



# Federal Register

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Thursday,  
July 12, 2007

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## Part II

### Department of Health and Human Services

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Centers for Medicare & Medicaid Services

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42 CFR Parts 409, 410, et al.

**Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Centers for Medicare & Medicaid Services**

42 CFR Parts 409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, 485, and 491

[CMS-1385-P]

RIN 0938-AO65

**Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions**

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would address certain provisions of the Tax Relief and Health Care Act of 2006, as well as make other proposed changes to Medicare Part B payment policy.

We are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This proposed rule also discusses refinements to resource-based practice expense (PE) relative value units (RVUs); geographic practice cost indices (GPCI) changes; malpractice RVUs; requests for additions to the list of telehealth services; several coding issues including additional codes from the 5-Year Review; payment for covered outpatient drugs and biologicals; the competitive acquisition program (CAP); clinical lab fee schedule issues; payment for renal dialysis services; performance standards for independent diagnostic testing facilities; expiration of the physician scarcity area (PSA) bonus payment authorized by section 413 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA); conforming and clarifying changes for comprehensive outpatient rehabilitation facilities (CORFs); a process for updating the drug compendia at section 1861(t)(2)(B) of the Social Security Act (the Act); physician self-referral issues; beneficiary signature for ambulance transport services; durable medical equipment (DME) update; the chiropractic services demonstration; a Medicare economic index (MEI) data

change; technical corrections; issues related to therapy services; revisions to the ambulance fee schedule; the ambulance inflation factor for CY 2008; and the proposal to eliminate the exemption for computer-generated facsimile transmissions from the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for transmitting prescription and certain prescription-related information for Part D eligible individuals.

**DATES:** To be assured consideration, except for comments on section II.M.10 of the preamble, comments must be received at one of the addresses provided below, no later than 5 p.m. on Friday, August 31, 2007.

Comments on section II.M.10 “Alternative Criteria for Satisfying Certain Exceptions”, of the preamble must be received by no later than 5 p.m. on Friday, September 7, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS-1385-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link “Submit electronic comments on CMS regulations with an open comment period.” (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular 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-1385-P, P.O. Box 8018, Baltimore, MD 21244-8018.

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

3. *By express or overnight mail.* You may send 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-1385-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-

7195 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 and changes to the comprehensive outpatient rehabilitation facility.

Rick Ensor (410) 786-5617 for issues related to practice expense methodology.

Stephanie Monroe (410) 786-6864 for issues related to the geographic practice cost index and malpractice RVUs.

Craig Dobyski (410) 786-4584 for issues related to list of telehealth services.

Ken Marsalek (410) 786-4502 for issues related to the DRA imaging cap.

Catherine Jansto (410) 786-7762 for issues related to payment for covered outpatient drugs and biologicals.

Edmund Kasaitis (410) 786-0477 for issues related to the Competitive Acquisition Program (CAP) for part B drugs.

Anita Greenberg (410) 786-4601 for issues related to the clinical laboratory fee schedule.

Henry Richter (410) 786-4562 for issues related to payments for end-stage renal disease facilities.

August Nemec (410) 786-0612 for issues related to independent diagnostic testing facilities.

Karen Rinker (410) 786-0189 for issues related to the drug compendia.

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

physician self-referral rules for diagnostic tests and beneficiary signature for ambulance transport.

Lisa Ohrin (410) 786-4565 for issues related to physician self-referral rules.

Bob Kuhl (410) 786-4597 for issues related to the DME update.

Rachel Nelson (410) 786-1175 for issues related to the quality reporting system for physician payment for CY 2008.

Mary Ciccanti (410) 786-3107 for issues related to the reporting of anemia quality indicators.

James Menas (410) 786-4507 for issues related to payment for physician pathology services.

Dorothy Shannon (410) 786-3396 for issues related to the outpatient therapy cap.

Drew Morgan (410) 786-2543 for issues related to the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Roechel Kujawa (410) 786-9111 or Anne Tayloe (410) 786-4546 for issues related to the ambulance fee schedule.

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

#### SUPPLEMENTARY INFORMATION:

*Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code [CMS-1385-P] and the specific "issue identifier" that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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 VI.

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#### Acronyms

In addition, because of the many organizations and terms to which we refer by

acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA Abdominal aortic aneurysm  
 AAP Average acquisition price  
 ACOTE Accreditation Council for Occupational Therapy Education  
 ACR American College of Radiology  
 AFROC Association of Freestanding Radiation Oncology Centers  
 AHFS—DI American Hospital Formulary Service-Drug Information  
 AHRQ Agency for Healthcare Research and Quality (HHS)  
 AIF Ambulance inflation factor  
 AMA American Medical Association  
 AMA—DE American Medical Association Drug Evaluations  
 AMP Average manufacturer price  
 AOTA American Occupational Therapy Association  
 APC Ambulatory payment classification  
 APTA American Physical Therapy Association  
 ASA American Society of Anesthesiologists  
 ASC Ambulatory surgical center  
 ASP Average sales price  
 ASTRO American Society for Therapeutic Radiology and Oncology  
 ATA American Telemedicine Association  
 AWP Average wholesale price  
 BBA Balanced Budget Act of 1997 (Pub. L. 105-33)  
 BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113)  
 BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000  
 BLS Bureau of Labor Statistics  
 BMD Bone mineral density  
 BMI Body mass index  
 BMM Bone mass measurement  
 BN Budget neutrality  
 BSA Body surface area  
 CAD Computer-aided detection  
 CAH Critical access hospital  
 CAP Competitive acquisition program  
 CBSA Core-Based Statistical Area  
 CEM Cardiac event monitoring  
 CF Conversion factor  
 CFR Code of Federal Regulations  
 CMA California Medical Association  
 CMS Centers for Medicare & Medicaid Services  
 CNS Clinical nurse specialist  
 CORF Comprehensive Outpatient Rehabilitation Facility  
 COTA Certified Occupational Therapy Assistant  
 CPEP Clinical Practice Expert Panel  
 CPI Consumer Price Index  
 CPI-U Consumer price index for urban customers  
 CPT (Physicians') Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)  
 CRT—D Cardiac resynchronization therapy defibrillator  
 CT Computed tomography  
 CTA Computed tomographic angiography  
 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  
 DO Doctor of Osteopathy  
 DRA Deficit Reduction Act of 2005 (Pub. L. 109-432)  
 E/M Evaluation and management  
 ECI Employment cost index  
 EHR Electronic health record  
 EPC [Duke] Evidence-based Practice Centers  
 EPO Erythropoietin  
 ESRD End stage renal disease  
 F&C Facts and Comparisons  
 FAW Furnish as written  
 FAX Facsimile  
 FDA Food and Drug Administration (HHS)  
 FMR Fair market rents  
 FQHC Federally qualified health center  
 FR **Federal Register**  
 GAF Geographic adjustment factor  
 GAO General Accounting Office  
 GII Global Insight, Inc.  
 GPO Group purchasing organization  
 GPCI Geographic practice cost index  
 HCPAC Health Care Professional Advisory Committee  
 HCPCS Healthcare Common Procedure Coding System  
 HCRIS Healthcare Cost Report Information System  
 HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)  
 HHA Home health agency  
 HHS [Department of] Health and Human Services  
 HIT Health information technology  
 HMO Health maintenance organization  
 HPSA Health Professional Shortage Area  
 HRSA Health Resources Services Administration (HHS)  
 HUD [Department of] Housing and Urban Development  
 ICD Implantable cardioverter-defibrillator  
 ICF Intermediate care facilities  
 IDTF Independent diagnostic testing facility  
 IFC Interim final rule with comment period  
 IOTED International Occupational Therapy Eligibility Determination  
 IPPE Initial preventive physical examination  
 IPPS Inpatient prospective payment system  
 IV Intravenous  
 IVIG Intravenous immune globulin  
 IWPUT Intra-service work per unit of time  
 JCAAI Joint Council of Allergy, Asthma, and Immunology  
 LPN Licensed practical nurse  
 MA Medicare Advantage  
 MA—PD Medicare Advantage-Prescription Drug Plans  
 MD Medical doctor  
 MedCAC Medicare Evidence Development and Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee (MCAC))  
 MedPAC Medicare Payment Advisory Commission  
 MEI Medicare Economic Index  
 MIEA-TRHCA Medicare Improvements and Extension Act of 2006 (That is, Division B of the Tax Relief and Health Care Act of 2006 (TRHCA))

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173)

MNT Medical nutrition therapy

MP Malpractice

MRA Magnetic resonance angiography

MRI Magnetic resonance imaging

MSA Metropolitan statistical area

MSP Medicare Secondary Payer

MSVP Multi-specialty visit package

NBCOT National Board for Certification in Occupational Therapy, Inc.

NCCN National Comprehensive Cancer Network

NCPDP National Council for Prescription Drug Programs

NCQDIS National Coalition of Quality Diagnostic Imaging Services

NDC National drug code

NEMC New England Medical Center

NISTA National Institute of Standards and Technology Act

NLA National limitation amount

NP Nurse practitioner

NPP Nonphysician practitioners

NQF National Quality Forum

NTTAA National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113)

OACT [CMS'] Office of the Actuary

OBRA Omnibus Budget Reconciliation Act

OIG Office of Inspector General

OMB Office of Management and Budget

OPD Outpatient Department

OPPS Outpatient prospective payment system

OPT Outpatient physical therapy

OSCAR Online Survey and Certification and Reporting

PA Physician assistant

PC Professional component

PCF Patient compensation fund

PDP Prescription Drug Plan

PE Practice Expense

PE/HR Practice expense per hour

PEAC Practice Expense Advisory Committee

PECOS Provider Enrollment, Chain, and Ownership System

PERC Practice Expense Review Committee

PET Positron emission tomography

PFS Physician Fee Schedule

PLI Professional liability insurance

PPI Producer price index

PPS Prospective payment system

PQRI Physician Quality Reporting Initiative

PRA Paperwork Reduction Act

PSA Physician scarcity areas

PT Physical therapy

PT/INR Prothrombin time, international normalized ratio

RFA Regulatory Flexibility Act

RHC Rural health clinic

RIA Regulatory impact analysis

RN Registered nurse

RT Respiratory therapist

RUC [AMA's Specialty Society] Relative (Value) Update Committee

RVU Relative value unit

SBA Small Business Administration

SGR Sustainable growth rate

SLP Speech-language pathology

SMS [AMA's] Socioeconomic Monitoring System

SNF Skilled nursing facility

STS Society of Thoracic Surgeons

TA Technology Assessment

TC Technical Component

TENS Transcutaneous electric nerve stimulator

TRHCA Tax Relief and Health Care Act of 2006 (Pub. L. 109-432)

USP-DI United States Pharmacopoeia-Drug Information

WAC Wholesale acquisition cost

WAMP Widely available market price

Wet AMD Exudative age-related macular degeneration

WFOT World Federation of Occupational Therapists

## I. Background

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

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), "Payment for Physicians' Services." The Act requires that payments under the physician fee schedule (PFS) be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges.

### A. Development of the Relative Value System

#### 1. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989, Pub. L. 101-239, and OBRA 1990, (Pub. L. 101-508). The final rule, published November 25, 1991 (56 FR 59502), set forth the fee schedule for payment for physicians' services beginning January 1, 1992. Initially, only the physician work RVUs were resource-based, and the PE and malpractice RVUs were based on average allowable charges.

The physician 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 physician work RVUs for most codes in a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes for the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the Federal government, and

obtained input from numerous physician specialty groups.

Section 1848(b)(2)(B) of the Act specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide. We established a separate conversion factor (CF) for anesthesia services, and we continue to utilize time units as a factor in determining payment for these services. As a result, there is a separate payment methodology for anesthesia services.

We establish physician work RVUs for new and revised codes based on recommendations received from the American Medical Association's (AMA) Specialty Society Relative Value Update Committee (RUC).

#### 2. Practice Expense Relative Value Units (PE RVUs)

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 Act and required us to develop resource-based PE RVUs for each physician's service beginning in 1998. We were to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), amended section 1848(c)(2)(C)(ii) of the Act to delay implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based PE RVUs to resource-based RVUs.

We established the resource-based PE RVUs for each physician's service in a final rule, published November 2, 1998 (63 FR 58814), effective for services furnished in 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, resource-based PE RVUs did not become fully effective until 2002.

This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysicians (for example, registered nurses (RNs)) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physician's service in both the office setting and out-of-office setting. We have since refined and revised these inputs based on recommendations from the RUC. The AMA's SMS data provided aggregate

specialty-specific information on hours worked and PEs.

Separate PE RVUs are established for procedures that can be performed in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department. The difference between the facility and nonfacility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of providing the service, apart from payment under the PFS. The nonfacility RVUs reflect all of the direct and indirect PEs of providing a particular service.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) directed the Secretary of Health and Human Services (the Secretary) 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 to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating PE RVUs beginning in CY 2007 and provided for a 4-year transition for the new PE RVUs under this new methodology. We will continue to evaluate this policy and proposed necessary revisions through future rulemaking.

### 3. Resource-Based Malpractice (MP) RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require us to implement resource-based malpractice (MP) RVUs for services furnished on or after 2000. The resource-based MP RVUs were implemented in the PFS final rule published November 2, 1999 (64 FR 59380). The MP RVUs were based on malpractice insurance premium data collected from commercial and physician-owned insurers from all the States, the District of Columbia, and Puerto Rico.

### 4. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less often than every 5 years. The first 5-Year Review of the physician work RVUs was effective in 1997, published on November 22, 1996 (61 FR 59489). The second 5-Year Review went into effect in 2002, published in the CY 2002 PFS final rule (66 FR 55246). The third 5-Year Review of physician work RVUs went into effect on January 1, 2007 and was published in the CY 2007 PFS final rule with comment period (71 FR 69624) (although we note that this proposed rule contains certain additional proposals relating to the third 5-Year Review).

In 1999, the AMA's RUC established the Practice Expense Advisory Committee (PEAC) for the purpose of refining the direct PE inputs. Through March 2004, the PEAC provided recommendations to CMS for over 7,600 codes (all but a few hundred of the codes currently listed in the AMA's Current Procedural Terminology (CPT) codes). As part of the CY 2007 PFS final rule with comment period (71 FR 69624), we implemented a new methodology for determining resource-based PE RVUs and are transitioning this over a 4-year period.

In the CY 2005 PFS final rule with comment period (69 FR 66236), we implemented the first 5-Year Review of the malpractice RVUs (69 FR 66263).

### 5. Adjustments to RVUs Are Budget Neutral

Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than \$20 million from what they would have been if the adjustments were not made. In accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if adjustments to RVUs cause expenditures to change by more than \$20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than \$20 million.

As explained in the CY 2007 PFS final rule with comment period (71 FR 69624), due to the increase in work RVUs resulting from the third 5-Year Review of physician work RVUs, we are applying a separate budget neutrality (BN) adjustor to the work RVUs for services furnished during 2007. This approach is consistent with the method we use to make BN adjustments to the PE RVUs to reflect the changes in these PE RVUs.

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

To calculate the payment for every physician service, the components of the fee schedule (physician work, PE, and MP RVUs) are adjusted by a geographic practice cost index (GPCI). The GPICs reflect the relative costs of physician work, PE, and malpractice insurance in an area compared to the national average costs for each component.

Payments are converted to dollar amounts through the application of a CF, which is calculated by the Office of the Actuary (OACT) and is updated annually for inflation.

