometrial Ablation

We received requests from a manufacturer and physicians to price CPT code 56853, Hysteroscopy with endometrial ablation, in the office setting so that physicians providing this service in the nonfacility setting could receive an appropriate payment. (This service is currently valued only in the facility setting.) We have worked with the specialty society, the American College of Obstetricians and Gynecologists, to identify the required resources based on the typical practice. We propose to assign on an interim basis, the following direct

practice expense inputs in the nonfacility setting for this service.

- Clinical Staff: RN/LPN/MTA--72 minutes (18 pre-service and 54 service)
- Supplies: PEAC multispecialty visit supply package, Post-op incision care kit, 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.

We will request that the RUC review these inputs along with inputs of other codes still in need of refinement.

### iii. Photopheresis

We received a request from a supplier to review the direct practice expense inputs currently in our database

for the photopheresis service, CPT code 36522. These inputs are based on the original CPEP panel recommendations and the supplier does not believe they are reflective of the resources now being used. This service was not reviewed by the PEAC during the refinement process, and we agree that the direct inputs need to be revised for this service. We propose to assign, on an interim basis, the following nonfacility practice expense inputs, and we will request that the RUC review them as part of the practice expense refinement process.

- 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 drapesheet 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.

iv. 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 following table, Proposed Practice Expense Supply Item Additions for 2005, lists these additional supply items and the proposed associated prices that we will use in the practice expense calculation.

**Table 3**  
**Proposed Practice Expense Supply Item**  
**Additions for 2005**

<b>Supply Description</b>	<b>Unit Price*</b>	<b>Unit</b>	<b>*CPT code(s) associated with item</b>	<b>Supply Category</b>
acrylic tray-base material	1.775	oz	21421, 21452	Lab
adapter, luer lock	1.249	item	36515	Hypodermic, IV
adapter, spike (for syringe)	4.558	item	36515	Hypodermic, IV
adhesive, conductive (silver, liquid)	3.000	gm	88349	Lab
adhesive, cyanoacrylate (2ml uou).doc	28.988	item	65286	Pharmacy, Rx
airway adapter	12.500	item	94770	Accessory, Procedure
albuterol inhal soln (3ml vial)	0.436	item	95070	Pharmacy, Rx
alcohol ethyl 100%	0.028	ml	88348	Lab
applicator, cotton-tipped, sterile, 6in	0.056	item	127 codes	Wound Care, Dressings
applicator, wood, 6.5in	0.008	item	99348-49	Lab
bag system, 1000ml (for angiography waste fluids)	8.925	item	93501, 93505-10	Accessory, Procedure
balanced salt soln (BSS) (15ml uou)	1.600	item	59 codes	Pharmacy, Rx
battery, AA	0.450	item	95250	Office Supply, Grocery
blade, surgical, super-sharp	4.167	item	14 codes	Cutters, Closures, Cautery
blade, urethrotome	85.030	item	52270	Cutters, Closures, Cautery
blood collection tube holder	0.163	item	78110-11, 78120-22, 78130, 78191, 78725	Hypodermic, IV
blood collection tube needle	0.142	item	36514-16, 78110-11, 78120-22, 78130, 78191, 78725	Hypodermic, IV
blood pressure recording form, average	0.310	item	93784, 93786, 93788	Office Supply, Grocery
brush, protected airway specimen	13.000	item	31623, 31717	Accessory, Procedure
bur, surgical, sterile (drill)	4.792	item	28289	Accessory, Procedure
canned air (Dust-Off)	1.021	oz	88348	Office Supply, Grocery

cannula, anterior chamber, 18-27g	2.688	item	65815, 66020, 66030, 66250	Accessory, Procedure
catheter percutaneous fastener (Percu-Stay)	12.745	item	32201, 44901, 47525, 47530, 48511, 49021, 49041, 49061, 49423, 49424, 50021, 58823	Accessory, Procedure
catheter, (Glide)	62.000	item	36218, 36248	Accessory, Procedure
catheter, (SIM2F1)	17.000	item	36011-15, 36215-17, 36245-47	Accessory, Procedure
catheter, angiographic	16.200	item	93508, 93510, 93526	Hypodermic, IV
catheter, balloon inflation device	24.900	item	35470-76	Accessory, Procedure
catheter, balloon ureteral (Dowd)	65.000	item	52330	Accessory, Procedure
catheter, balloon, low profile PTA	431.500	item	35470, 35471, 35474	Accessory, Procedure
catheter, balloon, PTA	243.500	item	35472-73, 35475-76	Accessory, Procedure
catheter, curved	17.775	item	36218	Accessory, Procedure
catheter, hyperthermia, closed-end		item	77600-20	Hypodermic, IV
catheter, hyperthermia, open-end		item	77600	Hypodermic, IV
catheter, microcatheter (selective 3rd order)	337.880	item	36217, 36247	Accessory, Procedure
catheter, Swan Ganz	65.000	item	93501, 93526	Accessory, Procedure
catheter, ureteral, acorn tip	9.550	item	52007, 52010, 52327, 52330	Accessory, Procedure
clamp, circumcision	7.500	item	54150	Cutters, Closures, Cautery
collagen, dermal implant (2.5ml uou) (Contigen)	317.000	item	52327, 52330	Pharmacy, Rx
conformer, sterile, acrylic	20.000	item	68340	Accessory, Procedure
contact lens (hard) care kit	7.950	item	92325-26	Pharmacy, NonRx
contact lens (hard) extra strength cleaning solution	0.158	ml	92325-26	Pharmacy, NonRx
contact lens (RGP) polishing soln (Silo2 Care)	0.077	ml	92325	Pharmacy, NonRx
container, 2000ml, transfer pack	7.120	item	36515	Accessory, Procedure
container, 600ml, transfer pack	3.360	item	36515	Accessory, Procedure
cotton balls, sterile	0.022	item	115 codes	Wound Care, Dressings

cup, sterile, 12-16 oz	0.760	item	32201, 44901, 48511, 49021, 49041, 49061, 50021, 58823, 93501, 93505, 93508, 93510, 93526	Lab
cup, sterile, 8 oz	0.542	item	32201, 44901, 48511, 49021, 49041, 49061, 50021, 58823	Lab
cuvette, whole blood oximeter	115.000	item	93501, 93526	Hypodermic, IV
diamond knife cleaning rod	1.000	item	99348	Lab
drainage catheter, all purpose	88.430	item	44901, 47525, 47530, 48511, 49021, 49041, 49061, 49423, 50021, 50398, 58823	Accessory, Procedure
drainage catheter, chest	88.890	item	32201	Accessory, Procedure
drainage pouch, nephrostomy-biliary	13.250	item	32201, 44901, 47525, 47530, 48511, 49021, 49041, 49061, 49423, 50021, 50398, 58823	Accessory, Procedure
drape, sterile, incise, ophthalmic	4.900		67025, 67028, 67110, 67120	Gown, Drape
drape, sterile, split-sheet	10.243	item	212 codes	Gown, Drape
drape, sterile, table 44in x 76in	5.250	item	93501-10, 93526	Gown, Drape
electrode, Bugbee	115.000	item	52204, 52214, 52224, 52265, 52275, 55200, 55250	Accessory, Procedure
electrode, EEG (single)	1.638	item	95961, 95816	Accessory, Procedure
electrode, EGG (single)	2.917	item	91132, 95925-27, 95930	Accessory, Procedure
endoscopic deflecting brush	73.500	item	52007	Accessory, Procedure
film, x-ray, laser print	1.437	item	146 codes	Office Supply, Grocery
Floxin 0.3% otic soln	2.354	ml	69145, 69620	Pharmacy, Rx
forceps, endomyocardial biopsy	250.000	item	93505	Accessory, Procedure

forceps, Kelly	2.335	item	93501-10, 93526	Accessory, Procedure
gas, nitrogen	2.708	cu ft	88348-49	Lab
glass knife boat	0.200	item	88348	Lab
grid storage box (holds 50 grids)	3.750	item	88348	Lab
guidewire bowl w-lid, sterile	3.000	item	93501-10, 93526	Accessory, Procedure
guidewire, cerebral (Bentson)	14.500	item	36011-15, 36215-17, 36245-47	Accessory, Procedure
guidewire, low profile (SpartaCore)	101.250	item	35470-71, 35474	Accessory, Procedure
guidewire, steerable (Hi-Torque)	90.000	item	35470-76, 37203	Accessory, Procedure
guidewire, steerable (Transcend)	180.000	item	36217, 32647	Accessory, Procedure
guidewire, torque	41.000	item	35470-76	Accessory, Procedure
heparin 5,000 units-ml inj	0.509	ml	36514-15	Pharmacy, Rx
hyaluronic acid viscoelastic inj (Amvisc, 0.5ml uou)	61.000	item	65286, 65815, 66250	Pharmacy, Rx
hysteroscope ablation device	1,146.000	item	58563	Accessory, Procedure
Jessner's soln	0.240	ml	15788-89, 15792-93	Pharmacy, Rx
Kenalog 40 inj	1.830	ml	31830	Pharmacy, Rx
kit, AccuStick II Introducer System with RO Marker	82.620	kit	26 codes	Kit, Pack, Tray
kit, apheresis treatment	140.000	kit	36515	Kit, Pack, Tray
kit, barium enema	9.466	kit	75270, 74283	Kit, Pack, Tray
kit, BCR/ABL DNA probe	42.650	kit	88365	Kit, Pack, Tray
kit, slit catheter (for compartment pressure monitor)	73.750	kit	20950	Kit, Pack, Tray
kit, vasotomy		kit	55200, 55250	Kit, Pack, Tray
lacrimal duct stent-tube set	74.000	item	68815	Accessory, Procedure
lead citrate	0.510	gm	88348	Lab
manifold (for angiography)	6.682	item	93501, 93508, 93510, 93526	Accessory, Procedure
marker, gold, for radiosurgery-radiotherapy	29.667	item	77761-63	Accessory, Procedure
mask, CPR (RespAide)	16.950	item	92950	Accessory, Procedure
methoxsalen, sterile solution (UVADEX), 10ml vial	49.500	ml	36522	Pharmacy, Rx
microsponge, cellulose (10 pack uou)	3.620	item	22 codes	Wound Care, Dressings

mount, carbon spectro-pure (for SEM)	0.500	item	88349	Lab
nasal tip, olive	0.340	item	92512	Accessory, Procedure
nebulizer medication cup	0.140	item	95070	Accessory, Procedure
needle, arterial, percutaneous	3.150	item	93501, 93505, 93508, 93510, 93526	Hypodermic, IV
needle, bone biopsy	65.000	item	20225	Hypodermic, IV
needle, flexi, hyperthermia	12.000	item	77600-20	Hypodermic, IV
needle, micropigmentation (tattoo)	12.000	item	11920-21	Hypodermic, IV
needle, OSHA compliant (SafetyGlide)	0.454	item	37 codes	Hypodermic, IV
needle, retrobulbar (Atkinson)	1.825	item	67120, 67141	Hypodermic, IV
Omnipaque 350mg (125ml uou)	29.530	item	93508, 93510, 93526	Pharmacy, Rx
Omnipaque 350mg (50ml uou)	12.498	item	42550, 70370	Pharmacy, Rx
osmometer sample tip and cleaner	0.534	item	88348	Lab
osmometer std, 50 mOsm-kg, 2ml amp	17.000	ml	88348	Lab
osmometer std, 850 mOsm-kg, 2ml amp	17.000	ml	88348	Lab
pack, drapes, ortho, large	40.646	pack	102 codes	Kit, Pack, Tray
pack, drapes, ortho, small	1.128	pack	37 codes	Kit, Pack, Tray
pack, ophthalmology visit (w-dilation)	1.997	pack	65272-73, 65280-85, 65290, 65810-15, 65855-60, 66130, 66625-35, 67031, 68130	Kit, Pack, Tray
pack, protective, ortho, large	9.182	pack	99 codes	Kit, Pack, Tray
pack, protective, ortho, small	4.441	pack	38 codes	Kit, Pack, Tray
paper, weighing (glassine)	0.021	item	88348	Lab
phenol, liquified, USP	0.135	ml	15788-93	Pharmacy, Rx
Photo-Flo soln	0.021	ml	88348	Office Supply, Grocery
pipette bulb	0.271	item	88348-49	Lab
pipette, 9inch	0.054	item	88348-89	Lab
plasma antibody adsorption column (Prosorba)	1,150.000	item	36515	Accessory, Procedure
plasma LDL adsorption column (Liposorber)	1,300.000	item	36516	Accessory, Procedure
plasma leukocyte filter	49.719	item	36515	Accessory, Procedure
plasma separator (Liposorber)	100.000	item	36516	Accessory, Procedure
plate, surgical, mini-compression, 4 hole	226.000	item	21208	Accessory, Procedure

plate, surgical, mini-i, 16mm	147.000	item	21210	Accessory, Procedure
plate, surgical, reconstruction, left, 5 x 16 hole	719.000	item	21125-27, 21215	Accessory, Procedure
plate, surgical, reconstruction, template, 5 x 16 hole	50.000	item	21125-27, 21215	Accessory, Procedure
plate, surgical, rigid comminuted fracture	389.000	item	21461, 21462	Accessory, Procedure
plate, surgical, rigid comminuted fracture, template	29.000	item	21461, 21462	Accessory, Procedure
pressure bag		item	93501, 93508-10, 93526	Hypodermic, IV
prosthesis, voice button (Blom-Singer)	48.000	item	31611	Accessory, Procedure
scalpel, safety, surgical, with blade (#10-20)	2.143	item	54150, 54160, 54162	Cutters, Closures, Cautery
screw, surgical, auto-drive, 2.0mm x 4mm	37.000	item	21210	Accessory, Procedure
screw, surgical, Carroll-Girard, 9cm x 3.75in	92.000	item	21401	Accessory, Procedure
screw, surgical, lag, 2.4mm x 26mm	66.000	item	21461-62	Accessory, Procedure
screw, surgical, locking, 2.4mm x 16mm	74.000	item	21127, 21208, 21215	Accessory, Procedure
screw, surgical, self-tapping, 1.5-2.0mm	27.000	item	21100, 21452	Accessory, Procedure
screw, surgical, standard, 2.4mm x 14mm	42.000	item	21125	Accessory, Procedure
screw, surgical, standard, 2.7mm x 12mm	47.000	item	21125-27, 21208, 21215, 21461-62	Accessory, Procedure
sea salt	0.004	gm	15810-11	Office Supply, Grocery
sensor, manometry	25.000	item	91010-12, 91122	Accessory, Procedure
sheath, peel away	68.990	item	47530	Accessory, Procedure
skin refrigerant-anesthetic spray (Frigiderm)	5.000	oz	15780-86, 15788-93	Pharmacy, Rx
sodium acetate	0.064	gm	88348	Lab
sodium barbital	0.315	gm	88348	Lab
specimen block storage box	0.625	item	88348	Lab
splint, finger (metal-foam)	1.655	item	26700-05, 26720-25, 26740-42, 26750-55, 26770-75	Wound Care, Dressings
sucrose, reagent	0.037	gm	88348	Lab
suture device for vessel closure (Perclose A-T)	225.000	item	35470-75	Accessory, Procedure
suture, monocryl, 3-0 to 6-0, p, ps	9.887	item	15050, 15200, 15220, 15240, 15260	Cutters, Closures, Cautery

suture, nylon, 8-0 to 9-0	15.320	item	65270-72, 65275, 65420-26, 66130, 66250, 68115-30, 68320, 68330, 68340, 68360	Cutters, Closures, Cautery
suture, plain, gut, 2-0 to 6-0	4.262	item	41872	Cutters, Closures, Cautery
suture, polyester, 0 to 3-0 (Mersilene)	3.895	item	40840-45	Cutters, Closures, Cautery
suture, vicryl, 7-0	21.773	item	67120	Cutters, Closures, Cautery
syringe 12ml, coronary control	7.000	item	93508-10, 93526	Hypodermic, IV
syringe filter	2.040	item	88348	Hypodermic, IV
tape, foam, elastic, 2in (Microfoam)	0.003	inch	21120-23, 21315, 21355-56, 31820-25	Wound Care, Dressings
Toluidine Blue O (for microscopy)	0.580	gm	88348	Lab
towel clamp, plastic	0.556	item	93501-10, 93526	Accessory, Procedure
tracheostomy collar-neckband	3.235	item	31580-84, 31588, 31610	Wound Care, Dressings
tracheostomy dressing	3.240	item	31580-84, 31588, 31610	Wound Care, Dressings
tracheostomy tube	20.934	item	31370-82, 31580-84, 31588, 31610, 31613-14, 31750, 41140, 41145	Accessory, Procedure
transducer, pressure monitoring (for angiography)	9.520	item	93501, 93508, 93510, 93526	Accessory, Procedure
tray, bronchogram		tray	31708	Kit, Pack, Tray
tray, central line dressing change	2.430	tray	36514-16	Kit, Pack, Tray
tray, circumcision	25.173	tray	54150, 54160-62	Kit, Pack, Tray
tray, surgical skin prep, sterile	6.765	tray	134 codes	Kit, Pack, Tray
trichloroacetic acid 90% (sat soln)	0.855	ml	46900	Pharmacy, Rx
tubing set (Liposorber)	50.000	item	36516	Hypodermic, IV
tubing set, blood warmer	7.396	item	36514-16	Hypodermic, IV
tubing set, plasma exchange	173.333	item	36514	Hypodermic, IV
tubing set, plasma transfer	1.680	item	36515	Hypodermic, IV
tubing set, Y-type blood recipient	5.750	item	36515	Hypodermic, IV

tubing, pressure injection line (angiography)	3.170	item	93508, 93510, 93526	Accessory, Procedure
tubing, sterile, connecting (fluid administration)	1.950	item	93510, 93526	Accessory, Procedure
tubing, sterile, non-vented (fluid administration)		item	93501, 93508, 93510, 93526	Accessory, Procedure
tubing, suction, non-latex (2ft) with Frazier tip (1)	7.557	item	99 codes	Accessory, Procedure
underpad 2ft x 2ft (lab bench)	0.377	item	88348-49	Lab
vial, specimen-sample, 4ml	0.550	item	88348-49	Lab
wax sheet	0.285	item	88348	Lab

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We have identified certain supply items for which we were unable to verify the pricing information (see Table 4, Supply Items Needing Specialty Input for Pricing). Therefore, we are requesting commenters, particularly specialty organizations, to provide pricing information on items in this table along with documentation to support the recommended price. In addition, we are seeking information on the specific contents of the listed kits, so that we do not duplicate any supply items.

**Table 4**  
**Supply Items Needing Specialty Input for Pricing**

Code	2005 Description	Unit	Unit Price	Primary specialties associated with item	*CPT code(s) associated with item	Status of item
SL008	antibodies - detection	slide	30.90	lab, pathology	88365	See Note A.
	blood pressure recording form, average	item	0.31	cardiology	93784, 93786, 93788	See Note A.
	catheter, hyperthermia, closed-end	item		radiation oncology	77600-20	See Note A.
	catheter, hyperthermia, open-end	item		radiation oncology	77600	See Note A.
	edrophonium	ml	4.67	gastroenterology	91011	See Note A.
	hysteroscope, ablation device	item	1,146.00	ob-gyn	58563	See Note A.
	kit, BCR/ABL DNA probe	kit	42.65	pathology	88365	See Note A.
SA013	kit, detection	slide	8.50	pathology, neurology	88355, 88356	See Note A.
SA024	kit, photopheresis procedure	kit	809.00	dermatology, ob-gyn	36522	See Note A.
	kit, vasotomy	kit		urology	55200, 55250	See Note A.
	methoxsalen, sterile solution (UVADEX) 10 ml vial	ml	49.50	dermatology, radiation oncology	36522	See Note A.
	pressure bag	item		cardiology	93501, 93508, 93510, 93526	See Note A.
SL114	primary antibodies	slide	3.52	pathology, neurology	88355, 88356, 88358	See Note A.
	tray, bronchogram	tray		pulmonary disease	31708	See Note A.
	tubing, sterile, non-vented (fluid administration)	item		cardiology	93501, 93508, 93510, 93526	See Note A.

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

## v. Addition of Supply Item to CPT 88365, Tissue In Situ

## Hybridization

We received a request from a pathology society to add a DNA probe to the CPEP database for CPT 88365, tissue in situ hybridization. The society specified that 1.5 DNA probes are typically used in this service and the cost of one probe is \$42.65. Documentation supporting this price was also provided. We are proposing to add, on an interim basis, this supply to the practice expense database with the understanding that the inclusion of the item will be subject to forthcoming RUC review.

## vi. Ophthalmology Equipment

In the CPEP equipment data for many of the ophthalmology procedures, there is a duplication of time assigned to the screening lane and exam lane. In a majority of these identified procedures, the same timeframe was assigned to both the screening and exam lanes. While some of the procedures had not been refined by the PEAC, others were refined early on in the PEAC process before the PEAC agreed to assign only one equipment lane to each procedure because a patient can be in only one room at a time. In cases where both the screening and exam lanes are included, we are proposing to adjust the lane assignment by defaulting to the exam lane and, thus, we will delete the screening lane from these procedures. For all of the above

services where a lane change was made, time values were assigned to the exam lane in accordance with our established standard procedure. We are asking commenters, in particular, organizations representing ophthalmology, to review these proposed changes and submit specific comments on the appropriateness of the exam lane default.

vii. Other Practice Expense Issues:

Parathyroid Imaging, CPT 78070

We received comments from the RUC and the specialty society representing nuclear medicine that the practice expenses for CPT 78070, parathyroid imaging, which is valued in the nonphysician work pool, are too low. Because this procedure involves multiple imaging sessions, the organizations have requested that a different crosswalk of charge-based RVUs be used to more appropriately value the practice expenses involved with CPT 78070. We agree and are proposing to crosswalk the charge-based RVUs from CPT 78306, whole body imaging, to this procedure.

B. Geographic Practice Cost Indices (GPCIs)

[If you choose to comment on issues in this section, please include the caption "GPCI" at the beginning of your comments.]

1. Background

The Social Security Act (the Act) requires that payments vary among physician fee schedule areas according to the extent

that resource costs vary as measured by the Geographic Practice Cost Indices (GPCIs). In general, the fee schedule areas that existed under the prior reasonable charge system were retained under the physician fee schedule from calendar years 1992 to 1996. We implemented a comprehensive revision in the physician fee schedule payment areas (localities) in 1997, reducing the number of localities from 210 to 89. A detailed discussion of physician fee schedule areas can be found in the July 2, 1996 proposed rule (61 FR 34615) and the November 22, 1996 final rule (61 FR 59494).

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 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. This constitutes the fourth review of the work and practice expense GPCIs.

The malpractice GPCIs were reviewed and revised as part of the November 7, 2003 (68 FR 63196) physician fee schedule final rule. At the time of the publication of the November 2003 final rule, the U.S. Census data upon which the work and practice expense GPCIs are based were not yet available.

Section 412 of MMA amends section 1848(e)(1) of the Act and establishes 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 will be used for purposes of payment for services furnished on or after January 1, 2004 and before January 1, 2007. In addition, section 602 of 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.

Based on these MMA provisions, we revised the addenda published in the November 7, 2003 final rule (68 FR 63196) that

reflected both the transitional 2004 and 2005 malpractice GPCIs, as well as the work and practice expense GPCIs that were not updated (Addendum D and Addendum E, respectively) in an interim final rule with comment period entitled, "Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004," published January 7, 2004 (69 FR 1084). Due to the MMA provisions, no locality in these revised addenda has a work GPCI of less than 1.00. Additionally, the work, practice expense, and malpractice GPCIs for Alaska are set at 1.67.

We are proposing to revise the work and practice expense GPCIs beginning in 2005 based on updated U.S. Census data and Department of Housing and Urban Development fair market rent data.

## 2. Development of the Geographic Practice Cost Indices

The GPCIs were developed by a joint effort of the Urban Institute and the Center for Health Economics Research under contract to us. Indices were developed that measured the relative physician resource cost differences among areas compared to the national average in a "market basket" of goods. The market basket consists of the resources involved with operating a private medical practice. The resource inputs are—

- Physician work or net income (used to construct the physician work GPCI);
- Employee wages, office rents, medical equipment, supplies, and other miscellaneous expenses used to comprise the practice expense GPCI; and
- Professional liability insurance premiums (used to construct the malpractice GPCI).

The resource inputs and their respective weights for the resource costs associated with the work, practice expense, and malpractice expense associated with providing a physician service, were obtained from the 2003 AMA Physician Socioeconomic Characteristics publication (2003 Patient Care Physician Survey data) which measures physicians' earnings and overall practice expenses for 2000.

The weights for the 2004 GPCIs, as well as the proposed 2005 through 2007 GPCI revisions, are from the 2003 AMA survey and were used in the Medicare Economic Index (MEI) revision discussed in the November 2003 physician fee schedule final rule (68 FR 63245). Table 5 below shows the weights of the resource inputs, as defined by the MEI, those used for the original GPCIs, as well as the weights for the first, second, and third GPCI revisions. The MEI weights associated with the first and second GPCI updates (1995--2000 GPCIs) were not revised. In

addition, the MEI weights for the proposed fourth GPCI revision are also shown.

**Table 5: Historical View of MEI Weights**

<b>Input Component</b>	<u>Percentage of Practice Cost Indices</u>			
	<b>1992-1994 GPCIs</b>	<b>1995-2000 GPCIs</b>	<b>2001-2003 GPCIs</b>	<b>2004-2006 GPCI</b>
Physician Work	54.2	54.2	54.5	52.5
Practice Expense	40.2	41.0	42.3	43.7
Employee Wages	15.7	16.3	16.8	18.7
Rent	11.1	10.3	11.6	12.2
Miscellaneous	13.4	14.4	13.9	12.8
Malpractice	5.6	4.8	3.2	3.9
Total	100.0	100.0	100.0	100.0

a. Work Geographic Practice Cost Indices

As in previous GPCI updates, the median hourly earnings component is based on a 20 percent sample of U.S. Census data from workers in seven professional occupations. The actual reported earnings of physicians were not used to establish the GPCIs because Medicare payments (which are based on the GPCIs) are in part determinants of the earnings. Including physician wages in the physician work GPCI could, in effect, make the index dependent upon Medicare payments. Based upon 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.

Data from the 2000 decennial U.S. Census by county of seven professional occupations (architecture and engineering; computer, mathematical, and natural sciences; social scientist, social workers, lawyers; education, library, training; registered nurses; pharmacists; writers, artists, editors) were utilized in the development of the proposed work GPCIs.

**Table 6:**  
**Specific Occupation Categories Used in**  
**Development of Physician Work GPCI**

<b>Categories</b>	<b>Census 2000 Occupation Code</b>
Architecture and Engineering	130-156
Computer, Mathematical, and Natural Sciences	100-124,160-176
Social Scientists, Social Workers, Lawyers	180-215
Education, Training, and Library	220-255
Registered Nurses	313
Pharmacists	305
Writers, Artists, and Editors	260-296

The 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 into three geographic area categories:

1. By Individual Counties--The tabulations were requested for each county in a Consolidated Metropolitan Statistical Area (CMSA).
2. By Metropolitan Statistical Area (MSA)--The tabulations were requested by MSA for all counties that fall within an MSA.
3. By Rest of State--The tabulations were requested by rest of State for counties that are not in a CMSA or MSA.

The nonphysician professional wage data were subsequently assigned to each respective county within the MSA or Rest of State aggregations (or, in the case of CMSAs, the data were already at the county level), 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 utilized in previous updates to the GPCIs.

The work GPCIs reflect 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.

b. Practice Expense GPCIs

As in the past, we are proposing that the practice expense GPCI would be comprised of several factors that represent the major expenses incurred in operating a physician practice. The factors and the data sources we propose to use are detailed below. 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.

Employee Wage Indices--The employee wage index is based on special tabulations of 2000 census data, which are generated from the Long Form Questionnaire. These special tabulations provided by the Census Bureau are 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 provided by the U.S. Census Bureau using the same set of geographic aggregation rules discussed previously in the physician work GPCI section.

**Table 7**  
**Specific Occupations Used in Creating**  
**Employee Wage Index Update**

Categories	Census 2000 Occupation Code
<b>Administrative Support</b>	<b>500-593</b>
<b>Registered Nurses</b>	<b>313</b>
<b>Licensed Practical Nurses</b>	<b>350</b>
<b>Health Technicians</b>	<b>330, 332, 341, 351-354, 365</b>

Office Rent Indices-- Since no national data are readily available for physician office rents, some proxy must be used for this portion of the practice expense index. To construct the practice expense GPCIs, we need data that are widely and consistently available across all fee schedule areas. Although we searched for alternative commercial rental data that were both widely and consistently available across all fee schedule areas, we were unable to identify any reliable sources of commercial rental data.

As with the current practice expense GPCIs, the Department of Housing and Urban Development (HUD) Fair Market Rental (FMR) data for the residential rents were again used as the proxy for physician office rents. The proposed 2005 through 2007 practice expense GPCIs reflect the final fiscal year 2004 HUD FMR data. See Addendum E for a more detailed illustration of the actual office rent indices.

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. Additionally, physicians frequently locate their offices in areas that are residential, rather than commercial, in nature. Residential rates may, in fact, be a better measure of the

differences among areas in the physician office market than a general commercial rental index. In developing FMRs for metropolitan areas, HUD assumes that all counties within an MSA have the same rent. However, we believe that the rents in the New York City MSA vary too widely and propose that the FMR for this metropolitan area should be adjusted to account for this variation. For the New York City MSA, we used median gross rent from the 2000 Census to adjust the individual rents within counties in this MSA.

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 E 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 might 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 2004 and 2005.

c. Malpractice Expense GPCIs

The malpractice GPCIs were reviewed and revised as part of the November 7, 2003 (68 FR 63196) physician fee schedule final rule. Please refer to that final rule for a detailed discussion of the update to the malpractice GPCIs.

4. Calculation and Effect of the Proposed 2005 through 2007 Work and Practice Expense GPCIs

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 has been done in the past, fee schedule RVUs would again be 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. However, we propose to use more recent data, 2002 versus 1998 RVUs, in the county, locality, and national mapping in the proposed GPCIs. The payment effect associated with the use of these revised RVUs would generally be

negligible, in most cases resulting in changes at the third decimal point, if at all.

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. Since the changes represented by the proposed GPCIs could result in total payments either greater than or less than what would have been paid if the GPCIs were not updated, it would be 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. Since the law requires that each individual component of the fee schedule--work, practice expense, and malpractice expense--is separately adjusted by its respective GPCI, we propose to scale each of the GPCIs separately. To ensure budget neutrality prior to applying the MMA provisions, it would be necessary to--

- Decrease the proposed work GPCI by 0.9965;
- Decrease the proposed practice expense GPCI by 0.9930; and

- Increase the malpractice GPCIs that were published in the November 7, 2003 final rule by 1.0021.

As all geographic payment areas would 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 would be applied to all work GPCIs falling below 1.0. Additionally, the GPCIs for Alaska would all be set to 1.67 in accordance with MMA.

The locality specific effect of these proposed revisions to the work and practice expense GPCIs, as well as the revisions to the malpractice GPCIs published in the November 7, 2003 final rule, and the MMA provisions enacted December 8, 2003, are shown in Addendum F through Addendum H. Addendum F reflects the current GPCIs that were effective on January 1, 2004. Addendum F can be utilized as a baseline for purposes of comparison to the proposed GPCIs. Addendum H illustrates the proposed fully implemented 2006 GPCIs. Addendum G illustrates the proposed transitional 2005 GPCIs, which are one-half of the effect of the proposed fully implemented GPCI revisions as required by section 1848(e)(1)(C) of the Act.

Because the three GPCIs have different weights, the overall effect of the proposed changes cannot be achieved by summing the

individual effects of the revisions on the work, practice expense, and malpractice expense GPCIs. The overall effect of all three revised GPCI components on an area can be estimated by a comparison of the area's geographic adjustment factors (GAFs). The GAF for a specific payment area is the weighted composite of the three separate components. The GAF illustrates an estimate of the general effect on total payments across a specific fee schedule locality. The effects on individual physicians would vary depending on each physician's mix and volume of services.

To illustrate a comparison of the overall effect of the current and proposed GPCIs, Addendum J contains a comparison of the current 2004 GAFs to the proposed fully-implemented 2006 GAFs. Addendum I contains a comparison of the proposed transitional GAFs (2005) to the current 2004 GAFs. Both Addenda I and J are sorted in descending order of change. As Addendum J shows, no fee schedule area would experience a total decrease in its respective GAF by more than 3.5 percent, or increase by more than 7 percent, if the proposed GPCI revisions are fully implemented in 2006. The majority of payment areas would change by considerably less than these amounts. Nearly 75 percent of payment areas would change by less than 2 percent with the majority of these payment areas changing by less than 1 percent. Consequently, as illustrated by Addendum I, no fee schedule area

would experience a total decrease in its respective GAF of more than 1.6 percent, or an increase of more than 3.5 percent, in the transition year (2005).

The GPCIs measure relative cost differences among payment areas compared to the national average. The national average cost is represented by a value of about 1.000. A proposed GPCI revision showing a decrease from the current value does not necessarily mean that absolute costs in a payment area have decreased, only that the average costs of a payment area have decreased as compared to the national average costs.

## 5. Payment Localities

In the August 15, 2003 proposed rule, we requested comments on the composition of the current 89 Medicare physician payment localities to which the GPCIs are applied. In the November 7, 2003 final rule, we indicated that we received comments from various parties requesting that specific counties be removed from their current locality. We further indicated that we are continuing to examine alternatives for reconfiguring the current locality structure.

While we have considered alternatives, we have not yet been able to come up with 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. For example, if we were to establish a policy that if adjacent county geographic indices exceeded a threshold amount, the lower county could be moved to the higher county or a separate locality could be created, that approach would cause redistributions within a State.

Locality changes are budget-neutral with respect to the aggregate amount of Medicare money in a State. That is, reconfigurations of localities within a State do not result in any more Medicare money for the State in the aggregate, but only redistributions of money within a State. Since there will be both winners and losers in any locality reconfiguration, the State medical associations should be the impetus behind these changes. Since 1996, we have moved to Statewide areas in several States after receiving resolutions from State medical societies including support from physicians in losing areas, and after going through Notice and Comment rulemaking. 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.

### **C. Malpractice Relative Value Units (RVUs)**

[If you choose to comment on issues in this section, please include the caption "Malpractice RVUs" at the beginning of your comments.]

## 1. History of Relative Value Unit System

Section 1848(c)(2)(C) of the Act requires that each service paid under the physician fee schedule be comprised of three components: work, practice expense, and malpractice.

From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU.

Section 4505(f) of the BBA required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. With the implementation of resource-based malpractice RVUs in 2000 and the full implementation of resource-based practice expense RVUs in 2002, all physician fee schedule RVUs were resource-based, eliminating the last vestiges of charged-based payment.

## 2. 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
- 2002 Medicare payment data on allowed services and charges.

As was done in the initial development of resource-based malpractice expense RVUs in the November 2, 1999 final rule, we are proposing 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 propose to use actual 2001 and 2002 malpractice premium data and projected 2003 malpractice premium data for three reasons:

- These are the most current 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 utilized 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 two reasons: (1) 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. Because none of the State Departments of Insurance had 2003 market share information at the time of this data collection, 2003 premium data were not usable; and (2) the majority of private insurers were not amicable to releasing premium data to us. In the majority of instances, the private insurance companies would release their premium data only to the State Departments of Insurance.

Discussions with the industry lead 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 were able to collect 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). An average premium price was calculated (using 1996 through 1998 data) for all States except Kentucky, New Hampshire, New Mexico, and Washington, D.C. Similarly, an average premium price was calculated for the 1999 through 2001 period for all States except Kentucky, New Hampshire, New Mexico, and Washington, D.C. The percentage change in these premium prices was calculated as the percent difference between the 1999 to 2001 calculated average premium price and the 1996 to 1998 calculated average premium price. This percentage change was then applied 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 State 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.

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. Medicare uses its 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. Table 8 crosswalks Medicare specialties to ISO codes and to the St. Paul risk classes used.

**Table 8—Crosswalk of Medicare Specialties to IOS Codes  
and to the St. Paul Risk Classes Used**

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
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.

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 assigned an ISO code and a risk class. The unassigned specialties and the specialty to which they were assigned are shown in Table 9.

**Table 9—Crosswalk of Specialties to Similar Physician  
Specialties Assigned an ISO Code and a Risk Class**

<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 Therapy 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

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 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.

**Specialty-Weighted Approach**

The approach that we adopted in the November 1999 final rule and are proposing to use in this proposed rule, 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. Our proposed methodology is as follows:

(1) Compute a national average premium for each specialty. Insurance rating area malpractice premiums for each specialty were 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 had been 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 GPICIs) 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.

Table 10 shows the national average premiums for the years 1999 through 2003 for the 20 specialties for which we collected premium data. 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.

**Table 10—National Average Premiums for the Years 1999 Through 2003 for the 20 Specialties  
for Which We Collected Premium Data**

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 were not available.

(2) 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. Table 11 shows the risk factors, surgical and nonsurgical, by specialty.

**Table 11—Risk Factors, Surgical and Nonsurgical, by Specialty**

Medicare Code	Medicare Description	Nonsurgical Risk Factor	Surgical Risk Factor
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	3.90
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	7.46	7.46
22	Pathology	1.72	2.09
24	Plastic Surgery	6.92	6.92
25	Physical Med & Rehab	1.26	1.26
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
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.

(3) Calculate malpractice RVUs for each code. Resource-based malpractice RVUs were calculated for each procedure. The first step was to identify 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 would welcome any suggestions for alternative data sources to be used in determining risk-of-service.

As mentioned above, 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. These services are usually furnished by nonphysicians, in this example, audiologists and nurses, respectively. 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 propose 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 are proposing to retain the current charge-based malpractice RVUs for all services with zero work RVUs. We are open to comments and suggestions for constructing resource-based malpractice RVUs for codes with no physician work.

(4) 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 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 multiplied by the frequency count for that procedure to determine the total resource-based malpractice RVUs for each procedure. This was summed for all procedures to determine the total fee schedule proposed resource-based malpractice RVUs. This was compared to the total current resource-based malpractice RVUs, using the same

calculation and cases. 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 are shown in Addendum B. These values have been adjusted for budget neutrality on the basis of the most recent available data. The values do not reflect the final budget-neutrality adjustment, which we will make in the final rule based upon the more current Medicare claims data. We do not believe, however, that the values will change significantly as a result of the final budget-neutrality adjustment.

