Federal Register

Monday,
November 15, 2004

Book 3 of 4 Books
Pages 66235–66916

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, et al.
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–1429–FC]

RIN 0938–AM90

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

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

ACTION: Final rule with comment period.

SUMMARY: This final rule refines the resource-based practice expense relative value units (RVUs) and makes other changes to Medicare Part B payment policy. These policy changes concern: supplemental survey data for practice expense; updated geographic practice cost indices for physician work and practice expense; updated malpractice RVUs; revised requirements for supervision of therapy assistants; revised payment rules for low osmolar contrast media; changes to payment policies for physicians and practitioners managing dialysis patients; clarification of care plan oversight requirements; revised requirements for supervision of diagnostic psychological testing services; clarifications to the policies affecting therapy services; revised requirements for assignment of Medicare claims; addition to the list of telehealth services; and, several coding issues. We are making these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

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

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

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

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

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

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

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2005.

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

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1429–FC, P.O. Box 8012, Baltimore, MD 21244–8012.

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

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number 800–743–3951 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(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).

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

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

SUPPLEMENTARY INFORMATION:

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

Inspection of Public Comments: Comments received timely will be available for public inspection as they are processed, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 800–743–3951.

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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.

Table of Contents

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

AAA Abdominal aortic aneurysm
AAFP American Academy of Family Physicians
AAKP American Association of Kidney Patients
AANA American Association of Nurse Anesthetists
ABI Ankle brachial index
ABN Advanced beneficiary notice
ACC American College of Cardiology
ACLA American Clinical Laboratory Association
ACP American College of Physicians
ACPM American College of Preventative Medicine
ACR American College of Radiology
ADLs Activities of daily living
AFROC Association of Freestanding Radiation Oncology Centers
AGS American Geriatric Society
AHA American Heart Association
AMA American Medical Association
AOA American Osteopathic Association
APA Administrative Procedures Act
APTA American Physical Therapy Association
ASA American Society of Anesthesiologists
ASCP American Society for Clinical Pathology
ASN American Society of Nephrology
ASP Average sales price
ASTRO American Society for Therapeutic Radiation Oncology
ATA American Telemedicine Association
AWP Average wholesale price
BBA Balanced Budget Act of 1997
BBRA Balanced Budget Refinement Act of 1999
BIPA Benefits Improvement and Protection Act of 2000
BLS Bureau of Labor Statistics
BMI Body mass index
BSA Body surface area
CAH Critical access hospital
CAP College of American Pathologists
CAPD Continuous ambulatory peritoneal dialysis
CCPD Continuous cycling peritoneal dialysis
CDC Centers for Disease Control and Prevention
CF Conversion factor
CFR Code of Federal Regulations
CLIA Clinical Laboratory Improvement Amendment
CMA California Medical Association
CMS Centers for Medicare & Medicaid Services
CNMs Certified nurse midwives
CNS Clinical nurse specialist
COPD Chronic obstructive pulmonary disease
CORF Comprehensive outpatient rehabilitation facilities
CPEP Clinical Practice Expert Panel
CPI Consumer Price Index
CPO Care Plan Oversight
CPT [Physicians'] Current Procedural Terminology [4th Edition, 2002, copyrighted by the American Medical Association]
CRNAs Certified Registered Nurse Anesthetists
CT Computed tomography
CV Cardiovascular
CY Calendar year
DEXA Dual energy x-ray absorptiometry
DHS Designated health services
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DMERC Durable medical equipment regional carrier
DOI Departments of Insurance
DRE Digital rectal exam
DRG Diagnosis-related groups
DVT Deep venous thrombosis
EKG Electrocardiogram
E/M Evaluation and management
EPO Erythropoeitin
ESRD End-stage renal disease
FAX Facsimile
FMR Fair market rental
FQHC Federally qualified healthcare center
FR Federal Register
FY Fiscal year
GAF Geographic adjustment factor
GPCI Geographic practice cost index
GTT Glucose tolerance test
HBO Hyperbaric oxygen
HCPAC Health Care Professional Advisory Committee
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHS [Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
HOCM High osmolar contrast media
HPSA Health professional shortage area
HRSA Health Resources and Services Administration
HsCRP high sensitivity C-reactive protein
HUD Housing and Urban Development
IDTFs Independent diagnostic testing facilities
IMRT Intensity modulated radiation therapy
IOM Internet Only Manual
IPD Intermittent peritoneal dialysis
IPPE Initial preventive physical examination
IPPS Inpatient prospective payment system
ISO Insurance Services Office
IVIG Intravenous immune globulin
JUAs Joint underwriting associations
KCP Kidney Care Partners
KECC Kidney Epidemiology and Cost Center
LCD Local coverage determination
LMRP Local medical review policies
LOCM Low osmolar contrast media
LUPA Low utilization payment adjustment
MCM Medicare Carrier Manual
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MGMA Medical Group Management Association
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MPFS Medicare physician fee schedule
MSA Metropolitan statistical area
NAMCS National Ambulatory Medical Care Survey
NCD National coverage determination
NCIPC National Center for Injury Prevention and Control
NDC National drug code
NIH National Institutes of Health
NP Nurse practitioner
NPP Nonphysician practitioners
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act
OIG Office of Inspector General
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
OTA Occupational therapist assistant
OTPP Occupational therapists in private practice
PA Physician assistant
PAD Peripheral arterial disease
PC Professional component
PCF Patient compensation fund
PD Peritoneal dialysis
PEAC Practice Expense Advisory Committee
PET Positron emission tomography
PFS Physician Fee Schedule
PHSA Public Health Services Act
PIAA Physician Insurers Association of America
PIN Provider identification number
PLI Professional liability insurance
POS Prosthetics, orthotics and supplies
PPI Producer price index
PPS Prospective payment system
PRA Paperwork Reduction Act
PSA Physician scarcity area
PT Physical therapy
PTA Physical therapist assistant
PTPP Physical therapists in private practice
PVD Peripheral vascular disease
RFA Regulatory Flexibility Act

RHC Rural health clinic
RHHI Regional home health intermediary
RIA Regulatory impact analysis
RN Registered nurse
RNHCI Religious nonmedical health care institution
RPA Renal Physicians Association
RT Respiratory therapy
RTs Respiratory therapists
RUC [AMA's Specialty Society] Relative [Value] Update Committee
RUCA Rural-Urban commuting area
RVU Relative value unit
SAF Standard analytic file
SCHIP State Child Health Insurance Program
SGR Sustainable growth rate
SHIPs State Health Insurance Assistance Programs
SIR Society for Interventional Radiology
SLP Speech language pathology
SMR Standardized mortality ratio
SMS [AMA's] Socioeconomic Monitoring System
SNF Skilled nursing facility
TC Technical component
UAF Update adjustment factor
URR Urea reduction ratios
USPSTF U.S. Preventive Services Task Force

I. Background

A. Legislative History

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

B. Published Changes to the Fee Schedule

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

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

As required by the statute, we announced that the physician fee schedule update for CY 2004 was −4.5 percent; that the initial estimate of the sustainable growth rate for CY 2004 was 7.4 percent; and that the conversion factor for CY 2004 was $35.1339.

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

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

The information contained in the January 7, 2004 interim final rule concerning payment under the physician fee schedule superceded information contained in the November 7, 2003 final rule to the extent that the two are inconsistent.

C. Components of the Fee Schedule Payment Amounts

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

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

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

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

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

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

D. Development of the Relative Value System

1. Work Relative Value Units

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

The RVUs for radiology services were based on the American College of Radiology (ACR) relative value scale, which we integrated into the overall physician fee schedule. The RVUs for anesthesia services were based on RVUs from a uniform relative value guide. We established a separate CF for anesthesia services, and we continue to recognize

time as a factor in determining payment for these services. As a result, there is a separate payment system for anesthesia services.

2. Practice Expense and Malpractice Expense Relative Value Units

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

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

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

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

The proposed rule discussed policies that affected the number of RVUs on which payment for certain services would be based. The proposed rule also discussed policies related to implementation of the MMA. RVU changes implemented through this final rule are subject to the $20 million limitation on annual adjustments contained in section 1848(c)(2)(B)(ii)(II) of the Act.