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

$$\text{Payment} = [(\text{RVU work} \times \text{budget neutrality adjuster} \times \text{work GPCI}) + (\text{RVU PE} \times \text{PE GPCI}) + (\text{MP RVU} \times \text{MP GPCI})] \times \text{CF}.$$

### C. Most Recent Changes to the Fee Schedule

The CY 2007 PFS final rule with comment period (71 FR 69624) addressed certain provisions of the Deficit Reduction Act of 2005 (Pub. L. 109-432) (DRA) and made other changes to Medicare Part B payment policy to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This final rule with comment period also discussed GPCI changes; requests for additions to the list of telehealth services; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; policies related to private contracts and opt-out; policies related to bone mass measurement (BMM) services, independent diagnostic testing facilities (IDTFs), the physician self-referral prohibition; laboratory billing for the technical component (TC) of physician pathology services; the clinical laboratory fee schedule; certification of advanced practice nurses; health information technology, the health care information transparency initiative; updated the list of certain services subject to the physician self-referral prohibitions, finalized ASP reporting requirements, and codified Medicare's longstanding policy that payment of bad debts associated with services paid under a fee schedule/charge-based system is not allowable.

We also finalized the CY 2006 interim RVUs and issued interim RVUs for new and revised procedure codes for CY 2007.

In addition, the CY 2007 PFS final rule with comment period included revisions to payment policies under the fee schedule for ambulance services and announced the ambulance inflation factor (AIF) update for CY 2007.

In accordance with section 1848(d)(1)(E)(i) of the Act, we also announced that the PFS update for CY 2007 is -5.0 percent, the initial estimate for the sustainable growth rate (SGR) for CY 2007 is 1.8 percent and the CF for CY 2007 is \$35.9848. However, subsequent to publication of the CY 2007 PFS final rule with comment period, section 101(a) of Division B, Title I of the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432) (MIEA-TRHCA), which was enacted on December 22, 2006, amended section 1848(d) of the Act. [Division B of the Tax Relief and Health Care Act of 2006 is entitled Medicare and Other Health Provisions and its short title is the Medicare Improvements and Extension Act of 2006. Therefore, it is hereinafter referred to as "MIEA-TRHCA".] As a result of this statutory change the CF of \$37.8975 was maintained for CY 2007.

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

### A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

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

Practice expense (PE) is the portion of the resources used in furnishing the service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act.

Section 121 of the Social Security Amendments of 1994 (Pub. L. 103-432), enacted on October 31, 1994, required CMS to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. Until that time, PE RVUs were based on historical allowed charges. This legislation stated that the revised PE methodology must consider the staff, equipment, and supplies used in the provision of various medical and surgical services in various settings beginning in 1998. The Secretary has interpreted this to mean that Medicare payments for each service would be based on the relative PE resources typically involved with furnishing the service.

The initial implementation of resource-based PE RVUs was delayed

from January 1, 1998, until January 1, 1999, by section 4505(a) of the BBA. In addition, section 4505(b) of the BBA required that the new payment methodology be phased in over 4 years, effective for services furnished in CY 1999, and fully effective in CY 2002. The first step toward implementation of the statute was to adjust the PE values for certain services for CY 1998. Section 4505(d) of the BBA required that, in developing the resource-based PE RVUs, the Secretary must:

- Use, to the maximum extent possible, generally-accepted cost accounting principles that recognize all staff, equipment, supplies, and expenses, not solely those that can be linked to specific procedures and actual data on equipment utilization.
- Develop a refinement method to be used during the transition.
- Consider, in the course of notice and comment rulemaking, impact projections that compare new proposed payment amounts to data on actual physician PE.

In CY 1999, we began the 4-year transition to resource-based PE RVUs utilizing a "top-down" methodology whereby we allocated aggregate specialty-specific practice costs to individual procedures. The specialty-specific PEs were derived from the American Medical Association's (AMA's) Socioeconomic Monitoring Survey (SMS). In addition, under section 212 of the BBRA, we established a process extending through March 2005 to supplement the SMS data with data submitted by a specialty. The aggregate PEs for a given specialty were then allocated to the services furnished by that specialty on the basis of the direct input data (that is, the staff time, equipment, and supplies) and work RVUs assigned to each CPT code.

For CY 2007, we implemented a new methodology for calculating PE RVUs. Under this new methodology, we use the same data sources for calculating PE, but instead of using the "top-down" approach to calculate the direct PE RVUs, under which the aggregate direct and indirect costs for each specialty are allocated to each individual service, we now utilize a "bottom-up" approach to calculate the direct costs. Under the "bottom up" approach, we determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically required to provide each service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA's Relative Value Update

Committee (RUC). For a more detailed explanation of the PE methodology see the June 29, 2006 proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

### 1. Current Methodology

#### a. Data Sources for Calculating Practice Expense

The AMA's SMS survey data and supplemental survey data from the specialties of cardio-thoracic surgery, vascular surgery, physical and occupational therapy, independent laboratories, allergy/immunology, cardiology, dermatology, gastroenterology, radiology, independent diagnostic testing facilities (IDTFs), radiation oncology, and urology are used to develop the PE per hour (PE/HR) for each specialty. For those specialties for which we do not have PE/HR, the appropriate PE/HR is obtained from a crosswalk to a similar specialty.

The AMA developed the SMS survey in 1981 and discontinued it in 1999. Beginning in 2002, we incorporated the 1999 SMS survey data into our calculation of the PE RVUs, using a 5-year average of SMS survey data. (See the November 1, 2002 Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for CY 2002 final rule (66 FR 55246) (hereinafter referred to as CY 2002 PFS final rule).) The SMS PE survey data are adjusted to a common year, 2005. The SMS data provide the following six categories of PE costs:

- Clinical payroll expenses, which are payroll expenses (including fringe benefits) for nonphysician clinical personnel.
- Administrative payroll expenses, which are payroll expenses (including fringe benefits) for nonphysician personnel involved in administrative, secretarial or clerical activities.
- Office expenses, which include expenses for rent, mortgage interest, depreciation on medical buildings, utilities and telephones.
- Medical material and supply expenses, which include expenses for drugs, x-ray films, and disposable medical products.
- Medical equipment expenses, which include expenses depreciation, leases, and rent of medical equipment used in the diagnosis or treatment of patients.
- All other expenses, which include expenses for legal services, accounting, office management, professional association memberships, and any

professional expenses not previously mentioned in this section.

In accordance with section 212 of the BBRA, we established a process to supplement the SMS data for a specialty with data collected by entities and organizations other than the AMA (that is, the specialty itself). (See the Criteria for Submitting Supplemental Practice Expense Survey Data interim final rule with comment period (65 FR 25664, May 3, 2000).) Originally, the deadline to submit supplementary survey data was through August 1, 2001. In the CY 2002 PFS final rule (66 FR 55246), the deadline was extended through August 1, 2003. To ensure maximum opportunity for specialties to submit supplementary survey data, we extended the deadline to submit surveys until March 1, 2005 in the Revisions to Payment Policies Under the Physician Fee Schedule for CY 2004 final rule (November 7, 2003; 68 FR 63196) (hereinafter referred to as CY 2004 PFS final rule).

The direct cost data for individual services were originally developed by the Clinical Practice Expert Panels (CPEP). The CPEP data include the supplies, equipment, and staff times specific to each procedure. The CPEPs consisted of panels of physicians, practice administrators, and nonphysicians (for example, RNs) who were nominated by physician specialty societies and other groups. There were 15 CPEPs consisting of 180 members from more than 61 specialties and subspecialties. Approximately 50 percent of the panelists were physicians.

The CPEPs identified specific inputs involved in each physician's service provided in an office or facility setting. The inputs identified were the quantity and type of nonphysician labor, medical supplies, and medical equipment.

In 1999, the AMA's RUC established the Practice Expense Advisory Committee (PEAC). From 1999 to March 2004, the PEAC, a multi-specialty committee, reviewed the original CPEP inputs and provided us with recommendations for refining these direct PE inputs for existing CPT codes. Through its last meeting in March 2004, the PEAC provided recommendations for over 7,600 codes which we have reviewed and accepted. As a result, the current PE inputs differ markedly from those originally recommended by the CPEPs. The PEAC has now been replaced by the Practice Expense Review Committee (PERC), which acts to assist the RUC in recommending PE inputs.

#### b. Allocation of PE to Services

The aggregate level specialty-specific PEs are derived from the AMA's SMS survey and supplementary survey data. To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(i) *Direct costs.* The direct costs are determined by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically required to provide the service. The costs of these resources are calculated from the refined direct PE inputs in our PE database. These direct inputs are then scaled to the current aggregate pool of direct PE RVUs. The aggregate pool of direct PE RVUs can be derived using the following formula: (PE RVUs \* physician CF) \* (average direct percentage from SMS/(Supplemental PE/HR data)).

(ii) *Indirect costs.* The SMS and supplementary survey data are the source for the specialty-specific aggregate indirect costs used in our PE calculations. We then allocate the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the maximum of either the clinical labor costs or the physician work RVUs. For calculation of the 2008 PE RVUs, we are proposing to use the 2006 procedure-specific utilization data crosswalked to 2007 services. To arrive at the indirect PE costs:

- We apply a specialty-specific indirect percentage factor to the direct expenses to recognize the varying proportion that indirect costs represent of total costs by specialty. For a given service, the specific indirect percentage factor to apply to the direct costs for the purpose of the indirect allocation is calculated as the weighted average of the ratio of the indirect to direct costs (based on the survey data) for the specialties that furnish the service. For example, if a service is furnished by a single specialty with indirect PEs that were 75 percent of total PEs, the indirect percentage factor to apply to the direct costs for the purposes of the indirect allocation would be  $(0.75/0.25) = 3.0$ . The indirect percentage factor is then applied to the service level adjusted indirect practice expense allocators.

- We use the specialty-specific PE/HR from the SMS survey data, as well as the supplemental surveys for cardio-thoracic surgery, vascular surgery, physical and occupational therapy, independent laboratories, allergy/immunology, cardiology, dermatology, radiology, gastroenterology, IDTFs, radiation oncology and urology.

**Note:** For radiation oncology, the data represent the combined survey data from the American Society for Therapeutic Radiology and Oncology (ASTRO) and the Association of Freestanding Radiation Oncology Centers (AFROC). We incorporate this PE/HR into the calculation of indirect costs using an index which reflects the relationship between each specialty's indirect scaling factor and the overall indirect scaling factor for the entire PFS. For example, if a specialty had an indirect practice cost index of 2.00, this specialty would have an indirect scaling factor that was twice the overall average indirect scaling factor. If a specialty had an indirect practice cost index of 0.50, this specialty would have an indirect scaling factor that was half the overall average indirect scaling factor.

- When the clinical labor portion of the direct PE RVU is greater than the physician work RVU for a particular service, the indirect costs are allocated based upon the direct costs and the clinical labor costs. For example, if a service has no physician work and 1.10 direct PE RVUs, and the clinical labor portion of the direct PE RVUs is 0.65 RVUs, we would use the 1.10 direct PE RVUs and the 0.65 clinical labor portions of the direct PE RVUs to allocate the indirect PE for that service.

#### c. Facility/Nonfacility Costs

Procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, have two PE RVUs: Facility and nonfacility. The nonfacility setting includes physicians' offices, patients' homes, freestanding imaging centers, and independent pathology labs. Facility settings include hospitals, ambulatory surgical centers (ASCs), and skilled nursing facilities (SNFs). The methodology for calculating PE RVUs is the same for both, facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because the PEs for services provided in a facility setting are generally included in the payment to the facility (rather than the payment to the physician under the PFS), the PE RVUs are generally lower for services provided in the facility setting.

#### d. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components; a professional component (PC) and a technical component (TC), which may be performed independently or by different providers. When services have TC, PC, and global components that can be billed separately, the payment for the

global component equals the sum of the payment for the TC and PCs. This is a result of using a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global components, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global components, PC, and TCs for a service. (The direct PE RVUs for the TC and PCs sum to the global under the bottom-up methodology.)

#### e. Transition Period

As discussed in the CY 2007 PFS final rule with comment period (71 FR 69674), we are implementing the change in the methodology for calculating PE RVUs over a 4-year period. During this transition period, the PE RVUs will be calculated on the basis of a blend of RVUs calculated using our methodology described previously in this section (weighted by 25 percent during CY 2007, 50 percent during CY 2008, 75 percent during CY 2009, and 100 percent thereafter), and the CY 2006 PE RVUs for each existing code. PE RVUs for codes that are new during this period will be calculated using only the current PE methodology, and will be paid at the fully transitioned rate.

#### f. PE RVU Methodology

The following is a description of the PE RVU methodology.

##### (i) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific survey PE per physician hour data.

##### (ii) Calculate the Direct Cost PE RVUs

*Sum the costs of each direct input.*

*Step 1:* Sum the direct costs of the inputs for each service. The direct costs consist of the costs of the direct inputs for clinical labor, medical supplies, and medical equipment. The clinical labor cost is the sum of the cost of all the staff types associated with the service; it is the product of the time for each staff type and the wage rate for that staff type. The medical supplies cost is the sum of the supplies associated with the service; it is the product of the quantity of each supply and the cost of the supply. The medical equipment cost is the sum of the cost of the equipment associated with the service; it is the product of the number of minutes each piece of equipment is used in the service and the equipment cost per minute. The equipment cost per minute

is calculated as described at the end of this section.

*Apply a BN adjustment to the direct inputs.*

*Step 2:* Calculate the current aggregate pool of direct PE costs. To do this, multiply the current aggregate pool of total direct and indirect PE costs (that is, the current aggregate PE RVUs multiplied by the CF) by the average direct PE percentage from the SMS and supplementary specialty survey data.

*Step 3:* Calculate the aggregate pool of direct costs. To do this, for all PFS services, sum the product of the direct costs for each service from Step 1 and the utilization data for that service.

*Step 4:* Using the results of Step 2 and Step 3 calculate a direct PE BN adjustment so that the proposed aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it to the direct costs from Step 1 for each service.

*Step 5:* Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the Medicare PFS CF.

##### (iii) Create the Indirect PE RVUs

*Create indirect allocators.*

*Step 6:* Based on the SMS and supplementary specialty survey data, calculate direct and indirect PE percentages for each physician specialty.

*Step 7:* Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with a TC and PCs we are calculating the direct and indirect percentages across the global components, PCs and TCs. That is, the direct and indirect percentages for a given service (for example, echocardiogram) do not vary by the PC, TC and global component.

*Step 8:* Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVU, the clinical PE RVU and the work RVU.

For most services the indirect allocator is:

$\text{indirect percentage} * (\text{direct PE RVU} / \text{direct percentage}) + \text{work RVU}$ .

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional and technical components), then the indirect allocator is:  $\text{indirect percentage} * (\text{direct PERVU} / \text{direct percentage}) + \text{clinical PE RVU} + \text{work RVU}$ .
- If the clinical labor PE RVU exceeds the work RVU (and the service is not a

global service), then the indirect allocator is:  $\text{indirect percentage} * (\text{direct PERVU} / \text{direct percentage}) + \text{clinical PE RVU}$ .

(Note that for global services the indirect allocator is based on both the work RVU and the clinical labor PE RVU. We do this to recognize that, for the professional service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVU and the clinical labor PE RVU. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in the Table 1, the formulas were divided into two parts for each service. The first part does not vary by service and is the  $\text{indirect percentage} * (\text{direct PE RVU} / \text{direct percentage})$ . The second part is either the work RVU, clinical PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVU exceeds the work RVU (as described earlier in this step.)

*Apply a BN adjustment to the indirect allocators.*

*Step 9:* Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the physician specialty survey data. This is similar to the Step 2 calculation for the direct PE RVUs.

*Step 10:* Calculate an aggregate pool of proposed indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service. This is similar to the Step 3 calculation for the direct PE RVUs.