Because of the differences in the sizes of the three fee schedule components, implementation of the proposed resource-based malpractice RVUs will have 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.

Estimates of the effects on payment by specialty and selected high-volume procedures can be found in the impact section of this rule.

We are requesting comments on our proposed methodology and resource-based malpractice RVUs.

#### D. Coding Issues

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

[If you choose to comment on issues in this section, please include the caption "CODING-GLOBAL PERIOD" at the beginning of your comments.]

This code was included in the November 2, 1999 physician fee schedule final rule 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 has been brought to our attention that this global indicator is incorrect. The global indicator should be 090 since the RUC valuation of this service reflected a global period of 90 days

and we accepted this valuation. Therefore, we would correct the global indicator for this service to reflect a global period of 90 days (090).

## 2. Requests for adding services to the list of Medicare telehealth services

[If you choose to comment on issues in this section, please include the caption "CODING--TELEHEALTH" at the beginning of your comments.]

### a. Background

Section 1834(m) of the Act defines telehealth services as professional consultations, office and other outpatient visits, and office psychiatry services identified as of July 1, 2000 by CPT codes 99241 through 99275, 99201 through 99215, 90804 through 90809, and 90862. In addition, the statute required 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 or deleting services to the list of Medicare telehealth services. This process provides the public an opportunity on an ongoing basis to submit requests for adding a service. For more information on submitting a request for addition to the list of Medicare telehealth

services, visit our website at  
[www.cms.hhs.gov/physicians/telehealth](http://www.cms.hhs.gov/physicians/telehealth).

b. Submitted Requests for Addition to the List of Telehealth Services

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.

We received the following public requests for addition in CY 2003: Inpatient hospital care, emergency department visits, hospital observation services, inpatient psychotherapy, monthly management of patients with end-stage renal disease (ESRD), speech and audiologist services, case management, and care plan oversight.

Requests for additions submitted in CY 2003 are discussed below.

Inpatient hospital care, emergency department visits, hospital observation services, and inpatient psychotherapy

The American Telemedicine Association (ATA) and an individual practitioner submitted a request to add initial and subsequent inpatient hospital care as represented by CPT codes

99221 through 99223 and 99231 through 99233; hospital observation services (CPT codes 99217, 99218 through 99220); and individual psychotherapy furnished in an inpatient, partial hospitalization, or residential care facility setting (as defined by CPT codes 90816 through 90822). The requestors argue that the addition of hospital observation services, inpatient hospital care, and inpatient psychotherapy will reduce transfers from remote facilities to tertiary care facilities, decrease length of stay, improve diagnostic accuracy, plan of care strategies and patient outcomes, and also stabilize local health care systems. The requestors emphasize that adding individual psychotherapy in the inpatient and partial hospitalization setting is crucial for providing access to mental health services for the rural population. Additionally, the requestors believe that no current Medicare telehealth service can be billed when a patient is in observation status or is admitted as an inpatient. They also noted that the current psychiatry services paid for as telehealth services are not appropriate for mental health patients in the hospital, partial hospital, or residential facility settings.

The University of Kansas Medical Center requested that we add emergency department visits as defined by CPT codes 99281 through 99285 as telehealth services. The requestor stated that, for many rural hospitals, the attending physician in emergency cases is a local primary care or family physician who may not have sufficient experience with the complexities of emergent care. The requestor believes that adding emergency department visits will provide quicker access to an expert trauma or emergency physician and that the time saved could be life-saving for the patient.

#### CMS Review

As discussed in the June 28, 2002 **Federal Register** (67 FR 43862), we assign requests to one of two categories for review. Category 1 is comprised of services, which are similar in nature to an office or other outpatient visit, consultation, or office psychiatry. We review category 1 services to ensure that the roles of, and interaction among, the patient, physician, or practitioner at the distant site and telepresenter (if necessary) are similar to the current telehealth services.

Category 2 services would include services that are not similar to an office or other outpatient visit, consultation,

or office psychiatry. Because of the potential acuity of the patient in the hospital setting, we consider inpatient hospital care, emergency department visits, hospital observation services, and inpatient psychotherapy to fall into the second category of requests. As discussed on our website, for category 2 services, requestors must provide evidence indicating that the use of a telecommunications system produces similar diagnostic findings or therapeutic interventions as would face-to-face delivery of the same service.

For inpatient hospital care, hospital observation services, and inpatient psychotherapy, the requestors did not submit evidence indicating that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to the face-to-face delivery of the service. The requestors instead submitted various studies and articles regarding: the psychiatric diagnostic interview examination; school-based pediatric acute care to children; child and adolescent psychotherapy in clinics and schools; the use of telehealth technology to simplify case management and prior authorization; consultation on neurology cases; and nursing care to reduce hospitalization for heart failure.

These data are not directly relevant to the services that the requesters wanted to have added. They do not address whether the use of a telecommunications system produces similar diagnoses or therapeutic interventions by physicians or practitioners, as would the face-to-face delivery of inpatient hospital care, hospital observation services, and inpatient psychotherapy. With respect to emergency department visits, the requestor submitted a comparison study between emergency department telemedicine and face-to-face emergency department visits. However, this study did not take into account complex emergent care. Study participants were pre-selected based on cases with limited clinical intervention, for example, animal bites with no skin laceration or puncture wounds, insect bites without evidence of wheezing or airway compromise, sore throat, first degree burns--less than 5 percent, and nonurgent medical problems requiring a referral.

In the absence of sufficient, well-designed comparison studies showing that the use of a telecommunications system produces similar diagnoses or therapeutic interventions as would the face-to-face delivery of the requested services, we are proposing not to add these services to the list of telehealth services.

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 could be requested from an appropriate source.

End Stage Renal Disease--Monthly Management of Patients on Dialysis.

The ATA and an individual practitioner submitted a request that we add the monthly management of patients on dialysis, as represented by HCPCS codes G0308 through G0319, to the list of Medicare telehealth services. Under these codes, Medicare pays an increased monthly capitated payment amount for additional visits during the month (up to four). The requestors noted the shortage of nephrologists and the difficulty they have in visiting face-to-face with all patients on dialysis. Additionally, the requestors stated that many States, including Alaska, Hawaii, Montana, and Wisconsin, have remote community-based dialysis centers with underserved populations located a considerable distance from a nephrologist. To address this issue, consultations and patient care conferences are currently being provided using a telecommunications system to manage patients on dialysis

located in communities that do not have a nephrologist, including communities in Texas, where dialysis consultations and assessments using telecommunications are paid under the State's Medicaid program. Given the claims of a shortage of nephrologists and the new face-to-face visit requirements for physicians managing patients on dialysis, the requestors believe that permitting the management of dialysis patients through telehealth services is crucial.

#### CMS Review

The MCP G codes represent a range of services provided during a month, including a complete assessment of the patient and subsequent visits to monitor the patient's condition. We believe the types of services provided as part of the subsequent visits included in the codes are similar to the office and other outpatient visits currently on the list of Medicare telehealth services. Therefore, we believe these services would meet the criteria set forth in Category 1 of the process for adding services described above. However, we do not believe the complete assessment aspect of the MCP G codes is similar to existing telehealth services. For example, one aspect of a complete assessment would involve examination of the vascular access site. This is a specific

clinical examination that is not similar to other services on the list.

Therefore, we consider the request for addition of the complete assessment to the list of telehealth services to be a Category 2 request, requiring comparative analyses. In submitting their requests for addition to the list of Medicare telehealth services, the requestors included summaries of many studies related to renal dialysis patient monitoring. However, we do not believe the requestor provided comparative analyses illustrating that the use of a telecommunications system is an adequate substitute for the clinical examination of the vascular access site. We do not believe that the use of a telecommunications system is an adequate method for conducting a complete assessment of the ESRD beneficiary. We believe that a clinical examination of the vascular access site can be adequately performed only with a face-to-face, "hands on" examination of the patient.

However, we do believe the subsequent visits meet the criteria for approving a Category 1 request. That is, we believe the roles and interactions between the patient and the physician (or practitioner) are similar to those of office and other outpatient visits currently on the telehealth list.

This presents a unique scenario, wherein a portion of the services represented by the MCP G codes are eligible to add to the list, but one service (the complete assessment) is not. To address this issue, we propose to add the ESRD-related services with 2 or 3 visits per month and ESRD-related services with 4 or more visits per month as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, G0318 to the list of Medicare telehealth services. However, the complete assessment of the ESRD beneficiary would not be permitted through the use of a telecommunications system. A comprehensive visit including a clinical examination of the vascular access site must be furnished face-to-face "hands on" 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 and the 4-or-more visit MCP.

As noted previously, the MCP G codes are unique in that they reflect the ongoing care provided to ESRD patients by the physician or practitioner, on a monthly basis. These codes also reflect a range of services, from a monthly comprehensive assessment to monitoring the patient's overall condition and addressing individual issues and concerns as they arise during

the month. We believe these codes are distinguishable from other codes by the scope of services and the ongoing nature of the services provided. Therefore, we believe that it would be appropriate to permit the use of a telecommunications system for providing some of the visits required under the ESRD MCP and to add these codes to the list of Medicare telehealth services.

The MCP physician, for example, the physician or practitioner who provided the complete assessment, and other practitioners within the same group practice or employed by the same employer/entity, may furnish ESRD-related visits through a telecommunications system. However, the physician or practitioner who performs the complete assessment and establishes the plan of care should bill for the MCP in any given month.

Clinical Criteria— The complete assessment visit must be conducted face-to-face. For subsequent visits, the physician or practitioner at the distant site is required, at a minimum, to use an interactive audio and video telecommunications system that allows the physician or practitioner to provide medical management services for a maintenance dialysis beneficiary. For example, an ESRD visit conducted via

telecommunications system must permit the physician or practitioner at the distant site to perform an assessment of whether the dialysis is working effectively and whether the patient is tolerating the procedure well (physiologically and psychologically). During this assessment, the physician or practitioner at the distant site must be able to determine whether alteration in any aspect of the beneficiary's prescription is indicated, due to such changes as the estimate of the patient's dry weight.

Clarification on originating sites--The statute currently defines a telehealth originating site as a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally-qualified health center. ESRD facilities are not originating sites (dialysis facilities are not defined in the statute as originating sites). Subsequent visits (other than the comprehensive assessment) in any of the statutorily-covered settings could be provided via telecommunications equipment, including a physician's satellite office within a dialysis center. Adding dialysis facilities to the list of Medicare telehealth originating sites would require a legislative change.

Speech and Audiologist Services

The American Speech-Language Hearing Association (ASHA) requested that we add 36 audiology services (CPT code range 92541 through 92596) and 30 speech language pathology (SLP) services (CPT code range 31575 through 97703) to the list of Medicare telehealth services. The ASHA believes the cognitive nature of these services makes them well-suited for telehealth and noted several telehealth programs that have been successful at providing SLP and audiology services. For example, existing telehealth networks were cited as successfully providing diagnosis, treatment, and management recommendations for patients with speech language and hearing disorders.

#### CMS Review

Speech language pathologists and audiologists are not permitted under current law to provide and receive payment for Medicare telehealth services at the distant site. The statute permits only a physician, as defined by section 1861(r) of the Act or a practitioner as described in section 1842(b)(18)(C) of the Act (clinical nurse specialist, nurse practitioner, physician assistant, nurse midwife, clinical psychologist, and clinical social worker), to furnish Medicare telehealth services. We are exploring this issue as part of a report to

Congress (required by section 223(d) of BIPA) on additional sites and settings, geographic areas, and practitioners that may be reimbursed for the provision of telehealth services. At this time, we are not adding speech and audiology services to the list of Medicare telehealth services.

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

Two requests were submitted asking that we add medical team conferences as identified by CPT codes 99361 and 99362 and physician supervision (CPT codes 99374 and 99375) as telehealth services. Requestors stated that for these services, the use of a telecommunications system provides interdisciplinary medical teams serving remote underserved populations better access to the clinical expertise and decision making of specialty physicians. The requestors note that the current list of Medicare telehealth services, for example, consultations or office visits, cannot be used for case management and care plan oversight services because the patient is not typically present.

CMS Review

Medical team conferences and monthly physician supervision are already covered Medicare services and do not

require a face-to-face encounter with the beneficiary. Under the Medicare program, the use of a telecommunications system in furnishing a telehealth service is a substitution for the face-to-face requirements of a service. Since medical team conferences and monthly physician supervision do not require a face-to-face encounter with the patient, we cannot add these services to the list of Medicare telehealth services.

#### Review Summary

For the reasons stated above, we propose to add ESRD-related services as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317 and G0318 to the list of Medicare telehealth services.

Moreover, we would add the term 'ESRD-related visits' to the definition of Medicare telehealth services at CFR 410.78 and 414.65 as appropriate.

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

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

[If you choose to comment on issues in this section, please include the caption "CODING-RESPIRATORY THERAPY" at the beginning of your comments.]

In the 2001 final rule, we created 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) and 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, and 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 would alleviate some of this uncertainty. Since these services are typically performed by respiratory therapists, no physician work was assigned to G0237, and we are not proposing work RVUs for either G0238 or G0239.

Therefore, we are proposing to value these services using the nonphysician workpool.

We propose practice expense RVUS for G0238 equal to those for G0237. While these codes represent two different types of activities (G0237 involves therapeutic procedures specifically targeted at improving the strength and endurance of respiratory muscles such as pursed-lip breathing, diaphragmatic breathing, and paced breathing, and G0238 involves other activities such as teaching patients strategies for performing tasks with less respiratory effort and the performance of graded activity programs to increase endurance and strength of upper and lower extremities), we believe that the practice expense involved is substantially the same for both services and thus, propose to crosswalk the practice expense RVUs for G0237 to G0238.

G0239 represents situations in which two or more individuals are receiving services simultaneously (such as

those described above in G0237 or G0238) during the same time period. Although the practitioner must be in constant attendance, he or she need not be providing one-on-one patient contact. 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 will use 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 propose a malpractice RVU of 0.02, the malpractice RVU assigned to G0237, for these two G codes.

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

[If you choose to comment on issues in this section, please include the caption "CODING—BONE MARROW ASPIRATION" at the beginning of your comments.]

In the physician fee schedule final rule published on June 28, 2002 (67 FR 43864), we proposed creation of a new G-code that reflects a bone marrow biopsy and aspiration procedure performed on the same date, at the same encounter, through the same incision. While some commenters were

supportive of this proposal, other commenters felt that creation of a G-code was unnecessary and that any concerns with respect to payment could be addressed through application of the multiple procedure payment rules. In a final rule published on December 31, 2002 (67 FR 79992), we agreed that the code should go through the CPT process and did not make our proposal final.

To date, CPT has not addressed the issue. Therefore, we are proposing to create a G-code for this service in 2005. We believe that there is minimal incremental work associated with performing the second procedure through the same incision during a single encounter and are proposing an add-on G-code to reflect the additional physician work and practice expense. As we had stated in our previous proposal, 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, would be appropriate to use and Medicare's multiple procedure rules would apply. In this instance, the CPT codes for aspiration and biopsy would each be used.

G0XX1: Bone marrow aspiration performed with bone marrow biopsy through same incision on same date of service, add-on.

The code would be used when a bone marrow aspiration and a bone marrow biopsy are performed on the same day through a single incision. The physician would use the CPT code for bone marrow biopsy (38221) and G0XX1 for the second procedure (bone marrow aspiration).

Based on our estimation that the time associated with this G-code is approximately 5 minutes and based on a comparison to CPT code 38220 which has 34 minutes of intraservice time and a work RVU of 1.08 work, we are proposing 0.16 work RVUs for this proposed G-code. The proposed malpractice RVUs are 0.04 which are the current malpractice RVUS assigned to CPT code 38220. We are proposing the following practice expense inputs:

-Clinical staff time: Registered nurse-5 minutes

Lab technician-2 minutes

-Equipment: Exam table

We are also proposing a ZZZ global period for this add-on code since this code is related to another service and is included in the global period of the other service.

##### 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.

Between 2002 and 2004, the Medicare carriers increased the average amount paid for portable x-ray transportation across the country from about \$89 to \$112, an increase of about 25 percent (transportation is carrier-priced). Nonetheless, the Conference Report accompanying the Consolidated Appropriations Bill, HR 2673, (Pub. L. 108-199, enacted January 23, 2004) urged the Secretary to review and update the RVUs for Q0092 utilizing existing data.

In 2002, the National Association of Portable X-ray Providers had requested that we use their cost data to develop practice expense RVUs for the physician fee schedule services they provide. We asked the Lewin Group to evaluate the data using the same standards of review applied to other specialty survey data. The Lewin Group found that the data as presented were not adequately detailed to calculate a practice expense per hour based on the current practice expense methodology. Therefore, we did not use the data. However, in response to ongoing requests from the portable x-ray industry that we reexamine payments for this code, we have reevaluated this code.

This code is currently priced in the nonphysician work pool. Removing this code from the nonphysician work pool has 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 has a negative impact on many of the codes remaining in the nonphysician workpool. 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. In 2002, we received a comment from a supplier of portable x-rays

stating that the practice costs associated with set-up of portable x-ray equipment are not included in the Socioeconomic Monitoring System (SMS) and that there are sufficient differences among geographic regions in the performance of this procedure that warrant reclassifying this service as carrier-priced. We are interested in public 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 workpool.

#### 6. Venous mapping for hemodialysis

We are proposing to create 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. 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. This new code will allow us to track use of venous mapping for quality improvement purposes.

This G code would only be billed by the operating surgeon in conjunction with the following CPT codes: 36819, 36821, 36825, and 36832. Because CPT code 93971 and the new G-code would be used to describe a similar service, we would propose that we not permit payment for CPT code 93971 when this G-code is billed, unless code 93971 were being performed for a separately identifiable clinical indication in a different anatomic region.

The physician work, practice expense and professional liability expense for this new G code would be the same as those for CPT code 93971. Thus, we propose to crosswalk the RVUs for the new G-code from those of CPT code 93971. We would also assign this new G-code a global period of "XXX", which means that the global concept does not apply.

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

#### **A. Section 611--Initial Preventive Physical Examination**

[If you choose to comment on issues in this section, please include the caption "Section 611" at the beginning of your comments.]

## 1. Coverage of Initial Preventive Physical Examinations

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

Previously, Medicare law had not allowed for payment for routine physical examinations or checkups. Section 1862(a)(7) of the Act states that routine physical checkups are excluded services. This exclusion is described in §411.15(a) (Particular services excluded from coverage). In addition, we have interpreted section 1862(a)(1)(A) of the Act to exclude coverage for preventive physical examinations. This section provides that items and services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member as stated in §411.15(k). Since preventive services are not provided for diagnosis or treatment of illness, injury, or malformation, we determined that these services are not reasonable and necessary within the meaning of the statute.

To conform the regulations to the MMA, we are specifying 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 initial preventive physical examinations that meet the eligibility limitation and the conditions for coverage that we are specifying under §410.16--Initial Preventive Physical Examinations.

Coverage of initial preventive physical examinations is provided under Medicare Part B only. The MMA permits payment for one initial preventive physical examination 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.

We are proposing to add §410.16(b), Condition for Coverage of Initial Preventive Physical Examinations, and §410.16(c), Limitation on Coverage of Initial Preventive Physical Examinations, to provide for coverage of the various initial preventive physical examination services specified in the statute.

We are proposing to define several terms, as described specifically in §410.16, that would be used in implementing the statutory provisions, including definitions of the following terms--

- (1) Eligible beneficiary;

- (2) An initial preventive physical examination;
- (3) Medical history;
- (4) Physician;
- (5) Qualified nonphysician practitioner.
- (6) Social history;
- (7) Review of the individual's functional ability and level of safety;

Section 611 of the MMA defines an "initial preventive physical examination" to mean physicians' and certain qualified nonphysician practitioners' services 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 with respect to 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 nonphysician practitioner should be with respect to the following statutory screening and other preventive services authorized under Medicare Part B:

(1) Pneumococcal, influenza, and hepatitis B vaccine and their administration.

(2) Screening mammography.

(3) Screening pap smear and screening pelvic exam services.

(4) Prostate cancer screening services.

(5) Colorectal cancer screening tests.

(6) Diabetes outpatient self-management training services;

(7) Bone mass measurements.

(8) Screening for glaucoma.

(9) Medical nutrition therapy services for individuals with diabetes or renal disease.

(10) Cardiovascular screening blood tests.

(11) 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 recommendations, we are proposing to interpret the term, "initial preventive physical examination," for purposes of this new benefit to include all of the following:

(1) Review of the individual's comprehensive medical and social history, as those terms are defined in paragraph (a) of proposed §410.16.

(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 nonphysician practitioner 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 paragraph (a) of proposed §410.16, (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 nonphysician practitioner 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 nonphysician practitioner, 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 previous five elements of the initial preventive physical examination.

(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 exams, prostate cancer screening tests, diabetes outpatient self-management training services, bone mass measurements, screening for glaucoma, medical nutrition therapy services, cardiovascular screening blood tests, and diabetes screening tests.

We are requesting public comments on the definition of the term "initial preventive physical examination." For example, we have chosen not to define the term, "appropriate screening instrument," for screening individuals for depression, functional ability, and level of safety, as specified in the proposed rule, because we anticipate that the examining physician or qualified nonphysician practitioner will 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 United States Preventive Services Task Force, or other recognized medical professional group, would be acceptable for purposes of meeting the "appropriate screening instrument" provision. We ask that commenters making specific recommendations on this or any related issue provide documentation from the medical literature, current clinical practice guidelines, or the United States Preventive Services Task Force recommendations.

We recognize that the NCD process could be used to define more specifically the type or types of appropriate screening instruments for depression, functional ability, or level of safety and propose to include in §410.16(a) in elements (2) and (3) of the definition of an initial preventive physical examination a reference that would allow us to define these screening instruments more specifically through the national coverage determination ("NCD") process. The NCD process would include an opportunity for public comment on the medical and scientific issues related to the coverage of the new tests that may be brought to our attention in the future. Use of an NCD to establish a change in the scope of benefits is authorized by section 1871(a)(2) of the Act.

## 2. Payment for Initial Preventive Physical Examination

There is no current CPT code that contains the specific elements included in the initial preventive examination. Therefore, we are proposing to establish the following new HCPCS code, G0XX2, Initial preventive physical examination, to be used for billing for the initial preventive examination. As required by the statute, 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 should be identified using the existing appropriate codes.

a. Basis for Payment

Payment for this new HCPCS code will be based on the following:

1. Work RVUs--We are proposing a work value of 1.51 RVUs for G0XX2. This value is 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, and CPT code 93000 electrocardiogram, complete. CPT code 99203 has a work RVU of 1.34 and requires a detailed history, detailed examination, and medical decision making of low complexity, which we believe to be representative of the elements contained in the initial preventive health examination. CPT code 93000, which is for a routine ECG with the interpretation and report, has a work RVU of 0.17.

2. Malpractice RVUs--For the malpractice component of G0XX2, we are proposing 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 are proposing 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).

3. Practice Expense RVUs--For the practice expense component of G0XX2, we are proposing 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 are proposing practice expense RVUs of 0.54 based on the practice RVUs assigned to CPT code 99203 (0.48) and 93010 (0.06).

b. Evaluation and Management (E/M) Service

Since some of the components for a medically necessary E/M visit are reflected in this new HCPCS code, we are also proposing, 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 initial preventive physical examination. 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. The physician or qualified nonphysician practitioner 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 initial preventive physical examination.

c. Coinsurance and Part B Deductible

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

B. Section 613--Diabetes Screening Tests

[If you choose to comment on issues in this section, please include the caption "Section 613" at the beginning of your comments.]

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 as testing furnished to an individual at risk for diabetes including a fasting plasma glucose test and such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with 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 are proposing in §410.18 that Medicare cover—

- A fasting plasma glucose test; and
- Post-glucose challenge tests; either an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for nonpregnant 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. We are requesting comments regarding the specific tests, definitions, and eligibility criteria. The comments

that we receive will also be used to create the list of billing codes for covered tests and diagnosis codes that would be published in instructions for Medicare contractors.

The statutory provision describes an "individual at risk for diabetes" as having any of the following risk factors:

1. Hypertension.
2. Dyslipidemia.
3. Obesity, defined as a body mass index greater than or equal to 30 kg/m<sup>2</sup>.
4. Previous identification of an elevated impaired fasting glucose.
5. Previous identification of impaired glucose tolerance.
6. A risk factor consisting of at least two of the following characteristics:
  - a) Overweight, defined as a body mass index greater than 25 kg/m<sup>2</sup>, but less than 30.
  - b) A family history of diabetes.
  - c) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.
  - d) 65 years of age or older.

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 are proposing 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 propose to define "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 and complements the definition of diabetes that we published November 7, 2003 (68 FR 63195). We are specifically asking for comments regarding our new definition of "pre-diabetes." We are also requesting suggestions for the definition of "a family history of diabetes."

For individuals not meeting the "pre-diabetes" criteria, we are proposing that one diabetes screening test be covered per individual per year.

## 2. Payment

We are proposing to pay for the screening diabetes 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 propose to pay for these tests under CPT code 82947 Glucose; quantitative, blood (except reagent strip) 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 propose 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.

C. Section 612--Cardiovascular Screening Blood Tests

[If you choose to comment on issues in this section, please include the caption "Section 612" at the beginning of your comments.]

Section 612 of the MMA provides for Medicare coverage of cardiovascular screening blood tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease effective on or after

January 1, 2005.

## 1. Coverage

The Act requires coverage of tests for cholesterol and other lipid or triglycerides levels for this purpose. It also authorizes the Secretary to approve coverage of other screening tests for other indications associated with cardiovascular disease or an elevated risk for that disease, including indications measured by noninvasive testing, if the United States Preventive Services Task Force (USPSTF) recommended a blood test for that indication.

We invited comments about the types of tests from the American College of Physicians/ American Society of Internal Medicine, the American College of Cardiology, American Academy of Family Physicians, American Heart Association, College of American Pathologists, American Society for Clinical Laboratory Science, American Society for Clinical Pathologists, American Association for Clinical Chemistry, and the American Clinical Laboratory Association. Comments were received from the American Heart Association, American Academy of Family Physicians, the American Association for Clinical Chemistry, American Society for Clinical Laboratory Science,

the National Kidney Foundation, and the Vascular Disease Foundation, regarding the coverage of a number of cardiovascular screening tests in addition to the required blood lipid tests; for example, high sensitivity C-Reactive Protein (CRP), homocysteine, or Beta Natriuretic Protein (BNP), electrocardiograms, Doppler and noninvasive vascular tests, and a skin reflectance test.

We also reviewed the following 2001 recommendations of the USPSTF regarding screening for lipid disorders that are associated with cardiovascular disease:

a. Clinicians should routinely screen men aged 35 years and older and women aged 45 years and older for lipid disorders and treat abnormal lipids in people who are at increased risk.

b. Clinicians should routinely screen younger adults (men aged 20 to 35 and women aged 20 to 45) for lipid disorders if they have other risk factors for coronary heart disease.

c. No recommendation was made for or against routine screening for lipid disorders in younger adults (men aged 20 to 35 or women aged 20 to 45) in the absence of known risk factors for coronary heart disease.

d. Screening for lipid disorders should include measurement of total cholesterol (TC) and high-density lipoprotein cholesterol (HDL-C).

e. Evidence is insufficient to recommend for or against triglycerides measurement as a part of routine screening for lipid disorders.

Based on the statutory language and our review of the scientific literature, expert opinion, and the USPSTF recommendations, we are proposing coverage of the following three screening blood tests for conditions associated with cardiovascular disease:

- (1) A total cholesterol test.
- (2) A cholesterol test for high density lipoproteins.
- (3) A triglycerides test.

These tests should be performed as part of a panel and should be done after a 12-hour fast. We are also proposing coverage of each of these tests once every 5 years. The statute provides that the Secretary shall establish frequency standards for the coverage of cardiovascular screening blood tests, provided the frequency is no more often than once every 2 years. However, the scientific literature shows that cholesterol levels are fairly stable and do not fluctuate

drastically for those older than age 65. The USPSTF clinical considerations indicate that, while screening may be appropriate in older people, repeated screening is less important because lipid levels are less likely to increase after age 65. Under the USPSTF recommendations, routine measurement of total cholesterol and HDL cholesterol every 5 years is recommended by the National Cholesterol Education program Adult Treatment Panel II (ATP II), sponsored by the National Institutes of Health, and endorsed by the American Heart Association. In addition, the most recent Report of the Adult Treatment Panel (ATP III) includes similar recommendations. In all adults aged 20 years or older, a fasting lipoprotein profile (total cholesterol, LDL cholesterol, high density lipoprotein (HDL) cholesterol, and triglyceride) should be obtained once every 5 years. Since the LDL cholesterol can be calculated, the remaining tests, which are part of the lipid panel, are the tests we are proposing for coverage under this new benefit at a 5-year screening interval. We do not believe the evidence justifies or the statute allows for coverage of other cardiovascular screening blood tests at this time.

To facilitate our consideration of future coverage of other new types of cardiovascular screening blood tests, we have decided to add a provision to this proposed regulation that, in addition to the specific cardiovascular screening blood tests proposed for coverage in this proposed rule, would provide that other types of these tests may be covered under this new screening benefit, if we determine that this is appropriate through a National Coverage Determination (NCD). This provision would allow us to conduct a more timely assessment of other new types of cardiovascular screening blood tests that may have been approved for marketing by the Food and Drug Administration and recommended by the USPSTF than is possible under the standard rulemaking process. We intend to use the NCD process, which includes an opportunity for public comments, for evaluating the medical and scientific issues relating to the coverage of additional tests that may be brought to our attention in the future. Use of an NCD to establish a change in the scope of benefits is authorized by section 1871(a)(2) of the Act. These proposed coverage requirements are set forth in new section §410.17.

## 2. Payment

Section 612 of the MMA provides for Medicare coverage of cardiovascular screening blood tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for cardiovascular disease. The coverage is effective on or after January 1, 2005. We are proposing to pay for the screening cardiovascular disease tests at the same amounts paid for these tests when they are performed to diagnose an individual with signs and symptoms of cardiovascular disease. Medicare would pay for the tests under the clinical laboratory fee schedule. We propose to use the following CPT codes:

- 82465 Cholesterol, serum or whole blood, total.
- 83718 Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol).
- 84478 Triglycerides.
- 80061 Lipid Panel.

To indicate that the purpose of the test is for cardiovascular screening, we propose that the laboratory include in the diagnosis section of the claim the diagnosis code that provides the highest degree of accuracy and completeness in describing the diagnosis. We propose that the

applicable ICD-9-CM codes for cardiovascular screening blood tests be selected from the following:

- V81.0 Special screening for ischemic heart disease.
- V81.1 Special screening for Hypertension.
- V81.2 Special screening for other and unspecified cardiovascular conditions.

Because laboratories are required and accustomed to submitting diagnosis codes when requesting payment for testing, we believe including a screening diagnosis code for this purpose will not be unduly burdensome to them.

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 "Section 413" at the beginning of your comments.]

1. Background

Section 4043 of the Omnibus Budget Reconciliation Act (OBRA) of 1987 added section 1833(m) to the Act to provide incentive payments to physicians who furnish services to Medicare beneficiaries in Health Professional Shortage Areas (HPSAs). Under section 1833(m) of the Act, a 5 percent payment was added, beginning January 1, 1989, to the amounts

otherwise payable under the physician fee schedule to doctors who furnish covered services to Medicare patients in designated HPSAs. Section 6102 of OBRA 1989 further amended section 1833 of the Act to raise the amount of this incentive payment from 5 percent to 10 percent for services furnished after December 31, 1990. The OBRA 1989 amendment also increased eligible service areas to include both rural and urban HPSAs. The Congress established the HPSA incentive payments as incentives to attract new physicians to medically underserved communities and to encourage physicians in those areas to remain there.

Eligibility for receiving the 10 percent incentive payment is based on whether the specific location at which the service is furnished is within an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act (PHS)) as a HPSA. The Health Resources and Services Administration of the Department of Health and Human Services (HRSA) is responsible for designating shortage areas. HRSA designates several types of HPSAs. Some HPSAs are areas with shortages of primary care physicians, dentists, or psychiatrists. These shortage designations are referred to as geographic-based HPSAs. Also, there are HPSA designations

based on underserved populations within an area, which are referred to as population-based HPSAs.

Section 1833(m) of the Act provides incentive payments for physicians who furnish services in areas designated as HPSAs under section 332(a)(1)(A) of the PHS Act. These include all three types of geographic-based HPSAs (primary medical care, dental, and mental health). Consequently, physicians, including psychiatrists, furnishing services in a primary medical care HPSA are eligible to receive bonus payments. Medicare HPSA bonus payments apply to all physicians who perform covered services within a primary medical care HPSA, regardless of specialty. In addition, psychiatrists furnishing services in mental health HPSAs are eligible to receive incentive payments. We do not recognize dental HPSAs for the Medicare HPSA payment program because Medicare does not cover general dental services for its beneficiaries.

Since the inception of the Medicare HPSA incentive payment program, physicians have been responsible for indicating their eligibility for the incentive payment on the Medicare billing form. To facilitate the verification of eligibility, physicians have been notified by their Medicare

carriers when changes (withdrawals, revisions, or replacements) occur in HPSA designations. Using this information from carriers, physicians have been required to verify their eligibility and correctly code their Medicare claims using modifiers (QB for rural HPSAs and QU for urban HPSAs) to receive incentive payments.

## 2. New Legislation

### a. Physician Scarcity Areas

Section 413(a) of the MMA, provides a new 5 percent incentive payment to physicians furnishing services in physician scarcity areas. The MMA adds a new section 1833(u) of the Act which 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. Eligible physicians furnishing services in an area qualified as a physician scarcity area (PSA) and HPSA would be entitled to receive both incentive payments, that is, a 15 percent bonus payment. Eligibility for receiving both incentive payments is time limited (January 1, 2005 to January 1, 2008) because the 5 percent PSA bonus is scheduled to sunset on December 31, 2007.

The Congress created the new 5 percent incentive payment program to make it easier to recruit and retain both primary and specialist care physicians for furnishing services to Medicare beneficiaries in PSAs.

The two measures of physician scarcity are defined by the statute as follows:

1. The primary care scarcity areas are determined by the ratio of primary care physicians to Medicare beneficiaries.

2. The specialist care scarcity areas are determined by the ratio of specialty care physicians to Medicare beneficiaries.

- i. Primary Care

Consistent with section 1833(u) of the Act, we would identify eligible primary care scarcity counties by ranking each county by its ratio of primary care physicians to Medicare beneficiaries. From the list of primary care scarcity counties, 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. 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. All other physicians will be considered specialists for purposes of the 5 percent incentive payment. 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. This statutory provision does not include dentists, podiatrists, optometrists, and chiropractors.

ii. Specialist Care

To identify eligible specialist care scarcity areas, we would rank each county by its ratio of specialty physicians to Medicare beneficiaries. From the list of 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 will be considered eligible for the 5 percent incentive payment.

iii. The Goldsmith Modification

For purposes of counties identified as having a shortage of primary care or specialty care physicians, section 1833(u)(5) of the Act also requires that, to the extent feasible, we treat a rural census tract of a metropolitan statistical area (as determined under the most recent

modification of the Goldsmith Modification) as an equivalent area. The Goldsmith modification evolved from an outreach grant program sponsored by the Office of Rural Health Policy of HRSA. This program was created to establish an operational definition of rural populations lacking easy access to health services in Large Area Metropolitan Counties (LAMCs).

Dr. Harold F. Goldsmith and his associates created a methodology for identifying rural census tracts located within a large metropolitan county of at least 1,225 square miles. Using a combination of data on population density and commuting patterns, census tracts were identified as being so isolated by distance or physical features that they are more rural than urban in character.

#### iv. Rural-Urban Commuting Area

The original Goldsmith Modification was developed using data from the 1980 census. In order to more accurately reflect current demographic and geographic characteristics of the nation, the Office of Rural Health Policy, in partnership with the Department of Agriculture's Economic Research Service and the University of Washington, developed the Rural-Urban Commuting Area codes (RUCAs). Rather than being limited to LAMCs, RUCAs use urbanization, population density, and daily

commuting data to categorize every census tract in the country. RUCAs are the updated version of the Goldsmith Modification and are used to identify rural census tracts in all metropolitan counties.

Once all the full county PSAs are determined, we would identify, consistent with section 1833(u)(4)(C) of the Act, eligible PSAs by their 5-digit zip code area for the purpose of automatically providing the 5 percent incentive payment to eligible physicians. The zip code of the place of service is the only data element reported on the Medicare claim form that would allow automation. For zip codes that cross county boundaries, the statute specifically requires the use of the dominant county of the postal zip code (as determined by the U.S. Postal Service) if the Secretary uses the 5-digit postal zip code to identify areas eligible to receive the 5 percent payment. The statute 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 the CMS Website. Lastly, the statute provides no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise, regarding the identification of a county or area, the

assignment of a specialty of any physician, the assignment of a physician to a county, or the assignment of a postal ZIP Code to a county or other area.

b. Improvement to Medicare HPSA Incentive Payment Program

In addition to the creation of the 5 percent PSA incentive payment, section 413 of MMA amended section 1833(m) of the Act to mandate that we automate payment of the 10 percent HPSA incentive payment to eligible physicians for full county HPSAs without a requirement for the physician to identify the HPSA involved. When automation is not feasible, consistent with section 1833(m) of the Act as amended by section 413(b) of MMA, we plan to post a list of HPSAs on our website. When automation is not feasible, the billing of modifiers would still be required.

The statute provides for no administrative or judicial review of the identification of a county or area, the assignment of the individual physician's specialty, the assignment of a physician to a county or the assignment of a zip code to a county or area.

### 3. Provisions Related to Physician Scarcity Areas and HPSA Incentive Payment Program

#### a. Determination of Physician Scarcity Areas

As the statute prescribes, PSAs for primary care would be determined by the ratio of primary care physicians to the Medicare beneficiaries residing in that county or area. A primary care physician is defined by statute as a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist. The physician definition for determining primary care PSAs will be based on HRSA's physician designations for primary medical care HPSAs, which include all of the above physicians. In other words, the PSA definition for primary care will be identical to HRSA's, except for pediatricians. Furthermore, the statute provides that the primary care ratio include only primary care doctors in the active practice of medicine. Physicians whose practice is exclusively for the Federal Government or who provide only administrative services would not be included in the physician tally. PSAs for specialty care would be determined by the ratio of physicians who are not primary care physicians to the Medicare beneficiaries residing in that county or area. The specialist care PSA ratio would include all physicians other

than primary care physicians as defined in the statute. To the extent feasible, we also plan to include rural census tracts of metropolitan statistical areas (as determined under the most recent modification of the Goldsmith Modification), as identified at the zip code level, with sufficiently low physician-to-Medicare population ratios as equivalent to qualified full county scarcity areas. The calculation of physician scarcity ratios is being made by the North Carolina Rural Research and Policy Analysis Center using the most current Medicare beneficiary and physician data available. At this time, the North Carolina Rural Research and Policy Analysis Center can only determine physician scarcity for Goldsmith areas at the zip code level due to the fact that Medicare beneficiary data is currently unavailable at the census tract level.