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

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

A. Resource-Based Practice Expense Relative Value Units

1. Resource-Based Practice Expense Legislation

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

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

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

Further legislation affecting resource-based practice expense RVUs was included in the Medicare, Medicaid and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) enacted on November 29, 1999. Section 212 of the BBRA amended section 1848(c)(2)(C)(ii) of the Act by directing us to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations. These data would supplement the data we normally collect in determining the practice expense component of the physician fee schedule for payments in CY 2001 and CY 2002. (The 1999 and 2003 final rules (64 FR 59380 and 68 FR 63196, respectively, extended the period during which we would accept supplemental data.)

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

In the November 2, 1998 final rule (63 FR 58910), effective with services furnished on or after January 1, 1999, we established at 42 CFR 414.22(b)(5) a new methodology for computing resource-based practice expense RVUs that used the two significant sources of actual practice expense data we have available—the Clinical Practice Expert Panel (CPEP) data and the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysicians (for example registered nurses) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physicians service in both the office setting and out-of-office setting. The AMA's SMS data provided aggregate specialty-specific information on hours worked and practice expenses. The methodology was based on an assumption that current aggregate specialty practice costs are a reasonable way to establish initial estimates of relative resource costs for physicians' services across specialties. The methodology allocated these aggregate specialty practice costs to specific procedures and, thus, can be seen as a ''top-down'' approach.

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

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

a. Major Steps

A brief discussion of the major steps involved in the determination of the practice expense RVUs follows. (Please see the November 1, 2001 final rule (66 FR 55249) for a more detailed explanation of the top-down methodology.)

- *Step 1*—Determine the specialty specific practice expense per hour of physician direct patient care. We used the AMA's SMS survey of actual aggregate cost data by specialty to determine the practice expenses per hour for each specialty. We calculated the practice expenses per hour for the specialty by dividing the aggregate practice expenses for the specialty by the total number of hours spent in patient care activities.
- *Step 2*—Create a specialty-specific practice expense pool of practice expense costs for treating Medicare patients. To calculate the total number of hours spent treating Medicare patients for each specialty, we used the physician time assigned to each procedure code and the Medicare utilization data. The primary sources for the physician time data were surveys submitted to the AMA's RUC and surveys done by Harvard for the establishment of the work RVUs. We then multiplied the physician time assigned per procedure code by the number of times that code was billed by each specialty, and summed the products for each code, by specialty, to get the total physician hours spent treating Medicare patients for that specialty. We then calculated the specialty-specific practice expense pools by multiplying the specialty practice expenses per hour (from step 1) by the total Medicare physician hours for the specialty.
- *Step 3*—Allocate the specialty-specific practice expense pool to the specific services (procedure codes) performed by each specialty. For each specialty, we divided the practice expense pool into two groups based on whether direct or indirect costs were involved and used a different allocation basis for each group.

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

(ii) Indirect costs—To allocate the cost pools for indirect costs, including administrative labor, office expenses, and all other expenses, we used the total direct costs, or the 1998 practice expense RVUs, in combination with the physician fee schedule work RVUs. We converted the work RVUs to dollars using the Medicare CF (expressed in 1995 dollars for consistency with the SMS survey years).

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

b. Other Methodological Issues

i. Nonphysician Work Pool

As an interim measure, until we could further analyze the effect of the top-down methodology on the Medicare payment for services with physician work RVUs equal to zero (including the technical components of radiology services and other diagnostic tests), we created a separate practice expense pool. We first used the average clinical staff time from the CPEP data and the ''all physicians'' practice expense per hour to create the pool. In the December 2002 final rule, we changed this policy and now use the total clinical staff time and the weighted average specialty-specific practice expense per hour for specialties with services in this pool. In the next step, we used the adjusted 1998 practice expense RVUs to allocate this pool to each service. Also, for all radiology services that are assigned physician work RVUs, we used the adjusted 1998 practice expense RVUs for radiology services as an interim measure to allocate the direct practice expense cost pool for radiology.

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

ii. Crosswalks for Specialties Without Practice Expense Survey Data

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

iii. Physical Therapy Services

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

3. Practice Expense Proposals for Calendar Year 2005

a. Supplemental Practice Expense Surveys

i. Survey Criteria and Submission Dates

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

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

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

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

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

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

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

iii. Submission of Supplemental Surveys

We received surveys from the American College of Cardiology (ACC), the American College of Radiology (ACR), and the American Society for Therapeutic Radiation Oncology (ASTRO). Our contractor, The Lewin Group, evaluated the data and recommended that we accept the data from the ACC and the ACR, but indicated that the survey from ASTRO did not meet the precision criteria established for supplemental surveys and, thus, did not recommend using the ASTRO survey results at this time. We agreed with these recommendations. However, as explained in the August 5, 2004 proposed rule, the ACR and the ACC requested that we not use the data until we have a stable and global solution that is workable for all specialties that are currently paid using the nonphysician work pool. We agreed with these requests and proposed delaying use of these supplemental surveys until issues related to the nonphysician work pool can be addressed.

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

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

Comment: ASTRO stated that they appreciate the opportunity to submit data and, that they understand we will not be using the data in 2005. ASTRO further commented that, due to the specific practice patterns and practice environment of radiation oncology, new data, regardless of the response rate, may not meet the criteria. ASTRO further stated that they will continue to work with CMS and with the Lewin Group as this issue is analyzed. The Association of Freestanding Radiation Oncology Centers (AFROC) expressed concern that freestanding centers that have higher costs than hospital-based centers were underrepresented by the ASTRO survey. They also expressed concern about the reference in the Lewin Group report to crosswalking radiation oncology costs from another specialty. In addition, AFROC argued that we should not average costs associated with freestanding centers with those that are hospital-based, because the costs would be understated. They urged us to ensure that any assumption regarding representativeness of any survey data is justified.

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

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

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

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

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

As we explained in the January 7, 2004 **Federal Register** (69 FR 1093 through 1094), section 303(a)(1) of the MMA modifies section 1848(c)(2)(B) of the Act to provide an exemption from the budget neutrality requirements in 2006 for further increases in the practice expense RVUs for drug administration that may result from using survey data from specialties meeting certain criteria. The survey must include expenses for the administration of drugs and biologicals and be submitted by a specialty that receives more than 40 percent of its 2002 Medicare revenues from drugs. Urology received more than 40 percent of its 2002 Medicare revenues from drugs. Therefore, if we were to receive a practice expense survey of urologists by March 1, 2005

that included expenses for the administration of drugs and biologicals and the survey met the criteria we have established (and those of section 1848(c)(2)(I)(ii) of the Act), we would exempt the change in the practice expense RVUs for drug administration services from the budget neutrality requirements of section 1848(c)(2)(B) of the Act.

b. Practice Expense Advisory Committee (PEAC)

Recommendations on CPEP Inputs for 2005

- CPEP Refinement Process.

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

Comment: We received comments from the AMA that future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC with the help of a new ad hoc committee, now termed the Practice Expense Review Committee (PERC), comprised of former PEAC members. The RUC also noted that their Practice Expense Subcommittee remains committed to reviewing improvements to the practice expense methodology.

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

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

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

Response: Because the RUC is an independent committee, we are not in a position to set the requirements for RUC membership. However, we are confident that the RUC and the Health Care Professional Advisory Committee, which also sends practice expense recommendations directly to us, together represent two broad ranges of practitioners, both physician and nonphysician.

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

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

- PEAC Recommendations.

We proposed to adopt nearly all of the PEAC recommendations. However, we disagreed with the PEAC recommendation for clinical labor time for CPT code 99183, Physician attendance and supervision of hyperbaric oxygen therapy, per session, and proposed a total clinical labor time of 112 minutes for this service.

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

Response: We appreciate the hard work and perseverance on the part of the PEAC and the specialty societies that produced the recommended refinements for so many services. In addition, we do not believe that we circumvented the PEAC process in any way. We have the greatest respect for the PEAC and RUC recommendations that we received. However, we do have the final responsibility for all payments made under the physician fee schedule, and this can lead to disagreement with a specific recommendation. The RUC itself has always demonstrated its understanding and respect for our responsibility in this regard. With regard to the two services that we priced in the office, we stated explicitly in the proposed rule that we were requesting that the RUC review the practice expense inputs.