*Step 11:* Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8. This is similar to the Step 4 calculation for the direct PE RVUs.

*Calculate the Indirect Practice Cost Index.*

*Step 12:* Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

*Step 13:* Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service.

*Step 14:* Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors as under the current methodology.

*Step 15:* Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

*Step 16:* Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service.

**Note:** For services with TC and PCs, we calculate the indirect practice cost index across the global components, PCs and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC and global components.

*Step 17:* Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVU.

(iv) Calculate the Final PE RVUs

*Step 18:* Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17.

*Step 19:* Calculate and apply the final PE BN adjustment by comparing the results of Step 18 to the current pool of

PE RVUs. This final BN adjustment is required primarily because certain specialties are excluded from the PE RVU calculation for rate-setting purposes, but all specialties are included for purposes of calculating the final BN adjustment. (See "Specialties excluded from rate-setting calculation" below in this section.)

(v) Setup File Information

- *Specialties excluded from rate-setting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties such as midlevel practitioners paid at a percentage of the PFS, audiology, and low volume specialties from the calculation. These specialties *are* included for the purposes of calculating the BN adjustment.

- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

- *Identify professional and technical services not identified under the usual TC and 26 modifier:* Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated

global code for use in creating the indirect PE RVU. For example, the professional service code 93010 is associated with the global code 93000.

- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(vi) Equipment Cost Per Minute =

The equipment cost per minute is calculated as:

$$\frac{1}{(\text{minutes per year} * \text{usage})} * \text{price} * ((\text{interest rate} / (1 - (1 / ((1 + \text{interest rate}) * \text{life of equipment})))) + \text{maintenance})$$

Where:

*minutes per year* = maximum minutes per year if usage were continuous (that is, usage = 1); 150,000 minutes.

*usage* = equipment utilization assumption; 0.5.

*price* = price of the particular piece of equipment.

*interest rate* = 0.11.

*life of equipment* = useful life of the particular piece of equipment.

*maintenance* = factor for maintenance; 0.05.

TABLE 1.—CALCULATION OF PE RVUS UNDER PROPOSED METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est nonfacility	33533 CABG, ate- rial, single facility	71020 Chest x-ray nonfacility	71020TC Chest x-ray nonfacility	7102026 Chest x-ray nonfacility	93000 ECG, complete nonfacility	93005 ECG, tracing nonfacility	93010 ECG, report nonfacility
(1) Labor cost (Lab) ...	Step 1	AMA	.....	\$ 13.44	\$ 77.74	\$ 5.74	\$ 5.65	\$	\$ 6.12	\$ 6.12	\$
(2) Supply cost (Sup)	Step 1	AMA	.....	\$ 2.94	\$ 7.60	\$ 3.39	\$ 3.34	\$	\$ 1.19	\$ 1.19	\$
(3) Equipment cost (Eqp)	Step 1	AMA	.....	\$ 0.19	\$ 0.64	\$ 8.18	\$ 8.05	\$	\$ 0.12	\$ 0.12	\$
(4) Direct cost (Dir) ...	Step 1	.....	.....	\$ 16.37	\$ 85.34	\$ 17.31	\$ 17.54	\$	\$ 7.60	\$ 7.60	\$
(5) Direct adjustment (Dir Adj)	Steps 2-4	See footnote*	.....	0.584	0.584	0.584	0.584	0.584	0.584	0.584	0.584
(6) Adjusted labor	Steps 2-4	= Lab*Dir Adj	.....	\$ 7.85	\$ 45.40	\$ 3.35	\$ 3.30	\$	\$ 3.57	\$ 3.57	\$
(7) Adjusted supplies	Steps 2-4	= Sup*Dir Adj	.....	\$ 1.72	\$ 4.44	\$ 1.98	\$ 1.95	\$	\$ 0.70	\$ 0.70	\$
(8) Adjusted equip- ment	Steps 2-4	= Eqp*Dir Adj	.....	\$ 0.11	\$ 0.37	\$ 4.77	\$ 4.70	\$	\$ 0.07	\$ 0.07	\$
(9) Adjusted direct	Steps 2-4	.....	.....	\$9.56	\$ 49.84	\$ 10.11	\$ 10.24	\$	\$ 4.44	\$ 4.44	\$
(10) Conversion Fac- tor (CF)	Step 5	MFS	.....	\$34.1350	\$34.1350	\$34.1350	\$34.1350	\$34.1350	\$34.1350	\$34.1350	\$34.1350
(11) Adj. labor cost converted.	Step 5	= (Lab*Dir Adj)/CF	.....	0.23	1.33	0.10	0.10	.....	0.10	0.10	.....
(12) Adj. supply cost converted.	Step 5	= (Sup*Dir Adj)/CF	.....	0.05	0.13	0.06	0.06	.....	0.02	0.02	.....
(13) Adj. equip cost converted.	Step 5	= (Eqp*Dir Adj)/CF	.....	0.00	0.01	0.14	0.14	.....	0.00	0.00	.....
(14) Adj. direct cost converted.	Step 5	.....	.....	0.28	1.46	0.30	0.30	.....	0.13	0.13	.....
(15) Wrk RVU* Wrk Scaler.	Setup File	MFS	.....	0.81	29.66	0.19	.....	0.19	0.15	.....	0.15
(16) Dir_pct	Steps 6, 7	Surveys	.....	33.8%	32.6%	40.7%	40.7%	40.7%	37.7%	37.7%	37.7%
(17) Ind_pct	Steps 6, 7	Surveys	.....	66.2%	67.4%	59.4%	59.4%	59.4%	62.3%	62.3%	62.3%
(18) Ind. Alloc. formula (1st part).	Step 8	See Step 8	.....	((14)/ (16)) * (17)	((14)/ (16)) * (17)	((14)/ (16)) * (17)	((14)/ (16)) * (17)	((14)/ (16)) * (17)	((14)/ (16)) * (17)	((14)/ (16)) * (17)	((14)/ (16)) * (17)
(19) Ind. Alloc. (1st part).	Step 8	.....	.....	0.55	3.02	0.43	0.44	.....	0.21	0.21	.....
(20) Ind. Alloc. for- mulas (2nd part).	Step 8	See Step 8	.....	(15)	(15)	(15) + (11)	(11)	(15)	(15) + (11)	(11)	(15)
(21) Ind. Alloc. (2nd part).	Step 8	.....	.....	0.81	29.66	0.29	0.10	0.19	0.25	0.10	0.15
(22) Indirect Allocator (1st+2nd).	Step 8	.....	.....	1.36	32.68	0.72	0.53	0.19	0.47	0.32	0.15
(23) Indirect Adjust- ment (Ind Adj).	Steps 9-11	See footnote**	.....	0.362	0.362	0.362	0.362	0.362	0.362	0.362	0.362
(24) Adjusted Indirect Allocator.	Steps 9-11	= Ind Alloc* Ind Adj	.....	0.49	11.83	0.26	0.19	0.07	0.17	0.12	0.05
(25) Ind. Practice Cost Index (PCI).	Steps 12-16	See Steps 12-16	.....	0.966	0.941	1.060	1.060	1.060	1.237	1.237	1.237
(26) Adjusted Indirect Indirect	Step 17	= Adj. Ind Alloc*PCI	.....	0.48	11.13	0.28	0.21	0.07	0.21	0.14	0.07
(27) PE RVU	Steps 18-19	= (Adj Dir+Adj Ind) *budn.	.....	0.75	12.56	0.57	0.50	0.07	0.34	0.27	0.07

\* The direct adj = [current pe rvus \* CF \* avg dir pct] / [sum direct inputs] = [Step 2] / [Step 3].  
 \*\* The indirect adj = [current pe rvus \* avg ind pct] / [sum of ind allocators] = [Step 9] / [Step 10].

g. Discussion of Equipment Usage Percentage

We continue to receive comments regarding our use of the equipment usage assumption of 50 percent. MedPAC continues to support an unspecified higher utilization rate. Several interested parties, including the AMA RUC, have requested that we refine this usage percentage to somewhere in the range of 70 to 80 percent. Other interested parties contend that the current utilization rate is too high at 50 percent and should be refined downward to a lower usage percentage. If the equipment usage percentage is set too high, the result would be insufficient allowance at the service level for the practice costs associated with equipment. If the equipment usage percentage is set too low, the result would be an excessive allowance for the PE costs of equipment at the service level. We do not want to create disincentives for the use of equipment by arbitrarily increasing the equipment usage percentage. Conversely, we do not want to create incentives for the acquisition and potential over-utilization of equipment by arbitrarily decreasing the equipment usage percentage.

Although we acknowledge the across-the-board 50 percent usage rate we currently apply for all equipment does not capture the actual usage rates for all equipment, we do not believe that we have sufficient empirical evidence to justify an alternative proposal on this issue. We are interested in receiving comments relating to alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category-specific usage rate assumptions. We are committed to continuing our work with the physician community to examine equipment usage rate assumptions that ensure appropriate payments and encourage appropriate utilization of equipment.

Additionally, we would welcome any empirical data that would assist us in these efforts.

h. Equipment Interest Rate (Discussion)

As part of our calculation of the PE equipment costs, we take into consideration several factors, for example, the useful life of each piece of equipment and the typical interest that would be incurred in the purchase of the equipment. We updated the assigned useful life for all the equipment in our PE input database in the CY 2005 PFS final rule with comment period. However, we have used the same interest rate of 11 percent since the inception of the resource-based PE methodology in 1999. There has been much discussion regarding whether this is still the appropriate interest rate to utilize in the calculation of the equipment costs. The majority of comments on the CY 2007 PFS final rule with comment period requested an interest rate of prime plus 2 percent while a small number of commenters requested an interest rate significantly lower than prime plus 2 percent.

The current interest rate of 11 percent was assigned in 1997 based upon information provided by the Small Business Administration (SBA). This prevailing rate was based upon data regarding prevailing loan rates for small businesses from both national and regional lending associations. Although the SBA offered various interest rates, we believed that the 11 percent interest rate was most relevant for fee schedule services as this rate was based on equipment cost of over \$25,000 with a useful life of over 7 years.

We have analyzed 2007 SBA data on loans and applicable interest rates. According to the SBA, loans are based on the prime rate plus a fixed percentage based upon the amount of the loan and the usable life of the equipment purchased. The prime plus rates ranged from 9.4 percent to 13

percent. Using the same criteria as was used in 1997 (that is, equipment cost over \$25,000 with a useful life of over 7 years), the interest rates ranged from 10.1 percent to 13 percent.

Based upon our analysis of the revised SBA interest rate data, we believe 11 percent continues to be an appropriate assumption; therefore, we will retain the interest rate used in the calculation of equipment costs at 11 percent and no proposal is being made to adjust this rate.

2. PE Proposals for CY 2008

a. Radiology Practice Expense Per Hour

The American College of Radiology (ACR) presented CMS with information regarding the PE/HR that was used in the PE methodology for radiology in the CY 2007 PFS final rule with comment period. ACR suggested that we change our methodology in a way that would weight the survey data to provide an alternative method of representing large and small practices. We agreed to take their approach to our contractor, the Lewin Group, for further analysis. (We note that the Lewin Group, in its initial analysis of the ACR survey data, had also raised concerns about the representation of small high cost entities in the ACR survey data.) The Lewin Group reviewed ACR's approach and concluded that weighting the ACR survey by practice size more appropriately accounts for the small high cost entities in the final PE/HR. After reviewing both the ACR inquiry and the Lewin response, we also agree that ACR's approach more appropriately identifies the PE/HR for radiology.

For these reasons, we propose to revise the PE/HR associated with radiology using the survey data weighted by practice size. See Table 2 which identifies the PE/HR for all specialties, as well as both the current and proposed revisions to the PE/HR for radiology.

TABLE 2.—2008 SMS AND SUPPLEMENTAL SURVEY PE/HR INFLATED TO 2005 BASED UPON MEI GROWTH FACTORS  
[Includes proposed revision to radiology PE/HR]

Specialty	Clinical labor	Clerical payroll	Office expense	Supplies expense	Equipment expense	Other expense	Total expense
ALL PHYSICIANS .....	15.68	19.64	24.74	9.44	4.08	14.66	88.23
ALLERGY/IMMUNOLOGY .....	65.88	56.33	65.88	22.49	6.26	31.08	247.93
ANESTHESIOLOGY .....	14.41	4.72	7.52	0.51	0.51	7.52	35.19
CARDIAC/THORACIC SURGERY .....	24.38	22.50	21.50	2.63	2.63	17.75	91.38
CARDIOVASCULAR DISEASE .....	59.55	53.33	52.67	25.90	18.58	25.02	235.05
DERMATOLOGY .....	40.63	51.45	78.82	15.38	11.03	28.22	225.55
DIAGNOSTIC TESTING FACILITY .....	111.57	155.49	121.18	54.96	302.47	189.48	935.15
EMERGENCY MEDICINE .....	4.21	19.64	2.55	0.89	0.13	14.66	42.08
GASTROENTEROLOGY .....	30.16	39.56	48.41	8.20	5.90	13.33	145.55
GENERAL INTERNAL MEDICINE .....	11.99	18.36	22.82	7.78	2.68	8.42	72.04
GENERAL SURGERY .....	9.18	19.89	21.42	4.34	2.55	12.62	70.00
GENERAL/FAMILY PRACTICE .....	18.87	19.00	22.57	10.07	3.95	11.22	85.68

TABLE 2.—2008 SMS AND SUPPLEMENTAL SURVEY PE/HR INFLATED TO 2005 BASED UPON MEI GROWTH FACTORS—  
Continued

[Includes proposed revision to radiology PE/HR]

Specialty	Clinical labor	Clerical payroll	Office expense	Supplies expense	Equipment expense	Other expense	Total expense
INDEPENDENT LAB .....	84.79	25.76	19.09	19.84	8.83	21.60	179.93
NEUROLOGICAL SURGERY .....	10.97	32.64	36.47	2.30	1.79	20.53	104.68
NEUROLOGY .....	10.58	29.33	24.86	6.63	5.61	11.86	88.87
OBSTETRICS/GYNECOLOGY .....	20.91	23.97	31.49	9.31	4.08	14.28	104.04
ONCOLOGY .....	68.06	44.22	43.86	21.53	9.48	53.76	240.91
OPHTHALMOLOGY .....	32.00	32.90	43.48	13.77	10.71	26.90	159.76
ORTHOPEDIC SURGERY .....	21.17	36.34	37.87	13.13	4.85	24.35	137.70
OTHER SPECIALTY .....	11.86	16.58	24.61	6.25	2.42	11.22	72.93
OTOLARYNGOLOGY .....	21.93	32.13	41.95	9.56	7.14	21.93	134.64
PATHOLOGY .....	14.28	17.85	15.17	8.67	2.55	26.78	85.30
PEDIATRICS .....	15.81	16.45	24.10	13.01	2.17	10.97	82.49
PHYS MED/RHEUMATOLOGY .....	19.00	30.22	39.14	8.29	7.91	15.56	120.11
PHYSICAL THERAPY .....	13.25	8.21	17.11	3.05	2.70	9.85	54.15
PLASTIC SURGERY .....	19.13	25.88	41.31	23.59	7.27	32.13	149.30
PSYCHIATRY .....	2.17	6.50	13.39	0.51	0.51	9.18	32.26
PULMONARY DISEASE .....	8.80	15.81	20.02	3.32	2.04	8.80	58.78
RADIATION ONCOLOGY .....	68.82	32.38	48.83	6.38	39.33	32.85	228.59
RADIOLOGY .....	29.07	37.81	23.93	11.26	27.32	44.80	174.18
*RADIOLOGY .....	*32.62	*42.29	*28.95	*14.15	*39.62	*47.24	*204.86
UROLOGICAL SURGERY .....	27.90	42.33	53.79	14.43	11.25	23.45	173.14
VASCULAR SURGERY .....	25.79	23.04	22.56	4.06	5.78	14.50	95.73

\*Proposed revision to radiology PE/HR.