As previously discussed, section 1833(u) of the Act requires the automation of incentive payments for all PSAs, which we can only achieve by assigning zip codes to eligible areas. We propose the identification of qualified PSAs by zip code for automatic payment as follows:

- For zip codes that fall within a full county PSA, the bonus would be paid automatically.

- For full county PSAs, the dominant county of the 5-digit zip code, as determined by the U.S. Postal Service, would be used when the zip code area is not entirely located within the county. In some cases, a service may be provided in a county that is considered to be a PSA, but the zip code is not considered to be dominant for that area, which would not permit automation of the bonus payment. In order to receive the bonus for those areas, physicians would need to include a new physician scarcity modifier on the claim. We plan to establish and implement the new modifier through the Medicare Claims Processing Manual.
- For partial county PSAs (Goldsmith Modification), all zip code areas that are entirely located within the qualified Goldsmith area and all zip code areas that are partially located within a qualified Goldsmith area as long as the majority (51 percent) of the population located within the zip code area resides in the qualified Goldsmith area would be able to receive automatic payment.

Due to the complex nature of processing available physician and Medicare beneficiary data into a usable format to identify counties and areas with the lowest ratios, we

cannot make available a list of PSAs within this proposed rule. We are working closely with HRSA and its contractors to publish these lists in the physician fee schedule final rule.

b. Incentive Payments for Physician Scarcity Areas

Similar to the Medicare HPSA bonus payment program, eligibility for receiving the 5 percent bonus payment would be based on whether the specific location at which the service is furnished is within an area that is designated as a PSA. Furthermore, the statute requires us to restrict eligibility for receiving the incentive payments for physicians' services furnished within primary care PSAs to general practitioners, family practice practitioners, general internists, obstetricians, or gynecologists. Also prescribed by statute, dentists, podiatrists, optometrists, and chiropractors are not eligible to receive incentive payments for PSAs. Section 1833(u) of the Act specifically defines a physician as one described in section 1861(r)(1) of the Act, which does not include dentists, podiatrists, optometrists, and chiropractors.

To conform our regulations to the statute, we are proposing to add §414.66 to provide a 5 percent incentive payment to eligible physicians furnishing covered services in

eligible PSAs. We propose to add §414.66(a)(1) to specify that 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. The new incentive payment would apply to the professional services performed by physicians, including evaluation and management, surgery, consultation, and home, office and institutional visits. The technical component of physicians' services is not eligible because this component is not included in the definition of physicians' services at section 1861(q) of the Act as applied by the MMA. We are also proposing to add §414.66(b) to specify that physicians, other than primary care physicians, dentists, podiatrists, optometrists, and chiropractors, 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.

c. Improvement to Medicare HPSA Incentive Payment Program

As of January 1, 2005, most physicians eligible for the 10 percent HPSA incentive payment would no longer be required to determine whether their service areas are eligible for incentive payments and to modify their claims to receive those payments. The MMA requires us to automate bonus payments for physicians' services furnished in full county HPSAs.

Automation of full county HPSA incentive payments involves the same issues of automation as PSA incentive payments: the zip code of the place of service is the only data element reported on the claim form that would allow automation. Similarly, zip codes need to be cross-walked to full county HPSAs. The statute allows use of the same method of automation of incentive payments for full county HPSAs as for full county PSAs. We are proposing the identification of HPSAs by zip code for automatic payment as follows:

- For zip codes that fall entirely within a full or partial county HPSA, the bonus would be paid automatically.
- When the zip code area is not entirely located within the full county HPSA, only the dominant county of the 5-digit zip code as determined by the U.S. Postal Service would

be used for automatically paying the HPSA incentive payment.

- For all other zip code areas that are not entirely, but are to some extent, located within a designated HPSA (full county or partial), we would require physicians furnishing services in these areas to bill for the incentive payments by using the appropriate modifier on their Medicare claims. We propose to post on our website, prior to January 1, 2005, a list of zip codes that fully fall within a designated HPSA and a list of zip codes that partially fall within a designated HPSA, so that physicians can determine whether they would need to bill using a modifier.

Determination of zip codes eligible for automatic HPSA bonus payment would be made on an annual basis, and there would not be any mid-year updates. We would effectuate mid-year revisions made to designations by HRSA the following year for automatic bonus payment purposes.

#### d. Medicare HPSA Incentive Payments

The Medicare HPSA Incentive Payment program, which the Congress established under OBRA 1987, was implemented through the Medicare Claims Processing Manual. This proposed rule

would create §414.67 to conform the regulations to the law, as amended by OBRA 1987 and 1989.

We propose in §414.67 to provide a 10 percent incentive payment to eligible physicians furnishing covered services in eligible HPSAs. Section 414.67(a) would specify that physicians, regardless of specialty, furnishing services in a 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. We would also create §414.67(c) to specify that 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. Psychiatrists furnishing services in mental health HPSAs that do not overlap with primary care HPSAs are the only physicians eligible to receive the 10 percent incentive payment in those areas. In other words, these stand-alone mental health HPSAs are eligible areas for psychiatrists only to receive incentive payments.

E. Section 303—Payment Reform for Covered Outpatient Drugs and Biologicals

[If you choose to comment on issues in this section, please

include the caption "Section 303" at the beginning of your comments.]

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. Beginning in 2005, section 1847A of the Act 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. 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.

For further information on the submission of manufacturers' ASP data, see the interim final rule titled "Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals" published in the **Federal Register** on April 6, 2004 (69 FR 17935). It is accessible on the CMS website at <http://www.cms.hhs.gov/providers/drugs/default.asp>.

The methodology for developing Medicare drug payment allowances based on the manufacturer's submitted ASP data is described in this proposed rule and reflected in proposed revisions to the regulations at §405.517 and new Subpart K in part 414.

b. Provisions of the Proposed Rule

i. The ASP Methodology

Beginning in 2005, section 1847A of the Act establishes an ASP payment system for certain drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005. The most notable exceptions are described below in sections III.E.1.c through III.E.1.e.

ii. Calculation of ASP

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 manufacturer's 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.

Note that in the following discussions, the term "manufacturer's ASP" refers to the ASP data submitted to us by manufacturers at the NDC level and the term "ASP" used in isolation refers to the weighted average sales price for all drug products included within the HCPCS [billing and payment] code.

Section 1847A(b)(5) of the Act requires that the ASP be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

iii. Medicare Payment Allowances for Multiple Source Drugs

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.

iv. Medicare Payment Allowances for Single Source Drugs

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.

It has been brought to our attention that some physicians have concerns about their ability to purchase drugs at the Medicare payment amount of 106 percent of the ASP as these

physicians believe that they are small purchasers of the Medicare Part B drugs subject to this proposed rule and do not have access to the average discounts. It is our understanding that many physicians are members of purchasing groups, which do obtain discounts on drugs. We encourage physicians to consider participating in such groups in order to achieve advantageous prices. We are interested in comments regarding the extent to which physicians can become members of such buying groups and the possible effects of doing so.

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."

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."

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. These AWP payments, which will be updated quarterly, have not been revised by the ASP provisions.

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, 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. This will be updated quarterly based on the ASP reported to us by drug manufacturers.

e. Payment for Infusion Drugs Furnished through an Item of DME

In 2005, section 1841(o)(1)(D)(i) of the Act requires 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.

## 2. Provisions for Appropriate Reporting and Billing for Physicians' Services Associated with the Administration of Covered Outpatient Drugs

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 (also 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.

In the January 7, 2004 interim final rule with comment (69 FR 1094), we indicated that the Physicians Regulatory

Issues Team (PRIT) will review Medicare payment policy for drug administration and that we plan to consult with the AMA's CPT Editorial Panel and physician specialties affected by changes in payment for drugs and drug administration. We requested that the CPT Editorial Panel review all codes related to the administration of drugs and consider whether any revisions or additional codes are needed. At its February 2004 meeting, the CPT Editorial Panel established a workgroup, with representatives from affected specialties, to make recommendations on drug administration coding to the full Panel. In addition, the workgroup will be reviewing issues related to drug administration that were identified in the public comments on the January 7, 2004 Physician Fee Schedule rule. These comments raised the following two major issues:

1. Can the current coding distinction between chemotherapy and nonchemotherapy infusions allow for recognition of the resources needed to administer drugs with high toxicity or potential for serious side effects for diagnoses other than cancer? If not, are code revisions or new codes needed?

2. Does the current coding for chemotherapy administration capture all the support services provided by

oncology practices for chemotherapy patients? If not, are code revisions or new codes such as a cancer management code needed?

There were also a number of specific comments on individual codes raised by some specialties such as urology and ophthalmology. On June 21, 2004, the workgroup held a public meeting to receive input and comments about drug administration code changes under consideration. The workgroup is expected to report to the full CPT Editorial Panel on all these issues at its August 2004 meeting. Once we review the CPT Editorial Panel's work on this issue, we will consider whether it is necessary for us to make coding changes effective January 1, 2005 through the use of G codes, since the 2005 CPT book will already have been published. While the CPT Editorial Panel's work on this issue is important to us, we finally determine coding policy for Medicare; we also would welcome public comments on these issues. We would also welcome comments concerning any alternative methods of allocating practice expenses to the drug administration codes. (See section II.A.2. of this proposed rule for a discussion of allocation of practice expenses.) If coding changes are to be

made for next year, we would announce them in the physician fee schedule final rule effective January 1, 2005.

We also 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 items and services furnished by oncologists and drug administration services furnished by other specialties.

### 3. Blood Clotting Factor--Section 303(e)(1)--Items and Services Relating to Furnishing of Blood Clotting Factors

For clotting factors furnished on or after January 1, 2005, we propose to establish a separate payment of \$0.05 per unit to hemophilia treatment centers and homecare companies 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 separate payment to hemophilia treatment centers and homecare companies for the items and services associated with the

furnishing of blood clotting factor. In the proposed rule, Payment Reform for Part B Drugs (68 FR 50440), published in the **Federal Register** on August 20, 2003, we indicated that we are proposing to create a payment of \$0.05 per unit of clotting factor provided to Medicare beneficiaries by hemophilia treatment centers and homecare companies to appropriately pay for the administrative costs associated with furnishing the clotting factor. We did not propose the creation of separate payment for furnishing the clotting factor for individuals or entities other than hemophilia treatment centers and homecare companies.

We received comments from hemophilia organizations and specialty pharmacy providers of blood clotting factor. Most comments questioned our position to create a separate payment of \$0.05 per unit, stating that this amount would jeopardize the ability of these facilities to adequately supply the clotting factor. Commenters were concerned that the \$0.05 amount was too low and would cause many entities to discontinue providing the clotting factors and severely impact beneficiaries' access to clotting factor.

Based on a review of the General Accounting Office (GAO) report and data received from various clotting factor

providers, we believe a separate payment amount of \$0.05 per unit would 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 shall 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 January 1, 2005, payment for blood clotting factors will more closely reflect acquisition costs as payment will be based on the average sales price as reported by drug manufacturers plus 6 percent."

Therefore, in the absence of additional data, we believe that a separate payment amount of \$0.05 per unit for the cost

of delivering clotting factor is an appropriate amount beginning CY 2005 and we are proposing revisions to \$410.63 to reflect this amount. However, we are also seeking updated data and comments on the GAO report, as well as information on the fixed and variable costs of furnishing clotting factor. We recognize that there may be alternatives to a fee, which varies entirely based on the number of units of clotting factor furnished. We will 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. That information will enable us to effectively determine the appropriateness of the \$0.05 per unit amount.

#### 4. Supplying Fee

Section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, requires the Secretary to pay a supplying fee (less applicable deductible and coinsurance) to pharmacies for certain Medicare Part B drugs and biologicals, as determined appropriate by the Secretary. The types of Medicare Part B drugs and biologicals eligible for a supplying fee are 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 discussed 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 where payment is based on the Average Wholesale Price (AWP).

We propose to establish a separately billable supplying fee, effective January 1, 2005, when Medicare implements a different payment system for these drugs. We believe that a separately billable supplying fee of \$10 per prescription is an appropriate level, beginning CY 2005. We received data suggesting various amounts for the supplying fee. Retail chain pharmacies suggested a supplying fee of \$12 to \$15 per prescription. These pharmacies stated that on average it cost between \$10 to \$12 to dispense a prescription to a Medicare beneficiary. However, when supplying immunosuppressive and oral anti-cancer drugs to Medicare beneficiaries, they argued that costs increase due to factors such as coordination of benefits activities. The specialty pharmacies that exclusively or largely furnish immunosuppressive drugs submitted data indicating that they believe a supplying fee of \$44 (weighted average) to \$56 (unweighted average) was

appropriate. Pharmacies have pointed to the additional Medicare billing requirements as additional costs they had to incur, in the form of extra staff and time required to fulfill the billing requirements. We believe that a supplying fee of \$10 per prescription is appropriate, especially when combined with the savings the pharmacy will experience with the clarification and elimination of the billing and shipping requirements, as described below.

We point out that if we were to establish a supplying fee of \$44, then we expect that Medicare would be spending more money in 2005 on the supplying fees and immunosuppressive drugs than Medicare would have paid for immunosuppressive drugs in 2005 under the former system at 95 percent of AWP, when the supplying fee was bundled into payment for the drug.

Our goal is to assure that each beneficiary who needs covered oral drugs has access to those medications. We seek comments about the appropriateness of our proposed supplying fee amount as well as the components of a supplying fee that would assure beneficiary access to oral drugs. We believe that a supplying fee is intended to cover a pharmacy's activities to get oral drugs to beneficiaries. We seek data and information on the additional services these 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. We seek comment about 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.

#### 5. Billing Requirements

We propose to clarify or eliminate the following billing requirements in an effort to reduce a pharmacy's costs of supplying covered immunosuppressive and oral drugs to Medicare beneficiaries:

- Original signed order. We wish to clarify Medicare's policy regarding the necessity of an original signed order prior to 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. We hope that clarification of this requirement would 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.

- Assignment of Benefits Form. Currently, pharmacies must obtain a completed Assignment of Benefits form in order to receive payment from Medicare. Other payors do not impose this requirement. This requirement increases a pharmacy's cost of supplying covered drugs to Medicare beneficiaries. Section 1842(o)(3) of the Act requires that payment for drugs under Part B of Medicare can only be made on an assignment related basis. However, §424.55(a) implies that if a beneficiary does not sign an assignment of benefits form, then Medicare will not make payment to the supplier. It has been pointed out that this requirement increases costs to suppliers that are not reimbursed by Medicare. We believe that it is not necessary for an assignment of benefit form to be filled out for drugs covered under Part B since payment for them can

only be made on an assignment-related basis. We propose to eliminate use of the Assignment of Benefits form for Part B covered oral drugs as a means of reducing a pharmacy's costs of supplying such drugs to Medicare beneficiaries.

(Additional discussion on assignment of Medicare claims is in section IV.G of this preamble.)

- 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. Pharmacies must have a completed DIF in order to receive payment. This requirement increases a pharmacy's cost of supplying covered drugs to Medicare beneficiaries. The DIF is a one-time requirement that was established to facilitate implementation of the immunosuppressive drug benefit when Medicare covered the drugs for different periods of time to distinguish between transplant and non-transplant uses for immunosuppressive drugs. 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). In light

of this statutory revision, we have had discussions with the DMERCs about their elimination of the use of this form when billing DMERC drugs. The DMERCs plan to eliminate the use of this form effective October 1, 2004. We believe that a pharmacy's costs of supplying Part B covered oral drugs to Medicare beneficiaries would be reduced with this change.

#### 6. Shipping Time Frame

It has been suggested that Medicare guidelines for refill prescriptions allowed too short of a window between shipping the next month's prescription and the end of the current month. It has been argued that, as a result, a pharmacy "effectively" had to ship the product to a beneficiary using an overnight delivery service.

As indicated in section III.N of this preamble, on January 2, 2004, we revised the guidelines (effective February 2, 2004) regarding the time frame for subsequent deliveries of refills of DMEPOS products to occur no sooner than "approximately 5 days prior to the end of the usage for the current product" (see section 4.26.1 of Chapter 4 - Benefit Integrity of the Medicare Program Integrity Manual). This change allows shipping of refills on "approximately" the 25<sup>th</sup> day of the month in the case of a month's supply. We

emphasize the word "approximately"; while we believe 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. ("Days" refers to business days or shipping days applicable to the shipper, that is, a 6-day week in the case of the U.S. Postal Service.) We believe that this change eliminates the need for suppliers to use overnight shipping methods and allows shipping of drugs by less expensive ground service.

F. Section 952--Revisions to Reassignment Provisions--Section 952 of the MMA

[If you choose to comment on issues in this section, please include the caption "Section 952" at the beginning of your comments.]

Section 1842(b)(6) of the Act requires that payment may only be made to the physician or other person who furnished a service, or to the beneficiary for whom services were furnished, unless certain specified exceptions are met. Prior to the enactment of section 952 of the MMA, Medicare did not permit the reassignment of payments for services provided by an independent contractor physician or nonphysician

practitioner unless the services were performed on the premises of the facility or health care delivery system that submitted the bill. Therefore, if the services were furnished offsite, reassignment was prohibited (see section 1842(b)(6)(A)(ii) of the Act).

Section 1842(b)(6)(A)(ii) of the Act, as amended by section 952 of the MMA, allows a physician or nonphysician practitioner to reassign payment for Medicare-covered services, regardless of the site of service, as long as there is a contractual arrangement between the physician and nonphysician practitioner 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. We note that the expanded exception created by section 952 applies to those situations when an entity seeks to obtain the medical services of a physician or nonphysician practitioner.

Section 952 states that reassignment is permissible if the contractual arrangement between the entity that submits the bill for the service and the physician or nonphysician

practitioner who performs the service "meets such 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 nonphysician practitioner providing a service are both liable for any Medicare overpayments). The Conference Agreement also recommends that physician or nonphysician practitioners 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. We are proposing to revise §424.71 and §424.80 to reflect these safeguards, as well as the expanded exception established by section 952.

Given the myriad relationships and financial arrangements potentially permitted by section 952, the purpose of joint and several liability is to encourage both parties to the contractual arrangement to exercise oversight of billings submitted to the Medicare program by holding them each fully

accountable. Since physician or nonphysician practitioners will be subject to liability for claims that are submitted to the Medicare program by entities to which they have reassigned payments, it follows that a physician or nonphysician practitioners should have access to the billings submitted on their behalf.

We note that 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). Arrangements involving reassignment must not violate any other applicable Medicare laws or regulations governing billing or claims submission, including, but not limited to, those regarding "incident to" services, payment for purchased diagnostic tests, and payment for purchased test interpretations.

In addition, 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),

"[w]e 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 codified at §411.351 in the definition of "physician in the group practice."

We are aware that the changes in the reassignment rules based on section 952 of the MMA may create new fraud and abuse vulnerabilities, which may not become apparent until the program has experience with the new contractual arrangements addressed in section 952 of the MMA. Parties should be mindful that contractual arrangements involving reassignment may not be used to camouflage inappropriate fee-splitting arrangements or payments for referrals. We are soliciting public comment on potential program vulnerabilities and on possible additional program integrity safeguards to guard against such vulnerabilities. We intend to monitor reassignment arrangements for potential program abuse.

G. Section 642--Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home

[If you choose to comment on issues in this section, please include the caption "Section 642" at the beginning of your comments.]

Beginning for dates of service on or after January 1, 2004, Medicare pays for intravenous immune globulin administered in the home. This 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. Manual instructions implementing this MMA provision have been issued and can be found at [http://www.cms.hhs.gov/manuals/pm\\_trans/R6BP.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R6BP.pdf) and [http://www.cms.hhs.gov/manuals/pm\\_trans/R74CP.pdf](http://www.cms.hhs.gov/manuals/pm_trans/R74CP.pdf). We are also proposing to revise §410.10 to address this statutory change.

H. Section 623--Payment for Renal Dialysis Services

[If you choose to comment on issues in this section, please include the caption "Section 623" at the beginning of your comments.]

1. Background

We are proposing changes affecting payments to ESRD facilities that result from enactment of the MMA and would be effective January 1, 2005. Section 1881(b) of the Act, as amended by section 623 of the MMA, directed the Secretary to revise the current composite rate payment system. The statute has several major provisions that require the development of revised composite payment rates, as follows:

- An update of 1.6 percent.
- An add-on to the composite rate for the difference between current payments for separately billable drugs and biologicals and payments based on the revised drug pricing methodology using acquisition costs.
- Case-mix adjustments for a limited number of patient characteristics.
- Application of a budget neutrality adjustment. The statute also allows the Secretary to adjust the payment rates by a geographic index as the Secretary determines to be appropriate which would be phased-in over a multiyear period.

By January 1, 2005, we plan to implement the proposed revisions affecting the composite payment rate which would include the following:

- An increase of 1.6 percent to the basic composite payment rate.
- Proposed revisions to the pricing of separately billable drugs and biologicals.
- A drug add-on to the composite rate to reflect the difference between current payments for separately billable drugs and biologicals, and payment based on the revised drug pricing methodology using acquisition costs.

We propose to implement the patient characteristics adjustments and the related budget neutrality adjustments by April 1, 2005. (See detailed discussion later in this section.)

## 2. Legislative History

Section 2991 of the Social Security Amendments of 1972 (Pub. L. 92-603), established Medicare's end stage renal disease (ESRD) program. This law extended Medicare coverage to individuals who have permanent kidney failure, require either dialysis or transplantation, and meet certain other eligibility requirements. The End Stage Renal Disease Program Amendments of 1978 (Pub. L. 95-292) added section 1881(b)(2)(B) to title XVIII of the Act.

That legislation provided for the establishment of a

prospective reimbursement methodology for the payment of dialysis treatments provided by renal dialysis facilities. Further changes to the ESRD payment system were made by section 2145 of Pub. L. 97-35, which amended section 1881 of the Act, requiring the development of a prospective reimbursement system for outpatient maintenance dialysis that promotes home dialysis. The payment system required either the reimbursement of home dialysis and in-facility dialysis under "composite" rates, or the use of some other more efficient method determined to promote home dialysis more effectively.

On February 12, 1982, we published a proposed rule on reimbursement for outpatient maintenance dialysis services (47 FR 6556) and we published the final rule on May 13, 1983 (48 FR 21254). This regulation implemented section 1881 of the Act, as amended by section 2145 of Pub. L. 97-35, and provided that each ESRD facility will receive a fixed composite payment rate per dialysis treatment, adjusted for geographic differences in area wage levels. Payment for in-facility and home dialysis treatments was established using a composite payment rate reflecting the costs of both modalities. Separate composite payment rates were established

for hospital-based and independent dialysis facilities. The regulation also included a process under which facilities could obtain exceptions to their composite payment rates under specified circumstances.

The average composite payment rate per treatment, effective on August 1, 1983, was \$123 for independent ESRD facilities and \$127 for hospital-based facilities. The composite rate was designed to provide payment for a package of goods and services needed to furnish dialysis treatments that included certain routinely provided drugs, laboratory tests, supplies, and equipment. Unless specifically included in the composite payment rate, other injectable drugs and laboratory tests medically necessary for the care of the dialysis patient are separately billable.

Prior to January 1, 2004, drugs not paid on a cost or prospective payment basis were paid based on the lower of the actual charge or 95 percent of the AWP (section 1842(o)(1) of the Act, as added by section 4556 of the BBA of 1997 (Pub. L. 105-33)). Sections 303 through 305 of the MMA make revisions to payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. For CY 2004, the MMA provides that drugs not paid on a cost or

prospective payment basis will be paid at 85 percent of the AWP determined as of April 1, 2003. However, there are several exceptions to this general rule, including payment of ESRD drugs and biologicals. In CY 2004, drugs and biologicals furnished in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities are paid at 95 percent of AWP. We note that hospital-based ESRD facilities are paid reasonable costs for separately billable drugs, except for Erythropoietin/Epoietin (EPO).

EPO is an anti-anemia drug administered to certain patients with ESRD. Medicare Part B pays for EPO and its administration if it is furnished by an approved ESRD facility as part of an outpatient dialysis service or by a supplier of home dialysis equipment and supplies to ESRD patients in their homes as part of home dialysis services. Most dialysis is furnished to ESRD patients on an outpatient basis or is self-administered in the home.

Section 1881(b)(11) of the Act expressly excludes payment for EPO furnished to ESRD patients from the composite rate for dialysis services. The costs of EPO are, therefore, billed separately by an ESRD facility or by a supplier of home dialysis equipment and supplies and are paid in addition to

the facility's composite rate. Any EPO-related costs, such as the cost of its administration or overhead costs associated with its storage, however, are subsumed in the facility's composite rate.

Section 413.174(f)(3) requires that we prospectively determine the EPO amount pursuant to section 1881(b)(11)(B)(ii) of the Act. Section 4201(c) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101-508), however, amended section 1881(b)(11) of the Act to establish a new EPO payment methodology. OBRA 90 directed, effective January 1, 1991, that payment for EPO furnished to ESRD patients by Medicare-approved dialysis facilities or suppliers of home dialysis equipment and supplies for home use be made on a per-unit basis. OBRA 90 also established a maximum payment amount of \$11 per 1,000 unit doses rounded to the nearest 100 units. Subsequently, section 13556(a)(2) of OBRA 93 was enacted, which further amended section 1881(11)(b)(B)(ii) of the Act to reduce the maximum payment level to \$10 per 1,000 units effective January 1, 1994. Although we have the authority to revise the rate, we continue to pay at the rate of \$10 per 1,000 units.

Section 9335(a) of Pub. L. 99-509 required the Secretary to reduce the initially established composite payment rates by \$2.00 per treatment effective October 1, 1986. This reduction was partially reversed as a result of the enactment of section 4201(a)(2) of Pub. L. 101-508, which increased the composite payment rates in effect as of September 30, 1990 by \$1.00 per treatment, but effectively froze the methodology for their calculation, including the data and definitions used, as of that date. Section 222 of Pub. L. 106-113, provided for a 1.2 percent increase to the payment rates effective January 1, 2000, and also provided for another 1.2 percent increase effective January 1, 2001. Section 422(a)(1) of Pub. L. 106-554, raised the amount of the January 1, 2001 payment increase by another 1.2 percent for a total increase of 2.4 percent effective January 1, 2001.

Section 422 of Pub. L. 106-554 also directed the Secretary to develop a Prospective Payment System (PPS) that expanded the bundle of routine services reflected in the composite rate to include separately billable laboratory tests and drugs "to the maximum extent feasible". In addition, section 422(a) of Pub. L. 106-554 prohibited the granting of new composite rate payment exceptions for services furnished

after December 31, 2000. Because a bundled ESRD payment system must be periodically updated, section 422(b) of Pub. L. 106-554 also required the development of an ESRD market basket to account for changes in price inflation, with discretionary consideration of other factors known to affect costs. Section 422(c) of Pub. L. 106-554 mandated the submission of a report to the Congress on the bundled payment system and ESRD market basket.

On May 12, 2003, the Secretary submitted the required report to the Congress. The report explained the major issues that must be addressed before a bundled ESRD PPS can be implemented, presented an ESRD composite rate market basket, and discussed the results from the first phase of our sponsored research to develop a bundled payment system. The report presented the following three major findings that are relevant to our efforts to revise the composite rate payment system:

- Current data sources are adequate for proceeding to develop a bundled ESRD PPS.
- Case-mix may be an important variable for risk adjusting payments, based on preliminary analysis.

- Current data provide a sound basis for monitoring patient outcomes in a revised ESRD payment system.

### 3. Summary of Section 623 of MMA

The following provisions in section 623 of the MMA, effective January 1, 2005, affect the composite payment rate methodology, as well as the pricing methodology for separately billable drugs and biologicals furnished by ESRD facilities:

a. Section 623(a)—The last sentence of section 1881(b)(7) of the Act, as amended by MMA, provides for an increase in the current composite payment rate of 1.6 percent.

b. Section 623(d)(1)—Section 1881(b)(13) of the Act, as added by MMA section 623(d)(1), provides for a revision to the current AWP pricing of separately billable drugs and biologicals; payment will be based on acquisition costs as determined by the OIG's study mandated under section 623(c) of the MMA. Insofar, as the OIG has not determined the acquisition costs, with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological.

c. Section 623(d)(1)—Section 1881(b)(12) of the Act, as added by MMA section 623(d)(1), also requires the establishment of a basic case-mix adjusted composite payment

rate that applies certain adjustments to the composite payment rate as follows:

- Adjustments for a limited number of patient characteristics.
- An adjustment that reflects the difference between current payments for separately billed drugs and biologicals and the revised pricing based on acquisition costs or other method as determined by the Secretary.
- A geographic adjustment, if the Secretary determine such an adjustment is appropriate with the possibility of a phase-in.
- A budget neutrality adjustment, so that aggregate payments under the basic case-mix adjusted composite payment rates for 2005 equal the aggregate payments that would have been made for the same period if section 1881(b)(12) of the Act did not apply.

#### 4. Provisions of the Proposed Rule

##### 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. The current wage-adjusted rates for each urban and rural area were published in Tables III and

IV of Program Memorandum A-01-19 issued February 1, 2001 and are applicable through the end of 2004. Section 623(a)(3) of the MMA requires that the composite rates in effect on December 31, 2004 be increased by 1.6 percent. We are publishing revised wage-adjusted composite rates that reflect the statutorily required 1.6 percent increase. Those rates are set forth in Tables I and II at the end of this section. These tables reflect the updated hospital-based and independent facility composite rate of \$132.40 and \$128.35, respectively, adjusted by the current wage index. The rates will be effective January 1, 2005. The rates shown in the tables do not include any of the basic case-mix adjustments required under section 623 of the MMA.

b. Revised Pricing Methodology for Separately Billable Drugs and Biologicals Furnished by ESRD Facilities

Section 623(d) of the MMA requires the Secretary to establish a basic case-mix adjusted PPS for dialysis services that are furnished beginning on January 1, 2005 by providers of services and renal dialysis facilities to individuals in a facility and to individuals at home. This system will include services comprising the composite rate as well as the difference between payment amounts for separately billed drugs

and biologicals (including erythropoietin) furnished by ESRD facilities and acquisition costs of such drugs and biologicals as determined by the OIG reports from the studies mandated by section 623(c) of the MMA.

For 2004, the payment amounts for separately billed drugs and biologicals (other than erythropoietin) furnished by ESRD facilities are determined by 95 percent of AWP. For 2005, the payment amounts for separately billed drugs and biologicals (including erythropoietin) furnished by ESRD facilities are described in section III.E of the NRPM. Insofar as the acquisition cost has not been determined by the OIG, then the Secretary shall determine the payment amount of the drug and biological.

For 2005 and subsequent years, the payment amounts for separately billed drugs and biologicals (including erythropoietin) furnished by ESRD facilities will be the acquisition cost or the amount that is derived from the ASP methodology in section 1847A of the Act, as the Secretary may specify.

See section III.E.1.d. of this proposed rule for further explanation of payment for separately billable drugs and biologicals furnished by renal dialysis facilities.

c. Composite Rate Adjustment to Account for Changes in Pricing of Separately Billable Drugs and Biologicals

Section 1881(b)(12) of the Act, as added by section 623(d) of the MMA, contains two provisions that specify how the drug add-on adjustment is to be handled in the revised ESRD payment system. First, subparagraph (B)(ii) of such section requires an adjustment to the composite payment rates to account for the difference between payment amounts for separately billed drugs (including erythropoietin) under the current payment system and acquisition costs as determined by the OIG. Second, subparagraph (E)(i) requires that the drug add-on adjustment be budget-neutral, that is, that it be designed to result in the same aggregate amount of expenditures as would have been made without the statutory policy change.

We need to determine the composite rate adjustment for drug add-on amount that simultaneously deals with both statutory requirements. That is, the aggregate amount of the composite rate adjustment for drug add-on amount needs to equal the aggregate amount of the drug spread (the difference between drug payments under the old system and acquisition costs).

In order to ensure that we satisfy both constraints, it is necessary to consider the proposed drug pricing in developing the adjustment to the composite rates. As discussed in section III.E.1.d. of this proposed rule, we are proposing 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 outlined in the OIG report. We have developed the proposed drug add-on adjustment using the ASP minus 3 percent drug prices. Section 2 below discusses the details of the calculation of the drug add-on adjustment. An alternative approach would be to use the 2003 acquisition prices from the OIG report, calculate the aggregate difference between such prices and payments for drugs under the AWP system, update this difference to 2005 and then apply the budget neutrality adjustment. Because the same budget-neutrality adjustment would be used both calculations, we believe that the drug add-on adjustment for the drug spread would be the same with both approaches. Therefore, we are proposing to use the ASP minus 3 percent prices as the basis for developing the drug add-on adjustment to the composite rate.

# 1. Options for Applying the Drug Add-on Adjustment to the Composite Payment Rate

Currently, separately billable ESRD drugs are paid differently to hospital-based and independent ESRD facilities. EPO is currently the only drug for which payment is uniform across ESRD facilities; EPO is paid at the current rate of \$10 per 1000 units. All other separately billed ESRD drugs provided by independent ESRD facilities are currently paid 95 percent of AWP prices. However, hospital based ESRD facilities are paid their reasonable cost for the other separately billed drugs they provide. Because they are paid on cost, hospital-based facilities have not made the profits from drug payment that independent facilities have enjoyed.

The statutory language describing the add-on adjustment to the composite rate does not specifically differentiate between hospital-based and independent facility composite rate adjustments. However, the drug add-on provision is included with the other provisions related to the basic case-mix adjusted composite rate system; thus, it could be argued that the drug add-on provision was intended to address ESRD industry concerns about the inadequacy of the composite payment rate. We believe these concerns apply equally to

hospital-based facilities and independent facilities.

Therefore, we are proposing a single adjustment to the composite payment rates for both hospital based and independent facilities.

An alternative option would be to develop a separate adjustment for hospital-based facilities for EPO and one for independent facilities for all of their separately billed drugs. The IG's report provided the acquisition costs we are using; it did not provide different acquisition costs for hospital-based and independent facilities. We believe that it would not be appropriate for us to use these data to create two separate adjustments. The following discussion outlines the development of the drug add-on adjustment under both options—a single factor and separate factors.

## 2. Computation of Drug Add-on Adjustment to the ESRD

### Composite Payment Rate

#### i. Data

To develop the drug add-on adjustment we used historical total aggregate payments for separately billed ESRD drugs for half of 2000 and all of 2001 and 2002. For EPO, these payments were broken down according to type of ESRD facility (hospital-based versus independent). We also used the number

of dialysis treatments performed by these two types of facilities over the same period.

ii. ASP minus 3 percent

We updated the ASP minus 3 percent prices, for the first quarter of 2004, to represent 2005 prices. We used the projected annual price growth factor for National Health Expenditure prescription drugs of 3.39 percent.

<b>TABLE 12</b>		
<b>Drugs</b>	<b>First Quarter 2004 Average Sales Price minus 3 percent</b>	<b>First Quarter 2005 Average Sales Price minus 3 percent</b>
Epogen	\$8.74	\$9.04
Calcitriol	0.66	0.68
Doxercalciferol	2.55	2.64
Iron_dextran	9.22	9.54
Iron_sucrose	0.34	0.35
Levocarnitine	7.15	7.39
Paricalcitol	3.86	3.99
Sodium_ferric_g lut	4.15	4.29
Alteplase, Recombinant	27.74	28.68
Vancomycin	3.40	3.52

iii. Current Medicare Reimbursement

We updated the first quarter 2004 Medicare payment amounts (95 percent of AWP), based on the January 2004 Single

Drug Pricer, for drugs other than EPO, to estimated 2005 payment amounts by using an estimated AWP growth of 3 percent. These growth factors are based on historical trends of AWPs. We did not increase the price for Epogen since payment was maintained at \$10.00 per thousand units prior to MMA.

<b>TABLE 13</b>	
<b>Drugs</b>	<b>Current Medicare Reimbursement Prices for 2005</b>
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

#### iv. Dialysis Treatments

We updated the number of dialysis treatments 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 should be due to enrollment. In 2005, we project there will be a total of 36.5 million treatments performed (5.1 million treatments will be performed

by hospital-based facilities and 31.4 million treatments by independent facilities).

v. Drug Payments

We updated the total aggregate Epogen drug payments for each hospital-based and independent facilities using historical trend factors. For 2003 through 2005, the 2002 payment level was increased each year by trend factors of 2.8 percent for hospital-based facilities and by 9.4 percent for independent facilities.

Using drug growth factors for drugs paid for by Medicare Part B carriers, which were calculated from historical data, we updated the aggregate spending for separately billable drugs, other than EPO, for independent facilities. We used 24.7 percent for 2003, 23.3 percent for 2004, and 21.4 percent for 2005 as factors because historical growth of ESRD drugs is similar to that for drugs paid for by Part B carriers. These factors are projected to approach the level of National Health Expenditure prescription drug growth. For 2005, we estimate that spending will reach \$185 million for Epogen provided in hospital-based facilities, and \$2,664 million for drugs provided in independent facilities (\$1,568 million for Epogen and \$1,096 million for other drugs).

## vi. Add-On Calculation and Budget Neutrality

For each of the ten drugs, we calculated the percent by which ASP minus 3 percent prices are projected to be less than reimbursement amounts under the current system for 2005. For Epogen, this amount is 10 percent. We applied this 10 percent figure to the total aggregate drug payments for Epogen in hospital-based facilities, resulting in a difference of \$18 million. We then calculated a weighted average of the percentages by which ASP minus 3 percent would be below current Medicare reimbursement prices for the top 10 ESRD drugs. We weighted these percentages by using the 2002 Medicare reimbursement values contained in the OIG report for the ten drugs. This procedure resulted in a weighted average of 19 percent. Since these ten drugs represented 98 percent of drugs payments, we applied the weighted average to 100 percent or all of aggregate drug spending projections for independent facilities, producing a projected difference of \$516 million.