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

Response: Based on our concern that the PEAC recommendation of 20 minutes of clinical staff time during the intra-service period undervalued the clinical staff time, we proposed increasing this time to 90 minutes in the proposed rule. This was, of course, subject to comment. We believe there is some merit to the claim that the clinical staff may be monitoring more than one chamber at a time. Therefore, we are adjusting the time for the intra-service period from the proposed 90 minutes to 60 minutes in recognition of this point. We will continue our examination of this issue and entertain ongoing dialog with all interested organizations and individuals familiar with this service to assure the accuracy of the intra-service time.

Comment: The Cardiac Event Monitoring Provider Group Coalition expressed concern about the PEAC recommendations that would substantially reduce the clinical staff time associated with cardiac monitoring services. Of particular concern to the Coalition was the 70 percent reduction in time for CPT code 93271, the code for cardiac event monitoring, receipt of transmissions, and analysis. Although all these services are currently priced in the nonphysician work pool and this decrease in the staff times has no immediate impact, the commenter was concerned that, when the nonphysician work pool is eliminated, these services will be undervalued. The commenter also believed that the PEAC recommendations may not have reflected all the supplies and equipment utilized in these services and included a complete list of necessary supplies

and equipment. The American College of Cardiology (ACC) presented these services at the PEAC meeting and commented they had been unable to collect sufficient data so that the PEAC could make an appropriate recommendation.

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

• Adjustments To Conform With PEAC Standards

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

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

Response: The PEAC recommended that the discharge day management time apply only to 10-day and 90-day global services and we were complying with this recommendation. We also believe that this PEAC recommendation is reasonable; it is hard to imagine what tasks a physician's clinical staff back in the office is performing for a patient during the period that the patient is undergoing a same-day procedure in the hospital outpatient department. However, the point made about 10-day global procedures is pertinent. We would suggest that the RUC reconsider whether the discharge day management clinical staff time should apply only to services that are typically performed in the inpatient setting. We also believe that it was appropriate to apply the PEAC standards to codes that were not refined or that were refined before the standards were developed. The application of these standards is not only fair, but can also help to avoid the possible rank order anomalies cited by the commenter.

Methacholine Chloride

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

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

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

Response: Because CPT code 95070 is valued in the nonphysician work pool, the PEAC's addition of methacholine to this procedure could not be captured by the practice expense RVUs. However, a J-code was established, J7674, *Methacholine chloride administered as inhalation solution through nebulizer, per 1mg,* so that this drug can be billed separately. Accordingly, we have deleted methacholine from the practice expense database.

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

• Nursing Facility and Home Visits.

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

Comment: A specialty group representing family physicians supported the acceptance of the PEAC recommendations for nursing facility visits, even though this resulted in a decrease for these services. The commenter stated that the decrease occurred because the original CPEP data was flawed and the clinical staff times were too high. The commenter also stated that the payments in the facility setting will increase for these services and that setting has the higher volume of visits. Other commenters representing long term care physicians, geriatricians and podiatrists expressed disappointment in these PEAC recommendations and stated that, while the PEAC did consider the views of long term care physicians, the PEAC failed to accept these views even though they were supported by data. These commenters believe the PEAC did not

recommend an appropriate increase based on a false assumption that the nursing home provides the staff. Another commenter contended that the new values do not adequately account for work performed by the physician's clinical staff. The commenter stated that the pre- and post-times for these codes are less than for the comparable office visit codes, even though it is clear that more clinical staff time is required for the nursing facility resident. One commenter suggested that these concerns would need to be addressed within the framework of the 5-year review. The specialty society representing homecare physicians also commented that, rather than challenging a flawed system, they will use the 5-year review process to have work and practice expense re-valuated for the home visit codes.

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

• Suggested Corrections to the CPEP Data.

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

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

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

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

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

Response: As stated by the commenters, this request was included in the PEAC recommendations but was inadvertently omitted from the proposed rule. We agree that the 10-day global period currently assigned to this procedure may not be appropriate because the physician performing the procedure most likely does not see the infant for a post-procedure visit. However, we believe that a 0-day global period rather than ''xxx'' should be assigned to this procedure. We generally use the ''xxx'' designation for diagnostic tests and no surgical procedure currently is designated as an ''xxx'' global service. We believe this will accomplish the same end because most any other service performed at the same time as the circumcision could be billed with the appropriate modifier. We are adjusting the practice expense database to delete any staff time, supplies and equipment associated with the post-procedure office visit.

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

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

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

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

• Other Issues.

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

Response: In the past, we have published the practice expense RVUs for only a small number of noncovered codes which are listed in our national payment files that can be accessed via our physician web page under ''Medicare Payment Systems'' as part of the public use files at *www.cms.hhs.gov/physicians/.* Because we have not yet established a consistent policy regarding the publication of RVUs for noncovered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for noncovered services.

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

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

Comment: A specialty society representing vascular surgery expressed concern about the wide variations in practice expense RVUs that are sometimes derived under the current methodology. The commenter suggested that some outliers require additional focus to determine whether these are errors in the direct inputs or if they

reflect problems inherent in the methodology. According to the commenter, it would appear that some of the extreme variation is due to the high costs of certain disposable supplies in the office setting as well as high scaling factors. A few examples of outlier codes were provided. The commenter suggested that we consider an alternative methodology for payment of high-priced single-use items in the nonfacility setting.

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

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

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

c. Repricing of Clinical Practice Expense Inputs—Equipment

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

We contracted with a consultant to assist in obtaining the current price for each equipment item in our CPEP database. The consultant was able to determine the current prices for most of the equipment inputs and clarified the specific composition of each of the various packaged and standardized rooms or ophthalmology ''lanes'' currently identified in the equipment practice expense database (for example, mammography room or exam lane). We proposed to delete the current ''room'' designation for the radiopharmaceutical receiving area and, in its place, list separately the equipment necessary for each procedure as individual line items.

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

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

In addition, we proposed the following database revisions:

Assignment of Equipment Categories

We proposed that equipment be assigned to one of the following six categories: documentation, laboratory, scopes, radiology, furniture, rooms-lanes, and other equipment. These categories would also be used to establish a new numbering system for equipment that would more clearly identify them for practice expense purposes.

Consolidation and Standardization of Item Descriptions

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

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

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

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

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

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

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

Comment: The American Society for Therapeutic Radiology and Oncology (ASTRO) submitted information and the requested documentation for fifteen items, often supplying two or more pricing sources.

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

Comment: Commenters representing manufacturers and providers expressed concern about the reduction in payment (9 percent) for external counterpulsation (ECP), G0166. The commenters questioned the proposed change made to the life of the ECP equipment, from seven to five years, used for this service. Commenters did not believe this was supported by the AHA information (which indicated that similar diagnostic cardiovascular equipment has an equipment life of five years) and requested that this timeframe be applied to the ECP equipment for this service. The American College of Cardiology also questioned the change to the ECP equipment life. The commenters also questioned the allocation for maintenance and indirect costs applied under the practice expense methodology

as well as the time allocated for this service. As a final point, some of the commenters requested that we adjust the work RVUs assigned to this G-code to that of an echocardiogram (CPT code 93307) and include it in the nonphysician work pool.

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

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

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

Comment: The American College of Cardiology (ACC) agreed with the pricing for the ambulatory blood pressure monitor, provided prices for the ECG signal averaging system (E55035), but provided no documentation for these prices. They stated that the echocardiography digital acquisition ultrasound referenced in table 2 was no longer in the marketplace and that a digital workstation was now typically used. They requested that an appropriate equipment code be available for this item and provided a price range for this item (although without the supporting documentation). ACC also recommended that the pacemaker programmer (E55013) be removed from the equipment list because it is provided at no cost to the physician. Removal of this item from the PE database was also supported by a manufacturer that commented on the rule.

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

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

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

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

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

Comment: The American Gastroenterological Association (AGA) expressed concern about the reduction in RVUs for CPT code 91065, a breath hydrogen test. They believe that the newer equipment listed in the practice expense database does not reflect the analyzer that is typically used, which is more expensive, and noted that the costs for the reagents have also increased.

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

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

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

Comment: The Society for Vascular Surgery (SVS), Society for Vascular Ultrasound and Society of Diagnostic Medical Sonography all expressed appreciation for the refinement to the inputs that apply to vascular ultrasound services. However, the commenters requested that we incorporate the requested refinements for the other ancillary equipment present in a vascular ultrasound room into other similar procedures. SVS specifically listed the following CPT codes: 93875–9 and 93990.