## b. RUC Recommendations for Direct PE Inputs and Other PE Input Issues

The following discussions are proposals concerning direct PE inputs.

## (i) RUC Recommendations

In 2004, the AMA's Relative Value Update Committee (RUC) established a new committee, the Practice Expense Review Committee (PERC), to assist the RUC in recommending direct PE inputs (clinical staff, supplies, and equipment) for new and existing CPT codes.

The PERC reviewed the PE inputs for nearly 300 existing codes at its meetings held in February 2007 and April 2007. (A list of these reviewed codes can be found in Addendum C.)

In the CY 2007 PFS final rule with comment period, we addressed several issues concerning direct PE inputs and encouraged specialty societies to pursue further review of these inputs through the RUC/PERC process. The following discussions summarize the PERC recommendations regarding these issues:

## Cardiac Catheterization Procedures

At the recent April RUC meeting, the PERC considered recommendations for the family of CPT codes 93501 through 93556 for cardiac catheterization. The American College of Cardiology, in cooperation with the Society of Cardiac Angiography and Interventions and the Cardiovascular Outpatient Center Alliance, developed PE inputs for the nonfacility setting for 13 of the 28 CPT

codes in this family. The PERC considered the proposed new or updated PE input recommendations for 13 cardiac catheterization CPT codes.

- Of these 13 codes, 8 were not previously valued in the nonfacility setting (as recommended at the January 2002 PEAC meeting), including CPT codes 93539, 93540, 93542, 93543, 93544, 93545, 93555, and 93556.

- The recommended revised PE inputs for the other 5 codes (last valued in the nonfacility setting at the January 2004 PEAC meeting), included CPT codes: 93501, 93505, 93508, 93510, and 93526.

We are proposing to accept the PERC recommendations for the direct PE inputs for the nonfacility setting for the CPT codes 93501, 93505, 93508, 93510, 93526, 93539, 93540, 93542, 93543, 93544, 93545, 93555, and 93556.

The specialty societies recommended that the remaining 15 codes in the cardiac catheterization family remain carrier-priced, or be assigned an "NA" for the practice expense in the office setting. It was noted that these codes were rarely if ever performed in the office setting and the specialties recommended no direct PE inputs. Assigning these CPT codes as "NA" for PE in the nonfacility setting would conform to PFS policy for other services without PE inputs. Therefore, we are proposing that the PE for the following CPT codes will not be valued or applicable to the nonfacility setting: 93503, 93511, 93514, 93524, 93527,

93528, 93529, 93530, 93531, 93532, 93533, 93561, 93562, 93571, and 93572.

## Obstetric/Gynecologic PE

The PERC recommended changes to the content and the price of the pack, pelvic exam (supply code SA051) valued at \$0.95. We agreed with the recommendation to add a non-sterile sheet (drape) 40 in by 60 in (supply code SB006) priced at \$0.222 to the pelvic exam pack resulting in the new price of \$1.172. This change affected 236 CPT codes for obstetric/gynecologic services containing the pelvic exam pack. In addition, we accepted the PERC recommendations to standardize the equipment used in post-operative visits to include both a power table and fiberoptic light in the PE database for 70 obstetric/gynecologic codes.

## Dual Energy X-Ray Absorptiometry (DEXA)

The PERC considered revisions to the direct PE inputs for CPT codes 77080, 77081, and 77082 that contained recommendations established by 5 distinct specialty organizations. These recommended inputs were revised to comply with established PERC standards, such as removing some labor inputs for CPT code 77082 because this procedure is always performed with CPT code 77081 and all revisions were agreed to by the presenting specialty. The resulting recommended inputs more appropriately reflect the resources used to furnish these services and were

adopted by the PERC. We agree with the PERC and have made adjustments to the PE database.

#### Computer-Aided Detection (CAD) Codes

The specialty society for radiological services reviewed the direct inputs for CPT codes 77051 and 77052 and recommended that no changes to the PE inputs were needed. The PERC concurred with this decision and we are in agreement.

In addition to the above, the PERC also addressed the following issues:

#### Nuclear Medicine Services

The specialty society representing nuclear medicine recommended that the direct PE inputs for 2 CPT codes contained CPEP inputs and needed to be updated to agree with 2004 PEAC-approved inputs. The PERC recommended that the PE database reflect these changes and we agreed. However, we discovered that there were 4 other related codes which also had CPEP inputs. We made the appropriate adjustments to substitute the PEAC inputs for the CPEP for CPT codes 78600, 78607, 78206, 78647, 78803 and 78807. The specialty society also noted that 7 CPT codes required the revision of x-ray related supplies, including the number of x-ray films, developer solution, and film jackets. The PERC forwarded these recommendations and we have made the appropriate changes to the PE database for the following CPT codes: 78600, 78601, 78605, 78606, 78607, 78610 and 78615.

#### Transcatheter Placement of Stent(s)

At the request of the specialty societies representing radiology and interventional radiology, the PERC agreed to consider the direct PE inputs for the nonfacility setting for 3 CPT codes, 37205, 37206, and 75960, for transcatheter placement of stent(s). These PE inputs to value these procedures in the nonfacility setting were approved by the PERC. Among the supplies, a "vascular stent deployment system", valued at \$1,645, was noted by the society as the typical stent used for CPT codes 37205 and 37206 requiring 2 such stents for the placement in the initial vessel and 1 stent for each subsequent vessel, respectively. We reviewed a published clinical research study which was forwarded by the specialty society that indicated that 1 stent was typical for the procedure of CPT code 37205. Absent any further verification from the specialty, we have, therefore, included only 1 stent in this code.

The complete PERC recommendations and the revised PE database can be

found on the CMS Web site at <http://cms.hhs.gov/PhysicianFeeSched/PFSFRN/> (under CMS-1385-P).

#### (ii) Remote Cardiac Event Monitoring

As discussed in the CY 2007 PFS final rule with comment period, direct PE inputs for remote cardiac event monitoring (CEM) services represented by CPT codes 93012, 93225, 93226, 93231, 93232, 93270, 93271, 93733, and 93736 were revised on an interim basis to reflect the unique circumstances surrounding the provision of these services. Unlike most physicians' services, CEM services are furnished primarily by specialized IDTFs that, due to the nature of CEM services, must operate on a 24/7 basis. The specialty group which represents suppliers that furnish CEM services believes that these services require additional direct PE inputs, such as telephone line charges associated with trans-telephonic transmissions and fees associated with providing Web access for storage and transmission of clinical information to the patient's physician. We continue to work with the specialty group regarding the specific direct PE inputs, as well as the components for the indirect PE allocation, based on surveys conducted by the specialty group. To clarify and further the results of our discussions with and information provided by the specialty group, we are asking for comments on the appropriateness of the above mentioned direct PE inputs. In addition, we invite comments on any additional direct inputs and components of the indirect PE allocations which would be appropriate for these services, along with supporting documentation to justify their inclusion for PE purposes.

#### (iii) Prothrombin Time, International Normalized Ratio (PT/INR)

In the CEM discussion in the CY 2007 PFS final rule with comment period, we included some minor PE revisions on an interim basis for PT/INR services represented by Healthcare Common Procedure Coding System (HCPCS) codes, G0248, *Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: Demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing* and G0249, *Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes*

*provision of materials for use in the home and reporting pwi of [prothrombin] test results to physician; per four tests.* Based on comments received and subsequent discussions with entities that furnish these PT/INR services, we have adjusted the time in use for the home monitor equipment for G0249 to 1440 minutes to reflect that the monitor is dedicated for use 24 hours a day and unavailable for others receiving this service. We invite comments on this change, as well as comments on any additional direct inputs which would be appropriate to this service, along with supporting documentation to justify their inclusion for PE purposes.

#### (iv) Positron Emission Tomography (PET) Codes Clinical Labor Time

We received comments from the specialty society representing nuclear medicine regarding a discrepancy in the clinical labor time for CPT codes 78811, 78812, and 78813 which are PET codes for tumor imaging. The specialty noted that the clinical labor time indicated in the PE database differs by 7 minutes from the time that was previously recommended by the PERC in April 2004. We agree with the specialty society that the PE database labor inputs for these 3 PET codes are incorrect and have made the appropriate adjustments to the PE database.

#### (v) Nuclear Medicine PE Supplies

The specialty society representing nuclear medicine commented that the PE database currently contains supply items that are inappropriate for certain procedures and provided the information to make the corrections. For respiratory imaging procedures represented by CPT codes 78587, 78591, 78593, 78594, 78630, 78660, 78291, and 78195, the specialty society noted specific IV supply items to be deleted from procedures where they are not required. For a thyroid imaging procedure represented by CPT code 78020, x-ray supply items were recommended for deletion. In addition, the society recommended adding supply items for respiratory imaging procedures, including nose clips, masks, and nebulizer kits, as appropriate, to CPT codes 78584, 78585, 78591, 78593, 78594, 78586, 78587, 78588, and 78596. For a kidney function study represented by CPT code 78725, injection supply items were noted as missing and the specialty society requested that these be added. We propose to accept these direct PE input corrections and have revised our PE database accordingly.

(vi) Arthroscopic Procedure Nonfacility Inputs

During the CY 2007 PFS rulemaking, we noted that at the October 2006 RUC meeting a proposal was discussed for the establishment of nonfacility direct PE inputs for the arthroscopic procedures represented by CPT codes 29805, 29830, 29840, 29870, and 29900. At this October 2006 RUC meeting, the orthopedic specialty society declined to consider the valuation of these procedures for the nonfacility setting, based on the belief that these procedures are not safely performed in the physician office. The RUC agreed at that time and no recommendations were issued. Subsequent to the publication of the CY 2007 PFS final rule with comment period in which we supported the RUC recommendation, we again discussed this valuation with physicians who are currently performing these procedures in the office. Because we believe that the RUC process is the most appropriate to provide these nonfacility inputs, we again referred the physicians providing these services to work with the RUC-represented orthopedic specialty society; however, they informed us that the orthopedic specialty society had recently again declined to support them in bringing the direct PE inputs to the April 2007 RUC/PERC meeting for consideration in valuing these services in the nonfacility setting.

Absent specific recommendations from the RUC and because some physicians are already performing these

procedures in the office setting, we are seeking comments regarding the appropriateness of establishing nonfacility PE inputs for these arthroscopic procedures when they are provided in the office setting. We also invite comments as to the specific direct PE inputs, following the RUC-approved standardized format, that are typical in the provision of each above listed arthroscopic procedure furnished in the physician's office. We will review these comments to determine whether or not it is appropriate to propose on an interim basis PE inputs for these codes in the nonfacility setting in our final rule.

(vii) Nonfacility Inputs for CPT Code 52327

We received comments from the society representing urologists requesting that we remove all of the nonfacility PE inputs for CPT code 52327, *Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material*. The specialty society reasoned that the nonfacility PE value is inappropriate since the procedure is never performed in the physician office; it is specific to the pediatric population; and, as such, is always performed with general anesthesia. We agree with the specialty society that this procedure is incorrectly valued for the nonfacility setting and propose to accept their recommendation to remove the nonfacility direct PE inputs and have revised the PE database accordingly.

(viii) Maxillofacial Prosthetics

We have been working with the society representing maxillofacial prosthetists since 2005 to establish nonfacility direct inputs for the prosthetic services represented by the CPT code series, 21076 through 21087. The current PE database reflects the labor, supplies, and equipment needed to perform each procedure. However, we do not have pricing information and documentation for many supply items. The society provided information and documentation for equipment prices, but because specific time-in-use information was not provided, we developed time-in-use in 2006 for each equipment item in each procedure. For CY 2007, these equipment inputs were utilized under the new PE methodology to calculate the nonfacility PE RVUs for these procedures. We have asked the specialty society to provide the supply pricing information with appropriate documentation and also to provide accurate time-in-use data for each equipment item for each procedure. However, we have not received the requested information to date. Consequently, unless such information is provided, the PE database will continue to have no prices associated with these supplies. For each equipment item, we propose to cap each time-in-use to 25 minutes until specific information is received regarding the actual time-in-use. See Table 3 for the outstanding supply prices and Table 4 for the equipment time-in-use information that is needed.

TABLE 3.—MAXILLOFACIAL PROSTHESIS SUPPLIES NEEDING PRICING AND SUPPORTING DOCUMENTATION

Supply item	CPT codes associated with supply item
paper, articulating .....	21076, 21079, 21081, 21082, 21083, 21084, and 21085.
paste, registration .....	21076, 21079, 21080, 21081, 21082, 21083, 21084, and 21085.
alloy framework, laboratory processing .....	21076, 21079, 21080, 21081, 21082, 21083, 21084, and 21085.
paste, pressure indicator .....	21076, 21079, 21080, 21081, 21082, 21083, 21084, and 21085.
wax, boxing .....	21076, 21077, 21079, 21081, 21082, 21083, 21084, 21085, 21086 and 21087.
triad tray material .....	21076, 21082, 21083 and 21084.
wire, orthodontic .....	21076, 21079, 21080 and 21085.
reline material, Trusoft .....	21076, 21079, 21081, 21082, 21083 and 21084.
silicone .....	21077, 21086 and 21087.
adhesive, facial .....	21077, 21080, 21086 and 21087.
wax, baseplate .....	21077, 21079, 21080, 21081, 21082, 21083, 21084, 21085, 21086 and 21087.
impression material, final .....	21077, 21080, 21081, 21082, 21083, 21084, 21085, 21086 and 21087.
monoplex eye .....	21077, 21080, 21086 and 21087.
syringe, impression .....	21077, 21079, 21080, 21081, 21082, 21083, 21084, 21085, 21086 and 21087.
acrylic, dental .....	21077, 21079, 21080, 21081, 21082, 21082, 21083, 21084, 21085, 21086 and 21087.
polyurethane sheets (quantity as rolls) .....	21077, 21080, 21086, and 21087.
burs, dental .....	21079, 21080, 21081, 21082, 21083, 21084 and 21085.
teeth set .....	21079, 21080 and 21081.
Greenstick compound .....	21080, 21081, 21082, 21083, 21084 and 21085.