Combining the 2005 figures of \$18 million and \$516 million, for a total of \$534 million and then distributing this over a total projected 36.5 million treatments would result in a single add-on to the per treatment composite rate

of 11.3 percent. By making this adjustment to the composite rate, we estimate that the aggregate payments to ESRD facilities would be budget neutral with respect to drug payments.

Alternatively, we could produce separate drug add-on adjustments for hospital-based and independent facilities using the same methodology. Under this option, we could distribute the \$18 million difference in EPO payments to hospital-based facilities based on data projecting 5.1 million treatments resulting in a hospital-based facility drug add-on adjustment of 2.7 percent. We would distribute the \$516 million difference in drug payments (including EPO) to independent facilities using projected treatments of 31.4 million, resulting in a drug add-on adjustment of 12.8 percent for independent facilities.

Drug prices used in the computation of the proposed drug add-on adjustment to the ESRD composite payment rate, may be revised based on later data and will be reflected in the final rule.

### 3. Composite Rate Effect of Proposed Drug Add-on Adjustment

We used a single drug add-on adjustment for both hospital-based and independent ESRD facilities, the proposed

adjustment to the composite rate would be 1.113. Separate adjustments would provide a 1.128 adjustment for independent facilities and 1.027 for hospital-based facilities. The following table illustrates the effect on the composite payment rates under the two potential drug add-on options. (Case-mix budget neutrality adjustments are not reflected in this table).

TABLE 14			
Facility Type	CY 2005 Base Rate	Separate Add-on	Single Add-on
Independent	\$128.35	\$144.78	\$142.85
Hospital Based	\$132.41	\$135.99	\$147.37

Under the single add-on, the proportionately higher rate for hospital-based facilities would be consistent with section 1881(b)(7) which requires that our payment methods differentiate between hospital-based facilities and others. Separate add-on adjustments would result in a significantly higher composite payment rate for independent facilities, than hospital-based facilities, that is, \$8.79 higher per treatment.

#### d. Patient Characteristic Adjustments

##### 1. Statutory Authority

The current ESRD composite payment rates do not adjust for variation in patient characteristics or case mix. Section 1881(b)(12)(A) of the Act, as added by section 623(d)(1) of the MMA, requires that the outpatient dialysis services included in the composite rate be case-mix adjusted. Specifically, the statute states that "The Secretary shall establish a basic case-mix adjusted prospective payment system

for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to individuals at home. The case-mix under the system would be for a limited number of patient characteristics." In the following sections, we describe the development of the methodology for the proposed patient characteristic case-mix adjusters required under the MMA.

## 2. Background

Case-mix measures utilizing patient characteristics have been used in a number of prospective payment systems. Use of a case-mix measure permits targeting of greater payments to facilities that treat more costly resource-intensive patients. However, the legislative mandate to establish a case-mix adjustment for services included in the composite rate based on a limited number of patient characteristics presents a unique challenge.

The composite rate represents payment for a fixed bundle of routine services provided to ESRD patients as part of a dialysis treatment. Generally, the items and services needed to provide a dialysis treatment do not vary significantly across patients. Moreover, the bills for composite payment rate services furnished to ESRD patients, which are generally

submitted monthly, do not identify the specific items and services provided on a case-by-case basis. In addition, the Medicare cost reports identify only aggregate costs for composite rate services at the facility level. Therefore, any case-mix adjustment based on patient characteristics obtained from the bills for outpatient ESRD services and applied to the composite rate will reflect only variation in composite rate costs at the facility level.

Earlier research by Hirth (1999) and Dor (1992) found that if case-mix adjustments applied only to composite rate items and services the adjustments played a limited role in predicting variation in costs per treatment because case-mix and dialysis treatment patterns are very similar across facilities. However, more recent analyses conducted under our contract with the University of Michigan, Kidney, Epidemiology and Cost Center (KECC) found that patient level case-mix adjustment would be more relevant in a bundled payment system that includes both composite rate and separately billable items and services. KECC's research studies relied on an extensive set of variables to define patient case-mix. These variables included patient characteristics, a large number of specific comorbidities and clinical measures (including

primary diagnosis) and other (non-Medicare) insurance coverage, as well as the duration of ESRD. We relied on linear regression analyses used in the studies to assess the relationship of patient characteristics and comorbidity measures to per session cost and Medicare payments to facilities. These studies relied on data from our administrative files.

We are continuing and expanding the research project in support of the development of a fully bundled case-mix adjusted system. We are continuing to explore alternative models and options with more detailed analysis of patient characteristics as part of the legislatively mandated report to the Congress in the fall of 2005.

Despite the difficulty in developing a patient characteristic case-mix adjustment, we were able to develop case-mix adjustment factors for a limited number of patient characteristics, consistent with the legislative mandate. As expected, these adjusters are only modest predictors of variation in average costs for composite services. In developing the proposed patient characteristic adjustments, we used our available administrative data. Because facilities do not list individual composite rate items and services on the

dialysis bill, billing data do not identify resources used by each patient. In addition, facilities can underreport or not report comorbid conditions. Therefore, these bills are not useful for deriving average facility input costs. Since there are not any current requirements to list comorbid conditions on the dialysis bill, we used a combination of data sources to determine co-morbidities for ESRD patients on maintenance dialysis. These include the Medicare claims history file as well as the CMS Form 2728 (ESRD Medical Evidence Report) which provides information on the cause of ESRD and lists 20 possible co-morbidities present at the onset of a patient's ESRD. The Form 2728 is completed only at the initiation of dialysis treatment. It is not updated to reflect more recent medical conditions.

Nonetheless, we found selected variables from the Form 2728 to be valid predictors of cost per treatment for the proposed case-mix adjustment, and the Form 2728 was also useful in developing our proposed case-mix adjustments. As discussed below, the Form 2728 variables were supplemented by additional information we obtained from billing records.

### 3. Development of the Proposed Adjustments for Patient Characteristics

We are proposing a methodology to establish a basic case-mix adjusted composite rate system using a limited number of patient characteristic variables developed from existing our administrative files. We analyzed a number of patient level variables including age, gender, alcohol and drug dependence, inability to ambulate/transfer, current smoker, number of years since ESRD onset, weight, height, mean BUN, and mean creatinine clearance, as well as a number of comorbidities.

As a means to estimate how average cost variations among facilities are influenced by selected patient characteristics, extensive analyses were performed to develop a proposed "basic case-mix adjusted PPS, for a limited number of patient characteristics," as specified in the statute. We analyzed the average cost per dialysis session (including both hemodialysis and Method I peritoneal dialysis converted to equivalent 3 times per week hemodialysis sessions) from national data gathered for the years 2000, 2001, and 2002.

A stepwise regression was used to select a limited set of variables that were predictive of average facility cost per treatment. We used data pooled over a three-year period because we found the regression coefficients to reflect a

consistent pattern over three years. We used data pooled over a three-year period to minimize the potential for volatility in the regressive coefficients. The analysis controlled for selected variables that influence facility costs, but are not case-mix related. These variables included wage index, the natural log of the number of dialysis sessions provided annually by the facility, type of facility, chain affiliation, and percentage of patients with urea reduction ratio (URR) as a measure of dialysis dose equal to or greater than 65 percent. The proposed model is based not only on the predictive power of these measures, but also upon objectivity (for example, discrete variables: age/gender), clinical plausibility, and practicality (that is, availability) of data collection. The variables used were assessed for their clinical plausibility by clinicians from the University of Michigan and CMS. Physicians assessed a proposed list to determine relationship of the proposed comorbidities to ESRD patients, and clinical practice/patterns.

In addition to exploring a number of potential case-mix variables, we examined two methods, that is, linear and log linear models of the composite rate costs. We selected the log linear model in order to yield patient specific case-mix

adjustments which can be multiplied by a dialysis facility's otherwise applicable composite rate payment. In this proposed rule, we provide a detailed example of the calculation of the proposed case-mix adjusted composite rate payments.

#### 4. Proposed Patient Characteristic Adjustments

As discussed in the background section above, the basic case-mix system is constrained by the composite rate and the data available for these adjustments. While we analyzed a number of variables, four patient characteristic variables were found to be modest predictors of cost variation among ESRD facilities. These patient characteristic variables include gender, age, and two comorbidities (AIDs and PVD) (See table 3 for specific ICD 9 codes for these comorbidities). Each of the gender categories was also divided into three age categories so that one adjustment factor could be developed to encompass both gender and age. The proposed patient characteristic adjustments are discussed below.

##### i. Gender and Age

We are proposing adjustments for both gender and age. We found that gender and age were strong predictors of facility cost variations. In addition, data on gender and age are readily available, and are objective measures. After

examining a number of options for age, we are proposing under 65, 65-79, and over 80 as the three categories for age. We attempted to develop a case-mix adjuster specific to the under 18 age group. However, the population in that age group that was included in the data used to develop the case-mix adjustments was too small, and was generally concentrated in a very small number of facilities.

While we recognize that pediatric patients are more costly to treat, those patients are generally treated in specialized pediatric facilities. As provided in MMA, those facilities can request adjustments to their composite payment rates through the exceptions process. This process will enable pediatric facilities to obtain payments that specifically recognize the higher cost associated with treating these patients. In developing the age adjustments, data for those patients were grouped into the under 65 age category. We note that adjustments for both gender and age are consistent with the MA risk adjustment models for ESRD patients.

ii. Proposed Comorbidity Adjustments:

As discussed above, the effect of the costs of dialysis for a number of conditions were analyzed. These included

several comorbidities that did not have a statistically significant relationship to facility costs. In other cases, the lack of data precluded inclusion of a comorbid condition in the proposed patient characteristic adjustments. That is, we are unable to propose any adjustments based on data that cannot be routinely reported, (for example, some data elements that are reported only on the Form 2728). For the reasons discussed above, the Form 2728 is not an appropriate source of information since it is not updated after a patient enters the ESRD program. Two variables not currently available on the Medicare bill are weight and height. Weight and height are used to compute a patient's body mass index (BMI). Our analysis indicates that patients with extremely low or high BMI are costly to treat. Since BMI is directly related to a patient's dialysis prescription, we believe this factor could be an important measure of resource consumption related to the composite payment rate. We also believe that the length of time a patient is dialyzed could directly affect composite rate costs. We are currently exploring the feasibility of developing a mechanism to collect these data on the ESRD bill. In addition, we are soliciting comments on other data elements

that could be added to the bill that could be relevant predictors of composite rate costs.

We also examined whether having cancer was predictive of higher resource used. We examined all cancers reported within the last 3 to 10 years as reported on our claims history file or the Form 2728. While a patient's history of cancer was associated with higher costs, we found this measure to be too broad to be clinically meaningful. We will continue to evaluate this condition as a potential variable for refinement purposes. As ESRD facilities begin reporting patient comorbidities, we expect that we will be in a better position to identify the specific cancer diagnoses that may be related to increased composite rate costs.

We also explored whether diabetes as a comorbidity is predictive of high resource use. We found that the predictive power of diabetes was dependent on whether PVD was part of the model. PVD was always statistically significant, when accounted for, while most measures of diabetes were not strongly associated with facility costs. Therefore, we are proposing a case-mix adjustment for PVD diagnoses. We believe this adjustment appropriately addresses the higher costs associated with sicker diabetic patients. We note that about

73 percent of diabetes patients included in our data also had PVD. Another comorbid condition that was found to be a significant predictor of facility cost is AIDs. This diagnosis is currently coded as part of the claims data.

Another Form 2728 variable we examined was the presence of a substance (alcohol and drugs) dependence diagnosis. While the presence of substance abuse was found to be predictive of higher facility level costs, we are not proposing an adjustment for this comorbidity at this time since, the substance abuse diagnosis is underreported on the claims. We are soliciting comments on the variables included in the proposed patient characteristic adjustment as well as recommendations for the inclusion of other potential variables that may affect the costs of dialysis.

In summary, we are proposing to use a limited number of patient characteristics that do explain variation in reported costs for composite rate services consistent with the legislative requirement. The proposed adjustment factors are as follows:

<b>TABLE 15</b>		
<b>Female</b>	age <65 years	1.11
	age 65-79 years	1.00
	age >79 years	1.16
<b>Male</b>	age <65 years	1.21
	age 65-79 years	1.17
	age >79 years	1.23
<b>AIDS</b>		1.15
<b>PVD</b>		1.07

While the magnitude of some of the patient specific case-mix adjustments appears to be significant, facility variation in the case-mix is limited. This is because of the overall similarity of the distribution of patients among the eight case-mix classification categories across facility classification groups. This is reflected by the average case-mix adjustment based on 2002 data for the various types of ESRD facilities shown in the table below.

<b>TABLE 16</b>	
<b>Facility Type</b>	<b>Average Case Mix Adjustment</b>
All	1.1919
Independent	1.1917
Hospital Based	1.1936
Urban	1.1931

Rural	1.1865
Small (<5k treatments/yr.)	1.1911
Medium (5-10k treatments/yr.)	1.1910
Large (>10k treatments/yr.)	1.1924
Non-profit	1.1924
For-profit	1.1918

As illustrated from this table, regardless of the type of provider, the average case-mix adjustments for patient characteristics do not vary significantly. We are continuing research to develop a more fully bundled proposed model that is not constrained by the existing composite rate. We will continue to study the predictive value of comorbidities and facility and patient level variables as part of the ongoing research. In addition, we are aware that by limiting the number of variables for the patient characteristics adjustment applicable to the composite payment rate, we are limiting the predictive power of the model. We are planning to consider additional variables to refine and update the proposed patient characteristics. Once we have implemented this basic case-mix system, we will continue to analyze comorbidities (on the reported claims file) and will consider expanding the list of variables used in the patient classification adjustment. In addition, we will be working with our fiscal intermediaries to improve the reporting of comorbidities on claims.

## 5. Technical Description of Model Used to Develop the Proposed Patient Characteristic Adjustments

Both facility and patient level variables were used for the development of the proposed case-mix adjustment. Facility costs are based on Medicare allowable costs reported by facilities for dialysis and related services for which they are reimbursed through the composite rate. The sources of the cost data are the Medicare Independent Renal Dialysis Facility Cost Reports (Form CMS 265-94) and the Medicare Hospital Cost Reports (Form CMS 2552-96). We used the most current set of facility cost reports available (cost reports updated through December 2003 and made publicly available in March 2004).

All cost reports spanning any part of calendar years 2000, 2001 or 2002 were included in the development of the case mix adjusters. While for most facilities, especially independent facilities, a single cost report encompasses the entire calendar year; data for some facilities, most notably those whose reporting period spans two calendar years (for example, October through September rather than January through December) were pro-rated to calculate the average treatment cost during a calendar year. The resulting numbers of cost

reports used in the analyses are shown in the table below by facility type and year. Note that currently there are fewer cost reports available for analysis in 2002 because many facilities have not yet submitted cost reports for that year. The final version of this regulation will contain the most recent data available.

<b>TABLE 17</b>			
	<b>2000</b>	<b>2001</b>	<b>2002</b>
<b>Independent facilities</b>	3,027	3,034	2,508
<b>Hospital-based facilities</b>	477	466	456

The average treatment cost per dialysis session for each facility was calculated by dividing the total reported cost for dialysis and related services by the total number of dialysis treatments. The source of the reported cost for independent facilities was Worksheet B from Form CMS 265-94 and, for hospital-based facilities, Worksheet I-2 (Form CMS 2552-96). The source for the total number of dialysis treatments for independent facilities was worksheet Form CMS265-94 and, for hospital-based facilities, worksheet I-4 (Form CMS 2552-96). Note that, for CMS Form 2552-96 and CMS Form 265-94, values in the fields for renal dialysis and home program dialysis were used in the cost and treatment calculations. For the CMS Form 265-94 and the CMS Form 2552-96 (Worksheet C, and worksheet I-4, respectively) values in the field home program CAPD and home program CCPD were stated in terms of patient weeks, rather than the number of

treatments. These cells were multiplied by three to make them comparable to the number of hemodialysis sessions per week. The method used was consistent with the research (Dor, Held, Pauley 1992, Hirth, et.al.,1999, Griffiths, et.al., 1994, and Ozgen and Ozcan, 2002).

This method created an average Medicare allowable cost per dialysis treatment for each facility year of observation. Using the facility's Medicare billing number, cost report data were linked to claims data. For some facilities more than one billing number appears on claims and a list of correspondence among billing was used to link the claims to the cost report facility identifiers. This linkage was somewhat ambiguous for hospital facilities with satellite centers.

Patient level data was obtained from the Medicare claims data, and the Medical Evidence From (CMS 2728). ESRD patients were identified using the Renal Beneficiary and Utilization System (REBUS), Medical Evidence and Master Patient File Records. Dialysis-related services (for example, the number of dialysis sessions) were identified for ESRD patients by Billing source (72x: renal dialysis facility bills), revenue center codes and the Healthcare Common Procedure Coding System (HCPCS).

## 6. Study Sample

Regression models for the average cost per session were used to estimate the typical cost per session. The average cost per session can be influenced by facilities with exceptional costs or with exceptional case-mix measures. To insure that the sample would characterize the patterns across the majority of facilities rather than being influenced by a few exceptional, non-representative facilities, the following facilities were excluded:

- Facilities with missing data from the cost reports or claims data. Twelve percent of the facilities lacked reported data.
- Facilities with high or low average costs.
- Facilities with exceptions.
- Facilities with extremely high or low proportions of patients with relevant medical comorbidities.
- Small facilities.

Facilities with high or low average costs were determined based upon their composite rate. Facilities, having values for the log of the ratio of average costs to the composite rate of less than minus 0.5 or greater than 1.0 were excluded. This excluded less than 1 percent of facilities. Some

facilities, that is, those with extremely high or low values based on selected patient characteristics (for example, percent of patients having a specific comorbidities such as AIDs, HIV, or alcohol and drug dependence) and selected facility characteristics (for example, facility size or URR). As with average costs, facilities with extreme variables did not represent the normal distribution of patient characteristics across facilities. This excluded 1.6 percent of the facilities. In addition, we excluded small facilities with less than 20 full patient years of dialysis during the year because it was difficult to assess the relationship between case-mix and facility costs based on the experience of a small number of patients. Facilities treating a small number of patients represented approximately 6.9 percent of the total facilities.

The sample excluded facilities with exceptional reimbursement levels. These included facilities with exceptions, facilities with higher than average payments, for example, with \$3.00 or greater than the predicted composite rate payments. We excluded facilities based on our list of exceptions granted from November 1993 to July 2001. Some facilities were not included within the sample because their

average payments were greater than the calculated (predicted) composite rate for the individual facility. While for the majority of the facilities, average composite rate payments were exactly as predicted, for some facilities, the payments were \$3.00 greater than the predicted rate. These facilities were excluded because they were likely to be facilities with errors in reporting or facilities with exceptions. Of all of the facilities in the sample, 7.5 of the facilities were excluded from the sample.

#### 7. Developing Case-Mix Measures at Each Facility Based on Patient-Specific Data

Facility-level case-mix measures were defined using certain demographic and comorbidity indicators for the Medicare dialysis patients in each facility for CYs 2000 to 2002. In aggregating patient data by facility, case-mix measures for each patient were weighted by the number of hemodialysis-equivalent dialysis sessions received in each facility. This process gives approximately 12 times as much weight to the characteristics of patients receiving a full year of dialysis care at a particular facility as compared to a patient receiving only one month of care at that facility. The resulting facility-level case-mix measures reflect how

case-mix is distributed across individual treatments provided in the facility for Medicare dialysis patients. The number of dialysis sessions for each patient in each facility was obtained from Medicare outpatient institutional dialysis claims. The number of peritoneal dialysis patient days reported on each claim was multiplied by 3/7 to yield the number of hemodialysis-equivalent dialysis sessions provided during the time period covered by each claim. (For additional information see Phase I KECC Report, dated August 2002, p. 43).

#### 8. Statistical Models

We explored a number of statistical methods to model the relationship between composite rate costs and patient/facility characteristics. We explored both linear and log-linear ordinary least squares regression models for each year from 2000 to 2002 to predict the natural log of the ratio of each facility's composite rate costs divided by that facility's composite payment rate (without regard to exception payments).

##### i. Choice of Estimation Method:

We are proposing to use the log linear model in the methodology explained below in order to yield an easily administered case-mix adjuster which can be multiplied by the

patient's otherwise applicable composite payment rate. This case-mix adjustment system also controls for selected variables.

We used the cost to payment ratio (that is, the natural log of the ratio of reported costs compared to the composite rate calculated for each facility) as the dependent variable in the models. The analysis that supports our decision is described in detailed below. In order to determine how reimbursement levels could be adjusted to reflect the costs of treating different patients, estimates of how the cost of providing dialysis services (that is, the composite rate) varies according to the patient characteristics (for example, age gender and comorbidities) were completed. Because the reported cost per treatment for each facility, in part, reflects the level of reimbursement (for example, Medicare payments) that the facility received, the measure of facility costs used is defined as the ratio relative to the current standard reimbursement level for each facility. For the purposes of these analyses, the standard Medicare reimbursement payments for composite rate services (excluding those facilities with payment exceptions) were used. These currently vary across facilities based on the application of

the area wage index used to develop the patient characteristics adjustment. This wage index (that is, labor costs) was used to account for regional differences in labor costs, and includes an adjustment for hospital based versus independent facility status.

As we have indicated, the costs of treatment varies from the composite rate payment for a number of reasons, including differences in the patient case-mix. The ratio of average reported costs at each facility were compared with the calculated composite rate payment in order to measure any variation in costs (that is, facility costs) from the composite rate. This cost to payment ratio measures the extent to which costs at a facility are higher or lower than the payment that would be expected based on their labor costs and facility type. Regression analysis was used to determine the extent to which the ratio varied with the average case-mix for each facility.

The analysis indicated that a log transformation of this cost to payment ratio was less skewed and a better fit (that is, the predicted variables were closer to the actual values using the log transformation).

ii. Control Variables:

Apart from patient clinical and demographic characteristics, the proposed model also controls for selected other variables. These selected control variables include the wage index, the natural log of facility size (number of annual treatments), hospital-based/independent status, chain affiliation, and percent of patients with urea reduction ratios (URRs) greater than or equal to 65 percent. These control variables were included in the proposed model in order to account for the separate effect of facility variables and one readily available outcome variable on composite rate costs. These control variables were included in order to reduce potential distortion in the patient specific case-mix adjusters attributable to facility characteristics. We included the wage index to account for differences among facilities in area wage levels. We used facility size as a control factor because larger facilities, on average, have lower per treatment costs than smaller facilities. The hospital-based/independent classification was used because hospital based providers tend to have higher self-reported costs. Chain ownership is included in the model to account for differences among chains due to reporting conventions, as well as reflect similarities among facilities within chains.

The URR was included as a control variable to account for a quality of care outcome measure at each facility, thereby mitigating any potential bias between composite rate costs and quality of care on the model's coefficients.

iii. The Log-linear Model for Facility Costs

We identified a limited number of comorbidities that are strong predictors of composite rate costs and developed an estimated adjustment factor for each of these comorbidities. In order to yield an adjustor that can be multiplied with the composite rate payment, the model was used to estimate the facility's reported composite rate costs per treatment, divided by the composite payment rate calculated for each facility. The resulting ratio was modeled using case-mix and control variables. Analysis indicated that a log transformation of this ratio was less skewed and was better fit by the model (that is, predicted values were closer to actual values using the log transformation, especially for high cost facilities).

For facility  $j$ , the case-mix is measured by a vector of values, denoted by  $X_j$ . These values include both control variables and case-mix measures. The log of the ratio of cost per session ( $C_j$ ) to composite rate ( $R_j$ ) is denoted by

$Y_j = \log(C_j/R_j)$ . The multiple observations for three years are not indicated explicitly. The model equation is  $Y_j = X_j \beta + \varepsilon_j$ , where  $\beta$  is the vector of coefficients for the predictor variables and  $\varepsilon_j$  is an error term. This model is equivalent to the following model for cost for patient  $i$ , with a vector of individual characteristics  $X_{ij}$ , at facility  $j$ :  $C_{ij} = R_j e^{X_{ij}\beta}$ .

## 9. Identifying Factors for Case-Mix Adjustment

An evaluation of individual case-mix factors as potential risk adjusters was performed using several criteria to explain variation in facility costs. Consideration was also given to the validity of these potential case adjusters to costs based on clinical judgment, the stability of this relationship over time, the objectivity and accuracy of the data used to compute the factors, the reliability of information reported by different providers, and the feasibility of including them as risk adjusters.

Case-mix factors that explained statistically significant variation in facility costs were identified based on a regression model that used a stepwise selection method. Unless otherwise specified, case-mix measures represent the fraction of dialysis sessions in each facility that were

provided to patients having the relevant characteristic or comorbidity. Case-mix measures that were considered for selection in the model included age/gender groups (ages <65, 65-79 and 80+ years, separately for females and males), less than one year of treatment for ESRD, average weight among adult dialysis patients (ages $\geq$ 20), low body mass index among adult dialysis patients (BMI<18.5 kg/m<sup>2</sup>) and the presence of individual comorbidities that were previously described that were developed from a combination of data from the Medicare claims history file and the CMS Form 2728.

#### 10. Using the Model to Apply a Patient-Specific Case-Mix Adjustment to the Composite Rate

The regression coefficients that are estimated using facility cost model we discuss above can be used to apply a patient-specific case mix adjustment to the composite rate. This is accomplished by re-transforming the estimated coefficients to obtain relative factors for case mix adjustment. Based on a facility level cost model, where  $X_n$  is the proportion of patients in a facility having a specific characteristic (for example, a specific comorbidity), a one unit change in  $X_n$  can be used to characterize the difference between having and not having a specific patient

characteristic. The coefficient for  $X_n, \beta_n$ , then estimates the change in the dependent variable (the natural log of the ratio of average composite rate costs to the composite rate) corresponding to whether or not a patient has that characteristic. The estimated coefficients can be re-transformed as  $e^{X_n \beta_n}$  to obtain relative factors for  $n=1$  to  $N$  case-mix measures included in the model.

The relative factors can then be applied multiplicatively to the composite rate in order to derive a case mix adjusted composite rate. Since these relative factors were all estimated to have values of 1.00 or greater, an adjustment to the composite rate based on these factors would necessarily lead to higher payments by Medicare. However, the MMA provision requires that the modification to the composite rate payment system be budget neutral. For the purpose of this example only, a budget neutrality factor that is less than 1.00 must, therefore, also be applied, with the same factor being applied to all patients and all facilities.

For patient  $i$  in facility  $j$ , a case-mix adjusted composite rate,  $AR_{ij}$  is calculated as a function of the current composite rate,  $R_{ij}$ , the estimated budget neutrality factor,  $N$

(to be determined), and an overall relative factor for case mix adjustment,  $A_{ij}$ , where  $AR_{ij} = R_j * N * A_{ij}$ ,  $R_j = (\rho B_j W_j + (1-\rho)B_j)$ , and  $A_{ij} = e^{X_{ij}\beta}$ .

In the above equations,  $\rho$  is the fraction of costs attributed to labor and therefore subject to an adjustment for geographic differences in wages,  $1-\rho$  is the fraction of costs attributed to non-labor inputs,  $B_j$  is the base rate for facility  $j$ ,  $W_j$  is the CMS/BLS wage index for facility  $j$  (with 0.9 and 1.3 representing the minimum and maximum values for  $W_j$ , respectively),  $X_{ij}$  is a vector of case-mix measures for patient  $i$  at facility  $j$ , and  $B$  is the vector of coefficients estimated by the regression model. Parameters  $\rho_j$  and  $B_j$  vary according to whether facilities are independent or hospital-based and may also vary over time, while  $W_j$  is determined either by the MSA in which each facility is located or by the state location for facilities not in an MSA.

As suggested by the equations above, the coefficients estimated by the cost model can be used to derive an aggregate relative adjustment factor for each patient ( $A_{ij}$ ) based on their individual characteristics ( $X_i$ ). By applying this factor in a multiplicative fashion to the composite rate, it is also being applied multiplicatively to the wage index, so

that the dollar effect of the case-mix adjustment also varies across facilities according to regional differences in labor costs. That is, the case-mix adjustment will be larger in magnitude for facilities that face relatively high labor costs. This is appropriate if we expect the higher level of care that may be necessary for certain types of patients, such as those with PVD, to require additional staff time or more highly trained staff in locales with differential wage levels. An overall relative case-mix adjustment factor for patient  $i$ ,  $A_i$ , can be calculated based on the model as

$$A_i = e^{X_i\beta} = e^{X_{1i}\beta_1 + X_{2i}\beta_2 + \dots + X_{pi}\beta_p}.$$

However, since this is equivalent to

$A_i = e^{X_i} = e^{X_{1i} \cdot 1} * e^{X_{2i} \cdot 2} * \dots * e^{X_{ni} \cdot n}$ , the overall relative case-mix adjustment factor, or patient multiplier, can be calculated by multiplying together the relative adjustment factors for each case-mix measure. For every  $n=1$  to  $p$ ,  $X_{pi}$  corresponds to a 1 if that characteristic is present and a 0 if that characteristic is not present. For any characteristic that is not present,  $X_{pi}=0$  and  $e^{X_{pi} \cdot p}=1$ , such that the equation can be simplified by including only those terms that are relevant for each patient. For characteristics that are present,  $X_{pi}=1$ , and the equation can be further simplified by dropping  $X_{pi}$ .

Where the individual factors for case-mix adjustment are age/gender, PVD and AIDS, the equation used to calculate the relative factor for case mix adjustment can then be expressed as  $A_i = e^{\beta} = e^{\beta_{AS}} * e^{\beta_{PVD}} * e^{\beta_{AIDS}}$  where  $e^{\beta_{AS}}$  is the relative factor for the appropriate age and sex category (one of six age/sex groups),  $e^{\beta_{PVD}}$  is the relative factor for the relevant PVD category (whether PVD is present or absent) and  $e^{\beta_{AIDS}}$  is the relative factor for the appropriate AIDS category (whether AIDS is present or absent).

#### 11. Example

To illustrate, the proposed adjustment factors in section 4. above were used to derive a case-mix multiplier for a 7-year old male who has been diagnosed with PVD, but not AIDS. Using the proposed adjustment factors that correspond to males between the ages of 65 and 79 years and the presence of PVD, the overall case-mix multiplier for this patient is calculated as  $A = e^{Xb} = e^{\beta_{AS}} * e^{\beta_{PVD}} = 1.17 \times 1.07 = 1.2519$ .

A detailed example of the computation of the adjusted composite payment rate that includes the patient characteristics adjustments, as well as the applicable adjustments related to the ESRD drug payment revisions and budget neutrality, is provided later in this section I. below.

e. Geographic Index

Section 623(d)(1) of the MMA provides that the Secretary shall adjust the payment rates under this section by a geographic index as the Secretary determines to be appropriate. This section also specifies that, if the Secretary revises the current geographic adjustments applied to the composite payment rate, the revised adjustments must be phased in over a period of time. The current geographic adjustment (wage index) is a blend of two wage indexes, one based on hospital wage data collected by us from fiscal year 1986 and the other developed from 1980 hospital wage and employment data from the Bureau of Labor Statistics (BLS). The hospital and BLS proportions of the blended wage index are 40 percent and 60 percent. The actual wage index values and MSA/non-MSA designations currently used in connection with the composite rates were published in the August 15, 1986 **Federal Register** (51 FR 29412-29417). For the reasons discussed below, we have decided not to propose any changes to the current wage index adjustments at this time.

On June 6, 2003, OMB issued Bulletin 03-04 that announced new MSAs and two new sets of statistical areas, Micropolitan Statistical Areas and Combined Statistical Areas (CSAs). We

recognize that the new OMB definitions will have implications for the various payment systems we administer that reflect payment distinctions based on geographic location. Any changes adopted will not only result in payment redistributions among ESRD facilities, but will also affect hospitals, home health agencies, skilled nursing facilities, and rehabilitation providers.

Therefore, it is essential that we evaluate any proposals to revise the area definitions and assess the impact of changes in geographical areas on those payment systems that incorporate adjusters for area wage levels among urban and rural locations.

Although the MMA gives the Secretary discretion to revise the outdated wage indexes used in the composite rates, we believe that we should take no action to replace them with revised measures pending completion of our assessments.

Therefore, we are proposing to take no action at this time to revise the current set of composite rate wage indexes and the urban and rural definitions used to develop them. Once revisions to the urban and rural definitions are adopted, we may be in a better position to propose revisions to the

geographic adjustments applied to the case-mix adjusted composite payment rates.

For purposes of applying the required geographic adjustments to the case-mix adjusted composite rate payment system, we are proposing to continue using the wage index values and urban and rural designations that are currently applied to the composite payment rates.

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 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.

With respect to the drug payment add-on adjustment the total estimated difference between the current drug payment based on 95 percent of AWP and the payment amount generated from payment based on ASP minus 3 percent is reflected in the proposed adjustment which is designed so that aggregate

payments are budget neutral. (See section H.4.c.2. of this proposed rule for more detailed explanation of drug add-on adjustment).

In order to account for the payment effect related to the case-mix adjustment, we standardized the composite rate by dividing the rate by the average case-mix modifier of 1.1919. (See section 4.ii Proposed Comorbidity Adjustments). The resulting adjustment to the composite rate is .8390. However, we were not able to simulate the case-mix effects from the ESRD billing file because comorbidities are generally not included on the ESRD bill. (See section H.3. of this proposed rule for the discussion of the data issues.) We propose to refine our adjustments for case-mix once we have more complete data on the ESRD bill.

F. Payment Exceptions and the Revised Composite Payment Rates

Before the enactment of BIPA, an ESRD facility could apply for and receive prospective adjustments or exceptions to its otherwise applicable composite payment rate under specified circumstances. Section 1881(b)(7) of the Act and §413.182 contain the statutory and regulatory authorities for the provision of exceptions to the composite payment rates. Section 422(a)(2) of BIPA prohibited the granting of new

exceptions to the composite payment rates on or after December 31, 2000, except under very limited circumstances, which expired July 1, 2001. That prohibition remains in effect, with one exception. Section 623(b) of the MMA amended section 422(a)(2) of BIPA to afford pediatric facilities the opportunity to seek exceptions provided they did not have an exception rate in effect as of October 1, 2002. The statute defines a pediatric facility as a renal facility, 50 percent of whose patients are under age 18. On April 1, 2004, we opened an exception window for pediatric facilities. The exception window closes September 27, 2004.

Section 422(a)(2)(C) of BIPA provided that any ESRD composite rate exception in effect on December 31, 2000 would continue as long as the exception rate exceeds the applicable composite payment rate. The MMA did not revise that provision. Comparisons of a provider's exception rate and the standard composite payment rate are straightforward, because each payment rate was applied on a facility specific basis, without any adjustments for case-mix. However, in this proposed rule, we are proposing revised composite payment rates that are case-mix adjusted. The wage adjusted composite payment rates listed for each urban and rural area noted in

Tables I and II at the end of this section, although applied on a per treatment basis, are subject to case mix adjustments in accordance with section 623(d)(1) of the MMA. The proposed methodology for applying patient characteristic adjusters applicable to each treatment will determine the case-mix adjustment which will vary for each patient. Thus, an ESRD facility's average composite rate per treatment will depend on its unique case mix.

Our policy was not to increase any ESRD facility's exception rate when there has been a congressionally mandated update to the ESRD composite payment rates. When computing an exception amount, we take into consideration the ESRD facility's patient population and the higher costs relating to the patient mix. Since ESRD facilities can maintain their current exception rates, we would expect them to compare the exception rate to the basic case-mix adjusted composite rate to determine the best payment rate for their facility. We are proposing to allow each dialysis facility the option of continuing to be paid at its exception rate or at the basic case-mix adjusted composite rate (which includes all the MMA 623 payment adjustments). If the facility retains its exception rate, it would not be subject to any of the

adjustments specified in section 623 of the MMA. Whether a provider's exception rate in effect on December 31, 2000 will exceed its average case-mix adjusted composite payment rate is impossible for us to accurately determine. We believe that projections as to whether an ESRD facility's exception rate per treatment will exceed its average case-mix adjusted composite rate per treatment are best left to the entities affected. Therefore, we are proposing that each ESRD facility with composite rate exceptions currently in effect, and each pediatric ESRD facility granted an exception, must notify its fiscal intermediary in writing if it wishes to withdraw its exception and be subject to the basic case-mix adjusted composite payment rate methodology set forth in this notice.

We are proposing to allow an ESRD facility to notify its fiscal intermediary at any time if it wishes to give up its exception rate. Once a facility has notified its fiscal intermediary of its election to give up its exception rate, it would lose that exception rate, regardless of basis or amount, and be subject to the proposed case-mix adjusted composite payment rates beginning 30 days after the intermediary's receipt of the facility's notification letter. Facilities with exception rates will be required to notify their fiscal

intermediaries only if they wish to forego their exceptions. ESRD facilities electing to retain their exceptions do not need to notify their intermediaries. ESRD facilities without exceptions, of course, will be subject to the composite payment rates determined using the basic case-mix methodology described in this notice beginning January 1, 2005.

G. Summary of Composite Rate Revisions and Proposed Implementation

As set forth in this proposed 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 to reflect revisions to the drug pricing methodology for separately billable drugs, as discussed in section H.4.b. of this proposed rule. That increase represents the spread or difference between the payment amounts for separately billable drugs and biologicals and their acquisition costs based on the OIG's May 2004 report to the Secretary. The development and computation of the drug add-on adjustment are described in section H.4.c of this proposed rule. We have also proposed a 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 case-mix adjusters are explained in section H.4.d.4 of this proposed rule. The MMA requires that the basic case-mix adjusted composite payment rates be effective for services furnished beginning January 1, 2005. Despite the law's specificity with respect to effective date, the systems and operational changes necessary to apply the case-mix adjusters cannot be completed in time for a prospective January 1, 2005 effective date.

The 1.6 percent statutory increase and 11.3 drug add-on for independent and hospital-based facilities for separately billable drugs will be applied to the composite rates for all ESRD facilities beginning January 1, 2005. However, the computation of the case mix adjusters depends on age, sex, and specific comorbidities which must be obtained from the bills for each ESRD facility. Therefore, the combination of case-mix adjusters used to increase a provider's otherwise applicable composite payment rate depends on a provider's unique patient profile and is facility-specific. The correct computation of these facility-specific case-mix adjusters will require numerous programming, systems, billing, and instructional changes by us, fiscal intermediaries, and system

maintainers. In addition, providers and their fiscal intermediaries will require education and training not only on the basic features of the new ESRD PPS, but also on the proper reporting of patient and clinical information on the bills, essential for an accurate case mix adjustment in connection with each patient's claims.