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

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

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

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

Response: We revised the database to reflect this change.

Comment: American Academy of Neurology supplied information and the necessary documentation on several equipment items listed in table 2 associated with neurology services.

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

Comment: The American Clinical Neurophysiology Society (ACNS) stated that the payment for CPT code 95819, an EEG service, was substantially reduced. The Society believes it is due to a price reduction for the EEG equipment (E54006) used in this service that was listed in Addendum D of the

proposed rule. The commenter indicated that the proposed price does not include the review station and software which is needed for this service and provided documentation for appropriately pricing this item.

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

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

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

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

Response: We appreciate the commenter's remarks about the price of the electromagnetic therapy equipment, Diapulse. We have retained our price of $25,000 in the practice expense database because we do not have documentation that any higher-priced equipment is typically used. Similar to other modalities used in rehabilitation, including those used in wound care, we note that this procedure reflects comparable practice expense values.

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

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

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

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

BILLING CODE 4120–01–P

Table 2

Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

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

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

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

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

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

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

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

BILLING CODE 4120–01–C

d. Miscellaneous Practice Expense Issues

- Pricing for Seldinger Needle.

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

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

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

• Hysteroscopic Endometrial Ablation.

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

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

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

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

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

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

• Photopheresis.

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

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

+ *Supplies:* multispecialty visit supply package, photopheresis procedural kit, blood filter (filter iv set), IV blood administration set, 0.9 percent irrigation sodium chloride 500–1000 ml (2), heparin 1,000 units-ml (10), povidone solution-betadine, methoxsalen (UVADEX) sterile solution-10 ml vial, 1 percent-2 percent lidocaine-xylocaine, paper surgical tape (12), 2x3 underpad (chux), nonsterile 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.

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

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

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

• Pricing of New Supply Items.

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

We also identified certain supply items for which we were unable to verify the pricing information (*see* Table 4, Supply Items Needing Specialty Input for Pricing, in the August 5, 2004 proposed rule). We requested that commenters provide pricing information on these items along with documentation to support the recommended price. In addition, we also requested information on the specific contents of the listed kits, so that we do not duplicate any supply items.

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

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

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

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

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

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

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

Response: Unfortunately, ACC did not include the requested sufficient documentation, such as invoices or catalog web page links. We have asked ACC to forward this pricing documentation to us as soon as possible because it will be required for supplies to remain valued in the practice expense database. In the interim, for the 2005 fee schedule, we will maintain the prices currently in the practice expense database for the following supplies:

blood pressure recording form at $0.31, pressure bag (infuser) 500cc or 1000cc at $8.925, sterile, non-vented, tubing at $1.99.

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

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

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

BILLING CODE 4120–01–P

Table 3: Supplies Needing Specialty Input

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

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

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Notes:
A. Additional information required. Need detailed description (including kit contents), source, and current pricing information.
B. No/Insufficient documentation. Retained price in database, on interim basis. Forward documentation promptly.
C. Submitted price accepted.
D. Deleted per comment.
E. 2004 price retained on an interim basis. Forward documentation promptly.

BILLING CODE 4120–01–C

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

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

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

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

• Ophthalmology Equipment.

In cases where both the screening and exam lanes are included in the equipment list for the same ophthalmology service, we proposed to include only one lane because the patient could only be in one lane at a time. We proposed defaulting to the exam lane and, thus, we proposed deleting the screening lane from the practice expense inputs for these procedures. For the services where a lane change was made, time values were assigned to the exam lane in accordance with our established standard procedure.

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

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

• Parathyroid Imaging, CPT code 78070.

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

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

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

• Additional PE concerns.

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

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

Comment: We received comments from manufacturers, specialty societies representing renal physicians and vascular surgeons, and individual providers questioning the decrease in nonfacility practice expense RVUS for CPT code 36870, *Percutaneous thrombectomy, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis.* Some commenters believe this reduction occurred because the supplies listed in the database for this service reflect only one method of providing this service. While commenters acknowledged that the database includes the supplies used in approximately 50 percent of the instances this procedure is performed, the commenters claimed that other supplies may be used in the remaining occasions. Commenters requested that we add these other specific supplies to the database.

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

Comment: Societies representing dermatologic specialties expressed concern about the reduction in practice expense RVUs for a photodynamic therapy service, CPT code 96567. The commenters believe that this reduction is due to the application of the dermatology scaling factor based on updated practice expense utilization and requested that this be reconsidered. These commenters also expressed appreciation that there is now a separate HCPCS code to bill for levulan that is needed for this procedure, but stated that there are two medical supplies that need to be included in the practice expense database: bacitracin, and a topical anesthetic cream.

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

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

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

Comment: The society representing interventional pain physicians questioned the ''professional component only'' designation we assigned to the codes for the analysis of an implanted intrathecal pump, CPT codes 62367 and 62368, and the subsequent low RVUs for these services. The commenter stated that if the payment is left as proposed, more physicians would stop offering intrathecal pumps to patients.

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

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

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

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

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

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

Response: We appreciate the comments from NASS and look forward to receiving the survey results. In the interim, we have averaged the needle costs for the range indicated above by the specialty and have entered this figure, $660.50, as a placeholder for the 2005 fee schedule. Because of the large disparity between the lowest and highest needle costs, it is not reasonable to consider $660.50 as a true average cost for this supply item. We will continue to work with the specialty organizations in order to ensure that the 2006 fee schedule practice expense database reflects the value for the most typical needle used in these procedures.

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

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

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

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

B. Geographic Practice Cost Indices (GPCIs)

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

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

In addition, section 412 of the MMA amended section 1848(e)(1) of the Act and established a floor of 1.0 for the work GPCI for any locality where the GPCI would otherwise fall below 1.0. This 1.0 work GPCI floor is used for purposes of payment for services furnished on or after January 1, 2004 and before January 1, 2007. Section 602 of the MMA further amended section 1848(e)(1) of the Act for purposes of payment for services furnished in Alaska under the physician fee schedule on or after January 1, 2004 and before January 1, 2006, and sets the work, practice expense, and malpractice expense GPCIs at 1.67 if any GPCI would otherwise be less than 1.67.

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

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

1. Work Geographic Practice Cost Indices

As explained in the August 5, 2004 proposed rule, we used data from the 2000 decennial U.S. Census, by county, of seven professional occupations (architecture and engineering; computer, mathematical, and natural sciences; social scientists, social workers, lawyers; education, library, training; registered nurses; pharmacists; writers, artists, editors) in the development of the proposed work GPCIs. Physicians' wages are not included because Medicare payments are determinant of the physicians' earnings. Including physician wages in the physician work GPCI would, in effect, make the index dependent upon Medicare payments. Based on analysis performed by Health Economics Research, we believe that, in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals vary.

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

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

2. Practice Expense GPCIs

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

- *Employee Wage Indices*—The employee wage index is based on special tabulations of 2000 Census data and is designed to capture the median wage by county of the professional labor force. The employee wage index uses the median wages of four labor categories that are most commonly present in a physician's private practice (administrative support, registered nurses, licensed practical nurses, and health technicians). Median wages for these occupations were aggregated by county in the same manner as the data for the work GPCI.
- *Office Rent Indices*—The HUD FMR data for the residential rents were again used as the proxy for physician office rents as they are in the current practice expense GPCIs. The proposed 2005 through 2007 practice expense GPCIs reflect the final fiscal year 2004 HUD FMR data. We believe that the FMR data remain the best available source for constructing the office rent index. The FMR data are available for all areas, are updated annually, and retain consistency from area-to-area and from year-to-year. A reduction in an area's rent index does not necessarily mean that rents have gone down in that area since the last GPCI update. Since the GPCIs measure area costs compared to the national average, a decrease in an area's rent index means that that area's rental costs are lower relative to the national average rental costs. Addendum X illustrates the changes in the rental index based upon the new FMR data.
- *Medical Equipment, Supplies, and other Miscellaneous Expenses*—The GPCIs assume that items such as medical equipment and supplies have a national market and that input prices do not vary among geographic areas. We were again unable to find any data sources that demonstrated price differences by geographic areas. As mentioned in previous updates, some price differences may exist, but these differences are more likely to be based on volume discounts rather than on geographic areas. The medical equipment, supplies, and miscellaneous expense portion of the practice expense geographic index will continue to be 1.000 for all areas in the proposed GPCIs, except for Alaska which will have an overall practice expense GPCI set at 1.67 for 2005 and 2006.