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TABLE 4.—EQUIPMENT TIME-IN-USE INFORMATION NEEDED FOR MAXILLOFACIAL PROSTHESIS CODES PROCEDURES NOTED BELOW WITH AN X

Equipment Item	CPT code 21076	CPT code 21077	CPT code 21079	CPT code 21080	CPT code 21081	CPT code 21082	CPT code 21083	CPT code 21084	CPT code 21085	CPT code 21086	CPT code 21087
Articulator .....	X	X	X	X	X	X	X	X	X	X	X
Chair, dental w-upholstery .....	X	X	X	X	X	X	X	X	X	X	X
Compressor air .....	X	X	X	X	X	X	X	X	X	X	X
Convection oven .....	X	X	X	X	X	X	X	X	X	X	X
Delivery unit .....	X	X	X	X	X	X	X	X	X	X	X
Dust collecting unit .....	X	X	X	X	X	X	X	X	X	X	X
Grinding and polishing unit .....	X	X	X	X	X	X	X	X	X	X	X
Handpiece, highspeed .....	X	X	X	X	X	X	X	X	X	X	X
Handpiece, laboratory .....	X	X	X	X	X	X	X	X	X	X	X
Handpiece, slow speed .....	X	X	X	X	X	X	X	X	X	X	X
Light curing unit .....	X	X	X	X	X	X	X	X	X	X	X
Light, dental, ceiling mount .....	X	X	X	X	X	X	X	X	X	X	X
Steamer, portable .....	X	X	X	X	X	X	X	X	X	X	X
Triad unit .....	X	X	X	X	X	X	X	X	X	X	X
Trimmer, dental model .....	X	X	X	X	X	X	X	X	X	X	X
Ultrasonic cleaning unit .....	X	X	X	X	X	X	X	X	X	X	X
Washout and curing unit .....	X	X	X	X	X	X	X	X	X	X	X
Whip mix combo unit .....	X	X	X	X	X	X	X	X	X	X	X
Whip mixer .....	X	X	X	X	X	X	X	X	X	X	X

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(ix) Requests for Increases in Supply Prices

We received a request from the specialty society for obstetrics and gynecology to increase the price of supply item (kit, hysteroscopic tubal implant for sterilization) for CPT code 58565, *Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants* for this code which was created for CY 2005. This hysteroscopic implant kit is priced at \$980 and the specialty is now requesting a price of \$1,245, providing an invoice for documentation. The specialty reports that the higher price is attributed to a manufacturer change in design and materials and submitted the manufacturer's documents supporting these changes that were used to secure FDA approval. Therefore, we are proposing to accept the new price of \$1,245 for the hysteroscopic implant kit

due to the changes made in the modified model and have made this change in the PE database.

(x) Supply and Equipment Items Needing Specialty Input

We have identified certain supply and equipment items for which we were unable to verify the pricing information (see Table 5: Supply Items Needing Specialty Input for Pricing and Table 6: Equipment Items Needing Specialty Input for Pricing). During the CY 2007 PFS rulemaking, we listed both supply and equipment items for which pricing documentation was needed from the medical specialty societies and, for many of these items, we received sufficient documentation containing specific descriptors and pricing information in the form of catalog listings, vendor Web pages, invoices, and manufacturer quotes. We have accepted the documented prices for many of these items and these prices are

reflected in the PE RVUs in Addendum B of this proposed rule. The items listed in Tables 6 and 7 represent the outstanding items from CY 2007 and new items added from the current RUC recommendations. We are requesting that commenters provide pricing information on items in these tables along with acceptable documentation, as noted in the footnote to each table, to support recommended prices. We are also requesting that specialty societies review the direct inputs in PE database for the procedures performed by the specialty to verify that all supplies and equipment contain prices. For supplies or equipment that have previously appeared on this list, and for which we received no or inadequate documentation, we are proposing to delete these items unless we receive adequate information to support current pricing by the conclusion of the comment period for this proposed rule.

TABLE 5.—SUPPLY ITEMS NEEDING SPECIALTY INPUT FOR PRICING

Code	2006/7 Description	Unit	Unit price	Primary associated specialties	Associated *CPT code(s)	Prior item status on table	Commenter response and CMS action	2008 Item status refer to note(s)
SC088 ..	Fistula set, dialysis, 17g.	item ....	.....	Dermatology .....	36522 .....	Yes .....	Specialty to submit asap.	B
SD140 ..	pressure bag .....	item ....	8.925	Cardiology .....	93501, 93508, 93510, 93526.	Yes .....	Specialty to submit asap.	B, C
SL119 ..	Sealant spray .....	oz .....	.....	Radiation Oncology ...	77333 .....	Yes .....	Specialty to submit price per ounce, asap.	B

TABLE 5.—SUPPLY ITEMS NEEDING SPECIALTY INPUT FOR PRICING—Continued

Code	2006/7 Description	Unit	Unit price	Primary associated specialties	Associated *CPT code(s)	Prior item status on table	Commenter response and CMS action	2008 Item status refer to note(s)
SD213 ..	tubing, sterile, non-vented (fluid administration).	item ....	1.99	Cardiology .....	93501, 93508, 93510, 93526.	Yes .....	Specialty to submit asap.	B, C
	Stent, vascular, deployment system.	Kit .....	\$1,645	Radiology, Interventional Radiology.	37205, 37206	No .....	Specialty to submit price, kit contents and typical quantity needed.	A

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**Note:** Acceptable documentation includes—Detailed description (including system components), source, and current pricing information, such as copies of catalog pages, hard copy from specific web pages, invoices, and quotes (letter format okay) from manufacturer, vendors or distributors. Unacceptable documentation includes—phone numbers and addresses of manufacturer, vendors or distributors, website links without pricing information, etc.

**Note A:** Additional documentation required. Need detailed description (including kit contents), source, and current pricing information (including pricing per specified unit of measure in database). Accept copies of catalog pages or hard copy from specific Web pages. Phone numbers or addresses of manufacturer, vendors or distributors are not acceptable documentation.

**Note B:** No/Insufficient received. Retained price in database on an interim basis. Forward acceptable documentation promptly.

**Note C:** Submitted price accepted.

**Note D:** Deleted per comment or CMS.

**Note E:** 2007/8 price retained on an interim basis. Forward acceptable documentation promptly.

TABLE 6.—EQUIPMENT ITEMS NEEDING SPECIALTY INPUT FOR PRICING AND PROPOSED DELETIONS

Code	2006/7 Description	2007/8 Price	Primary specialties associated with item	* CPT code(s) associated with item	Prior status on table	Commenter response and CMS Action	2008 Item status refer to note(s)
EQ269 ..	Ambulatory blood pressure monitor.	3000	Cardiology .....	93784, 93786, 93788.	Yes .....	Interim price of \$1920 basis maintained, pending receipt of documentation.	A, E
	Camera mount-floor .....	2300	Dermatology .....	96904 ...	Yes .....	Specialty to submit, asap	A, E
	Cross slide attachment ....	500	Dermatology .....	96904 ...	Yes .....	Specialty to submit, asap	A, E
	Dermal imaging software	4500	Dermatology .....	96904 ...	Yes .....	Specialty to submit, asap	A, E
	Dermoscopy attachments	650	Dermatology .....	96904 ...	Yes .....	Specialty to submit, asap	A, E
EQ008 ..	ECG signal averaging system.	8,250	Cardiology, IM .....	93278 ...	Yes .....	Interim price of \$17,900 basis maintained, pending receipt of documentation.	A, E
	Lens, macro, 35–70mm ...	.....	Dermatology .....	96904 ...	Yes .....	Specialty to submit, asap	A, E
ED039 ...	plasma pheresis machine w/UV light source.	37,900	Radiology, Dermatology ..	36481, G0341.	Yes .....	Specialty to submit, asap	A, E
	Psychology Testing Equipment.	.....	Psychology .....	96101, 96102.	No .....	Specialty to submit, asap	A, E
ER070 ...	Portal imaging system (w/ PC work station and software).	377,319	Radiation oncology .....	77421 ...	Yes .....	Specialty to submit, asap	A, E
	Strobe, 400watts (Studio)(2).	1500	Dermatology .....	96904 ...	Yes .....	Specialty to submit, asap	A, E

\* CPT codes and descriptions only are copyright 2007 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

**Note:** Acceptable documentation includes—Detailed description (including system components), source, and current pricing information, such as copies of catalog pages, hard copy from specific web pages, invoices, and quotes (letter format okay) from manufacturer, vendors or distributors. Unacceptable documentation includes—phone numbers and addresses of manufacturer, vendors or distributors, website links without pricing information, etc.

**Note A:** Additional documentation required. Need detailed description (including kit contents), source, and current pricing information (including pricing per specified unit of measure in database). Accept copies of catalog pages or hard copy from specific Web pages. Phone numbers or addresses of manufacturer, vendors or distributors are not acceptable documentation.

**Note B:** No/Insufficient received. Retained price in database on an interim basis. Forward acceptable documentation promptly.

**Note C:** Submitted price accepted.

**Note D:** Deleted per comment or CMS.

**Note E:** 2007/8 price, where specified, retained on an interim basis. Forward acceptable documentation promptly.

*B. Geographic Practice Cost Indices (GPCIs)*

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

caption “GEOGRAPHIC PRACTICE COST INDICES (GPCIs)” at the beginning of your comments.]

We are required by section 1848(e)(1)(A) and (C) of the Act to develop separate Geographic Practice Cost Indices (GPCIs) to measure

resource cost differences among localities; and, to review and, if necessary, adjust the GPCIs at least every 3 years. We have completed the review of GPCIs for CY 2008 and are proposing new GPCIs. These proposed GPCIs are published in Addendum E. We note that the physician work GPCIs listed in Addendum E do not reflect the 1.000 floor that was in place during 2006 and 2007. This floor expires as of January 1, 2008 in accordance with section 102 of the MIEA-TRHCA.

In developing a GPCI, section 1848(e)(1)(A)(i) and (ii) of the Act require that the PE and malpractice (MP) GPCIs reflect the full relative cost difference while section 1848(e)(1)(A)(iii) of the Act requires that the physician work GPCIs reflect only one-quarter of the relative cost differences. Section 1848(e)(1)(C) of the Act also specifies that if more than 1 year has elapsed since the last GPCI revision, we must phase in the adjustment over 2 years, applying only one-half of any adjustment in each year. All GPCIs are developed through a comparison to a national average for each component, and the RVUs for different services uniformly weight each component.

#### 1. GPCI Update

A detailed description of the methodology used to develop and update the GPCIs can be found in the CY 2004 PFS proposed rule (68 FR 49039, August 15, 2003). There are three components of the GPCIs (physician work, PE, and MP) and each relies on its own data source.

##### a. Physician Work

The physician work GPCI is developed using the median hourly earnings from the 2000 Census of workers in six professional specialty occupation categories which we use as a proxy for physician wages and calculate to reflect one-quarter of the relative cost differences. Physician wages are not included in the occupation categories because Medicare payments are a key determinant of physicians' earnings; therefore, including physician wages in the physician work GPCI would, in effect, make the index dependent upon Medicare payments. The physician work GPCI was updated in 2001, 2003, and 2005 using data from the 2000 Census; the proposed CY 2008 physician work GPCI is also based on the 2000 Census data. Because all updates since 2001 have relied on the 2000 Census data, the changes observed in the physician work GPCI in the update years are due to minor changes

in utilization and budget neutrality factors; for 2008, Addendum E shows that there have been small changes in the physician work GPCI. Section 102 of the MIEA-TRHCA required application of a 1.000 floor on the work GPCI in payment localities where the work GPCI was less than 1.000. This provision expires on December 31, 2006. The 2008 proposed physician work GPCI reflects the removal of this floor.

##### b. Practice Expense

The PE GPCI is developed from three data sources:

(i) *Employee Wages*: We use 2000 Census median hourly earnings of four occupation categories. The physician work GPCI was updated in 2001, 2003, and 2005 using data from the 2000 Census.

(ii) *Office Rents*: We use residential apartment rental data produced annually by the Department of Housing and Urban Development (HUD) as a proxy for physician office rents. In 2001, 2003, and 2005, we used rents in the HUD 40th percentile. In 2008, we have calculated the GPCI using rents in the 50th percentile for the physician office rent proxy. We are proposing to use the 50th percentile because although HUD generally allows payment for subsidized housing up to the 40th percentile, in some areas it allows payment up to the 50th percentile. We made this change to reflect the trend toward higher rents across the country.

Fair Market Rents (FMRs) are gross rent estimates including rent and utilities. HUD calculates the FMRs annually using: (1) Decennial Census data; (2) American Housing Surveys conducted by the Census Bureau for HUD to enable HUD to develop revisions between Census years; and (3) random-digit dial surveys to enable HUD to develop gross rent change factors. The American Housing Surveys cover 11 areas annually, rotating among the 44 largest metropolitan areas. The random-digit dial component surveys 60 FMR areas annually.

The FMR is set as a percentile point in the distribution of rents for standard housing occupied by people who moved within the previous 15 months. The current FMR definition is the 40th percentile rent (the amount below which 40 percent of units are rented). Each year, the 50th percentile rent is also calculated by HUD and available through the HUDUSER Web site.

In 2000, HUD changed its FMR policy to increase access to housing for families receiving Section 8 rent subsidy vouchers (65 FR 58870). To do so, HUD increased FMRs from the 40th percentile to the 50th percentile in areas

where subsidized families were highly concentrated in certain census tracts, given evidence that affordable housing was not well-distributed. Only metropolitan areas with more than 100 census tracts are considered for possible increase to the 50th percentile rent. FMRs can be moved from 40th to 50th percentile or back from 50th to 40th percentile.

In the case of the office rent index for the PE GPCI, FMRs have been used to capture geographic differences in rental costs, in the absence of a consistent commercial rent index that covers all metropolitan and nonmetropolitan areas in the U.S. It has been used as a measure of the "average rent" in a market. However, since 2000, the FMRs have been a mixture of the 40th percentile and 50th percentile rents. FMR areas move between the two cutoffs. For example, in California, 9 counties had FMRs set at the 50th percentile in 2004. In 2007, only 2 of these 9 counties were still at the 50th percentile level for the FMR, out of 4 total counties at the 50th percentile level.

As described above in this section (and as detailed in 65 FR 58870), the criteria for setting the FMR at the 40th or 50th percentile are based on concentrations of subsidized households. There is no reason to assume that commercial rents would follow the same patterns.

Therefore, we believe the 50th percentile, or median, rents calculated by HUD will be a more consistent, fair measure of geographic differences for the purpose of proxying for commercial rents.

Rent data produce the most significant changes because they are based on annual changes in HUD rents and are therefore more volatile than the wage (Census) data. While commenters have suggested that we explore sources of commercial rental data for use in the GPCI, we do not believe there is a national data source better than the HUD data.

(iii) *Equipment and Supplies*: We assume that items such as medical equipment and supplies have a national market and that input prices do not vary among geographic areas. As mentioned in previous updates, some price differences may exist, but we believe these differences are more likely to be based on volume discounts rather than on geographic market differences. Equipment and supplies are factored into the GPCIs with a component index of 1.000.

##### c. Malpractice

The MP GPCI is calculated based on insurer rate filings of premium data for

a \$1 million to \$3 million mature "claims made" policy along with premium or surcharge data for mandatory patient compensation funds (PCFs). The MP GPCI is the most volatile of the GPCIs. This GPCI was updated in 2001 and 2003 as scheduled with the physician work and PE GPCIs; but, there was an unscheduled update of the MP GPCI in 2004 (68 FR 49043) to reflect increases in MP premiums nationwide. The 2008 MP update reflects the most recent premium data available. The physician work and PE GPCIs are being updated at the same time.

The periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in our PFS proposed rule the year before they would take effect in order to provide an opportunity for public comment and further revisions in response to comments prior to implementation. As mentioned above, these proposed GPCIs are shown in Addendum D.

## 2. Payment Localities

### a. Background

The Medicare statute requires that PFS payments be adjusted for certain differences in the relative costs among areas. The statute requires an adjustment which reflects differences among areas for the relative costs of the mix of goods and services comprising PEs (other than MP expenses) compared to the national average. The statute also requires adjustment for the relative costs of MP expenses among areas compared to the national average. Finally, the statute requires adjustment for one-quarter of the difference between the relative value of physicians' work effort among areas and the national average of such work effort.

The physician work component represents 52.466 percent of the national average fee schedule payment amount. Thus, the statutory requirement for geographic adjustment of only one-quarter of the differences in the physician work component means that, on average, only 13.117 percentage points of physician work are geographically adjusted, and, on average 39.349 percentage points of the physician work component are not adjusted and represent a national fee schedule amount.