Given these requirements, the lead time necessary for systems changes, and the anticipated time necessary for providers and their fiscal intermediaries to familiarize themselves with and correctly apply the basic case-mix adjustments, we are proposing an April 1, 2005 effective date.

As an alternative to an April 1, 2005 effective date for the patient characteristic case mix adjustments, we considered two options for an April 1, 2005 prospective implementation date that would effectively comply with the MMA's January 1, 2005 effective date. Under the first option, we would implement the patient characteristic adjustments on April 1, 2005 and reprocess bills and adjust payments to January 1, 2005. Under this option, the budget neutrality adjustment related to the patient characteristic factors would not be applied to the composite rate until bills are reprocessed.

The second option that we considered was to make payment to facilities starting January 1, 2005, at the budget neutralized composite rate, until the systems changes for the case-mix adjustment can be implemented, April 1, 2005. Payment at this rate would avoid overpayments, and thus, the need to recoup moneys that may occur when we retroactively process the claims for case-mix adjustments on April 1, 2005. Under this option, facilities would receive approximately 16 percent less than they would otherwise be entitled to on January 1, 2005.

We rejected both of these alternatives. Both options require the reprocessing and adjustment of bills for the first quarter of 2005. In addition, because of the likelihood of payment error due to the complexity of the process and costly implementation and potential disruption of payment to ESRD facilities, we believe that these options are problematic. Given that the expected impact of the patient characteristic adjustments on ESRD facility payments will, for the most part, be minimal, we believe that applying the adjustments prospectively from April 1, 2005 provides a smoother transition to the new payment methodology.

Finally, this notice provides for a budget neutrality reduction of .8390 percent to the case-mix adjusted composite payment rates. Our budget neutrality methodology is explained in section H.4.f. of this proposed rule. Because section 623(d) of the MMA requires that budget neutrality be applied in the context of implementing the case-mix adjusted composite rate payment system, we are proposing that the effective date of the budget neutrality adjustment should also be April 1, 2005. If we applied the budget neutrality adjustment in January, rather than when the case-mix adjustment is applied in April, the result would be that all the composite rates would go down.

We are specifically soliciting comments on these options of the proposed rule. However, the 1.6 percent statutory increase to the composite payment rates, and the drug add-on for separately billable drugs, will be effective January 1, 2005, as these adjustments are easily implemented prospectively.

#### **IV. Example of Payment Calculation Under the Proposed Case Mix Adjusted Composite Rate System**

The following example presents 2 patients dialyzing at Neighbor Dialysis, an independent facility in Baltimore, MD.

Patient #1, John Smith, is a 71-year old male who has been diagnosed with PVD and AIDS. Patient #2, Jane Doe, is a 59-year old female who has been diagnosed with PVD.

Calculation of Basic Composite Rate for Neighbor Dialysis:

Wage adjusted Composite Rate for independent facilities in Baltimore, Md. (Table I)	\$134.93
Wage adjusted Composite Rate increased by proposed drug add-on adjustment( $\$134.93 \times 1.113$ )	\$150.18
Adjusted Facility Composite Rate after budget neutrality ( $150.18 \times .8490$ )	\$126.00

Calculation of Case-mix Adjusted Payments:

Patient #1 -- John Smith:

Male age 65-79 years	1.17
AIDS	1.15
PVD	1.07

<b>Case-mix adjusted rate for John Smith</b> <b>(<math>\\$126.00 \times 1.17 \times 1.15 \times 1.07</math>)</b>	<b>\$181.40</b>
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Patient #2 -- Jane Doe:

Female age < 65 years	1.11
PVD	1.07

<b>Case-mix adjusted rate for Jane Doe</b> <b>(<math>\\$126.00 \times 1.11 \times 1.07</math>)</b>	<b>\$149.65</b>
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Table 18

	COMPOSITE PAYMENT RATES EFFECTIVE JANUARY 1, 2005			
	FOR URBAN RENAL FACILITIES			
MSA				
CODE	NAME OF MSA	STATE	HOSPITAL	INDEPENDENT
0040	ABILENE	TX	127.58	123.18
0060	AGUADILLA	PR	127.57	123.18
0080	AKRON	OH	137.39	133.68
0120	ALBANY	GA	127.57	123.18
0160	ALBANY-SCHENECTADY-TROY	NY	129.93	125.70
0200	ALBUQUERQUE	NM	135.60	131.77
0220	ALEXANDRIA	LA	129.70	125.46
0240	ALLENTOWN-BETHLEHEM	PA-NJ	134.75	130.87
0280	ALTOONA	PA	133.79	129.84
0320	AMARILLO	TX	130.03	125.80
0360	ANAHEIM-SANTA ANA	CA	145.72	142.64
0380	ANCHORAGE	AK	146.35	146.35
0400	ANDERSON	IN	131.74	127.63
0405	ANDERSON	SC	127.57	123.18
0440	ANN ARBOR	MI	145.80	142.71
0450	ANNISTON	AL	127.57	123.18
0460	APPLETON-OSHKOSH-NEENAH	WI	132.60	128.56
0470	ARECIBO	PR	127.57	123.18
0480	ASHEVILLE	NC	130.57	126.39
0500	ATHENS	GA	127.57	123.18
0520	ATLANTA	GA	130.07	125.84
0560	ATLANTIC CITY	NJ	134.72	130.82
0600	AUGUSTA	GA-SC	130.08	125.85
0620	AURORA-ELGIN	IL	140.21	136.70
0640	AUSTIN	TX	135.14	131.29
0680	BAKERSFIELD	CA	141.64	138.25
0720	BALTIMORE	MD	138.55	134.93
0733	BANGOR	ME	129.34	125.09
0760	BATON ROUGE	LA	131.80	127.71
0780	BATTLE CREEK	MI	134.05	130.11
0840	BEAUMONT-PORT ARTHUR	TX	130.85	126.67
0845	BEAVER COUNTY	PA	138.52	134.89
0860	BELLINGHAM	WA	132.87	128.85
0870	BENTON HARBOR	MI	127.57	123.18
0875	BERGEN-PASSAIC	NJ	142.22	140.71
0880	BILLINGS	MT	132.16	128.08

0920	BILOXI-GULFPORT	MS	127.57	123.18
0960	BINGHAMTON	NY	130.00	125.77
1000	BIRMINGHAM	AL	131.83	127.73
1010	BISMARCK	ND	130.64	126.47
1020	BLOOMINGTON	IN	129.78	125.54
1040	BLOOMINGTON-NORMAL	IL	129.69	125.45
1080	BOISE CITY	ID	135.23	131.39
1123	BOSTON-SALEM-BROCKTON	MA	139.45	135.89
1125	BOULDER-LONGMONT	CO	140.62	137.15
1140	BRADENTON	FL	128.79	124.47
1145	BRAZORIA	TX	134.02	130.08
1150	BREMERTON	WA	129.14	124.87
1163	BRIDGEPORT-NORWALK-DANBURY	CT	141.49	138.08
1240	BROWNSVILLE-HARLINGEN	TX	129.79	125.56
1260	BRYAN-COLLEGE STATION	TX	128.68	124.37
1280	BUFFALO	NY	133.55	129.59
1300	BURLINGTON	NC	127.57	123.18
1303	BURLINGTON	VT	131.37	127.24
1310	CAGUAS	PR	127.57	123.18
1320	CANTON	OH	131.51	127.40
1350	CASPER	WY	136.29	132.52
1360	CEDAR RAPIDS	IA	131.05	126.92
1400	CHAMPAIGN-URBANA-RANTOUL	IL	133.39	129.39
1440	CHARLESTON	SC	131.44	127.33
1480	CHARLESTON	WVA	135.86	132.06
1520	CHARLOTTE-ROCK HILL	NC-SC	129.79	125.57
1540	CHARLOTTESVILLE	VA	133.15	129.15
1560	CHATTANOOGA	TN-GA	132.45	128.39
1580	CHEYENNE	WY	131.21	127.06
1600	CHICAGO	IL	142.79	139.48
1620	CHICO	CA	139.53	135.98
1640	CINCINNATI	OH-KY- IN	137.22	133.50
1660	CLARKSVILLE-HOPKINSVILLE	TN-KY	127.57	123.18
1680	CLEVELAND	OH	141.66	138.27
1720	COLORADO SPRINGS	CO	135.83	132.03
1740	COLUMBIA	MO	140.08	136.56
1760	COLUMBIA	SC	130.43	126.24
1800	COLUMBUS	GA-AL	128.15	123.79
1840	COLUMBUS	OH	134.12	130.19
1880	CORPUS CHRISTI	TX	131.52	127.41
1900	CUMBERLAND	MD-WVA	128.22	123.87
1920	DALLAS	TX	134.47	130.56
1950	DANVILLE	VA	127.57	123.18
1960	DAVENPORT-MOLINE	IA-IL	133.12	129.11
2000	DAYTON-SPRINGFIELD	OH	137.82	134.14
2020	DAYTONA BEACH	FL	127.85	123.47
2030	DECATUR	AL	127.57	123.18

2040	DECATUR	IL	131.69	127.57
2080	DENVER	CO	143.60	140.35
2120	DES MOINES	IA	135.21	131.36
2160	DETROIT	MI	143.03	139.73
2180	DOTHAN	AL	127.57	123.18
2200	DUBUQUE	IA	132.63	128.61
2240	DULUTH	MN-WI	130.10	125.88
2290	EAU CLAIRE	WI	128.84	124.53
2320	EL PASO	TX	128.41	124.08
2330	ELKHART-GOSHEN	IN	129.30	125.01
2335	ELMIRA	NY	132.63	128.60
2340	ENID	OK	129.51	125.24
2360	ERIE	PA	131.82	127.74
2400	EUGENE-SPRINGFIELD	OR	133.37	129.37
2440	EVANSVILLE	IN-KY	134.10	130.16
2520	FARGO-MOORHEAD	ND-MN	133.83	129.88
2560	FAYETTEVILLE	NC	127.57	123.18
2580	FAYETTEVILLE-SPRINGDALE	AR	127.57	123.18
2640	FLINT	MI	141.83	138.45
2650	FLORENCE	AL	127.57	123.18
2655	FLORENCE	SC	127.57	123.18
2670	FORT COLLINS-LOVELAND	CO	131.49	127.38
2680	FT LAUDERDALE-POMPANO BEACH	FL	137.23	133.51
2700	FORT MYERS-CAPE CORAL	FL	129.73	125.49
2710	FORT PIERCE	FL	130.09	125.87
2720	FORT SMITH	AK-OK	128.97	124.67
2750	FORT WALTON BEACH	FL	127.57	123.18
2760	FORT WAYNE	IN	129.32	125.05
2800	FORT WORTH-ARLINGTON	TX	133.06	129.04
2840	FRESNO	CA	142.09	138.72
2880	GADSDEN	AL	128.48	124.17
2900	GAINESVILLE	FL	130.25	126.06
2920	GALVESTON-TEXAS CITY	TX	137.86	134.20
2960	GARY-HAMMOND	IN	138.47	134.85
2975	GLENS FALLS	NY	128.98	124.68
2985	GRAND FORKS	ND	129.26	124.98
3000	GRAND RAPIDS	MI	133.41	129.44
3040	GREAT FALLS	MT	132.09	128.01
3060	GREELEY	CO	134.34	130.43
3080	GREEN BAY	WI	133.34	129.33
3120	GREENSBORO-WINSTON SALEM-HIGH PT	NC	129.67	125.42
3160	GREENVILLE-SPARTANBURG	SC	130.15	125.95
3180	HAGERSTOWN	MD	132.79	128.78
3200	HAMILTON-MIDDLETOWN	OH	134.87	130.98
3240	HARRISBURG-LEBANON-CARLISLE	PA	133.92	129.97
3283	HARTFORD-NEW BRITAIN-BRISTOL	CT	140.38	136.90

3290	HICKORY	NC	127.57	123.18
3320	HONOLULU	HI	141.73	138.34
3350	HOUMA-THIBODAUX	LA	128.02	123.66
3360	HOUSTON	TX	137.24	133.53
3400	HUNTINGTON-ASHLAND	WVA-KY-OH	130.11	125.88
3440	HUNTSVILLE	AL	127.57	123.18
3480	INDIANAPOLIS	IN	135.16	131.30
3500	IOWA CITY	IA	143.23	140.37
3520	JACKSON	MI	134.43	130.53
3560	JACKSON	MS	128.82	124.51
3580	JACKSON	TN	127.57	123.18
3600	JACKSONVILLE	FL	130.77	126.58
3605	JACKSONVILLE	NC	127.75	123.37
3620	JANESVILLE-BELOIT	WI	128.39	124.05
3640	JERSEY CITY	NJ	138.46	134.84
3660	JOHNSON CITY-BRISTOL	TN-VA	127.57	123.18
3680	JOHNSTOWN	PA	133.36	129.36
3690	JOLIET	IL	140.66	137.19
3710	JOPLIN	MO	127.97	123.61
3720	KALAMAZOO	MI	143.25	139.98
3740	KANKAKEE	IL	130.84	126.66
3760	KANSAS CITY	MO-KS	133.22	129.21
3800	KENOSHA	WI	137.39	133.69
3810	KILLEEN-TEMPLE	TX	128.12	123.75
3840	KNOXVILLE	TN	127.83	123.45
3850	KOKOMO	IN	132.39	128.34
3870	LA CROSSE	WI	131.00	126.87
3880	LAFAYETTE	LA	132.84	128.83
3920	LAFAYETTE	IN	128.65	124.33
3960	LAKE CHARLES	LA	130.17	125.97
3965	LAKE COUNTY	IL	141.41	137.98
3980	LAKELAND-WINTER HAVEN	FL	127.57	123.18
4000	LANCASTER	PA	135.38	131.54
4040	LANSING-EAST LANSING	MI	135.98	132.18
4080	LAREDO	TX	127.57	123.18
4100	LAS CRUCES	NM	127.57	123.18
4120	LAS VEGAS	NV	141.01	137.58
4150	LAWRENCE	KS	131.82	127.73
4200	LAWTON	OK	130.27	126.08
4243	LEWISTON-AUBURN	ME	128.39	124.06
4280	LEXINGTON-FAYETTE	KY	130.21	126.01
4320	LIMA	OH	133.29	129.29
4360	LINCOLN	NE	129.96	125.72
4400	LITTLE ROCK-N LITTLE ROCK	AR	135.96	132.17
4420	LONGVIEW-MARSHALL	TX	127.57	123.18
4440	LORAIN-ELYRIA	OH	134.22	130.30
4480	LOS ANGELES-LONG BEACH	CA	146.35	145.02

4520	LOUISVILLE	KY-IN	134.40	130.50
4600	LUBBOCK	TX	129.87	125.63
4640	LYNCHBURG	VA	128.00	123.63
4680	MACON-WARNER ROBINS	GA	129.46	125.19
4720	MADISON	WI	135.45	131.63
4763	MANCHESTER-NASHUA	NH	131.20	127.04
4800	MANSFIELD	OH	130.40	126.20
4840	MAYAGUEZ	PR	127.57	123.18
4880	MCALLEN-EDINBURG-MISSION	TX	127.57	123.18
4890	MEDFORD	OR	133.00	128.99
4900	MELBOURNE-TITUSVILLE	FL	130.19	125.99
4920	MEMPHIS	TN-AR-MS	135.10	131.23
4940	MERCED	CA	138.45	134.83
5000	MIAMI-HIALEAH	FL	138.47	134.85
5015	MIDDLESEX-HUNTERDON	NJ	134.87	130.99
5040	MIDLAND	TX	135.10	131.24
5080	MILWAUKEE	WI	136.75	133.02
5120	MINNEAPOLIS-ST PAUL	MN-WI	136.11	132.33
5160	MOBILE	AL	129.00	124.70
5170	MODESTO	CA	138.05	134.41
5190	MONMOUTH-OCEAN	NJ	133.08	129.06
5200	MONROE	LA	129.18	124.90
5240	MONTGOMERY	AL	130.14	125.92
5280	MUNCIE	IN	131.36	127.22
5320	MUSKEGON	MI	131.68	127.57
5345	NAPLES	FL	130.55	126.35
5360	NASHVILLE	TN	132.71	128.70
5380	NASSAU-SUFFOLK	NY	146.35	144.35
5403	NEW BEDFORD-FALL RIVER-ATTELBORO	MA	131.79	127.70
5483	NEW HAVEN-WATERBURY-MERIDEN	CT	137.50	133.80
5523	NEW LONDON-NORWICH	CT	137.24	133.52
5560	NEW ORLEANS	LA	130.68	126.50
5600	NEW YORK	NY	146.35	146.35
5640	NEWARK	NJ	141.09	137.67
5700	NIAGARA FALLS	NY	130.31	126.11
5720	NORFOLK-NEWPORT NEWS	VA	129.67	125.42
5775	OAKLAND	CA	146.35	145.92
5790	OCALA	FL	128.79	124.48
5800	ODESSA	TX	129.63	125.38
5880	OKLAHOMA CITY	OK	134.67	130.78
5910	OLYMPIA	WA	135.49	131.66
5920	OMAHA	NE-IA	132.99	128.98
5950	ORANGE COUNTY	NY	132.46	128.39
5960	ORLANDO	FL	132.46	128.39
5990	OWENSBORO	KY	127.57	123.18
6000	OXNARD-VENTURA	CA	146.28	145.05

6015	PANAMA CITY	FL	127.57	123.18
6020	PARKERSBURG-MARIETTA	WVA-OH	130.89	126.73
6025	PASCAGOULA	MS	135.50	131.67
6080	PENSACOLA	FL	128.26	123.91
6120	PEORIA	IL	136.83	133.10
6160	PHILADELPHIA	PA-NJ	141.48	138.07
6200	PHOENIX	AZ	137.96	134.32
6240	PINE BLUFF	AR	127.57	123.18
6280	PITTSBURGH	PA	138.69	135.09
6323	PITTSFIELD	MA	133.87	129.91
6360	PONCE	PR	127.57	123.18
6403	PORTLAND	ME	132.96	128.94
6440	PORTLAND	OR	139.91	136.40
6453	PORTSMOUTH-DOVER-ROCHESTER	NH-ME	128.29	123.95
6460	POUGHKEEPSIE	NY	135.84	132.03
6483	PROVIDENCE-PAWTUCKET- WOONSOCKET	RI	134.58	130.69
6520	PROVO-OREM	UT	130.42	126.22
6560	PUEBLO	CO	137.23	133.52
6600	RACINE	WI	129.52	125.26
6640	RALEIGH-DURHAM	NC	132.93	128.90
6660	RAPID CITY	SD	128.78	124.47
6680	READING	PA	133.16	129.15
6690	REDDING	CA	138.98	135.39
6720	RENO	NV	144.32	142.52
6740	RICHLAND-KENNEWICK	WA	131.96	127.89
6760	RICHMOND-PETERSBURG	VA	129.76	125.53
6780	RIVERSIDE-SAN BERNARDINO	CA	143.65	140.40
6800	ROANOKE	VA	130.33	126.13
6820	ROCHESTER	MN	134.23	130.31
6840	ROCHESTER	NY	134.50	130.60
6880	ROCKFORD	IL	136.62	132.85
6920	SACRAMENTO	CA	144.16	141.12
6960	SAGINAW-BAY CITY- MIDLAND	MI	138.22	134.57
6980	ST CLOUD	MN	129.55	125.29
7000	ST JOSEPH	MO	132.19	128.12
7040	ST LOUIS	MO-IL	135.07	131.21
7080	SALEM	OR	136.70	132.96
7120	SALINAS-SEASIDE-MONTEREY	CA	144.09	140.88
7160	SALT LAKE CITY-OGDEN	UT	131.27	127.13
7200	SAN ANGELO	TX	127.57	123.18
7240	SAN ANTONIO	TX	129.30	125.03
7320	SAN DIEGO	CA	144.75	142.04
7360	SAN FRANCISCO	CA	146.35	145.92
7400	SAN JOSE	CA	146.35	145.68
7440	SAN JUAN	PR	127.57	123.18
7480	SANTA BARBARA-LOMPOC	CA	139.14	135.58
7485	SANTA CRUZ	CA	140.64	137.18

7490	SANTA FE	NM	129.81	125.59
7500	SANTA ROSA-PETALUMA	CA	146.35	145.59
7510	SARASOTA	FL	131.98	127.90
7520	SAVANNAH	GA	129.72	125.48
7560	SCRANTON-WILKES BARRE	PA	133.66	129.70
7600	SEATTLE	WA	136.87	133.14
7610	SHARON	PA	132.08	128.00
7620	SHEBOYGAN	WI	129.28	125.01
7640	SHERMAN-DENISON	TX	127.57	123.18
7680	SHREVEPORT	LA	133.23	129.23
7720	SIOUX CITY	IA-NE	132.47	128.40
7760	SIOUX FALLS	SD	130.62	126.44
7800	SOUTH BEND-MISHAWAKA	IN	130.13	125.92
7840	SPOKANE	WA	138.38	134.75
7880	SPRINGFIELD	IL	137.27	133.56
7920	SPRINGFIELD	MO	129.48	125.21
8003	SPRINGFIELD	MA	133.39	129.39
8050	STATE COLLEGE	PA	137.91	134.25
8080	STEUBENVILLE-WEIRTON	OH-WVA	131.46	127.35
8120	STOCKTON	CA	146.35	145.06
8160	SYRACUSE	NY	141.36	139.77
8200	TACOMA	WA	136.53	132.76
8240	TALLAHASSEE	FL	129.91	125.67
8280	TAMPA-ST PETERSBURG-CLEARWATER	FL	132.27	128.21
8320	TERRE HAUTE	IN	127.57	123.18
8360	TEXARKANA	TX-AR	135.59	131.75
8400	TOLEDO	OH	140.91	137.45
8440	TOPEKA	KS	135.89	132.10
8480	TRENTON	NJ	135.66	131.82
8520	TUCSON	AZ	134.02	130.07
8560	TULSA	OK	133.31	129.30
8600	TUSCALOOSA	AL	133.86	129.91
8640	TYLER	TX	132.17	128.09
8680	UTICA-ROME	NY	130.41	126.22
8720	VALLEJO-FAIRFIELD-NAPA	CA	146.35	146.18
8725	VANCOUVER	WA	139.12	135.53
8750	VICTORIA	TX	127.57	123.18
8760	VINELAND-MILLVILLE-BRIDGETON	NJ	132.48	128.41
8780	VISALIA-PORTERVILLE	CA	142.02	140.48
8800	WACO	TX	127.81	123.43
8840	WASHINGTON	DC-MD-VA	141.74	138.35
8920	WATERLOO-CEDAR FALLS	IA	129.50	125.24
8940	WAUSAU	WI	130.90	126.74
8960	WEST PALM & DELRAY BEACH	FL	131.84	127.75
9000	WHEELING	WVA-OH	131.83	127.74

9040	WICHITA	KS	136.67	132.93
9080	WICHITA FALLS	TX	127.57	123.18
9140	WILLIAMSPORT	PA	130.24	126.04
9160	WILMINGTON	DE-NJ-MD	136.71	132.97
9200	WILMINGTON	NC	128.74	124.42
9243	WORCESTER-LEOMINSTER	MA	132.43	128.37
9260	YAKIMA	WA	132.24	128.18
9280	YORK	PA	132.45	128.39
9320	YOUNGSTOWN-WARREN	OH	137.25	133.54
9340	YUBA CITY	CA	137.02	133.29

**Table 19**

COMPOSITE PAYMENT RATES EFFECTIVE JANUARY 1, 2005				
FOR RURAL RENAL FACILITIES				
MSA				
CODE	NAME OF MSA	STATE	HOSPITAL	INDEPENDENT
AL	ALABAMA	AL	127.57	123.18
AK	ALASKA	AK	146.35	146.35
AZ	ARIZONA	AZ	128.68	124.35
AR	ARKANSAS	AR	127.57	123.18
CA	CALIFORNIA	CA	137.00	133.27
CO	COLORADO	CO	128.21	123.86
CT	CONNECTICUT	CT	136.02	132.22
DE	DELAWARE	DE	128.76	124.44
FL	FLORIDA	FL	127.75	123.37
GA	GEORGIA	GA	127.57	123.18
HI	HAWAII	HI	140.40	136.92
ID	IDAHO	ID	127.83	123.45
IL	ILLINOIS	IL	127.57	123.18
IN	INDIANA	IN	127.57	123.18
IA	IOWA	IA	127.57	123.18
KS	KANSAS	KS	127.57	123.18
KY	KENTUCKY	KY	127.57	123.18
LA	LOUISIANA	LA	127.57	123.18
ME	MAINE	ME	127.57	123.18
MD	MARYLAND	MD	130.27	126.08
MA	MASSACHUSETTS	MA	135.99	132.19
MI	MICHIGAN	MI	132.98	128.97
MN	MINNESOTA	MN	127.57	123.18
MS	MISSISSIPPI	MS	127.57	123.18
MO	MISSOURI	MO	127.57	123.18
MT	MONTANA	MT	127.87	123.50
NE	NEBRASKA	NE	127.57	123.18
NV	NEVADA	NV	133.20	129.20
NH	NEW HAMPSHIRE	NH	132.24	128.18
NM	NEW MEXICO	NM	128.68	124.36
NY	NEW YORK	NY	127.78	123.40
NC	NORTH CAROLINA	NC	127.57	123.18
ND	NORTH DAKOTA	ND	127.70	123.31
OH	OHIO	OH	128.66	124.34
OK	OKLAHOMA	OK	127.57	123.18
OR	OREGON	OR	132.66	128.64
PA	PENNSYLVANIA	PA	132.54	128.48
PR	PUERTO RICO	PR	127.57	123.18
RI	RHODE ISLAND	RI	130.86	126.69
SC	SOUTH CAROLINA	SC	127.57	123.18
SD	SOUTH DAKOTA	SD	127.57	123.18
TN	TENNESSEE	TN	127.57	123.18
TX	TEXAS	TX	127.57	123.18

UT	UTAH	UT	128.56	124.24
VT	VERMONT	VT	127.57	123.18
VA	VIRGINIA	VA	127.57	123.18
WA	WASHINGTON	WA	131.35	127.21
WV	WEST VIRGINIA	WV	128.43	124.09
WI	WISCONSIN	WI	127.57	123.18
WY	WYOMING	WY	131.29	127.15

**Table 20**  
Comorbidities

AIDS

042 Human immunodeficiency disease

Peripheral vascular disease

0400 Gas gangrene  
 4151 Pulmonary embolism and infarction  
 41511 Pulmonary embolism and infarction, iatrogenic  
 pulmonary embolism  
 and infarction  
 440 Atherosclerosis  
 4400 Atherosclerosis of aorta  
 4401 Atherosclerosis of renal artery  
 4402 Atherosclerosis of native arteries of the  
 extremities  
 44020 Atherosclerosis of native arteries of the  
 extremities,  
 unspecified  
 44021 Atherosclerosis of native arteries of the  
 extremities,  
 with intermittent claudication  
 44022 Atherosclerosis of native arteries of the  
 extremities,  
 with rest pain  
 44023 Atherosclerosis of the extremities with ulceration  
 44024 Atherosclerosis of the extremities with gangrene  
 44029 Atherosclerosis of native arteries of the  
 extremities,  
 with ulceration  
 4403 Atherosclerosis of bypass graft of the extremities  
 44030 Atherosclerosis of bypass graft of the extremities  
 of  
 unspecified graft  
 44031 Atherosclerosis of bypass graft of the extremities  
 of  
 autologous vein bypass graft  
 44032 Atherosclerosis of bypass graft of the extremities  
 of  
 nonautologous biological bypass graft  
 441 Aortic aneurysm and dissection  
 4410 Aortic aneurysm and dissection,dissection of aorta  
 44100 Aortic aneurysm and dissection,dissection of aorta,  
 unspecified site

44101 Aortic aneurysm and dissection,dissection of aorta,  
thoracic  
44102 Aortic aneurysm and dissection,dissection of aorta,  
abdominal  
44103 Aortic aneurysm and dissection,dissection of aorta,  
thoracoabdominal  
4411 Thoracic aneurysm, ruptured  
4412 Thoracic aneurysm without mention of rupture  
4413 Abdominal aneurysm, ruptured  
4414 Abdominal aneurysm without mention of rupture  
4415 Aortic aneurysm of lunspecified site, ruptured  
4416 Thoracoabdominal aneurysm, ruptured  
4417 Thoracoabdominal aneurysm without mention of  
rupture  
4419 Aortic aneurysm and dissection of unspecified site  
without  
mention of rupture  
442 Other aneurysm  
4420 Other aneurysm of artery of upper extremity  
4421 Other aneurysm of renal artery  
4422 Other aneurysm of iliac artery  
4423 Other aneurysm of artery of lower extremity  
4428 Other aneurysm of other specified artery  
44281 Other aneurysm of other specified artery, artery of  
neck  
44282 Other aneurysm of other specified artery,  
subclavian artery  
44283 Other aneurysm of other specified artery, splenic  
artery  
44284 Other aneurysm of other specified artery, other  
visceral artery  
44289 Other aneurysm of other specified artery, other  
4429 Other aneurysm of unspecified site  
443 Other peripheral vascular disease  
4430 Other peripheral vascular disease, Raynaud's  
syndrome  
4431 Other peripheral vascular disease, thromboangiitis  
obliterans  
[Buerger's disease]  
4432 Other peripherovascular diseases, other arterial  
dissection  
44321 Other peripherovascular diseases, other arterial  
dissection,  
dissection of carotid artery  
44322 Other peripherovascular diseases, other arterial  
dissection,  
dissection of iliac artery

44323 Other peripherovascular diseases, other arterial dissection,  
dissection of renal artery  
44324 Other peripherovascular diseases, other arterial  
dissection,  
dissection of vertebral artery  
44329 Other peripherovascular diseases, other arterial  
dissection,  
dissection of other artery  
4438 Other peripheral vascular disease, other specified  
peripheral  
vascular disease  
44381 Other peripheral vascular disease, other specified  
peripheral  
vascular disease, peripheral angiopathy in diseases  
classified elsewhere  
44389 Other peripheral vascular disease, other specified  
peripheral  
vascular disease, other  
4439 Peripheral vascular disease, unspecified  
444 Arterial embolism and thrombosis  
4440 Arterial embolism and thrombosis, of abdominal  
aorta  
4441 Arterial embolism and thrombosis, of thoracic aorta  
4442 Arterial embolism and thrombosis, of arteries of  
the extremities  
44421 Arterial embolism and thrombosis, of arteries of  
the  
extremities, upper extremity  
44422 Arterial embolism and thrombosis, of arteries of  
the  
extremities, lower extremity  
4448 Arterial embolism and thrombosis, of other  
specified artery  
44481 Arterial embolism and thrombosis, of other  
specified artery,  
upper extremity  
44489 Arterial embolism and thrombosis, of other  
specified artery,  
lower extremity  
449 Arterial embolism and thrombosis, of unspecified  
artery  
4450 Atheroembolism, of extremities  
44501 Atheroembolism, of extremities, upper extremity  
44502 Atheroembolism, of extremities, lower extremity  
446 Polyarteritis nodosa and allied conditions  
4460 Polyarteritis nodosa and allied conditions,  
polyarteritis nodosa

451 Phlebitis and thrombophlebitis  
 4510 Phlebitis and thrombophlebitis of superficial  
 vessels of lower  
 extremities  
 4511 Phlebitis and thrombophlebitis, of deep vessels of  
 lower  
 extremities  
 45111 Phlebitis and thrombophlebitis, of deep vessels of  
 lower  
 extremities, femoral vein  
 45119 Phlebitis and thrombophlebitis, of deep vessels of  
 lower \  
 extremities, other  
 4512 Phlebitis and thrombophlebitis, of lower  
 extremities,  
 unspecified  
 45181 Phlebitis and thrombophlebitis, of other, sites  
 iliac vein  
 45182 Phlebitis and thrombophlebitis, of other sites, of  
 superficial  
 veins of upper extremities  
 45183 Phlebitis and thrombophlebitis, of other sites, of  
 deep veins of  
 upper extremities  
 45184 Phlebitis and thrombophlebitis, of  
 upperextremities, unspecified  
 45189 Phlebitis and thrombophlebitis, other  
 4519 Phlebitis and thrombophlebitis, unspecified  
 453 Other venous embolism and thrombosis  
 4530 Other venous embolism and thrombosis, Budd-Chiari syndrome  
 4531 Other venous embolism and thrombosis,  
 Thrombophlebitis migrans  
 4532 Other venous embolism and thrombosis of vena cava  
 4533 Other venous embolism and thrombosis of renal vein  
 4538 Other venous embolism and thrombosis of other  
 specified sites  
 4539 Other venous embolism and thrombosis of unspecified  
 site

# I. Section 731(b)--Coverage for Routine Costs of

## Category A Clinical Trials

[If you choose to comment on issues in this section, please  
 include the caption "Section 731(b)" at the beginning of

your comments.]

Section 1862(m) of the Act, as added by Section 731(b) of the MMA, prohibits the Secretary from excluding payment for the routine costs of care furnished to a Medicare beneficiary participating in a clinical trial of a Category A device based on a determination that such care is not "reasonable and necessary" under section 1862(a)(1). In effect, this section authorizes Medicare to cover the routine costs of clinical trials involving Category A devices. Category A (experimental/investigational) devices are defined in §405.201 as innovative medical devices about which the Food and Drug Administration (FDA) has major questions about safety and effectiveness.

For a trial to qualify for payment of routine costs, it must meet certain criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards. Current criteria are established in the National Coverage Determination Manual (CMS Pub. 100-3, Manual section 310.1).

In addition, the MMA established additional criteria for trials initiated before January 1, 2010 to ensure that the devices involved in these trials be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Guidelines for

determining if a device meets this requirement will be defined through the NCD process.

Section 411.15(o) currently precludes Medicare payment for Category A devices. We would not revise this section because the MMA does not require Medicare to pay for the cost of the Category A device (as opposed to the cost of routine care associated with the trial of a Category A device).

We are proposing changes to §405.207. As currently written, this section precludes coverage of services related to a noncovered device. Since the Category A device is noncovered, we would amend this section to allow coverage of routine care services related to a noncovered Category A device. In addition, we propose language to cross-reference §405.201 concerning coverage of Category B (nonexperimental/investigational) devices. We would not be changing coverage of Category B devices, but providing consistency by placing information on Category A and Category B devices in the same section.

J. Section 629--Part B Deductible

[If you choose to comment on issues in this section, please include the caption "Section 629" at the beginning of your comments.]

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 propose 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. Finally, we plan to publish an annual notification in the **Federal Register**, announcing each upcoming year's Part B deductible. This notification for the Part B deductible will be included as part of the annual notice we currently publish announcing Medicare's Part B premiums and actuarial rates.

K. Section 512--Hospice Consultation

[If you choose to comment on issues in this section, please

include the caption "Section 512" at the beginning of your comments.]

#### 1. Coverage of Hospice Consultation Services

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 employee of a hospice agency. Payment will 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.

The decision to elect hospice services is a personal choice and is generally a decision made between the individual and his or her physician (probably the physician making the terminal diagnosis). Therefore, we believe that most individuals will seek this type of service from their own physician. 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/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, typically those who determine the beneficiary's terminal diagnoses, can provide for these evaluation and management 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 in hospitals and through services of social workers, case managers, and other health care professionals. To the extent that beneficiaries have already received Medicare-covered evaluation and counseling with respect to end-of-life care, the hospice evaluation and counseling would seem duplicative. We intend to monitor data regarding these services to assess whether Medicare is paying for duplicative services.

We are proposing to cover the services described above for a terminally ill beneficiary, at the request of the

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. Since the beneficiary or his/her physician decides to obtain this service from the hospice medical director or physician employee, 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 will 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 services. The statute requires the physicians to 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 is receiving payment for these services through the use of evaluation and management (E&M) codes.

In the event that the individual's physician initiates the request for services of the hospice medical director or physician, 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 propose to add new §418.205 and §418.304(d) to implement section 512 of the MMA.

## 2. Payment for Hospice Consultation Services

Section 512(b) of the MMA amends section 1414(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 evaluation and management 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 are proposing to establish a new HCPCS code, G0xx4 Hospice - evaluation and counseling services, pre-election. The hospice would use this HCPCS code to submit claims to the Regional Home Health Intermediary (RHHI) for payment for these services. Utilization of this code would allow us to provide payment for this service as well as enable us to monitor the frequency with which the code is used and to assess whether the code is used appropriately. 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 are proposing 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 Work RVU + 0.10 Malpractice RVU)\* (CF). This CPT code for an office or outpatient visit for the evaluation and management of a new patient represents a detailed history, detailed examination and medical decision making of low complexity, which, we believe, is quite similar to the components of this 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).

L. Section 302—Clinical Conditions for Coverage of Durable Medical Equipment (DME)

[If you choose to comment on issues in this section, please include the caption "Section 302" at the beginning of your comments.]

1. Legislative Requirement

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 for payment of covered items of durable medical equipment (DME). The law 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 practitioner and also require a prescription for these items.

Covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) have already been divided into classes of covered items, as established by the local medical review policies (LMRP) and local coverage determinations (LCD) issued by the durable medical equipment regional carriers (DMERCs). For example, the contractors have developed policies on long term home oxygen therapy, canes, crutches, wheelchairs, hospital beds, urological supplies, spinal orthoses, surgical dressing, and enteral and parenteral nutrition therapy. These and other policies for each of the four DMERCs are entered into the Medicare Coverage Database at [www.cms.hhs.gov/coverage](http://www.cms.hhs.gov/coverage).

These policies are developed based on clinical evidence and after discussion with clinical experts in the area. There are already a number of local coverage determinations and national coverage determinations that outline the clinical conditions for which these items are covered. These determinations outline the conditions for coverage, payment, and the documentation or testing

necessary to establish medical necessity. We propose to continue developing these clinical conditions of coverage through the local and national coverage determination process.

We are also proposing to expand the requirement for clinical conditions of coverage to medical supplies, appliances and devices defined in 42 CFR 410.36. These are commonly referred to as prosthetics, orthotics and supplies (POS). We believe items of POS require the same level of medical intervention and skill as DME. As with DME, there are already a number of local and national coverage determinations outlining appropriate clinical conditions for coverage and propose to continue this process.