3. Fee Schedule Payments

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

Fee schedule payments are the product of the RVUs, the GPCIs, and the conversion factor. Updating the GPCIs changes the relative position of fee schedule areas compared to the national average. Because the changes represented by the GPCIs could result in total payments either greater than or less than what would have been paid if the GPCIs were not updated, it is necessary to apply scaling factors to the proposed GPCIs to ensure budget neutrality (prior to applying the provisions of MMA that change the work GPCIs to a minimum of 1.0 and increase the Alaska GPCIs to 1.67 because these provisions are exempted from budget neutrality). We determined that the proposed work and practice expense GPCIs would have resulted in slightly higher total national payments. Because the law requires that each individual component of the fee schedule—work, practice expense, and malpractice expense—be separately adjusted by its respective GPCI, we proposed to scale each of the GPCIs separately. To ensure budget neutrality prior to applying the MMA provisions, we have made the following adjustments:

- Decreased the proposed work GPCI by 0.9965;

• Decreased the proposed practice expense GPCI by 0.9930; and

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

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

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

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

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

• It is based on the tenuous assumption that the relative differences in the prices of the input proxies accurately reflect relative changes in prices of corresponding physician practice cost components; and,

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

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

• Using data for four employee classes to measure relative compensation differences for all physicians' office staff which does not reflect the changes in medical practice that have occurred since the index was developed;

• Using residential real estate prices to reflect relative differences in physicians' office costs; and

• Using nationally uniform prices for supplies, equipment, and other expenses.

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

Another commenter asserts that these indices have not been verified by peer-reviewed published research since they were instituted and that we should replace the indices with data from nationwide studies that validate and update actual cost of practice data.

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

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

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

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

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

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

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

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

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

Response: We have no authority to extend the floor of the work GPCI, or to create a 1.00 floor for the practice expense and professional liability insurance GPCIs. Section 1848(c)(1)(A) of the Act requires that the index reflect resource costs relative to the national average, indicating that, aside from the MMA provision establishing a floor on the work GPCI through 2006, localities with costs below the national average have GPCIs below 1.00.

Comment: A specialty organization representing the long term care industry suggested that we phase in the new

GPCI values over a three-year period to minimize the impact of the changes.

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

4. Payment Localities

As discussed in the August 5, 2004 proposed rule, we have considered, and are continuing to examine, alternatives to the composition of the current 89 Medicare physician payment localities to which the GPCIs are applied.

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

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

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

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

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

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

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

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

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

Result of Evaluation of Comments

We will finalize the GPCIs as proposed.

C. Malpractice Relative Value Units (RVUs)

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

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

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

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

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

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

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

Discussions with the industry led us to conclude that the primary determinants of malpractice liability costs remain physician specialty, level

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

For 2001, we collected premium data from 48 States (for purposes of this discussion, State counts include Washington, DC and Puerto Rico). We were unable to obtain premium data from Kentucky, New Hampshire, New Mexico, and Washington, DC. To calculate a proxy for the malpractice premium data for these four areas in 2001, we began with the most current malpractice premium data collected for these areas, 1996 through 1998 (the last premium data collection that was undertaken). We calculated an average premium price (using 1996 through 1998 data) for all States except Kentucky, New Hampshire, New Mexico, and Washington, DC. Similarly, we calculated an average premium price for the 1999 through 2001 period for all States except Kentucky, New Hampshire, New Mexico, and Washington, DC. We calculated the percentage change in these premium prices as the percent difference between the 1999 to 2001 calculated average premium price and the 1996 to 1998 calculated average premium price. We then applied this percentage change to the weighted average 1996 to 1998 malpractice premium price for these four areas to arrive at a comparable 1999 to 2001 average premium price.

For 2002, we were able to obtain malpractice premium data from 33 States. Many State Departments of Insurance had not yet obtained premium data from the primary insurers within their States at the time of this data collection. For those States for which we were unable to obtain malpractice premium data, we calculated a national average rate of growth for 2002 and applied this national rate of growth to the weighted average premium for 2001 to obtain an average premium for 2002 for each county for which we were unable to obtain malpractice premium data for 2002.

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

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

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

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

Dominant Specialty Approach

The dominant specialty approach bases the malpractice RVUs upon the risk factor of only the dominant specialty performing a given service as long as the dominant specialty accounted for at least 51 percent of the total utilization for a given service. When 51 percent of the total utilization does not comprise the dominant specialty, this approach uses a modified specialty-weighted approach. In this modified specialty-weighted approach, two or more specialties are collectively defined as the dominant specialty. Starting with the specialty with the largest percentage of allowed services, the modified specialty-weighted approach successively adds the next highest specialty in terms of percentage of allowed services until a 50 percent threshold is achieved. The next step is to sum the risk factors of those specialties (weighted by utilization) in order to achieve at least 50 percent of the total utilization of a given service and then to use the factors in the calculation of the final malpractice RVU.

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

Specialty-Weighted Approach

The approach that we adopted in the November 1999 final rule and proposed

to use for 2005 bases the final malpractice RVUs upon a weighted average of the risk factors of all specialties performing a given service. The specialty-weighted approach ensures that all specialties performing a given service are accounted for in the calculation of the final malpractice RVU. Under the proposed methodology, we—

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

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

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

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

Certain codes have no physician work RVUs. The overwhelming majority of these codes are the technical components (TCs) of diagnostic tests, such as x-rays and cardiac catheterization, which have a distinctly separate technical component (the taking of an x-ray by a technician) and professional component (the interpretation of the x-ray by a physician). Examples of other codes with no work RVUs are audiology tests and injections. Nonphysicians, in this example, audiologists and nurses, respectively, usually furnish these services. In many cases, the nonphysician or entity furnishing the TC is distinct and separate from the physician ordering and interpreting the test. We believe it is appropriate for the malpractice RVUs assigned to TCs to be based on the malpractice costs of the nonphysician or entity, not the professional liability of the physician.

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

• *Rescale for budget neutrality.* The law requires that changes to fee schedule RVUs be budget neutral. The current resource-based malpractice RVUs and the proposed resource-based malpractice RVUs were constructed using entirely different malpractice premium data. Thus, the last step in this process is to adjust for budget neutrality by rescaling the proposed malpractice RVUs so that the total proposed resource-based malpractice RVUs equal the total current resource-based malpractice RVUs. The proposed resource-based malpractice RVUs for each procedure were then multiplied by the frequency count for that procedure to determine the total resource-based malpractice RVUs for each procedure. The total resource-based malpractice RVUs for each procedure were summed for all procedures to determine the total fee schedule proposed resource-based malpractice RVUs. The total fee schedule *proposed* resource-based malpractice RVUs were compared to the total *current* resource-based malpractice RVUs. The total current and proposed malpractice RVUs were equal and, therefore, budget neutral. Thus, no adjustments were needed to ensure that expenditures remained constant for the malpractice RVU portion of the physician fee schedule payment.

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

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

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TABLE 4:

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

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

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

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

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

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

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

TABLE 5:

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

TABLE 6:

ISO	Specialty	2001 Average	2002 Average	2003 Average	1996-1998 Average	2001-2003 Average[1]	Annual Trend[2]	Specialty MGPCI[3]	Normalized 2001-2003 Premium[4]	Risk Factor[5]
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 [6]	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

[1] A simple average of figures for 2001, 2002, and 2003.
[2] Annualized average growth rate between 1996 - 1998 and 2001 - 2003.

[3] An average of locality malpractice GPCIs using specialty-specific malpractice RVUs as weights.
[4] 2001 - 2003 premium divided by specialty MGPCI.
[5] (Normalized 2001 - 2003 Premium, .9289) x 1.51.
[6] Nephrology is set to 1.51 to be consistent with the risk factor taken from the rating manuals.
n/a siginifies that the premium data was not available.