In addition, the PE component represents 43.669 percent of the national average fee schedule payment amount. PEs are comprised of nonphysician employee compensation, office expenses (including rent), medical equipment, drugs and supplies,

and other expenses. As explained above in this section, we do not make a geographic adjustment relating to medical equipment, drugs, and supplies because there is a national marker for these items. Thus, only the categories of nonphysician employee compensation and rents are geographically adjusted. These categories represent, on average, 30.862 percentage points of the total PE, and 12.807 percentage points of PEs are not geographically adjusted.

In total, more than half (52.156 percent) of the average PFS amount is a national payment that is the same in all areas of the country; that is, 52.156 percent of the average fee is not geographically adjusted.

There are two additional points about the geographic indices that are important to note. First, as described above in this section, the data used to measure cost differences among localities are proxies for physician work, employee compensation and office rents. That is, wage data for various categories of employees are used to proxy the actual wages of physician employees. Second, the data used for such proxies are based on actual Census data only for a limited number of counties. The geographic adjustment factors (GAFs) for more than 90 percent of counties are developed using proxies based on larger geographic areas (for example, data for all rural areas in a State are combined and used to proxy the values for each rural county in a State). This aggregation is necessary for areas where county level data are not available. Thus, the underlying data are proxies for actual costs, and the resulting GPCIs do not measure perfectly the cost differences among localities.

Currently, there are 89 Medicare physician payment localities to which GPCIs are applied. The payment locality structure under the PFS was established in 1996 and took effect January 1, 1997. The development of this structure is described in detail in both the CY 1997 PFS proposed (61 FR 34615) and final rules (61 FR 59494). Before adoption of the current structure, there were 210 separate payment localities under the PFS. The 1997 payment locality revision was based and built upon the prior locality structure. The 22 then-existing statewide localities remained statewide localities. Localities were established in the remaining 28 States by comparing the area cost differences of the localities within these States. We ranked the existing localities within these remaining 28 States by costs in descending order. The GAF of the highest cost locality within a State was compared to the weighted average GAF

of lower price localities. If the difference between these GAFs exceeded 5 percent, the highest locality remained a distinct locality. If the GAFs associated with all the localities in a State did not vary by at least 5 percent, the State became a statewide locality. If the highest-priced locality remained a distinct locality, the process was repeated for the second highest price locality and so on until the variation among remaining localities fell below the 5 percent threshold. This ensured that the statewide or residual State locality has relatively homogenous resource costs. Subsequent to this process, 3 additional States with multiple localities were converted to statewide localities. Currently, there are 89 separate payment localities of which 34 are statewide. Recognizing that the GPCIs are necessarily proxies, this revision to the locality structure accomplished our major goals of appropriately paying for services furnished to Medicare beneficiaries, and simplifying payment areas.

### b. Revision of Payment Localities

Over time, changing demographics and local economic conditions may lead to increased variations in practice costs within payment locality boundaries. We are concerned about the potential impact of these variations and have been studying this issue and potential alternatives for a number of years. However, because changes to the GPCIs must be applied in a budget neutral manner (and under the current locality system, BN results in aggregate payments within each State remaining the same), there are significant redistributive effects to any change. Therefore, we are also concerned about the potential impact of locality revisions.

For the past several years, we have been involved in discussions with California physicians and their representatives about recent shifts in relative demographics and economic conditions among a number of counties within the current California payment locality structure. The California Medical Association (CMA) suggested that we use our demonstration authority to adopt an alternative locality configuration and avoid certain redistributive effects, but such an approach was not feasible (as discussed in the CY 2005 PFS final rule with comment period (70 FR 70151)). In the CY 2006 PFS proposed rule (70 FR 45784), we proposed to remove two counties from the "Rest of California" payment locality and create a new payment locality for each county. These two counties were the ones with the

largest difference between the county and locality GAFs. However, there was much more opposition than support for this proposal, in large part because of its negative effect on payments for the counties that would have remained in the “Rest of California” locality. For example, the CMA commented on this proposal stating, “a nationwide legislative solution that would provide additional funding \* \* \* is the only solution we are supporting at this time.” We did not finalize the proposal and described our reasons in the CY 2006 PFS final rule with comment period (70 FR 70151).

As indicated previously, we recognize that changing demographics and local economic conditions may lead to increased variations in practice costs within payment locality boundaries. We are concerned about the potential impact of these variations. But, we are also concerned about the redistributive effects of locality changes since changes must be applied in a budget neutral manner (and under the current locality system, BN results in aggregate

payments within each State remaining the same). In considering potential changes in payment localities, we believe it is important to evaluate both the potential impact of intralocality practice cost variations and the redistributive impacts. Therefore, we have identified and are soliciting comments on three possible locality reconfigurations, each of which strikes a different balance between intralocality variations and redistributive impacts. We are considering adopting one of these approaches for California in the final rule. Because of the importance of striking an appropriate balance with any such locality revisions, we want to proceed cautiously and evaluate the impacts in California before considering applying the policy more broadly in the future. We also seek comments about other potential approaches to locality revisions and about using a transition to phase-in changes in a new locality structure blending new and revised payments. We note that a transition could be complicated to administer, particularly with a concurrent 2-year

phase in of the new GPCI data. The three options are described as follows:

*Option 1:* Using the existing locality structure, apply a rule whereby if a county GAF is more than 5 percent greater than GAF for the locality in which the county resides it would be removed from the current locality. A separate locality would be established for each county that is removed. Based on the new fully phased-in GPCI data (that is, for CY 2009), application of this approach in California would remove three counties (Santa Cruz, Monterey, and Sonoma) from the Rest of California payment locality and Marin county from the Marin/Napa/Solano payment locality and create separate payment localities for each of these counties.

This approach focuses on counties for which there is the biggest difference between the county GAF and the locality GAF. Since we are considering applying this approach initially in California, Table 7 shows the impact for each of the counties and the Rest of California payment and Marin/Napa/Solano payment localities.

TABLE 7.—OPTION 1—APPLY 5 PERCENT THRESHOLD TO REMOVE COUNTIES FROM THEIR CURRENT PAYMENT LOCALITIES, CALIFORNIA IMPACT

Locality name	County name	New CY 2009 GAF, no locality change	New CY 2009 GAF, with locality change	Percent change, due to locality change
Santa Cruz .....	Santa Cruz .....	1.017	1.100	7.59%
Monterey .....	Monterey .....	1.017	1.080	5.83%
Sonoma .....	Sonoma .....	1.017	1.076	5.51%
Marin .....	Marin .....	1.112	1.173	5.19%
Napa/Solano .....	Solano .....	1.112	1.066	-4.33%
Napa/Solano .....	Napa .....	1.112	1.066	-4.33%
Rest of California .....	.....	1.017	1.012	-0.49%

This proposal is similar to the policy we previously proposed in the CY 2006 PFS proposed rule (70 FR 45784) (but, as discussed above in this section, we did not adopt in the final rule) to address the counties with GAFs that are most different from their current locality designation. At that time, we only considered the two counties with the greatest difference between the county and locality GAF—Santa Cruz and Sonoma. Given the new GAF data, we are again considering this approach to address locality issues, but we would make adjustments to any county in California in which the county GAF exceeds the locality GAF by more than 5 percent. Table 7 shows the impacts using fully phased-in CY 2009 GPCIs that would apply using the new GPCI data discussed in this proposed rule. The table compares the changes that would occur in CY 2009 under the

current locality structure with those that would occur under option 1. The table shows that compared to the fully phased-in CY 2009 GAFs that would occur under the current locality structure, under this option, the GAFs for Santa Cruz, Monterey and Sonoma would increase by 7.59 percent, 5.83 percent, and 5.51 percent respectively, and the GAF for the Rest of California locality would decrease by 0.49 percent. The GAF for Marin would increase by 5.19 percent while the GAF for Napa/Solano would decrease by 4.33 percent. The GAFs for all other California localities would not change.

*Option 2:* This approach is similar to option 1, but the new localities would be structured differently. We would use the same 5 percent threshold methodology but instead of creating four new localities in which each county becomes its own new locality, the three

counties that are removed from the Rest of California locality would become one new locality. Marin County would still be removed from the Marin/Napa/Solano locality to become its own locality. Application of this approach would remove three counties (Santa Cruz, Sonoma, and Monterey) from the Rest of California payment locality, and Marin County from the existing Marin/Napa/Solano payment locality. This approach groups together counties from the Rest of California locality that have the greatest difference between the county and locality GAF. These three counties have similar cost structures and grouping them together into one new locality is consistent with our goal of homogeneous resource costs within a locality. In addition, it creates fewer localities which is administratively simpler for both the Medicare program

and for physicians who might practice in multiple localities.

Again, since we are considering applying this approach initially in California, Table 8 shows the impact, using fully phased-in CY 2009 GPCIs, for each of the new localities and for the

localities that would remain. The table shows that compared to the fully phased-in CY 2009 GAFs that would occur under the current locality structure, under this option, the GAFs for the new Santa Cruz/Sonoma/Monterey locality would increase by 6.3

percent, and the GAF for the Marin County locality would increase by 5.19 percent. The GAFs would decrease by 0.49 percent for the Rest of California locality and by 4.33 percent for the Napa/Solano locality.

TABLE 8.—OPTION 2—APPLY FIVE PERCENT THRESHOLD TO REMOVE COUNTIES FROM THEIR CURRENT PAYMENT LOCALITIES, CALIFORNIA IMPACT, CREATE TWO NEW LOCALITIES

Locality name	County name	CY 2009 county GAF	CY 2009 GAF, no locality change	CY 2009 GAF, with locality change	Percent change, CY 2009 GAF, with locality change
Marin .....	Marin .....	1.173	1.112	1.173	5.19
Napa/Solano .....	Napa .....	1.080	1.112	1.066	-4.33
Napa/Solano .....	Solano .....	1.053	1.112	1.066	-4.33
Santa Cruz/Monterey/Sonoma .....	Santa Cruz .....	1.100	1.017	1.082	6.03
Santa Cruz/Monterey/Sonoma .....	Sonoma .....	1.076	1.017	1.082	6.03
Santa Cruz/Monterey/Sonoma .....	Monterey .....	1.080	1.017	1.082	6.03
Rest of California .....	.....	1.017	1.017	1.012	-0.049

*Option 3:* Apply a methodology similar to that used in the 1997 locality revisions, but applied at the county level rather than the “existing locality” level. That is, we sorted the counties by descending GAFs and compared the highest county to the second highest. If the difference is less than 5 percent, the counties were included in the same locality. The third highest is then compared to the highest county GAF. This iterative process continues until a county has a GAF difference that is more than 5 percent. When this occurs, that county becomes the highest county in a new payment locality and the process is repeated for all counties in the State. This methodology is also described in the CY 2006 PFS final rule with comment period (70 FR 70151). This approach would group counties within a State into localities based on similarity of GAFs even if the counties were not geographically contiguous.

This is a numerical organization of payment localities based on costs which will reduce the number of payment localities in California from 9 to 6 localities and will create a structure where areas with similar costs will be grouped together. This option alleviates the greatest variations in cost between counties in California. This proposal is unique in that the new localities are not contiguous. Currently, all localities encompass adjacent geographic areas. However, Table 9 shows that for most of the counties in California, geographic relationships are maintained within payment groups.

While this option groups counties with similar costs together, it does not address the issue of a county or locality that has costs very different from those of an adjoining county or locality. Under this option, it will still be possible for neighboring counties or localities to have significantly different cost structures and the associated

problems such as incentives to relocate across county lines would still exist.

This option is the most administratively burdensome option for CMS to implement because of the significant systems changes and provider education that would be required to reconfigure the California localities in this manner. It will also place a greater burden on practicing physicians who are more likely to experience a change in his or her practice’s locality. We are seeking comments on the extent of the administrative burden.

Since we are considering applying this approach initially in California, Table 9 shows the impact, using fully phased-in CY 2009 GPCIs, for each of the California counties. Table 9 shows that this approach would result in 6 total California payment localities. The changes would have a variety of impacts depending upon the counties involved. The changes are illustrated in Table 9.

TABLE 9.—OPTION 3—REVISION OF PAYMENT LOCALITIES

County	Current Medicare locality	Current county GAF	Proposed Medicare locality	Proposed locality GAF	Current locality GAF	Percent difference
San Mateo .....	San Mateo, CA .....	1.204	1	1.197	1.204	-0.6
San Francisco .....	San Francisco, CA .....	1.201	1	1.197	1.201	-0.3
Marin .....	Marin/Napa/Solano, CA .....	1.170	1	1.197	1.112	7.6
Santa Clara .....	Santa Clara, CA .....	1.148	2	1.119	1.148	-2.5
Contra Costa .....	Oakland/Berkeley, CA .....	1.134	2	1.119	1.131	-1.0
Alameda .....	Oakland/Berkeley, CA .....	1.129	2	1.119	1.131	-1.0
Orange .....	Anaheim/Santa Ana, CA .....	1.128	2	1.119	1.128	-0.8
Ventura .....	Ventura, CA .....	1.121	2	1.119	1.121	-0.2
Los Angeles .....	Los Angeles, CA .....	1.112	2	1.119	1.112	0.6
Santa Cruz .....	Rest of California .....	1.098	3	1.061	1.012	4.9
Napa .....	Marin/Napa/Solano, CA .....	1.077	3	1.061	1.112	-4.6
Monterey .....	Rest of California .....	1.077	3	1.061	1.012	4.9
Sonoma .....	Rest of California .....	1.074	3	1.061	1.012	4.9
San Diego .....	Rest of California .....	1.053	3	1.061	1.012	4.9

TABLE 9.—OPTION 3—REVISION OF PAYMENT LOCALITIES—Continued

County	Current Medicare locality	Current county GAF	Proposed Medicare locality	Proposed locality GAF	Current locality GAF	Percent difference
Santa Barbara	Rest of California	1.053	3	1.061	1.012	4.9
Solano	Marin/Napa/Solano, CA	1.051	3	1.061	1.112	-4.6
Sacramento	Rest of California	1.047	4	1.023	1.012	1.2
El Dorado	Rest of California	1.033	4	1.023	1.012	1.2
San Bernardino	Rest of California	1.023	4	1.023	1.012	1.2
Placer	Rest of California	1.021	4	1.023	1.012	1.2
Riverside	Rest of California	1.017	4	1.023	1.012	1.2
San Luis Obispo	Rest of California	1.015	4	1.023	1.012	1.2
San Joaquin	Rest of California	1.006	4	1.023	1.012	1.2
Yolo	Rest of California	0.995	5	0.962	1.012	-4.9
Stanislaus	Rest of California	0.979	5	0.962	1.012	-4.9
Mono	Rest of California	0.977	5	0.962	1.012	-4.9
Nevada	Rest of California	0.975	5	0.962	1.012	-4.9
Kern	Rest of California	0.973	5	0.962	1.012	-4.9
San Benito	Rest of California	0.971	5	0.962	1.012	-4.9
Sierra	Rest of California	0.967	5	0.962	1.012	-4.9
Amador	Rest of California	0.967	5	0.962	1.012	-4.9
Fresno	Rest of California	0.963	5	0.962	1.012	-4.9
Mendocino	Rest of California	0.960	5	0.962	1.012	-4.9
Madera	Rest of California	0.960	5	0.962	1.012	-4.9
Tuolumne	Rest of California	0.959	5	0.962	1.012	-4.9
Alpine	Rest of California	0.957	5	0.962	1.012	-4.9
Mariposa	Rest of California	0.956	5	0.962	1.012	-4.9
Tulare	Rest of California	0.950	5	0.962	1.012	-4.9
Butte	Rest of California	0.950	5	0.962	1.012	-4.9
Merced	Rest of California	0.949	5	0.962	1.012	-4.9
Calaveras	Rest of California	0.949	5	0.962	1.012	-4.9
Humboldt	Rest of California	0.947	5	0.962	1.012	-4.9
Lake	Rest of California	0.947	5	0.962	1.012	-4.9
Imperial	Rest of California	0.945	5	0.962	1.012	-4.9
Plumas	Rest of California	0.945	6	0.938	1.012	-7.3
Lassen	Rest of California	0.944	6	0.938	1.012	-7.3
Sutter	Rest of California	0.942	6	0.938	1.012	-7.3
Yuba	Rest of California	0.942	6	0.938	1.012	-7.3
Colusa	Rest of California	0.940	6	0.938	1.012	-7.3
Del Norte	Rest of California	0.940	6	0.938	1.012	-7.3
Modoc	Rest of California	0.938	6	0.938	1.012	-7.3
Shasta	Rest of California	0.937	6	0.938	1.012	-7.3
Kings	Rest of California	0.935	6	0.938	1.012	-7.3
Inyo	Rest of California	0.935	6	0.938	1.012	-7.3
Siskiyou	Rest of California	0.934	6	0.938	1.012	-7.3
Trinity	Rest of California	0.933	6	0.938	1.012	-7.3
Tehama	Rest of California	0.932	6	0.938	1.012	-7.3
Glenn	Rest of California	0.930	6	0.938	1.012	-7.3

We are soliciting comments on these options, as well as other approaches to refining localities both from the perspective of implementing one of these approaches in California in CY 2008, and also from the perspective of their applicability more broadly.