From a clinical perspective, we believe that it is appropriate for beneficiaries requiring DMEPOS to be under the care of a physician and for DMEPOS orders to occur in the context of routine clinical care. We believe it is good clinical practice for the beneficiary to be seen by the physician for their medical condition and the physician to decide whether or not an item of DMEPOS is appropriate during the face-to-face examination of the beneficiary. Since we expect a beneficiary to be seen by their physician for a specific medical condition, we do not believe that a requirement for a face-to-face examination for initial

orders and at the time of the prescription renewals for items of continued need (those DMEPOS items where an order is good for only a certain period of time and requires a follow-up examination by the physician) would place a burden on the physician or beneficiary, as it would be part of a necessary examination. We believe this to be the current practice in most cases.

Our goal is to encourage quality care, to mitigate any proliferation of use of these products and ensure that only patients that need items of DMEPOS receive them. To comply with the requirements of section 302(a)(2) of the MMA and to enhance quality and reduce fraud, we would establish basic requirements that apply to all items of durable medical equipment, prosthetics, orthotics, and supplies. We have identified a proliferation of use for some items of DMEPOS and we believe that engaging the physician or practitioner early in the process of ordering DMEPOS will assist us in mitigating any unnecessary proliferation of use.

This regulation proposes to make a face-to-face exam by the physician to determine the medical necessity and ordering an item of DMEPOS an explicit requirement for all initial orders of DMEPOS and at the time of prescription renewal for all DMEPOS continued need items. However, we

seek specific comments about whether specific items of DMEPOS should be exempt from the face-to-face examination requirement.

In order for us to verify the medical necessity for an item, the prescribing physician's or practitioner's records must document the need at the time the physician or practitioner examines the beneficiary. For example, a letter to the supplier or to us dated months after the date the examination was conducted and the order was written would not be sufficient verification.

## 2. Provisions Related to DMEPOS

To implement the provisions of the MMA, we would--

- Establish a requirement for a face-to-face examination by a physician, physician assistant (PA), clinical nurse specialist (CNS), or nurse practitioner (NP), as they are defined in the Act (the prescribing physician or practitioner) to determine the medical necessity of durable medical equipment, orthotics and prosthetics.
- Require that the prescribing physician or practitioner be independent from the DMEPOS supplier and may not be a contractor or an employee of the supplier.
- Establish a requirement that the face-to-face examination should be for the purpose of evaluating and treating the patient's medical condition and not

for the sole purpose of obtaining the prescribing physician's or practitioner's order for the DMEPOS.

We expect the prescribing physician or practitioner to conduct a sufficient examination of the patient's medical condition to ascertain the appropriate overall treatment plan and to order the DMEPOS as only one aspect of that treatment plan.

- Require an order prior to delivery for all items of durable medical equipment, prosthetics, or orthotics.
- Require that the order be dated and signed within 30 days after the face-to-face examination and include verification of the examination. We are soliciting comments on the appropriate verification process.
- Require the prescribing physician or practitioner to maintain appropriate and timely documentation in the medical records that support the need for all DMEPOS ordered.
- Provide that we would promulgate through contractor instructions other criteria required for payment, such as for prescription renewal requirements, repair, minor revisions and replacement. We are interested in comments on whether the Agency should establish national renewal requirements or permit contractor discretion.

- Provide that we would promulgate through the national coverage determination process or through the local coverage determination process additional clinical conditions for items of DMEPOS.

We propose to revise language in §410.36 and §410.38 to implement section 302(a)(2) of the MMA.

M. Section 614--Payment for Certain Mammography Services

[If you choose to comment on issues in this section, please include the caption "Section 614" at the beginning of your comments.]

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).

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. In the OPPS proposed rule, we will discuss our proposal for payment for diagnostic mammograms using the payments

established under the physician fee schedule. This proposal will parallel the current practice used for the payment of screening mammography services provided in the OPPS setting and will be effective January 1, 2005.

N. Section 305--Payment for Inhalation Drugs

[If you choose to comment on issues in this section, please include the caption "Section 305" at the beginning of your comments.]

1. Background

Lung diseases such as chronic obstructive pulmonary disease (COPD) affect large numbers of Medicare beneficiaries. COPD is the fourth largest cause of death in America behind heart disease, certain cancers, and stroke. We hope to reduce the number of new COPD cases by educating Americans about the disease, its causes, and ways to prevent it. We hope to improve the lives of Medicare beneficiaries and improve beneficiary access to treatment for those who already suffer from these conditions.

Depending on an individual's age and health, a number of steps can be taken to treat or prevent this. Because approximately 85 percent of those with COPD are smokers, the first step to avoid the disease is to stop smoking. Smoking has been linked to a large number of health problems and is a 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.

We have also recently approved services to address the needs of Americans suffering from COPD, including lung-volume reduction surgery, which, performed in more serious cases, removes the diseased lung tissue, allowing the rest of the lung to function better. Specifically, effective January 1, 2004, Medicare expanded coverage of lung volume reduction surgery to include patients, who are not high-risk surgical patients, who either have severe, upper-lobe emphysema, or have severe, non-upper-lobe emphysema with low exercise capacity.

A number of drugs are available to treat the persons with asthma or who develop COPD. These include agents, often inhaled, that expand the bronchial tubes, allowing the patient to breathe more freely. Access to these drugs for Medicare beneficiaries has been expanded by the MMA.

Nebulizers and metered dose inhalers (MDIs) are two different delivery methods to administer inhalation drugs to a beneficiary. A nebulizer works by aerosolizing liquefied inhalation drugs so that the medication can be

more easily inhaled into the lungs. For about 10 to 30 minutes, a beneficiary breathes the mist via compressor tubing hooked up to the nebulizer. An MDI consists of a canister of pressurized medication that is propelled directly into the airways of the lungs when a beneficiary presses on the inhaler and breathes in through the mouth, thereby allowing the medicine to take effect quickly.

Medicare Part B currently pays for nebulizers and inhalation drugs. However, Medicare Part B does not cover MDIs and, therefore, does not pay for inhalation drugs delivered by an MDI. An MDI is considered to be an item of disposable medical equipment (for which there is no current Part B benefit category) while a nebulizer is considered to be an item of DME.

The Part D drug benefit improves beneficiary access to inhalation therapy by covering MDIs (including the inhalation drugs they furnish) beginning January 1, 2006. In addition, the prescription drug discount card began offering discounts on MDIs effective June 1, 2004.

Since Medicare currently covers inhalation drugs provided through nebulizers, but not alternative forms of inhalation therapy, there are strong financial incentives toward use of the former compared to alternatives. Our review of the literature over the past decade did not find

that bronchodilators delivered via nebulizers were more effective than bronchodilators delivered via metered dose inhalers.

Since one delivery method is not clinically superior to the other, when Medicare covers both methods of delivery of inhalation therapy, the decision to prescribe one over the other will be made by the physician and beneficiary based on beneficiary needs and preferences consistent with applicable standards of medical practice. It would not be unlikely for many beneficiaries to choose the convenience of MDIs over nebulizers once the Medicare coverage imbalance is removed in 2006. Since MDIs are less expensive, very portable, and easier to use, it is likely there will be a substantial shift of Medicare beneficiaries from nebulizers to MDIs beginning in 2006, even absent the Medicare payment changes for nebulizers and inhalation drugs in 2005.

## 2. What Medicare Part B Currently Covers

Medicare Part B currently covers and pays for five separate items related to nebulizers. All of the items are subject to the standard Part B deductible and coinsurance.

### a. Nebulizers

Medicare Part B currently covers the rental of nebulizers. Nebulizers are in the "capped rental" category

of DME for payment purposes. Payment is made on a monthly basis during the period of medical need. Medicare pays 10 percent of the payment amount during the first three months and 7.5 percent during the next 12 months. Section 1834(a) of the Act specifies that the payment amount is equal to the amount paid for purchase of the nebulizer in 1986, indexed to current levels by the cumulative DME update factor specified in this subsection. Thus, Medicare will pay up to a cumulative total of 120 percent of the payment amount for 15 months of renting a nebulizer.

If the beneficiary needs a nebulizer for more than 15 months, and continues to rent it, Medicare makes no further payment for the equipment because the equipment has already been paid for. Medicare does continue to pay for maintenance and servicing of the nebulizer, as well as the inhalation drugs, but the supplier retains title to the equipment.

During the 10<sup>th</sup> month of continuous rental of a nebulizer, the supplier is required to offer the beneficiary a purchase option, and if the beneficiary accepts the offer and exercises the purchase option, the supplier transfers title to the nebulizer in the 13<sup>th</sup> month. In this case, Medicare would make its final monthly rental payment in the 13<sup>th</sup> month, and the title then would transfer

to the beneficiary. About 3 percent of beneficiaries exercise the purchase option.

In 2003, the average Medicare monthly rental payment for nebulizers was \$19.07 for the first three months and \$14.30 for the fourth through fifteenth month. Thus, Medicare would pay \$228.81 for a nebulizer if the beneficiary's period of medical need were 15 months. There are various types of nebulizers (compressor, ultrasonic, portable, disposable) and nebulizer accessories (breathing circuits, air filters, tubing extensions, mouthpieces, spare battery packs, DC adapters) available. Internet prices for compressor nebulizers range from \$50 to \$100, and prices for portable nebulizers range from \$100 to \$200, depending on the specific features of the nebulizer. The Medicare payment amount includes payment for delivery of the equipment. (Shipping costs for nebulizers available for purchase on the Internet range from free shipping up to \$25).

b. Maintenance and Servicing of Nebulizers

Medicare Part B makes an additional separate payment to the supplier for maintenance and servicing of the equipment (for parts and labor not covered by the supplier's or manufacturer's warranty). For nebulizers that are not purchased, but are used for more than 21

months, the servicing fee covers six-month periods beginning after the 21st month of use. As required by section 1834(a)(7) of the Act, Medicare's payment for maintenance and servicing is equal to the lesser of a reasonable and necessary maintenance and servicing fee, or 10 percent of the total purchase price of the equipment. For nebulizers that are purchased, Medicare may make a payment to the supplier for any necessary maintenance and servicing that is performed.

In 2003, the average service fee for nebulizers was \$19.07 per six-month period. Other than routine cleaning of the unit (that is, cleaning and changing filters, cleaning and disinfecting nebulizers, tubing, and mouthpieces), very little maintenance is required to maintain a nebulizer's peak performance. There is usually no scheduled maintenance for the nebulizer. Medicare pays for the usual frequency for replacement of accessories. Maintenance kits and replacement parts are available through online suppliers for approximately \$5 to \$15.

c. Inhalation Drugs

Medicare Part B pays for drugs that the nebulizer furnishes to a beneficiary. Unlike nebulizers, inhalation drugs are not an explicit benefit covered by statute. However, there was an administrative decision made early in

the program's history to cover inhalation drugs as a supply so that the nebulizer could work. Without the inhalation drugs, the nebulizer would not be effective for a beneficiary.

The two most common inhalation drugs used by beneficiaries are albuterol sulfate (a beta-adrenergic bronchodilator) and ipratropium bromide (an anticholinergic bronchodilator). A beneficiary may use one or the other of these inhalation drugs, and they are frequently prescribed together. Both albuterol sulfate and ipratropium bromide are manufactured in powder form, but are generally liquefied and furnished to beneficiaries in liquid form for use in a nebulizer. The beneficiary may use a solution of one drug, or a combination of both drugs, in addition to saline if necessary, with the nebulizer. The beneficiary may mix the solution, or the supplier may furnish the drug in a pre-mixed form (either commercially pre-mixed or pharmacy compounded). The shelf life of these drugs is at least 18 to 24 months, and they do not require any special storage arrangements such as refrigeration.

Medicare also pays for other inhalation drugs, such as budesonide (an inhaled corticosteroid), which are used in conjunction with albuterol sulfate and ipratropium bromide.

These drugs can also be administered using a nebulizer or an MDI.

d. Dispensing Fee

Medicare has paid a monthly \$5 dispensing fee for each covered inhalation drug or combination of drugs used in a nebulizer. The dispensing fee is paid for each drug dispensed, not the number of unit dose vials provided to the beneficiaries. Additionally, if two or more drugs are combined in single unit dose vials, only one dispensing fee will be paid per drug combination per month. A dispensing fee for saline is not separately billable or payable.

Inhalation drugs are the only drugs for which Medicare Part B currently pays a separate dispensing fee.

e. Beneficiary Training.

In 2003, CPT code 94664 was revised to include beneficiary training by a physician or physician's staff regarding use of a nebulizer, MDI, aerosol generator, or intermittent positive pressure breathing (IPPB) machine. The narrative terminology for the code currently is-- "Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB machine." The 2004 Medicare physician fee schedule payment for this service is \$13.44. This service has no physician work relative value units reflecting that the

training is typically performed by physician office staff. In 2004, this service has 0.32 practice expense relative value units (RVUs) and 0.04 malpractice RVUs. Additionally, the supplier of the nebulizer, under §424.57(c)(12), must "document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare covered-items safely and effectively." Beneficiary training by a physician or physician's staff regarding use of a nebulizer would meet the definition of "another qualified party" for purposes of this supplier requirement.

### 3. Medicare Spending for Nebulizers and Inhalation Drugs

In 2003, Medicare spent about \$1.6 billion for nebulizers and inhalation drugs. This amount includes--

- (a) About \$130 million for nebulizers (both rental and purchase) and nebulizer related accessories and supplies;
- (b) About \$13 million for servicing/maintenance fees;
- (c) About \$1.3 billion for albuterol sulfate and ipratropium bromide and another \$120 million for other inhalation drugs for a total of approximately \$1.4 billion. (This represents about 88 percent of Medicare spending for inhalation therapy.);

(d) About \$35.5 million for 7.1 million dispensing fees; and

(e) About \$4.5 million for beneficiary training under CPT code 94664 (though this figure also includes training for other items as well as nebulizers).

Medicare spending for inhalation drugs has grown rapidly. Preliminary data indicate that between 2001 and 2003, Medicare spending increased by 77 percent for albuterol sulfate and ipratropium bromide.

#### 4. Inspector General and General Accounting Office Studies

The HHS IG issued 10 reports between February 1996 and January 2004 about Medicare payments for albuterol sulfate and ipratropium bromide in excess of acquisition costs. In a report issued in September 2001, the General Accounting Office (GAO) also concluded that Medicare payment for these drugs was in excess of acquisition costs.

Table 1 of the Interim Final Rule regarding Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004, published in the January 7, 2004 **Federal Register** (69 FR 1084), showed that the acquisition cost (averaging IG and GAO results) was 34 percent of the Average Wholesale Price (AWP) for ipratropium bromide and 17 percent for albuterol sulfate. Prior to 2004, Medicare paid 95 percent of the AWP for each

of these drugs and beneficiary coinsurance was 20 percent of the Medicare payment amount. In the case of albuterol sulfate, the beneficiary coinsurance was more than the actual acquisition cost for the drug. During 2004, Medicare payment is 80 percent of the AWP for each of these drugs. Beginning with 2005, Medicare payment will be 106 percent of the Average Sales Price (ASP).

The IG report issued in January 2004 again concluded that Medicare payments were far in excess of acquisition costs for both albuterol sulfate and ipratropium bromide. The IG found that the Medicare 2004 payment (and payment in prior years) was a multiple of the actual acquisition costs for both drugs based on a comparison to the median price that the drug was available through wholesalers/distributors and group purchasing organizations (GPOs) and comparison to the manufacturer-reported Wholesale Acquisition Cost (WAC).

#### 5. Inhalation Drug Spread

In 2003, ipratropium bromide and albuterol sulfate were the third and seventh largest drugs in terms of Medicare spending for carrier paid drugs. The differences between Medicare's payment amount and acquisition costs (that is, spread) for albuterol sulfate and ipratropium bromide are among the largest spreads for drugs studied by

the IG and GAO. Based on the actual acquisition costs determined by IG and GAO studies, in 2003, Medicare paid an estimated nearly \$900 million in excess of acquisition costs for albuterol sulfate and ipratropium bromide.

The IG and GAO findings of large differences between Medicare payment amounts and acquisition costs for inhalation drugs provided the foundation for Congressional enactment of section 305 of the MMA. This section of the MMA sets Medicare payment for inhalation drugs at 106 percent of the ASP. (The Congressional Budget Office's November 20, 2003 pricing of the MMA estimated section 305 as having savings of \$4.2 billion over 10 years.)

Suppliers argue that inhalation drug spread has allowed them to fund activities related to care for beneficiaries with asthma or COPD that otherwise do not have a Medicare Part B benefit category. These other activities may include the following:

- Respiratory therapists on staff or in networks available on-call for home visits or telephone consultations.
- On-call pharmacists.
- Monthly calls to schedule medication refills.
- Continuous education on disease states, including monthly follow-ups.

- 24-hour support lines.
- On-call and/or monthly home delivery of medication and supplies.
- Quality improvement programs.

## 6. Nebulizers vs. MDIs

Medicare Part B currently covers only one type of inhalation therapy, nebulizers and inhalation drugs. Although Medicare Part B does not cover MDIs and the inhalation drugs they furnish, the new Part D benefit beginning in 2006 will cover these alternative hand-held inhalation therapy devices (MDIs). In addition, the discount card and \$600 transitional assistance payment for low-income beneficiaries will help seniors buy inhalers in 2004 and 2005, helping to bridge the gap until 2006 when coverage begins.

MDIs are the quickest and easiest way to take inhalation medication for most asthmatics and patients with COPD. The medication is propelled directly into the lungs, allowing it to take effect more quickly, and with fewer medication side effects. An MDI contains a specific number of "metered inhalations," and is made to deliver the prescribed amount of medication for the labeled number of doses (typically 200 doses, which is 8 doses per day for 25 days). Inhalation accessory devices, such as holding

chambers and spacers, are used to improve the direction and deposition of medication delivered by MDIs, making it easier for beneficiaries to use an MDI and making the MDI more effective in delivering the medicine to the lungs.

Since Medicare currently covers nebulizers and inhalation drugs, but not alternative forms of inhalation therapy, there are strong financial incentives toward use of the former compared to alternatives. Our review of the literature over the past decade, including two meta-analyses and over two dozen individual studies applicable to adults, did not find that bronchodilators delivered via nebulizer were more effective than when delivered via metered dose inhaler.

Since one delivery method is not clinically superior to the other, when Medicare covers both methods of delivery of inhalation therapy, the decision to prescribe one over the other will be made by the physician and beneficiary based on beneficiary needs and preferences consistent with applicable standards of medical practice. It would not be unlikely for many beneficiaries to choose the convenience of MDIs over nebulizers once the Medicare coverage imbalance is removed in 2006. Since MDIs are less expensive, very portable, and easier to use, it is likely there will be a substantial shift of Medicare beneficiaries

from nebulizers to MDIs beginning in 2006, even absent the Medicare payment changes for nebulizers and inhalation drugs in 2005.

Some claim that beneficiaries cannot use MDIs because they do not have the dexterity to use them. Use of an MDI requires proper inhalation techniques in order to receive the full benefit possible from the amount of medication included in each dose. Spacers and holding chambers extend the mouthpiece of the inhaler and increase the air volume into which the medication is atomized, allowing more time for the patient to breathe the medication and avoid misdirecting the medication onto the soft tissues inside the mouth where it will have little effect on lung function.

A nebulizer may also require a certain level of dexterity (that is, operating, maintaining, and cleaning the nebulizer correctly). There may also be beneficiaries who do not have the dexterity to use either an MDI or nebulizer, which would require the availability of alternative therapies, such as an IPPB machine to aid in the delivery of aerosol medication by increasing the depth of breathing more than the patient alone can achieve.

7. Payments Beginning in 2005 Including Provisions of the Proposed Rule

Our goal is to assure that each beneficiary who needs inhalation therapy has access to the most appropriate medication and delivery method. We expect that the combined changes to cover MDIs, adjust payments for inhalation drugs, and provide for an appropriate dispensing fee will improve beneficiary access and choice. We seek comments about an appropriate amount for a dispensing fee that would assure beneficiary access to inhalation medications provided through nebulizers.

We believe that a dispensing fee is intended to cover a pharmacy's activities to get inhalation drugs to beneficiaries. We seek data and information on the additional services these pharmacies provide to Medicare beneficiaries, the extent to which inhalation drugs can be furnished without these additional services and the extent to which such services are covered under Medicare. We are concerned about significant shifts in beneficiary access to inhalation therapy prior to implementation of the Part D drug benefit in light of the reduction in Medicare payment for inhalation drugs beginning in 2005, and also seek comments about whether the dispensing fee should include a somewhat higher, transitional payment.

Below we discuss, changes in payment for inhalation drugs and nebulizers beginning in 2005.

a. Nebulizers

Section 1834(a)(21) of the Act, as amended by section 302(c)(2) of the MMA, requires a reduction in Medicare payment, beginning with 2005, for specified items of DME, including nebulizers paid under code E0570. The reduction is the difference in payment amounts under Medicare and the median Federal Employees Health Benefits (FEHB) plan, as identified in IG testimony before the Senate Committee of Appropriations on June 12, 2002. Other codes for nebulizers and related equipment are not affected by the payment reduction.

b. Maintenance and Servicing of Nebulizers

Since the maintenance and servicing fee is equal to the first month's rental payment, the maintenance and servicing fee for nebulizers will also be reduced in 2005.

c. Inhalation Drugs

As discussed in the ASP payment section of this proposed rule, for the first quarter of 2005, the Medicare payment at ASP plus 6 percent is estimated to be \$0.04 per milligram for albuterol sulfate and \$0.30 per milligram for ipratropium bromide. While these figures represent estimated reductions from 2004 payment levels of about 90 percent, they are not necessarily the actual payment amounts for the first quarter of 2005. The actual payment

amounts will be based on ASP's calculated from the manufacturer ASP to be submitted for the third quarter of 2004.

Both albuterol sulfate and ipratropium bromide are generic drugs that have multiple manufacturers. Since these ASPs are average figures across all manufacturers, a pharmacy should be able to acquire albuterol sulfate and ipratropium bromide at these prices. Moreover, to the extent there is price variation among manufacturers, there will be some manufacturers with lower prices than others. In this case, a pharmacy might be able to obtain albuterol sulfate and ipratropium bromide at a price below the average.

The Medicare payment amount includes a 6 percent add-on. Assuming that ASP remains constant between the first and third quarters of 2004, the 6 percent add-on would be about \$1.00 for a typical month's supply of 450 milligrams of albuterol sulfate and about \$3.00 for a 90-day supply. Similarly, the 6 percent add-on would be about \$1.60 for a typical month's supply of 93 milligrams of ipratropium bromide and about \$4.80 for a 90-day supply. Because albuterol sulfate and ipratropium bromide are often prescribed together, Medicare payment at 106 percent of ASP would include, as additional payments above the acquisition

cost of the drugs, a total payment to the supplier of about \$2.60 for a 30-day supply and about \$7.80 for a 90-day supply of both drugs.

d. Dispensing Fee

Given the overall reduction in payment for inhalation drugs, we are concerned about beneficiary access to these drugs. Because shipping, handling, compounding, and other pharmacy activities would usually exceed the 6 percent payment above the drug acquisition cost, we believe that it is appropriate for Medicare to continue to pay a separate dispensing fee to pharmacies that furnish inhalation drugs to beneficiaries.

We propose to establish a separate dispensing fee for inhalation drugs. This separate dispensing fee will be in addition to the difference between what the supplier paid for the drug and the Medicare payment for the drug. For example, if a supplier purchased albuterol and ipratropium bromide for the average sales price, the supplier would receive from Medicare the separate dispensing fee amount plus what the supplier paid for the drugs plus \$7.80 for a 90-day supply. The \$7.80 is the amount included in the payment for the drugs since Medicare pays 6 percent above the average sales price.

As noted above, Medicare has paid a \$5 monthly dispensing fee for each covered inhalation drug or combination of drugs used in a nebulizer. Dispensing fees are paid by Medicaid and private insurers; we seek information about these dispensing fees for inhalation drugs and their applicability to Medicare. In addition, we seek comments about an appropriate dispensing fee amount to cover the shipping, handling, compounding, and other pharmacy activities required to get these inhalation medications to Medicare beneficiaries. We seek data and information that explains the direct labor and non-labor costs as well as indirect costs of overhead for these pharmacy activities as they relate to dispensing of inhalation drugs.

Consideration of dispensing fees needs to be viewed in the context of several important changes and clarifications in Medicare policy and billing requirements.

First, we are proposing to allow a prescription for inhalation drugs covering a 90-day period to be written by a physician and filled by a pharmacy. Current guidelines are that a pharmacy generally should not fill a prescription for inhalation drugs for more than a month's supply for a beneficiary. We believe that this requirement needs revision in the case of inhalation drugs for two key

reasons. Most beneficiaries who use inhalation drugs use them for extended periods of time and often use them for the rest of their lives. In addition, we understand that many inhalation drugs are delivered to a beneficiary through the mail. We understand that a mail-order prescription drug model works well for a 90-day prescription. We believe that there will be significant savings in shipping for a 90-day prescription rather than a monthly prescription.

We would expect that reasonableness would govern filling a monthly vs. a 90-day prescription with a physician writing and a pharmacy filling a monthly or a 90-day prescription depending on the circumstances of the beneficiary. For example, it would be reasonable to expect that the first time a beneficiary receives a prescription for a nebulizer and inhalation drugs that the prescription would be for a month. Similarly, it would be reasonable to expect that refill prescriptions for beneficiaries would be for a 90-day period. Carriers would continue to assess claims for dispensed quantities greater than what would be reasonable based on usual dosing guidelines. We would expect that the bulk of prescriptions would be for 90-day periods.

Second, we recently revised the guidelines regarding the time frame for delivery of refills of DMEPOS products to occur no sooner than "approximately 5 days prior to the end of the usage for the current product". As previously noted, inhalation drugs are often furnished to a beneficiary by mail. It has been suggested that Medicare guidelines for refill prescriptions allowed too short of a window between shipping the next month's prescription and the end of the current month. It was argued that as a result, a pharmacy "effectively" had to ship the product to a beneficiary using an overnight delivery service.

On January 2, 2004, we revised the guidelines (effective February 2, 2004) regarding the time frame for subsequent deliveries of refills of DMEPOS products to occur no sooner than "approximately 5 days prior to the end of the usage for the current product" (see section 4.26.1 of Chapter 4 - Benefit Integrity of the Medicare Program Integrity Manual). This change allows shipping of inhalation drugs on "approximately" the 25<sup>th</sup> day of the month in the case of a month's supply, and on "approximately" the 85<sup>th</sup> day in the case of a 90-day supply. We emphasize the word "approximately"; while we believe 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. ("Days" refers to business days or shipping days applicable to the shipper, that is, a 6 day week in the case of the US Postal Service.). We believe that this change eliminates the need for suppliers to use overnight shipping methods and allows shipping of inhalation drugs by less expensive ground service.

Third, we understand that some pharmacies believe that Medicare has a requirement that a pharmacy must obtain an original signed prescription before each prescription is dispensed. The Program Integrity Manual (section 5.1 of Chapter 5) addresses the ordering requirement for DMEPOS items. The Manual indicates that most DMEPOS items, including drugs, can be dispensed based on a verbal order from a physician. The Manual further indicates that a written order must be obtained before submitting a claim, but that such written order may be faxed, photocopied, electronic or pen and ink. The order for inhalation drugs must specify the name of the drug, the concentration (if applicable), dosage, and frequency of administration. We hope that clarification of this requirement would reduce a pharmacy's costs of supplying covered inhalation drugs to Medicare beneficiaries to the extent that pharmacies are

currently applying an original signed prescription requirement.

Fourth, Medicare regulations (§424.57) specify the requirements a DMEPOS supplier must meet in order to receive payment for a Medicare covered item. Section 424.57(c)(12) contains the proof of delivery requirement and indicates that a "supplier must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery." We recently revised the Program Integrity Manual (section 4.26 of Chapter 4) to address proof of delivery requirements for suppliers. As discussed in the Manual, the burden of proving delivery is left to the supplier. The Manual provides examples of the types of proof that are reasonable and acceptable, but it does not provide an all-inclusive list. Other acceptable proof-of-delivery methods may exist and may be employed by suppliers. This documentation is normally only requested by the contractor when a complaint is received that the item was not provided or received. The documentation is necessary to investigate the allegation. We believe that the current provisions on proof of delivery are adequate and appropriate for inhalation drugs.

Fifth, in section IV.H (Assignment of Medicare Claims—Payment to the Supplier) of this proposed rule, we propose

to change current regulations at §424.55 to eliminate the requirement that beneficiaries assign claims to suppliers in situations where suppliers are required by section 1842(o)(3) of the Act to accept assignment. This change would eliminate the need for suppliers to have a signed Assignment of Benefits (AOB) form from a beneficiary in order for Medicare to make payment. Because such section of the Act requires Medicare to make payment for drugs only on an assigned basis, this change would eliminate a billing requirement for drugs, including inhalation drugs. We believe that this change would reduce a pharmacy's costs of supplying covered inhalation drugs to Medicare beneficiaries to the extent that pharmacies are requiring a signed AOB form before submitting a claim.

We believe that the amount of dispensing fee needs to be considered in conjunction with--

- (1) Our proposal to allow 90-day prescriptions;
- (2) Our recent revision to allow the next month's refill prescription to be shipped approximately 5 business days prior to the end of usage for the product, that is, to allow shipping on the 25<sup>th</sup> of the month for a month's supply, and shipping on the 85<sup>th</sup> day in the case of a 90-day period;

(3) Our policy clarification regarding signed original orders before a prescription is filled;

(4) Our proof of delivery requirement revisions; and

(5) Our proposed change regarding the Assignment of Benefits form.

e. Beneficiary Training

Medicare Part B will continue to pay for beneficiary training by a physician's staff regarding use of a nebulizer, MDI, aerosol generator, or IPPB machine. Section 424.57(c)(12) specifies that "The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare covered-items safely and effectively." Beneficiary training by a physician or physician's staff regarding use of a nebulizer would meet the definition of "another qualified party" for purposes of this supplier requirement.

**IV. Other Issues**

A. Proposals Related to Therapy Services

1. Outpatient Therapy Services Performed "Incident To" Physicians' Services

[If you choose to comment on issues in this section, please include the caption "Therapy--Incident To" at the beginning of your comments.]

In last year's proposed rule, we requested comments on clarifying that the personnel qualifications of therapists in home health settings at §484.4 apply consistently to all therapy settings, including the offices of physical and occupational therapists, physicians, and nonphysician practitioners. We received comments from therapists, physicians, nontherapist health care providers and their representative organizations. After consideration of all comments, we now propose to revise 42 CFR 410.26, 410.59, 410.60 and 410.62 to reflect that physical therapy, occupational therapy, and speech-language pathology services provided incident to a physician's professional services are subject to certain limitations as described at section 1862(a)(20) of the Act.

Regulations in 42 CFR 485.705 specify that, in almost all settings, outpatient rehabilitative therapy services, (physical therapy (PT), occupational therapy (OT), or speech-language pathology (SLP)) can be furnished only by the following individuals meeting the qualifications in §484.4: physical therapists, occupational therapists, appropriately supervised physical therapist assistants, appropriately supervised occupational therapy assistants, and speech-language pathologists. Some States permit licensed physicians, physician assistants, clinical nurse

specialists, and nurse practitioners to furnish PT, OT, and SLP services also. Therapy services, and those who provide therapy services, must also meet the standards and conditions as specified in Medicare manuals.

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 such therapy services if they were furnished by a therapist, with the exception of the licensing requirement. We are proposing to amend 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.

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 services of the type described in section 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 evaluation and management services provided

incident to a physician or nonphysician practitioner such as recreational therapy, relaxation therapy, athletic training, exercise physiology, kinesiology, or massage therapy services.

## 2. Qualification Standards and Supervision Requirements in Therapy Private Practice Settings

[If you choose to comment on issues in this section, please include the caption "Therapy Standards and Requirements" at the beginning of your comments.]

Section 1861(p) includes 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 standards 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 specified level of therapist supervision that is required for the setting in which the services are provided (institutions and private practice therapist offices). For PTPPs and OTTPs, the regulations specify that the PT or OT meets only State licensure or certification standards 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 PT or OT private practice setting, the services must be personally supervised by the PTPP or OTTP. In response to a requirement to report to Congress on State standards for supervision of PTAs, CMS 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 only examined PTAs, which are more heavily regulated than OTAs). The Urban Institute study found that only 7 States require any "personal" PTA supervision by the PT, and all 7 required this level of supervision only periodically, every 14, 30 or 60 days. The remaining States and Washington, D.C. all have less stringent PTA supervision requirements, including: 7 States

and Washington, D.C. require full-time on-site supervision, which corresponds to Medicare's direct supervision level; 16 States require the equivalent of Medicare's general supervision level, which does not require the PT to be on site, but requires the PT to be in contact via telecommunication; and another 16 States have rules for periodic on-site PT visits. Most States permit a supervision level similar to the Medicare "general" supervision requirement for physical therapy services delivered in institutional settings. To provide a consistent therapy assistant supervision policy, we are proposing to revise the regulations at 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. This proposed change would no longer require the personal presence of the PTPP or OTTP when their PTAs or OTAs provide services in the private practice setting. We are particularly interested in receiving comments regarding the proposed PTA supervision change, from personal to direct, for the private practice setting as whether or not it will have implications for the quality of services provided, or for Medicare spending, either through increased capacity to provide these services, or, alternatively, 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 Balanced Budget Act of 1997.

Currently, the 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. These qualification requirements were removed during 1998 rulemaking--when the coverage conditions requiring survey and certification, at §486 Subpart D, for independently practicing PTs and OTs were replaced with a simplified carrier enrollment process for PTPPs and OTPPs. In our 1998 rule, at 63 FR 58868, we deleted the references at §410.59 and §410.60 to the requirements at §484.4 for PTs and OTs in private practice. At that time, the qualifications for the staff of the PTPP and OTPP, including PTAs and OTAs, were inadvertently removed because the coverage conditions at §486 Subpart D were no longer applicable. In order to provide a consistent policy regarding requirements for therapists and therapy assistants, we are proposing to restore the qualifications by adding at §410.59 and §410.60 the cross-reference to the qualifications at §484.4 for privately practicing therapists and their therapy assistants.

### 3. Other Technical Revisions

[If you choose to comment on issues in this section, please include the caption "Therapy Technical Revisions" at the beginning of your comments.]

We are making technical corrections to §410.62 to refer consistently to speech-language pathology in this section (currently the terms "speech pathology" and "speech-language pathology" are used interchangeably) and are revising §410.62(a)(2)(iii) to appropriately reference §410.61 (the current reference is to §410.63).

We are also 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 are making a technical change at §484.4 to correct the title "physical therapy assistant" to "physical therapist assistant."

We are also 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.

B. Low Osmolar Contrast Media

[If you choose to comment on issues in this section, please include the caption "LOW OSMOLAR CONTRAST MEDIA" at the beginning of your comments.]

Contrast media are used to enhance the images produced by various types of diagnostic radiological procedures. High osmolar contrast media (HOCM), initially developed for use with these procedures, was relatively inexpensive and payment for HOCM is subsumed in the payment for the technical component of these procedures. When the more expensive low osmolar contrast media (LOCM) were developed, estimates showed that if all radiologic studies requiring contrast media were to use LOCM, the costs to the Medicare program would have been substantial. At that time, there were no definitive studies showing that the benefits of using LOCM justified the very high additional costs.

When the Medicare physician fee schedule was established, findings of studies of patients receiving both types of contrast media had been published, and the American College of Radiology (ACR) had adopted criteria for the use of LOCM. We determined that the older, less expensive contrast media (HOCM) could be used safely in a large percentage of the Medicare population. However, we also decided that separate payment for LOCM should 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 be made for the use of LOCM in radiological procedures for patients meeting certain criteria. These criteria were established at §414.38.

Specifically, separate payment is made for all intrathecal, intravenous, and intra-arterial injections of LOCM, when it is used for nonhospital patients who have one or more of the following five medical conditions--

- A history of previous adverse reactions to contrast media, with the exception of a sensation of heat, flushing, or a single episode of nausea or vomiting;
- A history of asthma or allergy;
- Significant cardiac dysfunction, including recent or imminent cardiac decompensation, severe arrhythmias, unstable angina pectoris, recent myocardial infarction, and pulmonary hypertension;
- Generalized debilitation;
- Sickle cell disease.

Under these conditions, we pay for LOCM, utilizing HCPCS codes A4644 through A4646. The payment amount for LOCM is calculated according to the rules applicable to drugs provided incident to a physician's service. The amount is reduced by 8 percent to account for the allowance for contrast media already included in the technical component of the service.

ACR has requested that we allow further separate payment for LOCM by either expanding or eliminating the conditions. According to ACR, use of LOCM has become the standard in most radiology practices and benefits both physicians and patients. The benefits of uniform use of LOCM would include—

- The reduction of patient discomfort arising when HOCM is used instead of LOCM; and
- A reduction in physician resources now required to screen for high-risk patients.

The price differential between HOCM and LOCM is also decreasing. Universal use of LOCM, along with declining prices, will result in an efficient, and safer alternative to HOCM.

We are proposing 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. Before January 1, 2003, the criteria in §414.38 were also used to determine payment in the hospital setting. However, as instructed in our Program Memorandum A-02-120, issued November 22, 2002, hospitals that are subject to the outpatient prospective payment system (OPPS) no longer use these criteria. Instead, payment for both ionic and non-ionic contrast media (including LOCM) is packaged into the APC payment for the procedure. Under OPPS there is no longer a payment difference between LOCM and other contrast materials.

Effective January 1, 2005, payment for LOCM would be made on the basis of the average sales price 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 workpool and the CPEP inputs for these services are not used in calculating payment, we will continue to reduce payment for LOCM by eight percent to avoid any duplicate payment for contrast media.

C. Payments For Physicians and Practitioners Managing Patients on Dialysis

[If you choose to comment on issues in this section, please include the caption "MANAGING PATIENTS ON DIALYSIS" at the beginning of your comments.]

1. ESRD-Related Services Provided to Patients in Observation Settings

In response to comments received on billing procedures when the patient is hospitalized during the month, we stated in the November 7, 2003 **Federal Register** (68 FR 63220) that the physician may bill the code that reflects the number of visits during the month on days when the patient was not in the hospital (either admitted as an inpatient or in observation status). (We refer to Medicare's payment amount below as the monthly capitation

payment or MCP and the patient's normal attending physician for ESRD-related services as the MCP physician).