TABLE 7:

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	1.86
08	Family practice	1.79	4.26
10	Gastroenterology	2.05	3.49
11	Internal medicine	2.05	2.48
12	Osteopathic Manipulative Therapy	1.79	4.26
13	Neurology	2.52	2.74
14	Neurosurgery	12.00	12.00
16	Obstretics/Gynecology	2.15	5.63
18	Ophthalmology	1.24	2.31
20	Orthopedic surgery w/o Spinal	8.06	8.06
20	Orthopedic surgery with Spinal	8.89	8.89
22	Pathology	1.72	2.09
24	Plastic Surgery	6.92	6.92

Medicare Code	Medicare Description	Nonsurgical Risk Factor	Surgical Risk Factor
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

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Medicare Code	Medicare Description	Nonsurgical Risk Factor	Surgical Risk Factor
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.

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

Comments and Responses

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

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

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

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

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

Response: We agree with these comments and have revised the orthopedic surgery with spinal risk factor to reflect the risk factor identified in the rating manuals (8.89). In the proposed rule, the risk factors for orthopedic surgery with spinal and without spinal were taken from two separate sources (premium data and rating manuals, respectively) thus causing the anomalous result. See Table 7 for the revised orthopedic surgery risk factors.

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

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

Comment: One commenter states that the resource-based malpractice RVU methodology underestimates the cost of PLI for physicians who perform obstetric and gynecologic services. According to the commenter, eighty percent of OB/GYNs perform both obstetric and gynecologic services yet the risk factor for most services these physicians provide to Medicare beneficiaries is based on the much lower premiums paid by physicians who offer only gynecologic services.

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

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

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

Comment: One commenter requested that we consider the implementation of the resource-based malpractice expense RVUs interim until the agency has worked with the medical community to ensure that the data and methodology utilized to calculate the malpractice RVUs are appropriate.

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

Comment: Several commenters requested that we use a methodology that would only account for the dominant specialty in the calculation of the service-specific resource-based malpractice RVUs. Commenters stated that a dominant specialty approach would be consistent with the ''typical'' service approach that we use throughout the resource-based physician payment system. Commenters also feel that a dominant specialty approach would more appropriately reflect the actual premium resource costs associated with the performance of individual services.

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

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

approximately 2 specialties. High risk specialties such as neurosurgery, thoracic surgery, general surgery, and obstetrics and gynecology, which account for a small percentage of the total utilization but a large amount of total dollars, would no longer factor into the calculation of the malpractice RVU for this service. These four specialties alone account for nearly $300 million of the total dollars associated with a level III established office visit. The effect of removing these four high-cost, high-risk specialties from the calculation of the malpractice RVUs for this service would be an overall decrease in the malpractice RVUs, because the calculation would be based upon lower-cost, lower-risk specialties.

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

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

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

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

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

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

Comment: Tail coverage is designed to cover any claims that may be made against a new employee for services furnished on behalf of his or her old employer during the time that he or she is employed by the new employer. Several commenters suggested that we incorporate the cost of tail coverage in the determination of PLI annual premium data.

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

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

Response: Although it might be desirable to obtain premium data from every conceivable specialty in the practice of medicine, it is not possible to obtain this scope of data under the time constraints associated with collecting the most current premium data. In order to conduct surveys that collect the maximum amount of premium data from all geographic areas without being too intrusive to the State Departments of Insurance and private insurance companies, we chose to limit the scope of the data collection to the top 20 Medicare specialties. Further, utilizing PLI data from the top 20 Medicare specialties encompasses 80 percent of fee schedule services.

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

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

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

Comment: Several commenters recommended that the malpractice RVUs should remain stable. Commenters suggested that any budget neutrality adjustments, positive or negative, that might occur due to the 5-year review of malpractice RVUs should be made to the conversion factor and not to the malpractice RVUs.

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

Comment: One commenter recommended that the exceptions to the surgical risk factor be modified to include coding changes since the initiation of the resource-based malpractice RVUs in 2000. The previous update to the malpractice RVUs made service-specific exceptions, whereby certain codes were assigned the higher surgical risk factor in the calculation of their final malpractice RVU. The commenter specifically requested that due to CPT coding modifications, the following codes should also receive this same coding modification and receive the greater of their actual average risk factor or the risk factor for cardiac catheterization: 92973–92974, 93501–93533, 93580–93581, 93600–93613, and 93650–93652.

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

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

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

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

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

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

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

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

Response: Physician work RVUs are used to adjust for risk of service. Because technical component services do not have physician work RVUs, they are still valued using charge-based RVUs instead of the resource-based malpractice RVU methodology. We look forward to working with the ACR and other interested specialty organizations to examine alternative methodologies that would allow technical component services to also reflect resource-based malpractice RVUs.

Final Decision

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

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

D. Coding Issues

1. Change in Global Period for CPT Code 77427, *Radiation Treatment Management, Five Treatments*

This code was included in the November 2, 1999 physician fee schedule final rule (64 FR 59380) and was effective for services beginning January 1, 2000. In that rule, and subsequent rules, we have applied a global indicator of ''xxx'' to this code, meaning that the global concept does not apply. It was brought to our attention that this global indicator is incorrect and that the code should be assigned a 90-day global period because the RUC valuation of this service reflected a global period of 90 days which we had accepted. Therefore, we proposed to correct the global indicator for this service to reflect a global period of 90 days (090).

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

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

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

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

Result of Evaluation of Comments

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

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

As discussed in the proposed rule (69 FR 47510), section 1834(m) of the Act defines telehealth services as professional consultations, office and other outpatient visits, and office psychiatry services defined as of July 1, 2000 by CPT codes 99241 through 99275, 99201 through 99215, 90804 through 90809, and 90862. In addition, the statute requires us to establish a process for adding services to, or deleting services from, the list of telehealth services on an annual basis. In the CY 2003 final rule, we established a process for adding to or deleting services from the list of Medicare telehealth services (67 FR 79988). This process provides the public an opportunity on an ongoing basis to submit requests for adding a service. We assign any request to add a service to the list of Medicare telehealth services to one of the following categories:

• *Category 1:* Services that are similar to office and other outpatient visits, consultation, and office psychiatry services. In reviewing these requests, we look for similarities between the proposed and existing telehealth services in terms of the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.

• *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face ''hands on'' delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to a face-to-face delivery of the requested service.

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

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

• Inpatient hospital care (as represented by CPT codes 99221 through 99223 and 99231 through 99233).

• Emergency department visits (as defined by CPT codes 99281 through 99285).

• Hospital observation services (as represented by CPT codes 99217, 99218 through 99220).

• Inpatient psychotherapy (as defined by CPT codes 90816 through 90822).

• Monthly management of patients with end-stage renal disease (ESRD), (as represented by HCPCS codes G0308 through G0319).

• Speech and audiologist services (as defined by CPT code range 92541 through 92596).

• Case management (as identified by CPT codes 99361 and 99362)

• Care plan oversight services (as represented by CPT codes 99374 and 99375).

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

Moreover, we proposed to add the term ''ESRD–related visits'' to the definition of Medicare telehealth services at § 410.78 and § 414.65 as appropriate.

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

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

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

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

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

Response: We agree that the acuity for some patients may be the same in the emergency department as in a physician's office. However, we also believe that more acutely ill patients are more likely to be seen in the emergency department. Although telehealth is an acceptable alternative to face-to-face ''hands on'' patient care in certain settings, the potential for misdiagnosis and/or mismanagement, with more serious consequences, exists in high acuity environments like the emergency department when telehealth is used as a replacement for an onsite physician or practitioner. The practice of emergency medicine often requires frequent patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. We do not have evidence suggesting the use of telehealth could be a reasonable surrogate service for this type of care. In the absence of sufficient evidence that illustrates that the use of a telecommunications system produces

similar diagnoses or therapeutic interventions as would the face-to-face delivery of inpatient hospital care, emergency department visits, hospital observation services, and inpatient psychotherapy, we do not plan to add these services to the list of approved telehealth services. As discussed in the proposed rule, we believe that the current list of Medicare telehealth services is appropriate for hospital inpatients, emergency room cases, and patients designated as observation status. If guidance or advice is needed in these settings, a consultation may be requested from an appropriate source.

Comment: A telehealth association and a telehealth network requested that we clarify what consultation codes could be used for hospital inpatients, emergency room cases, and patients designated as observation status.