*C. Malpractice (MP) RVUs (TC/PC Issue)*

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

In the CY 1992 PFS final rule (56 FR 59527), we described in detail how malpractice (MP) RVUs are calculated for CPT codes and, when professional liability insurance (PLI) is not available, how we crosswalk or assign RVU values to codes. Following the initial calculation of resource-based MP RVUs,

the MP RVU are then subject to review by CMS at 5-year intervals. Reviewing the MP RVUs every 5 years ensures that MP RVU values reflect any marketplace changes in the physician community’s ability to acquire PLI. Alternatively, there are some technical services which have assigned MP RVU values that have never been part of the review process. Consequently, the MP RVU values assigned to these technical services have not been revised since their initial assignment. The reason these services have never been reviewed is directly related to a lack of suitable data on the cost of PLI for technical staff or imaging centers.

In response to our review of the MP RVUs of services, the RUC’s PLI Workgroup brought to our attention the fact that there are approximately 600

services that have a technical component MP RVU that is greater than the professional component MP RVU. The RUC has asked CMS to change the technical component MP RVU values, stating that, as physicians have to pay the larger PLI premiums, there should be higher RVUs associated with the professional portions of these services. In the RUC’s comments to CMS, the RUC made two alternative suggestions:

1. CMS should “flip” the MP RVUs associated with each of the component parts, so the technical component MP RVUs are assigned the value of the professional component RVUs, and the professional component are assigned the MP RVUs of the technical component MP RVUs; or
2. CMS should make the RVUs of the technical component MP RVUs equal to

the MP RVUs of the professional component.

We are not accepting the first suggestion. The professional portion of the MP RVUs have undergone review and are derived from actual data, and are an integral part of our resource-based methodology. We do not believe, in the absence of evidence, that our data or conclusions for the professional MP RVUs are inaccurate. It would not be consistent with our resource-based fee schedule methodology to make changes in the professional RVUs that are not supported by actual data.

Because no data have been offered to demonstrate that the malpractice costs for the technical portion of these services are the same as for the professional portion of these services, we also do not believe it would be appropriate to accept the second suggestion at this time. To ensure that any changes we make to any MP RVUs are resource-based, we need more information from the affected community. Specifically, we would like to better understand how, and if, technicians employed by facilities purchase PLI or how their professional liability is insured. In addition, we are soliciting comments on what types of PLI are carried by facilities that perform technical services.

We appreciate the RUC's recommendation and are interested in addressing their concerns. Ideally, we would like to develop a resource-based methodology for the technical portion of the MP RVUs. However, at this time we do not have data that would support such a change. Therefore, we are soliciting comments on how we could obtain the necessary data to create resource-based RVUs for these services.

#### *D. Medicare Telehealth Services*

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

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

Section 1834(m)(4)(F) of the Act defines telehealth services as professional consultations, office visits, and office psychiatry services, and any additional service specified by the Secretary. In addition, the statute required us to establish a process for adding services to or deleting services from the list of telehealth services on an annual basis.

In the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of

Medicare telehealth services. This process provides the public an ongoing opportunity to submit requests for adding services. We assign any request to make additions 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 for 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.

Since establishing the process, we have added the following to the list of Medicare telehealth services: Psychiatric diagnostic interview examination; ESRD services with two to three visits per month and four or more visits per month (although we require at least one visit a month, in person "hands on", by a physician, CNS, NP, or PA to examine the vascular access site); and individual medical nutrition therapy.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2006 are considered for the CY 2008 proposed rule. For more information on submitting a request for an addition to the list of Medicare telehealth services, visit our Web site at [www.cms.hhs.gov/telehealth/](http://www.cms.hhs.gov/telehealth/).

##### 2. Submitted Requests for Addition to the List of Telehealth Services

We received the following requests for additional approved services in CY 2006: (1) Subsequent hospital care; (2) neurobehavioral status exam; and (3)

neuropsychological testing. The following is a discussion of the requests submitted in CY 2006.

##### a. Subsequent Hospital Care

The American Telemedicine Association (ATA) submitted a request to add subsequent hospital care (as represented by HCPCS codes 99231 through 99233). The ATA mentioned that the AMA CPT panel deleted the codes for follow-up inpatient consultation (as described by HCPCS codes 99261 through 99263) and that the codes for subsequent hospital care are used instead of the deleted codes. The requestor described two scenarios in which subsequent hospital care services could be furnished as a telehealth service. The first scenario would involve a specialty physician who furnishes an inpatient consultation as a telehealth service and follows the specific problem (for which the consultation was requested) with subsequent hospital care (inpatient visits). The second scenario involves an attending or admitting physician who furnishes initial hospital care in-person (not as telehealth) and provides subsequent hospital care as a telehealth service. The requestor explained that the ability to provide health care services when the practitioner is not onsite is critical to the survival of many rural and critical access hospitals (CAHs). The requestor believes that subsequent hospital care should be considered a category 1 service because it is similar to an inpatient consultation (which is currently on the list of telehealth services) and that an inpatient consultation is a more complex service than subsequent hospital care.

Additionally, an individual practitioner explained that the complete diagnostic and therapeutic plan cannot be established for an infectious disease patient in a single consultation and noted that follow-up inpatient consultations were previously allowed as telehealth services. The practitioner believes that telehealth is appropriate for allowing the physician or practitioner at the distant site to be a "primary care giver" (in the inpatient hospital setting); however, stated that supporting data is needed.

##### CMS Review

As mentioned by the requestors, the AMA deleted follow-up inpatient consultation (as described by CPT codes 99261 through 99263). Effective January 1, 2006, these CPT codes no longer exist and were removed from the PFS. As such, a conforming change was made to remove these codes from the list of Medicare telehealth services. CPT

instructs physicians and practitioners to use subsequent hospital care instead of the deleted codes. However, subsequent hospital care describes a broader set of services than the deleted codes (follow-up inpatient consultation).

In the CY 2005 PFS proposed rule (69 FR 47511), we discussed a previous request to add subsequent hospital care to the list of Medicare telehealth services. Given the potential acuity of the patient (patients tend to be more acutely ill in the hospital setting), we concluded that subsequent hospital care was not similar to existing telehealth services (for example, an office visit, office psychology, or consultation). Therefore, we indicated that we considered subsequent hospital care as a category 2 service. We were not able to approve subsequent hospital care for telehealth because no comparative analyses were submitted indicating that the use of a telecommunications system is an adequate substitute for subsequent hospital care furnished in-person (which is a requirement for category 2 services).

Given the potential acuity level of the patient in the hospital setting, we continue to believe that many services furnished within the scope of the subsequent hospital service codes are not similar to current telehealth services. We continue to have concerns about using a telecommunications system as a substitute for the on-going (in person) evaluation and management (E/M) of a hospital inpatient. Therefore, we propose to not add subsequent hospital care as described by HCPCS codes 99231 through 99233 to the list of Medicare telehealth services.

We recognize that in deleting the codes for follow-up inpatient consultation services, CPT instructs physicians to use the codes for subsequent hospital care instead of those for follow-up inpatient consultation. Therefore, we are considering the possibility of approving subsequent hospital care with specific limitations; for example, approving subsequent hospital care for telehealth only when the codes are used for follow-up inpatient consultation (and not for inpatient visits). As such, we are requesting specific comments as to what conditions (or requirements) we could apply to subsequent hospital care, so that subsequent hospital care reflects a follow-up inpatient consultation.

#### b. Neurobehavioral Status Exam and Neuropsychological Testing

The ATA also submitted a request to add neurobehavioral status exam (as described by HCPCS code 96116) and neuropsychological testing (HCPCS

codes 96118 through 96120) to the list of Medicare telehealth services. The requestor explained that these services are provided during testing of the cognitive function of the central nervous system (CNS). The requestor believes that the HCPCS codes currently approved for telehealth are not appropriate for reporting neurobehavioral status exam and neuropsychological testing, and that these services are category 1 services.

The requestor also explained that the neurobehavioral status exam and neuropsychological testing are provided to patients located in a physician's or practitioner's office, CAH, rural health clinic (RHC), or Federally qualified health center (FQHC), and that physicians and clinical psychologists are typically the practitioners who furnish these services.

#### CMS Review

##### Neurobehavioral Status Exam

The neurobehavioral status exam is furnished by a physician or psychologist and includes an initial assessment and evaluation of mental status for a psychiatric patient. In this regard, we believe the neurobehavioral status exam is similar to psychiatric diagnostic interview examination (which is currently approved as a Medicare telehealth service). Therefore, we propose to add neurobehavioral status exam as represented by HCPCS code 96116 to the list of Medicare telehealth services.

We would revise § 410.78 and § 414.65 to include neurobehavioral status exam as a Medicare telehealth service.

##### Neuropsychological Testing

We believe that neuropsychological testing services are category 2 services because, as explained further below in this section, the roles of and interaction among the physician or practitioner at the distant site and beneficiary at the originating site are not similar to existing telehealth services (for example, office visits, consultation, and office psychiatry). We currently do not include the administration of other CNS tests on the list of telehealth services.

Neuropsychological testing is typically used to predict the presence and possible causes of brain damage using a complex battery of tests such as the Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales, and Wisconsin Card Sorting Test. These are a unique series of test instruments that are not similar to other services on the list of telehealth services. For example, neuropsychological testing evaluates a

broad range of brain and nervous system functioning such as attention span and memory; visual, auditory, and tactual input; verbal communication; spatial perception; the ability to analyze information, form mental concepts, and make judgments. The comprehensive evaluation and assessment of brain and nervous system functioning is typically not a component of the services currently on the list of telehealth services. Moreover, neuropsychological testing requires administration by a trained professional and involves a unique interactive dynamic between the physician, practitioner (or technician) who administers the test and the patient. For example, to assess tactual performance the patient may be blindfolded for portions of the test; to assess sensory perception, the practitioner who administers the test touches the patient's fingers, assigning a number to each finger. In some cases a significant amount of time is necessary to complete a neuropsychological test battery (for example, the Halstead-Reitan Neuropsychological Battery could take up to 5 or 6 hours to complete).

Because we consider neuropsychological testing to be a category 2 service, we need to evaluate whether this is a service for which telehealth can be an adequate substitute for a face-to-face encounter. The requestor did not provide any comparative analyses illustrating that the use of a telecommunications system is an adequate substitute for the in-person administration of neuropsychological testing. Instead, the requestor submitted various summaries of studies and case reports addressing clinical consultation, psychotherapy, enrollment and consent of psychiatric research participants, health promotion, and health education. One comparison study between psychiatric services furnished in person and via an interactive audio and video telecommunications system was submitted. However, the study focused on the use of telehealth to furnish consultation and short-term psychotherapy (which are currently approved as Medicare telehealth services). Therefore, the information submitted was not sufficient to enable us to determine whether the use of a telecommunications system would affect the diagnosis or treatment plan as compared to a face-to-face delivery of neuropsychological testing services.

In furnishing neuropsychological testing as a telehealth service, it is our understanding that the physician, or practitioner (or technician) who actually administers the test would be located at

the distant site (rather than being present with the patient, in-person, and “hands on” at the originating site). We are interested in receiving comments as to whether the administration of a neuropsychological test battery could be furnished adequately when the practitioner is not physically present with the patient.

Moreover, we understand that in some cases neuropsychological testing is administered by a computer with a qualified health care professional present (for example, in administering the Wisconsin Card Sorting Test). However, we question whether a patient with suspected or confirmed brain damage or mental illness such as schizophrenia can be taught how to use a computer by a practitioner who is in a remote location. Therefore, we also request specific comments as to whether a neuropsychological patient could be instructed and supervised adequately to take the Wisconsin Card Sorting Test through an interactive audio and video telecommunications system. We are proposing not to add neuropsychological testing (as described by HCPCS codes 96118 through and 99620) to the list of Medicare telehealth services.

#### *E. Specific Coding Issues related to PFS*

##### 1. Reduction in the Technical Component (TC) for Imaging Services Under the PFS to the Outpatient Department (OPD) Payment Amount

[If you choose to comment on issues in this section, please include the caption “CODING—REDUCTION IN TC FOR IMAGING SERVICES” at the beginning of your comments.]

As we noted in the CY 2007 PFS final rule with comment period (71 FR 69624), effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848 of the Act to require that, for imaging services, if—“(i) The technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule \* \* \* without application of the geographic adjustment factor \* \* \*, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services \* \* \* for such service for such year, determined without regard to geographic adjustment \* \* \*, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such technical component for such year.”

As required by the statute, for imaging services (described in this section) furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount.

Section 5102(b)(2) of the DRA exempts the estimated reduced expenditures from this provision from the PFS BN requirement. Section 5102(b)(1) of the DRA defines imaging services as “imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.”

To apply section 5102(b) of the DRA, we needed to determine the CPT and alpha-numeric HCPCS codes that fall within the scope of “imaging services” defined by the DRA provision. As we indicated in the CY 2007 PFS final rule with comment period (71 FR 69659), in general, we believe that imaging services are those that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury. We began by considering the CPT 7XXXX series codes for radiology services, and then added other CPT codes and alpha-numeric HCPCS codes that describe imaging services. We then excluded nuclear medicine services that were non-imaging diagnostic or treatment services. We also excluded all codes for unlisted procedures since we would not know in advance of any specific clinical scenario whether or not the unlisted procedure was an imaging service.

We excluded all mammography services, consistent with the statute. We excluded radiation oncology services that were not imaging or computer-assisted imaging services. We also excluded all HCPCS codes for imaging services that are not separately paid under the OPPS since there would be no corresponding OPPS payment to serve as a TC cap. We excluded any service where the CPT code describes a procedure for which fluoroscopy, ultrasound, or another imaging modality is included in the code whether or not it is used, or for which an imaging modality is employed peripherally in the performance of the main procedure, for example, CPT code 31622, *bronchoscopy with or without*

*fluoroscopic guidance* and CPT code 43242, *upper gastrointestinal endoscopy with transendoscopic ultrasound-guided intramural or transmucosal fine needle aspiration/biopsy(s)*. In these cases, we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality, or the use of an imaging technology cannot be segregated from the performance of the main procedure. Note that we included carrier-priced services since these services are within the statutory definition of imaging services and are also within the statutory definition of PFS services (that is, carrier-priced TCs of PET scans).