In comments on the August 15, 2003 proposed rule, the Renal Physicians Association (RPA) indicated that the observation area is not an uncommon setting for outpatient face-to-face encounters to occur and the observation area should be an approved site-of-service for physician-dialysis patient encounters that count toward the MCP visit total. We indicated in the final rule, however, that observation services would not be counted as a visit under the MCP, but would be paid separately. Prior to this, long-standing Medicare policy had subsumed ESRD-related observation visits within the MCP.

Upon further review of this issue, we now agree with RPA's comment and propose 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.

## 2. Payment for Outpatient ESRD-Related Services For Partial Month Scenarios

Since changing our payments for 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 where the comprehensive visit may not have been furnished: for example, when the patient is hospitalized during the month, or receives a kidney transplant before the monthly comprehensive visit is furnished. To address this issue, we propose 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."

The G codes G0324 through G0327 would be used to bill 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 there was 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.

We believe that modifying the definition of the per diem G codes (as identified by G0324 through G0327) would provide a consistent way to bill for these partial month scenarios. However, this proposed change to the descriptions of G0324 through G0327 is intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the MCP. Use of these per diem codes would be limited to the scenarios

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") may not use the per diem codes.

**Clarification on Billing for Transient Patients**

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 cannot bill using the per diem codes. In this case the transient physician or practitioner treating the patient must furnish a complete assessment and bill for ESRD-related services under the MCP.

We are currently evaluating the criteria for defining a transient patient and welcome comments on when a patient should be considered transient.

D. Technical Revision

[If you choose to comment on issues in this section, please include the caption "TECHNICAL REVISION" at the beginning of your comments.]

In §411.404, Medicare noncoverage of all obesity-related services is used as an example. Since we are currently revising this coverage policy, we are proposing to omit this example.

E. Diagnostic Psychological Tests

[If you choose to comment on issues in this section, please include the caption "DIAGNOSTIC PSYCHOLOGICAL TESTS" at the beginning of your comments.]

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. Additionally, the physician or nonphysician practitioner who is treating the patient must order all diagnostic tests in order for these tests to be considered reasonable and necessary. These tests must be furnished under at least a general level of physician supervision,

that is, the test is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.

However, certain diagnostic tests require either direct or personal supervision. Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. Personal supervision means the physician must be in attendance in the room during the performance of the procedure. Physician supervision at the specified level is required throughout the performance of the test. Services furnished without the required level of supervision are not reasonable and necessary, and Medicare payment is precluded.

Section 410.32(b)(2)(iii) does permit an exception to these physician supervision level requirements for clinical psychologists and independently practicing psychologists (who are not clinical psychologists) to personally perform diagnostic psychological testing services without physician supervision. However, diagnostic psychological tests performed by anyone other than a clinical psychologist or

independently practicing psychologist must be provided under the general supervision of a physician as defined above. Accordingly, clinical psychologists and independently practicing psychologists have not been permitted to supervise others in the administration of diagnostic psychological tests.

In §410.71(d), we require a clinical psychologist who furnishes diagnostic, assessment, preventive, and therapeutic services directly to individuals to hold a doctoral degree in psychology and to be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices. Program instructions define an independently practicing psychologist as an individual who is not a clinical psychologist and practices independently of an institution, agency, or physician's office. Examples include, but are not limited to, educational psychologists and counseling psychologists. Any psychologist who is licensed or certified to practice psychology in the State or jurisdiction where he or she is furnishing services may qualify as an independent psychologist. It is our understanding that all States, the District of Columbia, and Puerto Rico license psychologists, but that some trust territories do not. In the jurisdictions that do not issue

licenses, an independently practicing psychologist may be any practicing psychologist.

The American Psychological Association (APA) requested that we re-evaluate our regulations regarding clinical psychologists' supervision of diagnostic psychological tests. The APA also provided additional information concerning provision of these services.

According to the APA, clinical psychologists generally have seven years of graduate education in the study of human behavior and are highly trained in the selection, administration, and interpretation of psychological tests. In addition, according to our payment data, the majority of health care practitioners, other than physicians, performing psychological and neuropsychological testing services under the central nervous system codes (CPT codes 96100 through 96117) are psychologists. We agree that clinical psychologists possess core knowledge in test measurement and development, psychometric theory, specialized psychological assessment techniques, statistics, and the psychology of behavior that uniquely qualifies them to direct test selection and interpret test data.

Therefore, we are proposing to change the supervision requirements regarding who can supervise diagnostic psychological testing services.

Having ancillary staff supervised by clinical psychologists would enable these practitioners with a higher level of expertise to oversee psychological testing. It could also potentially relieve burdens on physicians and healthcare facilities.

Additionally, in rural areas, we anticipate that permitting psychologists to supervise diagnostic psychological testing services would reduce delays in testing, diagnosis, and treatment that could result from the unavailability of physicians to supervise the tests.

We propose that the appropriate level of supervision of diagnostic psychological tests by clinical psychologists be general supervision, the level required of physicians supervising the same services.

We are proposing to revise the regulations at §410.32(b)(2)(iii) to permit clinical psychologists to supervise the performance of diagnostic psychological and neuropsychological testing services. This proposal extends solely to clinical psychologists, and it does not include independently practicing psychologists.

#### F. Care Plan Oversight

[If you choose to comment on issues in this section, please include the caption "CARE PLAN OVERSIGHT" at the beginning of your comments.]

Care Plan Oversight (CPO) refers to the supervision of patients under Medicare-covered home health or hospice care requiring complex multi-disciplinary care modalities, including regular development and review of plans of care. In the December 8, 1994 physician fee schedule final rule (59 FR 63423), we established separate payment for CPO when performed by physicians. The Balanced Budget Act (BBA) of 1997 extended to nonphysician practitioners (NPPs) the right to receive payment for Medicare physicians' services that fall within their scope of practice under State law. In the November 1, 2000 final rule (65 FR 65407), we created HCPCS codes G0181 and G0182 for reporting home health and hospice CPO, respectively. We also clarified in that rule that services of NPPs, practicing within the scope of State law applicable to their services, could be billed as CPO services.

To certify a patient for home health services, a physician must review the patient records and sign the plan of care. Our policy has been that the physician who bills for CPO must be the same physician who signs the plan of care and that, according to the statute, (sections

1814(a)(2)(C) and 1835(a)(2)(A) of the Act), only a physician can sign the plan of care for home health services. The effect of these two provisions, both of which were in place prior to the BBA of 1997, created a problem with respect to an NPP billing for CPO in the home health setting.

We propose to revise §414.39 to clarify that NPPs can perform home health CPO even though they cannot certify a patient for home health services and sign the plan of care. However, we are also proposing the conditions under which NPP services may be billed for CPO; we established these conditions in consultation with our contractor medical directors and CMS medical staff. In general, 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.

G. Assignment of Medicare Claims--Payment to the Supplier.

[If you choose to comment on issues in this section, please include the caption "Assignment" at the beginning of your comments.]

Current regulations require 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. Over time, however, the Act has been amended in various sections to require suppliers, in some instances, to accept assignment for a Medicare covered service regardless of whether or not the beneficiary actually assigns the claim to the supplier. (This would include situations in which services are furnished by a participating physician or supplier.) In these instances, the requirement in our current regulations at §424.55(a) that the beneficiary assign the claim to the supplier is now unnecessary. Therefore, we are proposing 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 where suppliers are required by statute to accept assignment.

We believe the creation of this 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.

## **V. 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.

Section 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 reasonable and customary business practice; therefore, the burden for this collection requirement is exempt under 5 CFR 1320.3(b)(2)&(3).

Section 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.

Sections 410.36 and 410.38 require that the physician must document in the medical records the need for the prosthetic, orthotic, durable medical equipment, and/or supplies being ordered.

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-P)

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:Martin@omb.eop.gov). FAX (202) 395-6974.

## **VI. 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.

## **VII. Regulatory Impact Analysis**

[If you choose to comment on issues in this section, please include the caption "IMPACT" at the beginning of your comments.]

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 proposed rules with economically significant effects (that is, a proposed 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 estimate that the physician fee schedule provisions included in this proposed rule will redistribute more than \$100 million in 1 year. We are also estimating that the combined effect of several provisions of the MMA implemented in this proposed rule will increase spending by more than \$100 million. Other MMA provisions implemented in this proposed rule are estimated to reduce spending by more than \$100 million. We are considering this proposed rule to be economically significant because its provisions are estimated to result in an increase, decrease or aggregate redistribution of Medicare spending that will exceed \$100 million. Therefore, this proposed 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 proposed 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 proposed rule would have minimal impact on small hospitals located in rural areas. Of 431 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 proposed rule and described further below, we are proposing significant changes to the payments for drugs.) These physicians are concentrated in the specialties of oncology, urology, and rheumatology. 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.

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 proposed rule is estimated to impact more than 5 percent of the total number of small entities. Based on our analysis of the 697 nonprofit ESRD facilities considered small entities in accordance with the above definitions, we estimate that the combined impact of the proposed 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 proposed 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 \$270 million for FY 2005. The specific effects of the provisions being implemented in this proposed rule are explained in greater detail below.

We have examined this proposed 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 propose to use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we propose to refine resource-based practice expense RVUs and make 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 proposing 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 proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. The relevant sections of this proposed 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 proposing 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, 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 proposed policy in CY 2005. We apply a uniform adjustment factor to make the aggregate number of proposed practice expense RVUs equal the number estimated that would be paid under current policy.

Table 21 shows the specialty level impact on payment of changes being proposed 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 96.7 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.

We modeled the impact of changes to the practice expense methodology and illustrated the effect in table 21 below. The column labeled "Practice Expense RVU Refinements" shows the effect of the refinements we are making to the practice expense methodology for 2005. For instance, we are incorporating refined practice expense inputs recommended by the PEAC into the methodology as well as updating the prices of medical equipment. We are also adding 2003 utilization data for codes that did not exist in the 1997 through 2002 period.

In general, updating the methodology with 2003 utilization data has little or no impact on total payments to a specialty but the practice expense values for specific services may change. In general, the largest changes to a practice expense RVU will occur when a code was established

after 2002 and we did not have any Medicare utilization data to determine the specialty that performs the service. In these cases, we either assigned the code to a specialty cost pool based on the specialty most likely to do the service or we used the "all physician" scaling factors to determine the code's practice expense RVUs. While we are trying to minimize instability in the practice expense RVUs for new services by assigning the specialty that is most likely to perform the service when we have no utilization data, the addition of utilization to the methodology may still result in some change to the practice expense RVUs during the first few years a code is in existence.

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 add-on 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 nearly 4 percent reduction in payments shown in table 21.

Payments to vascular surgeons will increase approximately 3 percent as a result of the refinements.

The increase in payment is attributed to the repricing of medical equipment used in performing noninvasive vascular diagnostic tests that will increase the practice expense RVUs for procedure codes 93880, 93923, 93925, 93970 and other codes in that family. The estimated 2 percent increase in payment from the practice expense refinements for interventional radiology is primarily due to the establishment of nonfacility pricing for procedure codes 35470 to 35476. The 3 percent increase in payment to oral and maxillofacial surgeons is largely attributed to the refinement of medical supplies for procedure codes 21210 and 21215. 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). As stated in the November 7, 2003 **Federal Register** (68 FR 63204), the changes to the nonfacility practice expense RVUs for these codes were delayed by 1 year to allow the PEAC to reconsider its earlier recommendation to us to reflect input from representatives of specialties that provide these services in nursing homes. The PEAC reconsidered its recommendations with input from these specialties. Our acceptance of the PEAC recommendations is

resulting in a decrease in the nonfacility practice expense RVUs for the nursing facility visit codes.

The column labeled "Survey Data" shows the impact on payment from using the supplemental practice expense survey from the College of American Pathologists (CAP). Using this survey together with making the technical component practice expense RVUs equal to the difference between the global and professional component practice expense RVUs and the other practice expense refinements will increase payments to pathologists by approximately 2 percent and independent laboratories by more than 6 percent. As we indicated above, 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.

The column labeled "Total" in Table 21 below shows the payment impact by specialty of all the changes described

above. If we change any of these proposals following our consideration of comments, these figures may change.

**Table 21**  
Impact of Practice Expense RVU Changes  
on Total Medicare Allowed Charges  
by Physician, Practitioner and Supplier Subcategory

Specialty	Medicare Allowed Charges (\$ in Millions)	Practice Expense RVU Refinements	Survey Data	Total
Physicians:				
ALLERGY/IMMUNOLOGY	\$ 161	-1%	0%	-1%
ANESTHESIOLOGY	\$ 1,416	0%	0%	0%
CARDIAC SURGERY	\$ 359	0%	0%	0%
CARDIOLOGY	\$ 6,583	0%	0%	0%
COLON AND RECTAL SURGERY	\$ 111	0%	0%	0%
CRITICAL CARE	\$ 130	0%	0%	0%
DERMATOLOGY	\$ 1,870	0%	0%	0%
EMERGENCY MEDICINE	\$ 1,672	0%	0%	0%
ENDOCRINOLOGY	\$ 280	0%	0%	0%
FAMILY PRACTICE	\$ 4,448	0%	0%	0%
GASTROENTEROLOGY	\$ 1,636	0%	0%	0%
GENERAL PRACTICE	\$ 998	0%	0%	0%
GENERAL SURGERY	\$ 2,258	0%	0%	0%
GERIATRICS	\$ 117	-1%	0%	-1%
HAND SURGERY	\$ 57	1%	0%	1%
HEMATOLOGY/ONCOLOGY	\$ 1,753	0%	0%	0%
INFECTIOUS DISEASE	\$ 401	0%	0%	0%
INTERNAL MEDICINE	\$ 8,846	0%	0%	0%
INTERVENTIONAL RADIOLOGY	\$ 190	2%	0%	2%
NEPHROLOGY	\$ 1,248	1%	0%	1%
NEUROLOGY	\$ 1,200	0%	0%	0%
NEUROSURGERY	\$ 490	0%	0%	0%
NUCLEAR MEDICINE	\$ 85	0%	0%	0%
OBSTETRICS/GYNECOLOGY	\$ 582	0%	0%	0%
OPHTHALMOLOGY	\$ 4,583	-1%	0%	-1%
ORTHOPEDIC SURGERY	\$ 2,902	0%	0%	0%
OTOLARNGOLOGY	\$ 815	0%	0%	0%
PATHOLOGY	\$ 869	-1%	3%	2%
PEDIATRICS	\$ 59	-1%	0%	-1%
PHYSICAL MEDICINE	\$ 677	0%	0%	0%

PLASTIC SURGERY	\$	281	0%	0%	0%
PSYCHIATRY	\$	1,093	0%	0%	0%
PULMONARY DISEASE	\$	1,446	0%	0%	0%
RADIATION ONCOLOGY	\$	1,164	0%	0%	0%
RADIOLOGY	\$	4,690	0%	0%	0%
RHEUMATOLOGY	\$	413	0%	0%	0%
THORACIC SURGERY	\$	463	0%	0%	0%
UROLOGY	\$	1,699	0%	0%	0%
VASCULAR SURGERY	\$	487	3%	0%	3%
Practitioners:					
AUDIOLOGIST	\$	28	-4%	0%	-4%
CHIROPRACTOR	\$	656	0%	0%	0%
CLINICAL PSYCHOLOGIST	\$	490	0%	0%	0%
CLINICAL SOCIAL WORKER	\$	313	0%	0%	0%
NURSE ANESTHETIST	\$	481	0%	0%	0%
NURSE PRACTITIONER	\$	552	-1%	0%	-1%
OPTOMETRY	\$	664	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	\$	36	3%	0%	3%
PHYSICAL/OCCUPATIONAL THERAPY	\$	990	-1%	0%	-1%
PHYSICIAN ASSISTANT	\$	410	0%	0%	0%
PODIATRY	\$	1,383	0%	0%	0%
Suppliers:					
DIAGNOSTIC TESTING FACILITY	\$	876	1%	0%	1%
INDEPENDENT LABORATORY	\$	530	0%	6%	6%
PORTABLE X-RAY SUPPLIER	\$	91	0%	0%	0%
Other:					
ALL OTHER	\$	93	0%	2%	2%
ALL PHYSICIAN FEE SCHEDULE	\$	66,395	0%	0%	0%

As discussed in Section II.C of this rule, we are proposing 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 proposed impacts on the specialty level payments. See Table 22, "Specialty Impact of Malpractice RVUs Revisions", for a

breakdown of the impacts of these revisions on individual specialties. Of the 54 specialties shown, 15 specialties (representing a total of 40 percent of Medicare allowed charges) experience no estimated change. Total Medicare payments for an additional 32 specialties are estimated to increase or decrease between 0.1 percent and 0.5 percent. We estimate that 7 specialties will experience a total payment increase or decrease of more than 0.5 percent as a result of the malpractice RVU changes. If we change any of these proposals following our consideration of comments, these figures may change.

**Table 22**  
Specialty Impact of Malpractice RVU Revisions

Specialty	Allowed Charges <sup>1</sup>	Percent of Total Charges	Percent Change <sup>2</sup>
DERMATOLOGY	1,870,318,730	2.8%	0.7%
PLASTIC SURGERY	280,508,065	0.4%	0.6%
ORAL/MAXILLOFACIAL SURGERY	35,598,814	0.1%	0.6%
COLON AND RECTAL SURGERY	110,683,908	0.2%	0.6%
GASTROENTEROLOGY	1,635,616,057	2.5%	0.5%
GENERAL SURGERY	2,257,836,035	3.4%	0.5%
CRITICAL CARE	130,256,300	0.2%	0.5%
INFECTIOUS DISEASE	395,195,230	0.6%	0.4%
GERIATRICS	116,547,182	0.2%	0.3%
PSYCHIATRY	1,092,801,668	1.7%	0.3%
PULMONARY DISEASE	1,445,180,432	2.2%	0.3%
NURSE PRACTITIONER	549,723,060	0.8%	0.2%
PATHOLOGY	868,617,850	1.3%	0.2%
NEUROLOGY	1,199,069,489	1.8%	0.2%
PHYSICAL MEDICINE	676,516,230	1.0%	0.2%
INDEPENDENT LABORATORY	529,571,661	0.8%	0.2%
OPTOMETRY	664,163,601	1.0%	0.2%
NEPHROLOGY	1,247,164,211	1.9%	0.1%
VASCULAR SURGERY	486,263,563	0.7%	0.1%

OBSTETRICS/GYNECOLOGY	578,322,768	0.9%	0.1%
INTERNAL MEDICINE	8,821,789,552	13.4%	0.1%
ENDOCRINOLOGY	279,359,088	0.4%	0.1%
ANESTHESIOLOGY	1,415,251,017	2.1%	0.0%
HEMATOLOGY/ONCOLOGY	1,553,937,401	2.4%	0.0%
CARDIOLOGY	6,580,625,617	10.0%	0.0%
OPHTHALMOLOGY	4,583,221,470	7.0%	0.0%
NURSE ANESTHETIST	481,060,016	0.7%	0.0%
THORACIC SURGERY	463,428,857	0.7%	0.0%
RADIATION ONCOLOGY	1,162,754,357	1.8%	0.0%
ALL OTHER	92,826,859	0.1%	0.0%
CLINICAL SOCIAL WORKER	313,327,455	0.5%	0.0%
GENERAL PRACTICE	995,188,403	1.5%	0.0%
UROLOGY	1,689,047,785	2.6%	0.0%
INTERVENTIONAL RADIOLOGY	189,980,663	0.3%	0.0%
EMERGENCY MEDICINE	1,671,773,516	2.5%	0.0%
FAMILY PRACTICE	4,442,795,644	6.7%	0.0%
DIAGNOSTIC TESTING FACILITY	876,242,174	1.3%	0.0%
PHYSICIANS ASSISTANT	409,700,298	0.6%	-0.1%
PEDIATRICS	58,880,964	0.1%	-0.1%
AUDIOLOGIST	27,930,180	0.0%	-0.1%
CLINICAL PSYCHOLOGIST	490,006,176	0.7%	-0.1%
CARDIAC SURGERY	359,324,850	0.5%	-0.1%
PORTABLE X-RAY SUPPLIER	91,026,934	0.1%	-0.1%
HAND SURGERY	56,595,222	0.1%	-0.1%
OTOLARNGOLOGY	814,914,443	1.2%	-0.1%
RHEUMATOLOGY	405,622,764	0.6%	-0.1%
NUCLEAR MEDICINE	85,239,821	0.1%	-0.1%
CHIROPRACTOR	656,312,519	1.0%	-0.2%
RADIOLOGY	4,689,652,801	7.1%	-0.3%
PODIATRY	1,382,552,109	2.1%	-0.4%
ORTHOPEDIC SURGERY	2,902,084,841	4.4%	-0.4%
NEUROSURGERY	489,366,546	0.7%	-0.6%
ALLERGY/IMMUNOLOGY	160,728,139	0.2%	-0.9%
PHYSICAL/OCCUPATIONAL THERAPY	990,284,755	1.5%	-1.3%

<sup>1</sup> 2003 Allowed Charges

<sup>2</sup> Percent change based upon percent change in total payment.

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. We believe it is highly likely that the statutory formula in section 1848(d)(4) will produce an update of less than 1.5 percent for 2005. Therefore, we estimate that the physician fee schedule update for 2005 will be 1.5 percent. We are currently forecasting payment reductions under the SGR system for 2006 and later years. As in the past, we will include a complete discussion of our methodology for calculating the SGR in the final rule.

Table 23 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 and Obstetrics/Gynecology. There are unique issues related to drug administration that will further affect these specialties that are presented in detail below).

**Table 23**

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	-2%	1.5%	0%
ANESTHESIOLOGY	\$ 1,416	0%	1.5%	2%
CARDIAC SURGERY	\$ 359	0%	1.5%	1%
CARDIOLOGY	\$ 6,583	0%	1.5%	2%
COLON AND RECTAL SURGERY	\$ 111	1%	1.5%	2%
CRITICAL CARE	\$ 130	0%	1.5%	2%
DERMATOLOGY	\$ 1,870	1%	1.5%	3%
EMERGENCY MEDICINE	\$ 1,672	0%	1.5%	2%
ENDOCRINOLOGY	\$ 280	0%	1.5%	2%
FAMILY PRACTICE	\$ 4,448	0%	1.5%	1%
GASTROENTEROLOGY	\$ 1,636	0%	1.5%	2%
GENERAL PRACTICE	\$ 998	0%	1.5%	1%
GENERAL SURGERY	\$ 2,258	1%	1.5%	2%
GERIATRICS	\$ 117	-1%	1.5%	1%
HAND SURGERY	\$ 57	0%	1.5%	2%
INFECTIOUS DISEASE	\$ 401	0%	1.5%	2%
INTERNAL MEDICINE	\$ 8,846	0%	1.5%	1%
INTERVENTIONAL RADIOLOGY	\$ 190	2%	1.5%	4%
NEPHROLOGY	\$ 1,248	1%	1.5%	2%
NEUROLOGY	\$ 1,200	0%	1.5%	2%
NEUROSURGERY	\$ 490	-1%	1.5%	1%
NUCLEAR MEDICINE	\$ 85	0%	1.5%	1%
OPHTHALMOLOGY	\$ 4,583	-1%	1.5%	0%
ORTHOPEDIC SURGERY	\$ 2,902	0%	1.5%	1%
OTOLARNGOLOGY	\$ 815	0%	1.5%	2%
PATHOLOGY	\$ 869	2%	1.5%	4%
PEDIATRICS	\$ 59	-1%	1.5%	1%
PHYSICAL MEDICINE	\$ 677	0%	1.5%	2%
PLASTIC SURGERY	\$ 281	1%	1.5%	2%
PSYCHIATRY	\$ 1,093	0%	1.5%	2%
PULMONARY DISEASE	\$ 1,446	0%	1.5%	2%
RADIATION ONCOLOGY	\$ 1,164	0%	1.5%	1%
RADIOLOGY	\$ 4,690	0%	1.5%	1%
THORACIC SURGERY	\$ 463	0%	1.5%	2%

VASCULAR SURGERY	\$	487	3%	1.5%	4%
Practitioners:					
AUDIOLOGIST	\$	28	-4%	1.5%	-2%
CHIROPRACTOR	\$	656	-1%	1.5%	1%
CLINICAL PSYCHOLOGIST	\$	490	0%	1.5%	1%
CLINICAL SOCIAL WORKER	\$	313	0%	1.5%	1%
NURSE ANESTHETIST	\$	481	0%	1.5%	2%
NURSE PRACTITIONER	\$	552	-1%	1.5%	0%
OPTOMETRY	\$	664	0%	1.5%	1%
ORAL/MAXILLOFACIAL SURGERY	\$	36	4%	1.5%	5%
PHYSICAL/OCCUPATIONAL THERAPY	\$	990	-2%	1.5%	-1%
PHYSICIAN ASSISTANT	\$	410	0%	1.5%	1%
PODIATRY	\$	1,383	-1%	1.5%	1%
Suppliers:					
DIAGNOSTIC TESTING FACILITY	\$	876	1%	1.5%	3%
INDEPENDENT LABORATORY	\$	530	6%	1.5%	8%
PORTABLE X-RAY SUPPLIER	\$	91	0%	1.5%	1%
Other:					
ALL OTHER	\$	93	2%	1.5%	3%
ALL PHYSICIAN FEE SCHEDULE	\$	66,395	0%	1.5%	2%

Table 24 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 preventive office visit, G0XX2). 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 refer to § 414.22(b)(5)(i). The table shows the estimated change in payment rates based on provisions of this proposed rule and the estimated physician fee schedule update. If we change any of the provisions following the consideration of public comments, these figures may change.

**Table 24**

Impact of Proposed 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	\$ 38.28	1%	\$ 29.87	\$ 29.94	0%
17000		Destroy benign/premalignant lesion	\$ 60.49	\$ 61.39	1%	\$ 35.84	\$ 45.48	27%
27130		Total hip arthroplasty	N/A	N/A	N/A	\$1,370.28	\$1,382.50	1%
27236		Treat thigh fracture	N/A	N/A	N/A	\$1,088.01	\$1,103.20	1%
27244		Treat thigh fracture	N/A	N/A	N/A	\$1,115.27	\$1,133.51	2%
27447		Total knee arthroplasty	N/A	N/A	N/A	\$1,475.95	\$1,492.02	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	\$1,122.90	1%
43239		Upper GI endoscopy, biopsy	\$321.85	\$336.15	4%	\$ 159.43	\$ 162.58	2%
45385		Lesion removal colonoscopy	\$497.71	\$514.65	3%	\$ 288.24	\$ 293.71	2%
66821		After cataract laser surgery	\$240.83	\$237.62	-1%	\$ 237.09	\$ 230.80	-3%
66984		Cataract surg w/iol, 1 stage	N/A	N/A	N/A	\$ 684.39	\$ 683.67	0%
67210		Treatment of retinal lesion	\$577.98	\$599.92	4%	\$ 560.81	\$ 573.01	2%
71010	26	Chest x-ray	\$ 9.33	\$ 9.47	2%	\$ 9.33	\$ 9.47	2%
71020	26	Chest x-ray	\$ 11.20	\$ 11.37	2%	\$ 11.20	\$ 11.37	2%
76091	26	Mammogram, both breasts	\$ 96.33	\$ 97.40	1%	N/A	N/A	N/A
76091		Mammogram, both breasts	\$ 44.80	\$ 45.10	1%	\$ 44.80	\$ 45.10	1%
76092	26	Mammogram, screening	\$ 84.76	\$ 85.27	1%	N/A	N/A	N/A
76092		Mammogram, screening	\$ 36.22	\$ 36.38	0%	\$ 36.22	\$ 36.38	0%
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%

90806		Psytx, off, 45-50 min	\$ 97.45	\$ 98.91	1%	\$ 93.72	\$ 95.12	1%
90807		Psytx, off, 45-50 min w/e&m	\$103.80	\$104.98	1%	\$ 101.18	\$ 102.32	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%
92004		Eye exam, new patient	\$126.57	\$129.61	2%	\$ 89.24	\$ 90.58	2%
92012		Eye exam established pat	\$ 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	\$ 829.58	2%
92982		Coronary artery dilation	N/A	N/A	N/A	\$ 602.63	\$ 615.83	2%
93000		Electrocardiogram, complete	\$ 26.51	\$ 26.91	2%	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	\$108.01	1%	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	\$ 97.40	2%	\$ 71.69	\$ 72.38	1%
99204		Office/outpatient visit, new	\$135.53	\$137.57	2%	\$ 105.66	\$ 107.25	2%
99205		Office/outpatient visit, new	\$172.13	\$174.71	1%	\$ 140.39	\$ 142.49	1%
99211		Office/outpatient visit, est	\$ 21.28	\$ 21.98	3%	\$ 8.96	\$ 9.10	2%
99212		Office/outpatient visit, est	\$ 37.71	\$ 38.66	3%	\$ 23.52	\$ 24.25	3%
99213		Office/outpatient visit, est	\$ 52.65	\$ 53.06	1%	\$ 35.47	\$ 35.24	-1%
99214		Office/outpatient visit, est	\$ 82.14	\$ 83.00	1%	\$ 57.87	\$ 58.74	2%
99215		Office/outpatient visit, est	\$119.11	\$121.27	2%	\$ 93.34	\$ 95.12	2%
99221		Initial hospital care	N/A	N/A	N/A	\$ 66.83	\$ 68.22	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%
99231		Subsequent hospital care	N/A	N/A	N/A	\$ 33.23	\$ 34.11	3%
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%
99238		Hospital discharge day	N/A	N/A	N/A	\$ 69.82	\$ 70.87	2%
99239		Hospital discharge day	N/A	N/A	N/A	\$ 95.21	\$ 91.71	-4%
99241		Office consultation	\$ 50.03	\$ 50.40	1%	\$ 33.98	\$ 34.49	2%
99242		Office consultation	\$ 91.48	\$ 92.47	1%	\$ 69.45	\$ 70.11	1%
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%
99245		Office consultation	\$220.29	\$224.35	2%	\$ 181.09	\$ 184.56	2%
99251		Initial inpatient consult	N/A	N/A	N/A	\$ 35.84	\$ 36.00	0%
99252		Initial inpatient consult	N/A	N/A	N/A	\$ 71.69	\$ 72.76	1%
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%
99255		Initial inpatient consult	N/A	N/A	N/A	\$ 193.03	\$ 195.55	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%
99282		Emergency dept visit	N/A	N/A	N/A	\$ 27.63	\$ 27.67	0%
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%
99285	Emergency dept visit	N/A	N/A	N/A	\$ 149.72	\$ 151.97	2%
99291	Critical care, first hour	\$242.69	\$257.32	6%	\$ 203.12	\$ 207.68	2%
99292	Critical care, add'l 30 min	\$107.91	\$114.45	6%	\$ 101.56	\$ 103.84	2%
99301	Nursing facility care	\$ 71.69	\$ 66.32	-7%	\$ 61.61	\$ 66.32	8%
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%
99311	Nursing fac care, subseq	\$ 40.70	\$ 34.49	-15%	\$ 30.62	\$ 34.49	13%
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	N/A	N/A
99350	Home visit, est patient	\$169.89	\$165.23	-3%	N/A	N/A	N/A
G0317	ESRDrelsvc 4+/mo;20+yr	\$303.18	\$307.73	2%	\$ 303.18	\$ 307.73	2%
G0318	ESRDrelsvc 2-3/mo;20+yr	\$252.40	\$256.19	2%	\$ 252.40	\$ 256.19	2%
G0319	ESRDrelsvc 1/mo;20+yr	\$201.62	\$204.65	2%	\$ 201.62	\$ 204.65	2%
G0XX2	Preventive Office Visit	N/A	\$124.30	N/A	N/A	82.24	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 (procedure codes 90780 through 90788, 96400, 96408 through 96425, 96520, and 96530) of 32 percent for 2004 and 3 percent for 2005. Table 25 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 and 0 percent for 2006. The amounts shown in the table include the effect of the 1.5 percent update for 2004 and 2005. The 2006 payment amount shown in the table reflects the

2005 conversion factor because the 2006 physician fee schedule update is currently unknown.

With the exception of procedure code 96412 declining by 17 percent (which occurred because resource-based pricing replaced the use of charge-based RVUs when the services were removed from the nonphysician work pool), the MMA permanently increases payment for all of these services from a low of 17 percent for procedure code 90781 to 321 percent for procedure code 90782. The volume-weighted average permanent increase in payment among these drug administration services is approximately 105 percent (109 percent for oncologists and 94 percent for other physicians). Including the effect of the transition makes the volume-weighted increase in payment for these codes more than 170 percent from 2003 to 2004 and 110 percent from 2003 to 2005. The payment amount for procedure code 96400 in 2002 was \$5.07. Payment for this code increased substantially to \$37.52 in 2003 when, at the request of the American Urological Association (see 67 FR 79981 published on December 31, 2002), we removed this code from the nonphysician work pool. Including the effect of the additional changes required by MMA, we expect payment for this code to be \$49.65 by 2006. Thus, the payment increase for procedure code 96400 between 2002 and 2006 is 879

percent. As indicated earlier, we are continuing to consider coding and RVU changes for drug administration services for 2005 based on the results of the CPT review and our consideration of public comments. If we change any of the RVUs for these codes as a result of CPT's review or the consideration of public comments, these figures may change.

**Table 25**

Impact of Proposed Rule and Physician Fee Schedule Update  
on Medicare Payment for Selected Drug Administration Services

		Non-Facility Payment						
				2005	2006	Percent	Percent	
				Payment*	Payment*	Change	Change	
		2002	2003	2004	w/Current	w/Current	2003 to	2002 to
CODE	DESCRIPTION	Payment	Payment	Payment	PE RVUs	PE RVUs	2006	2006
90780	IV infusion therapy, 1 hour	\$ 40.54	\$ 42.67	\$ 117.79	\$ 92.90	\$ 90.20	111%	122%
90781	IV infusion, additional hour	\$ 20.27	\$ 21.70	\$ 33.02	\$ 26.15	\$ 25.39	17%	25%
90782	Injection, sc/im	\$ 3.98	\$ 4.41	\$ 24.64	\$ 19.13	\$ 18.57	321%	367%
96400	Chemotherapy, sc/im	\$ 5.07	\$ 37.52	\$ 64.07	\$ 51.14	\$ 49.65	32%	879%
96408	Chemotherapy, push technique	\$ 35.11	\$ 37.52	\$ 154.76	\$ 122.96	\$ 119.38	218%	240%
96410	Chemotherapy, infusion method	\$ 55.75	\$ 59.22	\$ 217.35	\$ 171.75	\$ 166.75	182%	199%
96412	Chemo, infuse method add-on	\$ 41.63	\$ 44.14	\$ 48.30	\$ 37.86	\$ 36.76	-17%	-12%

\* Payment amounts reflect the current practice expense RVUs and a 1.5 percent update for 2005. The 2006 update is currently unknown. The payment amounts for 2006 were calculated using the 2005 conversion factor. If we were to make further revisions to the practice expense RVUs following the consideration of public comments and/or the CPT coding process, the payment amounts will be different.



Table 26 below shows the impact of the drug and physician fee schedule changes for selected specialties that receive a significant portion of their total Medicare revenues from drugs. Table 27 shows the combined payment impact of the drug and physician fee schedule payment changes on combined Medicare revenues. The first column ("Estimated Medicare Drug Revenues") shows estimated 2004 Medicare Drug Revenues using 2003 utilization adjusted for drug payment changes required in 2004 by the MMA. The next column ("% Change Medicare Drug Revenues") shows the payment impact of the adoption of the average sales price plus 6 percent (ASP+6) drug payment methodology in 2005 relative to 2004 on specialty drug payments. The payment impacts are based on ASP submissions from the 1<sup>st</sup> quarter of 2004. The ASP prices that will be used to determine payment in 2005 will begin with the 3<sup>rd</sup> quarter 2004 ASP submission and will be updated quarterly. To model the impact illustrated, we assumed an average increase in ASP prices of 3.39 percent (the national health expenditure prescription drug price growth factor) from the 1<sup>st</sup> quarter 2004 submission to the prices that will be used to determine 2005 payments. Table xxxxxxxx follows table xxxxxxx and shows the drug prices we used to determine the payment impact. The drug payment impacts are based on

those high volume drugs where we have validated the ASP price submission that represent the following percentages of 2003 drug payments: 72 percent for Hematology/Oncology, 94 percent for Urology, 97 percent for Rheumatology and 73 percent for Obstetrics/Gynecology. For drugs in which we did not complete our validation of the ASP submission before completing the proposed rule, we used the average payment change for other drugs provided by the specialty unless a special circumstance applied. (that is, for Hematology/Oncology and Obstetrics/Gynecology, we calculated the average reduction in payment for drugs excluding J9265, J2430, and J9390, three drugs having an unusually large reduction in payment as a result of coming off patent. We do not believe these reductions will be typical of other drugs furnished by oncologists and obstetrician/gynecologists).

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. We are using 2003 Medicare claims processed and paid through June 30, 2004 that we estimate are 96.7 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.

Assuming no change in utilization, we estimate that Medicare drug revenues for oncologists would decline by less than 8 percent as a result of policies adopted in this proposed rule. Oncologists administer a number of drugs that are changing in payments by different amounts. For instance, oncologists' highest Medicare revenue drug, Q0136 (EPOGEN; PROCRIT), would decline in payment by 7 percent while its second highest revenue drug, J9310 (RITUXAN), would increase in payment by 7 percent. Three drugs supplied by oncologists, J9265 (ONXOL TAXOL), J2430 (PAMIDRONATE DISODIUM), and J9390 (NAVELBINE), are coming off patent and their price would decline respectively by 81 percent, 71 percent, and 12 percent. The 2004 Medicare payment amounts for these three drugs respectively were equal to 81, 85 and 81 percent of the April 1, 2003 average wholesale price levels that applied or did not decrease proportionally after the drugs came off patent. These three drugs are estimated to account for only 7 percent of oncologists adjusted 2004 Medicare drug revenues but

contribute more than 5 percent of the approximate 8 percent total reduction in Medicare drug revenues that oncologists would experience as a result of adopting the ASP+6 payment methodology. While Medicare revenues to oncologists would decline from the reductions in payment for these three drugs, the cost to acquire these drugs has already declined. Thus, Medicare's payment, as with all other drugs experiencing payment changes, will be much closer to the cost the physician pays to acquire the drug.

Adoption of ASP+6 prices would reduce Medicare drug revenues for urologists by approximately 36 percent. This large reduction can be attributed to a 35 percent reduction in payment for two drugs: J9202 (ZOLADEX) and J9217 (LUPRON DEPOT-PED). While we estimate an even larger reduction in the ASP+6 price for J9217, our payment impact assumes that nearly all Medicare carriers are using the "least costly alternative" pricing and paying code J9217 at the J9202 price.