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

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

Response: We agree that the key components of a consultation are similar to inpatient hospital care, observation services, and emergency department visits. However, a consultation service is distinguished from the requested hospital services because it is provided by a physician or practitioner whose opinion or advice regarding evaluation and management of a specific problem is requested by another physician or appropriate source. The ongoing management of the patient's condition remains the responsibility of the practitioner who requested the consultation. As discussed in our response to another comment, a consultation may be provided as a Medicare telehealth service for hospital inpatients, emergency room cases, and patients designated in observation status.

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

End Stage Renal Disease—Monthly Management of Patients on Dialysis

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

Response: We agree with the comments.

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

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

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

Response: We believe that most physicians and practitioners will use telehealth services for providing additional visits required under the MCP as appropriate to manage their patients on dialysis. However, we would welcome specific data on best practice methods for furnishing ESRD-related services as telehealth services.

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

Response: As discussed in the proposed rule, the MCP represents a range of services provided during the month, including various physician and practitioner services, such as the establishment of a dialyzing cycle, outpatient evaluation and management of the dialysis visit(s), telephone calls, and patient management as well as clinically appropriate physician or practitioner visit(s) during the month. At least one of the visits must include a clinical examination of the vascular access site furnished face-to-face, ''hands-on'' by a physician, CNS, NP, or PA.

We considered the outpatient evaluation and management of the dialysis visits to be similar to an office

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

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

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

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

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

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

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

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

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

Medical team conferences and monthly physician supervision do not require a face-to-face encounter with the patient, and, thus, a telecommunications system may be used to accomplish them. However, Medicare payment for CPT codes 99361, 99362, and 99374 are bundled; no separate payment is made under the Medicare program for these services, and CPT code 99375 (physician supervision; 30 minutes or more) is invalid for Medicare payment purposes. We pay for monthly physician supervision as described by HCPCS codes G0181 and G0182.

Process for Adding Services to the List of Medicare Telehealth Services

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

One of the commenters believes that the decision to use a telehealth system should be up to the physician or practitioner at the distant site. The commenter argues that, if the physician or practitioner at the distant site is not comfortable in making a clinical judgment, the patient may be asked to travel to the physician's office for further examination.

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

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

Response: We believe that the current method for reviewing requests for addition already considers the criteria mentioned by the commenter. The process for adding services to the list of Medicare telehealth services provides the public an ongoing opportunity to propose services that they believe are appropriate for Medicare payment. Requestors may submit data showing that patients who receive the requested service via telecommunications system are satisfied with the service delivered and that the use of a telecommunications system does not change the diagnosis or therapeutic

interventions for the requested service. Additionally, we believe that having different categories of review allows us to add requested services that are most like the current telehealth services (for example, office visits, consultation, and office psychiatry) without subjecting these requests to a comparative analysis.

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

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

Response: The commenter's suggestion to use the term ''in-person'' to describe an encounter where the physician or practitioner and the beneficiary are physically in the same room has been noted. We will consider the commenter's suggestion as we discuss Medicare telehealth payment policy in the future.

Report to Congress

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

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

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

Result of Evaluation of Comments

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

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

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

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

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

Therefore, we proposed to value nationally the practice expense for these services using the nonphysician work pool. We proposed to crosswalk practice expense RVUs for G0238 to those for G0237 based on our belief that the practice expense for the activities involved is substantially the same for both services.

For G0239, we believe a typical group session to be 30 minutes in length and to consist of 3 patients. Therefore, for the practice expense RVUs for G0239, we proposed using the practice expense RVUs of G0237 reduced by one-third to account for the fact that the service is being provided to more than one patient simultaneously and each patient in a group can be billed for the services of G0329.

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

Comment: Commenters supported the national pricing for these 2 G–codes, G0238 and G0239. However, these organizations disagree with our RVU assignment. Specifically, most commenters disagreed with the lack of physician work RVUs and also believed that the malpractice RVU is inadequate to reflect the costs associated with the delivery of the services. These organizations contend that pulmonary rehabilitation services ''include a physician-directed individualized plan of care using multidisciplinary qualified health professionals to enhance the effective management of pulmonary diseases and resultant functional deficits.'' They believe that beneficiaries may receive pulmonary rehabilitation services at physician offices, outpatient departments of acute care hospitals, CORFs and rehabilitation clinics. The commenters noted that physicians and qualified nurse practitioners (NPs) and PAs order, supervise, and approve the plans of care for patients receiving respiratory therapy services, irrespective of the delivery setting.

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

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

basis, and we are requesting that the RUC or HCPAC consider this series of three G–codes at an upcoming meeting.

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

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

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

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

Result of Evaluation of Comments

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

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

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

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

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

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

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

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

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

Comment: Two physician specialty societies, representing radiologists and interventional radiologists, questioned the need for the proposed code, because the multiple surgical discount rule that reduces payment for a subsequent lower valued service applies, thereby taking into account any savings in physician work. If we choose to proceed with the proposal, the commenter recommended the RVUs be consistent with those determined using the current values for CPT codes 38220 and 38221 and the multiple surgical discount rule.

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

Result Of Evaluation of Comments

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

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

The Q-code for the set-up of portable x-ray equipment, Q0092, is currently paid under the physician fee schedule and is assigned an RVU of 0.33. In 2004, this produces a national payment of $12.32. This set-up code encompasses only a portion of the resources required to provide a portable x-ray service to patients. In 2003, portable x-ray suppliers received total Medicare payments of approximately $208 million. More than half of these payments (approximately $116 million) were for portable x-ray transportation (codes R0070 and R0075). The portable x-ray set-up code (Q0092) generated approximately $19 million in payments. The remainder of the Medicare payments for portable x-ray services (approximately $73 million) were for the actual x-ray services themselves.

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

Q0092 is currently priced in the nonphysician work pool. At the time we modeled this change for the proposed rule, removing this code from the nonphysician work pool had an overall negative impact on payments to portable x-ray suppliers (as a result of decreases to radiology codes that remain in the nonphysician work pool) and a negative impact on many of the codes remaining in the nonphysician work pool. An alternative to national pricing of portable x-ray set-up would be to require Medicare carriers to develop local pricing as they do currently for portable x-ray transportation. We requested comments on whether we should pursue national pricing for portable x-ray set-up outside of the nonphysician work pool or local carrier pricing for 2005, or whether we should continue to price the service in the nonphysician work pool.

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

Response: ACR requested that we delay incorporating their survey data for 1 year. Using the data for one code, as proposed by commenters, would be inconsistent with that request. We believe it is inappropriate to use the new survey data for this code but no other code. Even if we removed the set-up code from the nonphysician work pool and calculated its practice expense RVU using the ACR data, the increase in payment for the portable x-ray set-up code would be largely offset by lower payment for x-ray services. Payments for other services in the nonphysician work pool would also decline affecting other specialties, such as radiology, radiation oncology, cardiology, allergy, audiology and others. Further, the portable x-ray set-up code is yet to be refined, and we believe that the 45 minutes of staff time that is used to determine its value is likely overstated. We believe it is preferable to address refinement of the code and pricing the service outside of the nonphysician work pool together. Therefore, in 2005, we are continuing to price this service within the nonphysician work pool.

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

6. Venous Mapping for Hemodialysis

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

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

We proposed to crosswalk the RVUs for the new G-code from those of CPT code 93971 and also assigned this new G-code a global period of ''XXX,'' which means that the global concept does not apply.

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

- Commenters did not agree with restricting this code to the operating surgeon, stating that such a restriction could limit access and serve as a barrier in providing this service. They also stated that this proposed restriction is not reflective of current practice, since nonsurgeons often perform this procedure.
- Commenters did not agree with the proposed descriptor. They indicated that the proposed descriptor did not reflect the procedure as it is now performed and suggested (a) alternate wording, such as ''vascular mapping,'' ''autogenous AV fistula,'' and ''prosthetic graft,'' ''vessel mapping;'' (b) that two G-codes should be created to distinguish between a complete bilateral and unilateral or limited studies. Other commenters noted that the proposal did not distinguish between mapping by venography or ultrasound (duplex), and some commenters suggested creating an additional G-code to distinguish between these procedures.
- Commenters stated that the comparison to CPT code 93971 in the proposed rule undervalues the service. While there are differences, the closer analogue in terms of time and resources required is CPT code 93990, Duplex scans of hemodialysis access.

Response: We proposed the G-code to create the opportunity for us to analyze

the relationship between venous mapping utilization and fistula formation.

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

We believe that vessel mapping requires the assessment of the arterial and venous vessels in order to provide the information necessary for the creation of an autogenous conduit. Therefore, we are also revising payment for this code and will crosswalk it to CPT code 93990 for work, malpractice, and practice expense RVUs because these RVUs more appropriately reflect the work and resources of this new G-code. The G-code and descriptor for this service will be G0365, Vessel mapping of vessels for hemodialysis access (Services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow). This code can only be used in patients who have not had a prior hemodialysis access prosthetic graft or autogenous fistula and is limited to two times per year.

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

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

III. Provisions Related to the Medicare Modernization Act of 2003

A. Section 611—Preventive Physical Examination

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

In the August 5, 2004 proposed rule, we described a new § 410.16 (Initial preventive physical examination: conditions for and limitations on coverage) that would provide for coverage of the various IPPE services specified in the statute. As provided in the statute, this new coverage allows payment for one IPPE within the first 6 months after the effective date of the beneficiary's first Part B coverage period, but only if that coverage period begins on or after January 1, 2005. To implement the statutory provisions, we proposed definitions of the following terms:

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

In keeping with the language of section 611 of the MMA, we defined the term ''eligible beneficiary'' to mean individuals who receive their IPPEs within 6 months after the date of their first Medicare Part B coverage period, but only if their first Part B coverage period begins on or after January 1, 2005. This section also defines the term ''Initial Preventive Physical Examination'' to mean services provided by a physician or a qualified NPP consisting of: (1) A physical examination (including measurement of height, weight, blood pressure, and an electrocardiogram, but excluding clinical laboratory tests) with the goal of health promotion and disease detection; and (2) education, counseling, and referral for screening and other covered preventive benefits separately authorized under Medicare Part B.

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

- Pneumococcal, influenza, and hepatitis B vaccine and their administration;
- Screening mammography;
- Screening pap smear and screening pelvic exam services;
- Prostate cancer screening services;
- Colorectal cancer screening tests;
- Diabetes outpatient self-management training services;
- Bone mass measurements;
- Screening for glaucoma;
- Medical nutrition therapy services for individuals with diabetes or renal disease;
- Cardiovascular screening blood tests; and
- Diabetes screening tests.

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

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

2. Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument, which the physician or other qualified NPP may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process;

3. Review of the individual's functional ability and level of safety, as described in proposed § 410.16(a), (that is, at a minimum, a review of the following areas: Hearing impairment, activities of daily living, falls risk, and home safety), based on the use of an appropriate screening instrument, which the physician or other qualified NPP may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is further defined through the NCD process;

4. An examination to include measurement of the individual's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate by the physician or qualified NPP, based on the individual's comprehensive medical and social history and current clinical standards;

5. Performance and interpretation of an electrocardiogram;

6. Education, counseling, and referral, as appropriate, based on the results of the first five elements of the initial preventive physical examination; and

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

The proposed ''medical history'' definition includes the following elements:

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

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

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

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

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

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

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

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

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

Proposed payment for this code was based on the following:

- *Work RVUs:* We proposed a work value of 1.51 RVUs for G0344 (G0XX2 in proposed rule) based on our determination that this new service has equivalent resources and work intensity to those contained in CPT E/M code 99203, *new patient, office or other outpatient visit* (1.34 RVUs), and CPT code 93000 *electrocardiogram, complete* (0.17 RVUs), which is for a routine ECG with the interpretation and report.

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

- *Practice Expense RVUs:* For the practice expense component of G0344, we proposed practice expense RVUs of 1.65 in the nonfacility setting based on the practice RVUs assigned to CPT code 99203 (1.14) and CPT code 93000 (0.51). In the facility setting, we proposed practice expense RVUs of 0.54 based on the practice expense RVUs assigned to CPT code 99203 (0.48) and 93010 (0.06).

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

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

Analysis of and Response to Comments

We specifically solicited public comments on the definition of the term ''initial preventive physical examination,'' with supporting documentation. For example, we indicated that we chose not to define the term, ''appropriate screening instrument,'' for screening individuals for depression, functional ability, and level of safety, as specified in the rule, because we anticipated that the examining physician or qualified NPP may want to use the test of his or her choice, based on current clinical practice guidelines. We believe that any standardized screening test for depression, functional ability, and level of safety recognized by the American Academy of Family Physicians, the American College of Physicians-American Society of Internal Medicine, the American College of Preventive Medicine, the American Geriatrics Society, the American Psychiatric Association, or the USPSTF, or other recognized medical professional group, would be acceptable for purposes of meeting the ''appropriate screening instrument'' provision. We asked that commenters making specific recommendations on this or any related issue provide documentation from the medical literature, current clinical practice guidelines, or the USPSTF recommendations.

We received 71 public comments on the proposed rule regarding IPPE. Commenters included national and State professional associations, medical societies and medical advocacy groups, hospital associations, hospitals, managed care plans, physicians, senior advocacy groups, health care manufacturers, and others. Although a number of commenters expressed concern that the proposed rule was too prescriptive and not sufficiently targeted to prevention, a large majority of the commenters enthusiastically supported most of the coverage provisions of the proposed rule. Many of the commenters, however, suggested clarification and revision of the rule in a number of different areas, including the proposed definitions of ''initial preventive physical examination,'' ''physician,'' and ''qualified nonphysician practitioner.'' Commenters also raised questions regarding other issues, such as those relating to the need for us to educate Medicare beneficiaries and providers with respect to the new benefit, and to monitor the implementation of the new benefit. Finally, commenters offered suggestions and questions with regards to payment issues, evaluation and

management services (E/M) and coinsurance and Part B deductible issues.

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

Comment: A number of commenters expressed concern that in the proposed rule, we had gone beyond the coverage criteria that were specified in the statute for the new benefit. They noted that the additional criteria was too prescriptive and would only add confusion and an additional burden for physicians in determining what medical services are necessary for each beneficiary they evaluate. Several commenters indicated that while the proposed definition for the scope of the benefit was well-intentioned, the beneficiary's physician or other provider was the best person to determine what medical services are necessary in providing a thorough physical and to be responsive to the individual's age, gender, and particular health risks. In general, they suggested that we not interfere in a physician's judgment by attempting to standardize by Federal regulations the specific medical services to be included under the new benefit.

Response: Section 611 of the MMA defines the scope of the IPPE benefit as physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure and an electrocardiogram) with the goal of health promotion and disease detection, as well as certain education, counseling, and referral services with respect to other statutory screening and preventive services also covered under the Medicare statute. We believe that the statutory parenthetical language, (including measurement of height, weight, and blood pressure and an electrocardiogram) recognizes that other services could be contained within the IPPE benefit. We are using the authority under section 1871(a) of the Act through the rulemaking process to provide clarity as to the specific services that are to be included under the new benefit.

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

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

Comment: Three commenters indicated that this new benefit presents a unique opportunity to offer Medicare beneficiaries with a visit focused on prevention at the start of their Part B enrollment. They suggested, that we shift our focus in service element 1 of the definition of the new IPPE from a comprehensive to a more targeted priority list of modifiable risk factors, screening tests, and immunizations that are supported by the strongest evidence of effectiveness, and have been proven to improve the health of beneficiaries.

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

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

Response: We agree that information on work and travel history, and social activities may not be necessary for purposes of the new preventive physical examination and thus we are removing those elements from the minimum requirements for the ''social history'' definition. However, we believe it is important to retain three elements of the Social history definition in the final rule and they will be reflected in that document as follows:

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

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

Response: In applying our definition of ''past medical history'' we expect that physicians and qualified NPPs performing the IPPE will be able to ask about an array of medical illnesses, including prior diagnoses and treatment of conditions such as cancer, diabetes, risk factors for osteoporosis such as height loss or previous fractures, and history of coagulopathic disorders such as DVT. Therefore, we do not see a need to expand the proposed definition as the commenters have suggested, and we have decided to leave it unchanged in the final rule.

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

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

Comment: One commenter proposed that we not use the NCD process to revise the content of the IPPE in the future. The NCD process would be too slow or cumbersome to allow us to keep the content of the examination consistent with current clinical practice.

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

Comment: Several commenters requested that we clarify our intent as to whether the depression screening assessment in service element 2 will include consideration of the potential for depression as well as an assessment