We estimate a 6 percent reduction in Medicare drug revenues for rheumatology. Nearly all of this reduction can be attributed to a 6 percent reduction in Medicare payment for J1745 (REMICADE).

We estimate less than an 18 percent decrease in Medicare drug revenues for obstetrics/gynecology. However,

much of this revenue reduction can be attributed to an 81 percent reduction in payment for J9265 (ONXOL TAXOL) coming off patent. Even though this one drug is estimated to account for only 16 percent of obstetrics/gynecology adjusted 2004 Medicare drug revenues, it contributes 13 percent of the approximate 18 percent total reduction in Medicare drug revenues that obstetrics/gynecologists would experience as a result of adopting the ASP+6 payment methodology. As explained above, while Medicare revenues to obstetrics/gynecology would decline as a result of the price reduction for this code, Medicare's payment will be much closer to the price physicians pay to acquire the drug. We are estimating an average approximate reduction of 6 percent across other drugs supplied by obstetrics/gynecology.

The remaining columns of Table 26 show the potential impact on physician fee schedule services of changes being contemplated for 2005 for the specialties shown. The column labeled "Practice Expense and Malpractice RVU Changes" show the combined impact of the changes previously illustrated for these specialties in Tables 21 and 22. The column labeled "Drug Administration Payment Changes" shows a range of potential physician fee schedule impacts for 2005. The left side of this column shows the impact of the

changes required in payment by section 303(a)(4) of the MMA (that is, the change in the transition payment from 2004 to 2005) if we were to make no further changes to the payments or codes for drug administration services. However, because we are considering further changes to the payments or codes for drug administration once the AMA's CPT Panel review of this issue is complete, the right hand side of the column labeled "Drug Administration Payment Changes" reflects the amount that physician fee schedule payments would have to increase to make the net reduction across all Medicare revenues for these specialties equal to 2 percent. The next column shows the physician fee schedule update of 1.5 percent and the final column labeled "Total Physician Fee Schedule" Changes" shows the combined effect of all of the changes previously described. The left hand side of the column shows the combined effect of 1) the practice expense and malpractice RVU changes, 2) the maximum reduction in payment that could occur if we made no further changes to payments for drug administration and 3) the physician fee schedule update. The right hand side of the column shows the combined effect of 1) the practice expense and malpractice RVU changes, 2) the amount physician fee schedule revenues would have to increase to make the

reduction in total revenues equal to 2 percent and 3) the physician fee schedule update.

If we made no further changes to drug administration, physician fee schedule revenues would decline by 9 percent for oncology, be unchanged for urology and rheumatology, and increase by 1 percent for obstetrics/gynecology. Physician fee schedule revenues would have to increase by 12 percent for oncology, 19 percent for urology, 2 percent for rheumatology and 1 percent for obstetrics/gynecology for total revenues to these specialties to decline by 2 percent from adoption of the ASP + 6 percent drug payment methodology.

Table 27 shows the combined impact of changes we are making to Medicare drug and physician fee schedule payments for the same specialties shown in table 26. The column labeled "% of Total Medicare Revenues from Drugs" shows the proportion of total Medicare revenues received from drugs, while the next column shows the payment impact from adoption of the ASP+6 drug payment methodology. The following columns show the proportion of total Medicare revenues received from physician fee schedule services and the payment impact from physician fee schedule changes. All of the payment impacts are the same as those shown in Table 26. 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. These tables are intended to illustrate, assuming constant utilization, the combined impact of payment changes from 2004 to 2005 across all of the services that these specialties perform using the most recent data available to us. Thus, the last 3 columns show combined Medicare revenues from all sources and the combined Medicare payment impact from the earlier described changes being proposed or considered for 2005.

For example, as indicated in the Table 27, we estimate that approximately 70 percent of total 2004 Medicare revenues for oncologists are attributed to drugs. We estimate that Medicare revenues from drugs will decline by approximately 8 percent for oncology as a result of policies adopted in this proposed rule. Physician fee schedule services account for approximately 28 percent of oncology's 2004 Medicare revenues. If we made no other changes to the RVUs or codes for drug administration services and if there is no change in the utilization of services, we estimate that physician fee schedule payments to oncology would decline by approximately 9 percent from

2004 to 2005. In this scenario, combined Medicare payments to oncology would decline approximately 8 percent.

However, if we were to make further changes to physician fee schedule payments so they increased by 12 percent, we estimate the combined revenue reduction to oncology would be 2 percent.

We estimate that urology receives approximately 37 percent of their 2004 total revenues from drugs and 60 percent from physician fee schedule services. Because urology and other physician specialties receive a smaller share of their total Medicare revenues from drug administration services than oncology, they are less affected than oncology by the reduction in the drug administration transition payment percentage from 32 to 3 percent from 2004 to 2005. If we made no other changes to the RVUs or codes for drug administration services, we estimate that physician fee schedule revenues for urologists would increase by approximately 1 percent from 2004 to 2005. (While the reduction in payment for drug administration alone would slightly reduce urologists' physician fee schedule revenues, we estimate that any reduction would be offset by the physician fee schedule update). In this scenario, combined Medicare payments to urologists would decline approximately 13 percent.

However, if we were to make further changes to physician fee schedule payments so that they increased by 19 percent, we estimate the combined revenue reduction to urology would be 2 percent.

Rheumatology revenues from drugs are estimated to account for approximately 46 percent of their total revenues and would decline approximately 6 percent from adoption of the ASP+6 drug payment methodology. If we made no other changes to the RVUs or codes for drug administration services, we estimate that physician fee schedule revenues would be either unchanged or decline slightly in the aggregate and estimate a reduction in total Medicare revenues to rheumatology of approximately 3 percent. However, if we were to make further changes to physician fee schedule payments so they increased by 2 percent, we estimate the combined revenue reduction to rheumatologists would be 2 percent.

Medicare drug revenues represent 13 percent of total Medicare revenues for obstetrics/gynecology while physician fee schedule revenues account for 85 percent. We estimate that Medicare drug revenues for obstetrics/gynecology would decline by 18 percent and physician fee schedule revenues would increase 1 percent if we make no further changes to the RVUs or codes for drug administration services. In

this scenario, obstetrics/gynecology's combined Medicare revenues would decline by 2 percent. Any change to the drug administration codes that increases their payments would make the net revenue reduction equal to or less than 2 percent for obstetrics/gynecology.

**Table 26**

Impact of Drug and Physician Fee Schedule Payment Changes  
on Total Medicare Allowed Charges  
for Selected Specialties

Specialty	Drugs		Physician Fee Schedule				
	Estimated Medicare Drug Revenues (\$ in Millions)	% Change Medicare Drug Revenues	Medicare Allowed Charges (\$ in Millions)	Practice Expense & Malpractice RVU Changes	Drug Administration Payment Changes	Physician Fee Schedule Update	Total Physician Fee Schedule Changes
HEMATOLOGY/ONCOLOGY	\$ 4,363	-8%	\$ 1,753	0%	-10% to 10%	1.5%	-9% to 12%
UROLOGY	\$ 1,061	-36%	\$ 1,699	0%	-1% to 17%	1.5%	0% to 19%
RHEUMATOLOGY	\$ 373	-6%	\$ 413	0%	-2% to 0%	1.5%	0% to 2%
OBSTETRICS/GYNECOLOGY	\$ 88	-18%	\$ 582	0%	-1% to -1%	1.5%	1% to 1%

The amounts shown on the left-hand side of the column labeled "Drug Administration Payment Changes" offset a part of the increase these specialties received in 2004 as shown in the January 7, 2004 **Federal Register** (69 FR 1100). We estimate the 2003-2005 increase in physician fee schedule payments to these specialties (before application of the physician fee schedule update) to be 28 percent for oncology, 2 percent for obstetrics/gynecology, 4 percent for rheumatology and 2 percent for urology. Urology received an additional 2 percent increase in total physician fee schedule payments (again, before application of the update) from 2002 to 2003 (see 67 FR 80035-80036 published on December 31, 2002) as a result of the large increase in payment for CPT code 96400 making the 2002-2005 payment increase exceed 4 percent.

**Table 27**

Combined Payment Impact  
Drug and Physician Fee Schedule Payment Changes  
for Selected Specialties

Specialty	Drugs		Physician Fee Schedule			All Revenues		
	% of Total Medicare Revenues from Drugs	% Change Medicare Drug Revenues	% of Total Medicare Revenues from Fee Schedule	% Change Medicare Physician Fee Schedule Revenues		Combined Medicare Revenues All Sources (\$ in Millions)	Combined % Change All Medicare Revenues	
HEMATOLOGY/ONCOLOGY	70%	-8%	28%	-9% To 12%	\$	6,251	-8% To -2%	
UROLOGY	37%	-36%	60%	0% To 19%	\$	2,842	-13% To -2%	
RHEUMATOLOGY	46%	-6%	51%	0% To 2%	\$	818	-3% To -2%	
OBSTETRICS/GYNECOLOGY	13%	-18%	85%	1% To 1%	\$	684	-2% To -2%	



The above tables show those specialties that receive significant revenues from drugs and physician fee schedule services that could be further affected by the review of drug administration coding currently undertaken by the CPT Editorial Panel and any changes we may make after further consideration of this effort and public comments.

Although infectious disease physicians do receive significant revenues from drugs and drug administration, we are not showing them in this table because we have validated only drug payment data accounting for 27 percent of their allowed charges for drugs. Based on these data, we estimate an 11 percent reduction in their Medicare drug payments that account for approximately 6 percent of their total Medicare revenues. If total drug payment were to decline by 11 percent, we estimate that net revenues to infectious disease physicians will remain unchanged, absent any further changes in drug and drug administration coding. We are not showing DME and Other Medical Suppliers in the above table because they do not receive significant revenues for physician fee schedule services and will be unaffected by any further changes made to drug administration coding or RVUs because they do not bill for these services. However, they do receive a substantial portion of their total Medicare revenues from drugs that

are affected by the change to ASP+6 pricing. For DME/Other Medical Suppliers, 40 and 60 percent of Medicare revenues respectively are received from drugs and DME fee schedule services. These suppliers would receive an approximate reduction of 70 percent in their Medicare drug revenues from the adoption of ASP+6 drug prices due to the large reduction in payment for two high volume inhalation drugs (J7619 and J7644). These impacts will be reduced somewhat by the dispensing fee we are proposing for inhalation drugs. We estimate the total reduction in payment across all of the services provided by DME suppliers as a result of provisions of this proposed rule would be approximately 28 percent.

**Table 28**  
Drug Pricing Table Used for Payment Impacts

Code	Short Description	TRADE NAME	CY 2004 Pay Allowance Limit	Estimated CY 2005 Allowance Limit (ASP + 6%)	% Change
J0152	Adenosine injection	ADENOSCAN	\$ 66.56	\$ 69.78	5%
J0585	Botulinum toxin a per unit	BOTOX	\$ 4.43	\$ 4.69	6%
J0880	Darbepoetin alfa injection	ARANESP	\$ 21.20	\$ 18.10	-15%
J1441	Filgrastim 480 mcg injection	NEUPOGEN	\$ 267.79	\$ 267.04	0%
J1745	Infliximab injection	REMICADE	\$ 58.79	\$ 53.32	-9%
J2430	Pamidronate disodium /30 MG	AREDIA, PAMIDRONATE DISODIUM,	\$ 237.88	\$ 67.27	-72%
J2505	Injection, pegfilgrastim 6mg	NEULASTA	\$ 2,507.50	\$ 2,260.77	-10%
J2792	Rho(D) immune globulin h, sd	WINRHO	\$ 18.39	\$ 13.04	-29%
J3395	Verteporfin injection	VISUDYNE	\$ 1,404.26	\$ 1,368.79	-3%
J3487	Zoledronic acid	ZOMETA	\$ 194.54	\$ 202.50	4%
J7192	Factor viii recombinant	KOGENATE, HELIXATE, RECOMBINATE, REFACTO, BIOCLATE,	\$ 1.29	\$ 0.92	-29%
J7317	Sodium hyaluronate injection	HYALGAN, SUPARTZ, ORTHOVISC	\$ 124.11	\$ 110.07	-11%
J7320	Hylan G-F 20 injection	SYNVISC	\$ 204.03	\$ 188.88	-7%
J7507	Tacrolimus oral per 1 MG	PROGRAF	\$ 3.13	\$ 3.19	2%
J7517	Mycophenolate mofetil oral	CELLCEPT	\$ 2.55	\$ 2.54	0%
J7619	Albuterol inh sol u d	PROVENTIL, ALBUTEROL SULFATE, VENTOLIN	\$ 0.39	\$ 0.04	-89%
J7626	Budesonide inhalation sol	PULMICORT	\$ 4.04	\$ 3.91	-3%
J7644	Ipratropium brom inh sol u d	IPRATROPIUM BROMIDE	\$ 2.82	\$ 0.30	-89%
J9045	Carboplatin injection	PARAPLATIN	\$ 137.54	\$ 131.77	-4%
J9170	Docetaxel	TAXOTERE	\$ 301.40	\$ 287.59	-5%
J9201	Gemcitabine HCl	GEMZAR	\$ 111.33	\$ 107.46	-3%
J9202	Goserelin acetate implant	ZOLADEX	\$ 375.99	\$ 234.28	-38%
J9206	Irinotecan injection	CAMPTOSAR	\$ 130.24	\$ 123.86	-5%

J9217*	Leuprolide acetate suspnsion	LUPRON DEPOT, ELIGARD, LUPRON DEPOT-PED	\$ 500.58	\$ 234.28	-53%
J9219	Leuprolide acetate implant	VIADUR	\$ 4,831.40	\$ 2,190.71	-55%
J9265	Paclitaxel injection	TAXOL, ONXOL, NOV-ONXOL	\$ 138.28	\$ 25.84	-81%
J9310	Rituximab cancer treatment	RITUXAN	\$ 427.28	\$ 438.38	3%
J9350	Topotecan	HYCAMTIN	\$ 706.17	\$ 731.46	4%
J9355	Trastuzumab	HERCEPTIN	\$ 52.01	\$ 50.84	-2%
J9390	Vinorelbine tartrate/10 mg	NAVELBINE	\$ 76.19	\$ 64.67	-15%
Q0136	Non esrd epoetin alpha inj	PROCRIT	\$ 11.62	\$ 10.37	-11%
**Unlisted		ALOXI	\$ 307.80	\$ 202.51	-34%

\* The figures here for J9217 reflect the ASP prices submitted by the drug manufacturer. However, we assumed that Medicare carriers are applying "least costly alternative" pricing and are using the J9202 price for J9217.

\*\*Aloxi is the brand name for an antiemetic that is paid in 2004 at 95% of AWP using an unlisted code because the drug was approved by the FDA in the fall of 2003. Even though we do not have a code or volume for this drug from 2003 like we do for the other drugs shown in the table, we are showing it here because it is the highest growth injectable antiemetic drug currently on the market.

## 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 E and F illustrate the locality specific overall impact of this proposal. The GAF, as displayed in addenda E and F is a weighted composite index of the individual proposed 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. Revisions to Global Period

In section II.D.1, we are proposing a change in the global period for procedure code 77427, Radiation treatment management, five treatments from a global indicator of "xxx" (meaning that

the global concept does not apply) to "090" (meaning that there is a 90-day global period). We are not changing any of the RVUs for procedure code 77427 because this service was valued to reflect a global period of 90 days. The implication of this change is that any visit services provided in the 90-day global period that are related to procedure code 77427 will no longer be paid separately. We reviewed Medicare data and found that physicians rarely bill for services during the 90-day period following the date-of-service for procedure code 77427.

Therefore, we believe this proposal will have little effect on Medicare program expenditures and our payments to physicians.

## 2. Additions to the List of Medicare Telehealth Services

In section II.D.2, we are proposing to add 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.

## 3. National Pricing of G0238/G0239 (Respiratory Therapy Service Codes)

As discussed earlier in the preamble, we are proposing to use the nonphysician workpool to value two respiratory therapy service codes (G0238 and G0239) that are currently carrier priced. We believe that this proposed 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 would have a significant impact on Medicare expenditures.

#### 4. New HCPCS Code for Bone Marrow Aspiration

We are proposing a new HCPCS code for instances when a bone marrow aspiration and a bone marrow biopsy are performed on the same day through a single incision. Currently, we do not allow payment for both of these procedures on the same day. 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.

#### 5. New HCPCS Code for Venous Mapping

As stated earlier in the preamble, we are proposing a new HCPCS code for venous mapping for hemodialysis access placement. The primary reason for this new code is to enable us to track the use of venous mapping for quality improvement purposes. Since pricing for this service is not changing, there will be no impact on Medicare expenditures.

### 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. We estimate that this new benefit will result in

an increase in Medicare expenditures. These new payments will be 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 29—Medicare Cost Estimates for MMA Provision 611  
(in millions)

MMA provision	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Sec. 611	65	75	75	75	75

## 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 estimate 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 30 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 30 below.

TABLE 30—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 physician services

will result in an increase in Medicare payments that are shown in Table 31.

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 31.

TABLE 31—Medicare Cost Estimates for MMA Provisions  
(in millions)

MMA provision	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Sec. 413(a) Physician Scarcity Areas	30	50	50	20	0
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 proposed 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. We estimate that adoption of the ASP+6 payment methodology will result in Medicare savings for FY 2005 of \$180 million for section 303 of the MMA, \$140 million for section 304 of the MMA, and \$210 million for section 305 of the MMA. If we were to make no further changes to the coding or payment for drug administration services, we estimate Medicare savings of \$90 million for section 303 of the MMA and \$40 million for section 304 of the MMA. In addition, we are also proposing to pay a supplying fee of \$10 per Medicare Part B oral drug prescription. We estimate this proposal will increase Medicare expenditures by \$52 million from FY 2005 through FY 2009, assuming an average of two prescriptions per month. We are also proposing to pay a furnishing fee of \$0.05 per unit off clotting factor. This proposal is estimated to cost \$13 million from FY 2005 through FY 2009.

#### 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 proposed 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 32—Medicare Cost Estimates for MMA Provision 623  
(in millions)

MMA provision	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Section 623	40	50	50	60	60

### b. Impact on ESRD Providers

In order to understand the impact of the proposed 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 proposed revisions to the composite rate payment system as set forth in this proposed rule (proposed payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and proposed payments contain similar inputs. Therefore, we simulated proposed payments only for those ESRD facilities for which we are able to calculate both current payment and proposed payment.

Due to data limitations, we are unable estimate current and proposed payments for 592 facilities that bill for ESRD drugs. Of these 592 facilities, 174 are hospital based and 418 are independent. Therefore, 29 percent of hospital-based facilities and 11 percent of independent facilities are not shown in the impact table. 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 December 2003 update of CY 2003 Standard Analytical File (SAF) claims as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. While the December 2003 update of the 2003 SAF file is not complete, we wanted to use the most recent data available, and plan to use an updated version of the 2003 SAF file for the final rule.

**Table 33**

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	3,671	29.2	0.0	1.0	0.0	1.0
Independent	3,240	26.1	-0.6	1.0	-0.0	0.4
Hospital Based	431	3.1	5.7	1.1	0.1	7.0
Size						
Small <5000 treatment per year	1,313	4.0	-0.6	1.0	-0.1	0.3
Medium 5000-10000 treatments per yr	1,414	10.2	-0.7	1.0	-0.1	0.2
Large > 10000 treatments per year	944	15.0	0.6	1.0	0.0	1.7
Type of Ownership						
Not-for-profit	697	5.2	2.9	1.1	0.0	4.1
For-profit	2,710	21.9	-0.6	1.0	-0.0	0.4
Other	264	2.1	-0.1	1.0	0.0	1.0
Urban	2,701	23.6	0.1	1.0	0.1	1.2
Rural	970	5.6	-0.5	1.0	-0.5	-0.0
Region						
New England	125	1.2	1.3	1.1	0.1	2.4
Middle Atlantic	475	4.0	0.5	1.0	0.9	2.4
East North Central	540	4.5	0.4	1.0	-0.1	1.3
West North Central	255	1.7	1.4	1.1	-0.5	2.0
South Atlantic	886	6.9	-1.0	1.0	0.0	0.0

East South Central	309	2.2	-1.0	1.0	-0.7	-0.7
West South Central	522	4.1	-1.0	1.0	-0.2	-0.1
Mountain	194	1.3	0.6	1.1	-0.5	1.1
Pacific	339	3.0	1.4	1.1	-0.2	2.3
Puerto Rico	26	0.4	0.8	1.0	1.4	3.3

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 11.3% 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 36% 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 percent change between the proposed and current payments to ESRD facilities. The proposed payments includes the 1.6% increase, the 11.3% drug add-on, and the case-mix adjustments times treatments plus proposed 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 33 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. The first column of Table 33 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). Spending under the proposed change is 2004 ASP minus 3 percent for the top ten drugs plus 3.39 percent inflation factor times actual drug utilization from 2003 claims.

Proposed payment for drugs under MMA also includes the 11.3 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 the proposed payment for drugs including the 11.3 percent drug add-on amount to spending under current payments for drugs. In order to make column 4 comparable with rest of Table 33, current composite rate payments to ESRD facilities were included in both current and proposed 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 36 percent of their total revenues from separately billable

drugs and 64 percent of their total revenues from composite rate payment. Since the 1.6 percent increase is applied to the 64 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 proposed payment for drugs (including the 11.3 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 in section H.4.d of this proposed rule. Because MMA requires this adjustment be budget-neutral in the aggregate, there is no overall impact to the 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

proposed payments to ESRD providers with the case-mix adjustments compared to payments to providers without the case-mix adjustments. As described in section H.4.f, we standardized the composite rate to meet the MMA requirement that payment be budget-neutral with respect to aggregate payments. Therefore, there is no change for ESRD providers in aggregate. We note that when applying the case-mix adjustments, we did so at the summary level as shown in Table 33.

Column 7 shows the overall effect of all changes in drug and composite rate payments to ESRD providers. The overall effect measured as the difference between proposed payment with all MMA changes as proposed in this rule and current payment. Proposed payment is computed by multiplying the composite rate for each provider (with both 1.6 percent increase and the 11.3 percent add-on) times dialysis treatments from 2003 claims times the appropriate case-mix adjustment by provider category. In addition, proposed payment includes payments for separately billable drugs under the revised pricing methodology as described in section III-E-Section 303-Payment Reform for Outpatient Drugs and Biologicals, Subsection 1.d. 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 in section H.4.c, we are proposing a single drug add-on to the composite rates for both hospital based and independent facilities. The 7.0 percent increase in payments to hospital-based providers is largely due to the proposed single drug add-on to the composite rate. Many hospital based providers are not-for-profit, which may explain the larger than average increase in payments.

#### 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) has 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.

TABLE 34—Estimated Medicare Savings for MMA Provision 629  
(in millions)

MMA provision	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>	<b>FY 2008</b>	<b>FY 2009</b>
Sec. 629	110	290	440	590	770

#### 10. Section 512—Hospice Consultation Service

As explained in section III.K, 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 302—Clinical Conditions for Coverage of Durable Medical Equipment (DME)

As explained earlier in the preamble, to comply with the requirements of section 302 of the MMA and to enhance quality and reduce fraud, we are proposing to establish basic requirements that apply to all items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The impact to the Medicare program will be to improve quality of care because we are involving the physician early in the process when determining the medical necessity for items of DMEPOS. The physician community has stated that they are often asked to order an item of DMEPOS for their patient when they do not think the item is reasonable and necessary. We believe these requirements will result in no costs or savings to Medicare because if any additional spending from more physician visits occur it will be offset by savings from Medicare paying for less DMEPOS. However, we expect to continue evaluating this issue.

E. Other Issues

1. Outpatient Therapy Services Performed "Incident To" Physicians' Services

As discussed in section IV.A, we are proposing to amend 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.2, we are proposing to revise 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 proposed policy change would provide beneficiaries access to medically necessary therapy services, under a physician-certified plan of care. We believe that this change would 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 proposing to revise the regulations at §414.38 to eliminate the restrictive criteria for the payment of LOCM. This proposal will make payment for LOCM consistent across Medicare payment systems. By identifying 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, we estimate program costs as shown in the following table:

<b>TABLE 35</b>					
Regulatory Provision	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>	<b>FY 2008</b>	<b>FY 2009</b>
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 IV. E. provide clarification of current policy surrounding these issues. We do not believe these proposals would have a significant impact on Medicare expenditures.

#### 5. Supervision of Clinical Psychological Testing

We are proposing to change the supervision requirements regarding who can supervise diagnostic

psychological testing services. As previously discussed, having ancillary staff supervised by clinical psychologists would 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 would reduce delays in testing, diagnosis, and treatment that could result from the unavailability of physicians to supervise the tests. We believe that this proposal will have little impact on Medicare expenditures.

#### 6. Care Plan Oversight

As discussed in section IV.G, we are proposing to revise §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 proposal would have an impact on Medicare expenditures, since it is only clarifying that an NPP or a physician can provide care plan oversight for home health care.

#### 7. Assignment of Medicare Claims

The proposed 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.H, we believe the proposed changes will reduce the paperwork burden on beneficiaries and suppliers.

F. Alternatives Considered

This proposed 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.

The following is a discussion of additional points on the proposed changes required by section 302 of the MMA involving ordering items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

In developing the proposed changes to implement section 302 of the MMA, we did consider establishing "the face-to-face requirement," and "the order prior to delivery" requirement only for specific items of DMEPOS for which there has been an identified proliferation of use. However, we believe it is important that the physician or nonphysician practitioner determine the medical need for all items of DME. It is good clinical practice for

beneficiaries to be seen by the physician for their medical condition and at that time the physician will decide whether an item of DME is appropriate. It is our intent to make Medicare more consistent with private payers in that beneficiaries be seen by their physician for their medical condition, who then makes a diagnosis and orders any supplies needed to address their needs. Since we expect beneficiaries to be seen by their doctor for a specific medical condition, we do not believe that this would place a burden on the physician, as it would be part of a necessary examination.

We also note that in establishing these proposed requirements we do make exceptions for items of continued need, such as, glucose test strips or support surfaces. Once the physician has initially established the need, we do not require additional visits or additional documentation.

#### G. Impact on Beneficiaries

There are a number of changes made in this proposed 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). Taking into account the MMA and regulatory provisions of this proposed rule, we estimate beneficiary savings in FY 2005 of \$270 million. This figure could be less if we make further changes to Medicare's drug administration payments.

The MMA provisions that expand Medicare benefits include: section 611, adding a preventive office visit 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 preventive office visit 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). Indexing of the Part B deductible will result in an estimated cost to beneficiaries of \$110 million in 2005. 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.

The implementation of MMA provisions related to drugs and drug administration will reduce Medicare beneficiary liability for Medicare covered services. We estimate that implementation of sections 303 through 305 of the MMA will reduce Medicare beneficiary liability for drugs by \$360 million in FY 2005. If we were to make no further changes to Medicare's payments for drug administration, we estimate additional savings to Medicare beneficiaries of \$120 million in FY 2005. Provisions of this proposed rule that increase the supplying fee for immunosuppressive drugs and the furnishing fee for the clotting factor are estimated to increase beneficiary liability by \$36 million and \$10 million respectively, from FY 2005 through FY 2009.

We do not believe that the drug and drug administration payment changes required by the MMA are intended to lessen beneficiary access to care. By reducing beneficiary liability, we believe it is likely that beneficiary access to care will be improved. As indicated earlier, without any further change in payment for drug administration, the MMA increased payment for drug administration by more than 105 percent from 2003 to 2005 while making payment for drugs at 6 percent more than their

average sales price. 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.

As indicated above, we are considering making further changes to Medicare payment for drug administration based on the results of CPT's review of this issue or in response to public comment. Further, we are gathering Medicare utilization for drugs and drug administration beginning in 2002 and plan to analyze shifts or changes in utilization patterns as the information becomes available to us once the payment changes required by the MMA go into effect. 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. Similarly, section 305(b) requires the General Accounting Office to study the adequacy of Medicare payments for inhalation therapy.

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.

We believe early involvement of the physician in determining the medical necessity for items of DMEPOS will assist in improving the accuracy of Medicare program payments and the quality of care. In addition, it will also reduce out-of-pocket costs for unnecessary DMEPOS that may have otherwise been provided to Medicare 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 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 proposes to amend 42 CFR chapter IV as follows:

**PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

1. 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).

2. 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 immediate 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.

3. 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**

4. 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).

5. 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.

6. 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 individuals who receive their initial preventive physical examinations within 6 months after the effective 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.

Initial preventive physical examination means all of the following services furnished to an individual by a physician or other qualified nonphysician practitioner with the goal of health promotion and disease detection:

(1) Review of the individual's comprehensive medical and social history.

(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 nonphysician practitioner may select unless the appropriate screening instrument is further defined through a national coverage determination.

(3) Review of the individual's functional ability, and level of safety, based on the use of an appropriate screening instrument, which the physician or other qualified nonphysician practitioner may select unless the appropriate screening instrument is defined through a national coverage determination.

(4) An examination to include measurement of the individual's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the individual'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 written plan provided to the individual for obtaining the appropriate screening and other preventive services for the individual 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 Social Security Act (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 patient's family, including diseases that may be hereditary or place the individual at risk.

Physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

Qualified nonphysician practitioner for purposes of this provision 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 regulations at §410.74, §410.75, and §410.76).

Review of the individual's functional ability and level of safety. Review of the individual'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) Work and travel history.
- (3) Diet.
- (4) Social activities.
- (5) 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 paragraph (a) of this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in paragraphs (a) of 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 paragraph (a) of this section.

7. 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 applies:

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.

8. 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 plasma 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 Medicare, two screening tests per calendar year.

(2) Previously tested who were not diagnosed with pre-diabetes, or who have never been 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 birthing a baby weighing more than 9 pounds.

(f) Individuals not covered. For individuals previously diagnosed as diabetic, no coverage.

9. 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).

10. 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.

\* \* \* \* \*

11. Section 410.36 is amended by--

A. Revising the section heading.

B. Adding to paragraph (a), the paragraph heading "Condition for coverage medical supplies, appliances, and devices."

C. Revising paragraph (b).

D. Adding new paragraphs (c) and (d).

The additions and revisions read as follows:

**§410.36 Medical supplies, appliances, and devices:**

**Conditions for and limitations on coverage.**

(a) Conditions for coverage of medical supplies, appliances, and medical devices. \* \* \*

(b) Conditions for coverage. Medicare Part B pays for the medical supplies, appliances, and devices listed in paragraph (a) of this section when:

(1) The medical supplies, appliances, and devices are ordered by a physician, physician assistant, clinical nurse specialist, or nurse practitioner as defined in the Act.

(2) The physician or prescribing practitioner--

(i) Conducts a face-to-face examination to determine the medical necessity for medical supplies, appliances, and devices.

(ii) Conducts the face-to-face examination only for the initial order and at the time of the prescription renewal for items of continued need, such as glucose testing supplies.

(iii) Is independent from the DME supplier and may not be an employee or contractor of the supplier.

(3) A written order is completed and signed before delivery of these medical supplies, appliances, and devices to the beneficiary.

(4) The physician's or prescribing practitioner's order is dated and signed within 30 days after the face-to-face examination and the beneficiary's medical record includes verification of the face-to-face examination.

(5) The physician or prescribing practitioner documents in the beneficiary's medical record the need for the medical supplies, appliances, and devices being ordered.

(6) CMS may determine other criteria, such as prescription renewal requirements, repairs, minor revisions and replacement, through contractor instructions.

(c) Limitation. Medicare does not pay for a face-to-face examination for the sole purpose of the beneficiary's obtaining the physician or prescribing practitioner's order for the medical supplies, appliances, and devices.

(d) Clinical conditions for coverage. Clinical conditions for coverage, other than those set forth in paragraph (b) of this section, of medical supplies, appliances, and devices are determined through the national or local coverage determination process.

12. Section 410.38 is amended by--

A. Revising paragraph (g).

B. Adding paragraphs (h) and (i).

The revision and additions read as follows:

**§410.38 Durable medical equipment: Scope and conditions.**

\* \* \* \* \*

(g) Conditions for coverage. (1) Medicare Part B pays for durable medical equipment ordered by a physician, physician assistant, clinical nurse specialist, or nurse practitioner, as defined in the Act.

(2) The physician or prescribing practitioner must --

(i) Conduct a face-to-face examination to determine the medical necessity of each item of durable medical equipment.

(ii) Conduct the face-to-face examination for the initial order and at the time of the prescription renewal for items of continued need, such as infusion pumps or hospital beds.

(iii) Be independent from the DME supplier and cannot be an employee or contractor of the supplier.

(3) A written order must be completed and signed before delivery of any durable medical equipment to the beneficiary.

(4) The physician's or prescribing practitioner's order must be dated and signed within 30 days after the face-to-face examination and the beneficiary's medical record must include verification of the face-to-face examination.

(5) The physician or prescribing practitioner must document in the beneficiary's medical record the need for the durable medical equipment being ordered.

(6) CMS may determine other additional payment criteria, such as prescription renewal requirements, repairs, minor revisions and replacement, through contractor instructions.

(h) Limitation. Medicare does not pay for a face-to-face examination for the sole purpose of the beneficiary's

obtaining the physician's or prescribing practitioner's order for the durable medical equipment.

(i) Clinical conditions for coverage. Clinical conditions for coverage, not defined in paragraph (g) of this section, of durable medical equipment are determined through the national or local coverage determination process.

13. 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 for an occupational therapist or by an appropriately supervised occupational therapy assistant who meets 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 their State practice. When an occupational therapy service is provided incident to the service of 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.

\* \* \* \* \*

14. 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 for a physical therapist or by an appropriately supervised physical therapist assistant who meets 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 within the scope of their State practice. When a physical therapy service is provided incident to the service of a physician, physician's assistant, clinical nurse specialist, or nurse practitioner, the service and 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.

\* \* \* \* \*

15. 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 if they meet 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 within the scope of their State practice. When a speech-language pathology service is provided incident to the services of a physician, physician's 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.

\* \* \* \* \*

16. Section 410.63 is amended by--

- A. Revising paragraph (b) section heading.
- B. Adding a new paragraph (c).

The revision and addition reads as follows:

**§410.63 Hepatitis vaccine and blood clotting factors:**

**Conditions.**

(b) Blood clotting factors: Conditions. \* \* \*

(c) Blood clotting factors: Separate payment.

Effective January 1, 2005, Medicare pays hemophilia treatment centers and homecare companies that furnish blood

clotting factor a separate payment of \$0.05 per unit for the items and services associated with the furnishing of the blood clotting factor. These items and services 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.

17. 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) \* \* \*

(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, monthly end stage renal disease (ESRD)

related evaluation and management services and pharmacologic management furnished by an interactive telecommunications system if the following conditions are met:

\* \* \* \* \*

18. 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**

19. 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).

20. 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.

\* \* \* \* \*

21. 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. 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. A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion. 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.**

22. 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]**

23. Section 414.38 is removed.

24. 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 perform physician care plan oversight without certifying a patient for home health services (only a physician can certify a patient for home health care) if

the relationship with the physician who signs the plan of care meets one of the following conditions:

(i) The physician and NPP are part of the same group practice;

(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;

(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; or

(iv) The physician signing the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight.

(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; or

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

25. 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, monthly end stage renal disease (ESRD) related evaluation and management services and pharmacologic management furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

\* \* \* \* \*

26. Section 414.66 is added to read as follows:

**§414.66 Incentive payments for physicians scarcity areas.**

(a) Definition. As used in this section, the following definition applies—

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 (other than dentists, podiatrists, optometrists, chiropractors, and those identified in paragraph (a) of this section) 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.

27. Section 414.67 is added to 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.

(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.)

28. 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 Social Security 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. The payment for a drug furnished to an end-stage renal disease patient that is

separately billed by an end stage renal disease facility, including erythropoietin, cannot exceed 97 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.

#### **PART 418—HOSPICE CARE**

29. 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).

30. Section 418.205 is added to read as follows:

**§418.205 Special requirements for hospice pre-election evaluation and counseling services.**

(a) Definition. For purposes of this section, the following definition applies:

Terminal illness is defined as having a prognosis of 6 months or less if the disease or illness runs its normal course.

(b) Effective date for payment and requirements.

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 agency on behalf of a Medicare beneficiary who is terminally ill if the requirements of this section are met.

(1) The beneficiary: (i) Is certified as having a terminal illness.

(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--(i) An evaluation of an individual's need for pain and symptom management;

(ii) Counseling regarding hospice and other care options; and

(iii) May include advising the individual regarding advanced care planning.

(3) Provider of pre-election hospice services. (i) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(ii) The services cannot be furnished by other hospice personnel, 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.

(iii) If the beneficiary's physician is also the medical director or a physician employee of the hospice, the attending physician is not required to request or provide 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 rendered.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and 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.

31. Section 418.304 is amended by adding paragraph (d) to read as follows.

**§418.304 Payment for physician services.**

\* \* \* \* \*

(d) Payment for hospice evaluation and counseling services - pre-election. The intermediary makes payment for these services established in §418.205 to the hospice. As directed by the statute, payment for this service is set

at an amount established 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 under the physician fee schedule, other than the portion of such amount attributable to the practice expense component. Payment for this pre-election service is not calculated towards the hospice cap amount.

**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

32. 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).

33. 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.

34. 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.

\* \* \* \* \*

35. Section 424.80 is amended by—

A. Revising paragraph (b)(2).

B. Removing paragraph (b)(3).

C. Redesignating paragraphs (b)(4) through (6) as paragraphs (b)(3) through (5), respectively.

D. Revising paragraph (c).

E. Adding a new paragraph (d).

The revisions and addition read as follows:

**§424.80 Prohibition of reassignment of claims by suppliers.**

\* \* \* \* \*

(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**

36. 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]**

37. 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**

38. 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]**

39. 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.

Approved: \_\_\_\_\_

\_\_\_\_\_  
**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 alpha-numeric 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 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.

D = Deleted code. These codes are deleted effective with the beginning of the calendar year.

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.

F = Deleted/discontinued codes. Code not subject to a 90-day grace period.

G = Code not valid for Medicare purposes. Medicare does not recognize codes assigned this status. Medicare uses another code for reporting of, and payment for, these services.

H = Deleted modifier. Either the TC or PC component shown for the code has been deleted, and the deleted component is shown in the data base with the H status indicator. (Code subject to a 90-day grace period.)

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.)