Upon further review, we have determined that certain ophthalmologic procedures meet the DRA definition of imaging procedures, but were not included in the original list of imaging services subject to the OPPS cap. Therefore, we propose to add the following procedures to the list of procedures subject to the OPPS cap, effective January 1, 2008:

- 92135, *Scanning computerized ophthalmic diagnostic imaging (e.g., scanning laser) with interpretation and report.*
- 92235, *Fluorescein angiography (includes multiframe imaging) with interpretation and report.*
- 92240, *Indocyanine-green angiography (includes multiframe imaging) with interpretation and report.*
- 92250, *Fundus photography with interpretation and report.*
- 92285, *External ocular photography with interpretation and report for documentation of medical progress (e.g., close-up photography, slit lamp photography, goniphotography, stereophotography).*
- 92286, *Special anterior segment photography with interpretation and report; with specular endothelial microscopy and cell count.*

A complete list of codes that identify imaging services defined by the DRA OPPS cap provision was published in Addendum F of the CY 2007 PFS proposed rule (71 FR 49249 through 49252). We will update the list through program instructions to our contractors. To the extent that the same imaging service is coded differently under the PFS and the OPPS, we crosswalked the code under the PFS to the appropriate code under the OPPS that could be reported for the same service provided in the hospital outpatient setting.

2. Application of Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT codes 17311 through 17315)

[If you choose to comment on issues in this section, please include the caption "CODING—MULTIPLE PROCEDURE PAYMENT REDUCTION FOR MOHS SURGERY" at the beginning of your comments.]

Under the multiple procedure payment reduction policy, reimbursement for subsequent surgical procedures performed during the same operative session by the same physician is reduced by 50 percent. The Mohs surgery codes have been exempt from the multiple procedure payment reduction rules since the inception of the PFS (56 FR 59602, November 25, 1991).

The CPT Editorial Panel reviewed all of the codes on the -51 modifier exempt list to identify which codes should be exempt from the multiple procedure payment reduction rules. Based on the revisions to the code descriptors and a clearer understanding regarding the technical elements of the procedure, the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list. The code descriptors for Mohs surgery codes were developed to take into account the different level of physician work intensity based on anatomic site. The RVUs associated with the codes for each anatomic location were assigned, as they are for other procedures, after a thorough discussion by the RUC of all aspects of the service. RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately. Because the RVUs for these services do not take into account the efficiencies that occur when multiple procedures are performed in one session, we do not believe that these codes should continue to be exempt from the multiple procedure payment reduction. Therefore, we are proposing to eliminate the modifier -51 exemption and apply the multiple procedure payment reduction rules to these codes.

3. Payment for Intravenous Immune Globulin (IVIG) Add-On Code for Preadmission-Related Services

[If you choose to comment on issues in this section, please include the caption "CODING—PAYMENT FOR IVIG ADD-ON CODE" at the beginning of your comments.]

Intravenous immune globulin (IVIG) is a unique product derived from blood

plasma. Since its production depends on plasma collection, there may be constraints on the amount produced. There have been reported fluctuations in supply of this product and, in recent years, the demand for this product has grown because of off-label uses.

We recognize the importance of IVIG to patients who require it and are concerned about reports of problems with IVIG access and availability. We have initiated several actions in response to the concerns about the supply of IVIG. We have continued to improve the codes for reporting IVIG, including creating four new codes for liquid non-lyophilized IVIG for use effective July 1, 2007. In addition, as noted below in this section, we established a temporary additional payment for IVIG preadministration services to compensate physicians for the extra resources required to be expended due to market conditions in order to locate and obtain the appropriate IVIG products and to schedule patient infusions.

In 2006, we created the HCPCS code G0332, *Preadministration-related services for intravenous infusion of immunoglobulin, per infusion encounter* and established RVUs for the code based on the nonfacility PE RVUs for code G0319 (1.90 PE RVUs). Code G0319 describes ESRD-related services during the course of treatment, for patients 20 years of age and over; with one face-to-face physician visit per month.

The rationale for the PE valuation was that we believed the additional physician practice resources expended for preadministration-related services, particularly clinical labor, are comparable to the PE for the ESRD management code.

In 2007, we established RVUs for code G0332 based on a blend of the PE RVUs for ESRD codes G0319 and G0318. The RVUs were set at 1.97, a slight increase in the PE RVUs assigned to the code. For a discussion of the RVUs established for these services, see the CY 2007 PFS final rule with comment period (71 FR 69679).

The OIG recently published a report in April 2007 titled, "Intravenous Immune Globulin: Medicare Payment and Availability" (OEI-03-05-00404). The CMS comments on this report were included in Appendix B. We believe this report provides information on the availability and pricing for this product and sets the stage for further review of key issues that can bring greater understanding of the marketplace for this product.

We acknowledge the finding in the OIG report that increasing numbers of physicians are able to purchase IVIG below the Medicare ASP+6 percent payment rates. In the third quarter of 2006, 59 percent of sales to physicians were at prices lower than the Medicare payment rate, a substantial increase over the prior 3 quarters. We consider this to be an important development, as it suggests that although the OIG could not determine the underlying reasons that physicians have had issues with IVIG product availability, Medicare payment rates under the ASP+6 percent payment system have, over time, adjusted to substantial increases in IVIG market prices.

We have also requested that the OIG further study some of the issues we raised in our comments so that we can better understand the IVIG market.

We are concerned that the existence of the preadministration fee could further distort the market and provide inappropriate incentives for IVIG utilization. Despite these concerns, we want to ensure that beneficiaries continue to have access to IVIG. Therefore, we are proposing to continue payment for G0332 only through CY 2008 at the same level of PE RVUs as CY 2007. We invite comments on this policy.

4. Additional Codes from the 5-Year Review of Work RVUs

[If you choose to comment on issues in this section, please include the caption "CODING—ADDITIONAL CODES FROM 5-YEAR REVIEW" at the beginning of your comments.]

As discussed in the CY 2007 PFS final rule with comment period, we deferred the decisions on proposed changes to the work RVUs for a number of codes from the 5-Year Review for a year, either because we had not yet received the RUC recommendation or because we were suggesting that the RUC reevaluate the original recommendation. As we stated in that same rule, these additional codes are still considered part of the 5-Year Review. Table 10 shows the remaining codes, the requested and recommended RVUs, and CMS's proposal on the codes. We are proposing to accept all of the RUC recommendations, with the exception of CPT code 93325 which we are proposing to bundle (that is, work RVUs would be increasing for 33 codes, decreasing for 10 codes, and maintained for 15 codes).

TABLE 10.—REMAINING CODES FROM FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS

CPT <sup>1</sup> / HCPCS code	Mod	Descriptor	2007 work RVU	Requested work RVU	RUC REC	CMS proposal (agree/ disagree)	2008 Proposed work RVU <sup>2</sup>
19301 .....	.....	Partial mastectomy .....	6.03	10.00	10.00	Agree .....	10.00
33207 .....	.....	Insertion of heart pace- maker.	9.05	8.00	8.00	Agree .....	8.00
45300 .....	.....	Proctosigmoidoscopy dx ....	0.38	1.00	0.80	Agree .....	0.80
45303 .....	.....	Proctosigmoidoscopy dilate	0.44	1.50	1.50	Agree .....	1.50
45305 .....	.....	Proctosigmoidoscopy w/bx	1.01	1.25	1.25	Agree .....	1.25
45307 .....	.....	Proctosigmoidoscopy fb .....	0.94	1.70	1.70	Agree .....	1.70
45308 .....	.....	Proctosigmoidoscopy re- moval.	0.83	1.40	1.40	Agree .....	1.40
45309 .....	.....	Proctosigmoidoscopy re- moval.	2.01	1.50	1.50	Agree .....	1.50
45315 .....	.....	Proctosigmoidoscopy re- moval.	1.40	1.80	1.80	Agree .....	1.80
45317 .....	.....	Proctosigmoidoscopy bleed	1.50	2.00	2.00	Agree .....	2.00
45320 .....	.....	Proctosigmoidoscopy ab- late.	1.58	1.78	1.78	Agree .....	1.78
45321 .....	.....	Proctosigmoidoscopy volvul	1.17	1.75	1.75	Agree .....	1.75
45327 .....	.....	Proctosigmoidoscopy w/ stent.	1.65	2.00	2.00	Agree .....	2.00
46600 .....	.....	Diagnostic anoscopy .....	0.50	0.79	0.55	Agree .....	0.55
46604 .....	.....	Anoscopy and dilation .....	1.31	1.25	1.03	Agree .....	1.03
46606 .....	.....	Anoscopy and biopsy .....	0.81	1.20	1.20	Agree .....	1.20
46608 .....	.....	Anoscopy, remove for body	1.51	1.30	1.30	Agree .....	1.30
46610 .....	.....	Anoscopy, remove lesion ..	1.32	1.28	1.28	Agree .....	1.28
46611 .....	.....	Anoscopy .....	1.81	1.30	1.30	Agree .....	1.30
46612 .....	.....	Anoscopy, remove lesions	2.34	1.50	1.50	Agree .....	1.50
46614 .....	.....	Anoscopy, control bleeding	2.01	1.50	1.00	Agree .....	1.00
46615 .....	.....	Anoscopy .....	2.68	1.50	1.50	Agree .....	1.50
92002 .....	.....	Eye exam, new patient .....	0.88	0.88	0.88	Agree .....	0.88
92004 .....	.....	Eye exam, new patient .....	1.67	1.82	1.82	Agree .....	1.82
92012 .....	.....	Eye exam established pat	0.67	0.92	0.92	Agree .....	0.92
92014 .....	.....	Eye exam & treatment .....	1.10	1.42	1.42	Agree .....	1.42
92557 .....	.....	Comprehensive hearing test.	0.00	0.60	0.60	Agree .....	0.60
92567 .....	.....	Tympanometry .....	0.00	0.20	0.20	Agree .....	0.20
92568 .....	.....	Acoustic refl threshold tst ..	0.00	0.29	0.29	Agree .....	0.29
92569 .....	.....	Acoustic reflex decay test ..	0.00	0.20	0.20	Agree .....	0.20
92579 .....	.....	Visual audiometry (vra) .....	0.00	0.70	0.70	Agree .....	0.70
92601 .....	.....	Cochlear implt f/up exam < 7.	0.00	2.30	2.30	Agree .....	2.30
92602 .....	.....	Reprogram cochlear implt < 7.	0.00	1.30	1.30	Agree .....	1.30
92603 .....	.....	Cochlear implt f/up exam 7 >.	0.00	2.25	2.25	Agree .....	2.25
92604 .....	.....	Reprogram cochlear implt 7 >.	0.00	1.25	1.25	Agree .....	1.25
99325 .....	.....	Doppler color flow add-on	0.07	0.30	CPT	Disagree .....	Bundled
99304 .....	.....	Nursing facility care, init ....	1.20	1.88	1.61	Agree .....	1.61
99305 .....	.....	Nursing facility care, init ....	1.61	2.56	2.30	Agree .....	2.30
99306 .....	.....	Nursing facility care, init ....	2.01	3.60	3.00	Agree .....	3.00
99307 .....	.....	Nursing fac care, subseq ...	0.60	0.76	0.76	Agree .....	0.76
99308 .....	.....	Nursing fac care, subseq ...	1.00	1.39	1.16	Agree .....	1.16
99309 .....	.....	Nursing fac care, subseq ...	1.42	2.00	1.55	Agree .....	1.55
99310 .....	.....	Nursing fac care, subseq ...	1.77	2.35	2.35	Agree .....	2.35
99318 .....	.....	Annual nursing fac assessmnt.	1.20	1.88	1.71	Agree .....	1.71
99326 .....	.....	Domicil/r-home visit new pat.	2.27	2.85	2.27	Agree .....	2.27
99327 .....	.....	Domicil/r-home visit new pat.	3.03	3.75	3.03	Agree .....	3.03
99328 .....	.....	Domicil/r-home visit new pat.	3.78	4.26	3.78	Agree .....	3.78
99334 .....	.....	Domicil/r-home visit est pat	0.76	1.25	0.76	Agree .....	0.76
99335 .....	.....	Domicil/r-home visit est pat	1.26	2.00	1.26	Agree .....	1.26
99336 .....	.....	Domicil/r-home visit est pat	2.02	2.75	2.02	Agree .....	2.02
99337 .....	.....	Domicil/r-home visit est pat	3.03	4.05	3.03	Agree .....	3.03
99343 .....	.....	Home visit, new patient .....	2.27	2.65	2.27	Agree .....	2.27
99344 .....	.....	Home visit, new patient .....	3.03	3.60	3.03	Agree .....	3.03
99345 .....	.....	Home visit, new patient .....	3.78	4.26	3.78	Agree .....	3.78

TABLE 10.—REMAINING CODES FROM FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT <sup>1</sup> / HCPCS code	Mod	Descriptor	2007 work RVU	Requested work RVU	RUC REC	CMS proposal (agree/ disagree)	2008 Proposed work RVU <sup>2</sup>
99347 .....	.....	Home visit, est patient .....	0.76	1.10	0.76	Agree .....	0.76
99348 .....	.....	Home visit, est patient .....	1.26	1.70	1.26	Agree .....	1.26
99349 .....	.....	Home visit, est patient .....	2.02	2.50	2.02	Agree .....	2.02
99350 .....	.....	Home visit, est patient .....	3.03	3.45	3.03	Agree .....	3.03

<sup>1</sup> CPT codes and descriptions only are copyright 2007 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.  
<sup>2</sup> Proposed WRVU changes reflect E/M increases.

In Table 10, work RVUs are being proposed for CPT codes 92557, 92567, 92568, 92569, 92579, 92601, 92602, 92603 and 92604. These codes previously had no work RVUs assigned to them. However, based on surveys conducted by relevant specialty societies, the RUC recommended work RVUs as noted in the table, which we propose to accept.

We note that CPT code 93325, *Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)*, was submitted by CMS to the RUC as part of the third 5-Year Review. The RUC 5-Year Review workgroup recommended sending the code to the CPT Editorial Panel so that it could bundle CPT code 93325 into doppler echo code 93307. We believe that the technology of doppler imaging has evolved over the past 2 decades to enable color flow velocity and spectral analysis, both important components of doppler imaging, to be performed concurrently or in concert to obtain more accurate interpretation and documentation of the anatomy and physiologic function of the structure(s) and organ being evaluated. Therefore, we agree with the RUC and since the services described in 93325 have become intrinsic to the performance of other echocardiography services, we are proposing to bundle 93325 into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 and assign CPT code 93325 a status indicator of “B” (Bundled).

5. Anesthesia Coding (Part of 5-Year Review)

Although anesthesia services are paid under the PFS, under section 1848(b)(2)(B) of the Act, they are paid on the basis of an anesthesia code-specific base unit and time units that vary based on the actual anesthesia time of the case. Since anesthesia services do not have a work RVU per code as do other medical and surgical services, a work value must be imputed for each anesthesia code. The imputed value is

determined by multiplying the national average allowed charge for each anesthesia service by its anesthesia work share and dividing this amount by the general PFS conversion factor (CF). This places the work of the anesthesia service on the same relative value scale as all other physician services.

In the second 5-Year Review of anesthesia work implemented in 2002, the AMA RUC and the American Society of Anesthesiologists (ASA) used a building block approach to estimate the value of anesthesia work and compared this value to the imputed work value to determine whether the work of anesthesia services is properly valued. Under the building block approach, each anesthesia code was uniformly divided into five components; pre-anesthesia, equipment and supply preparation, induction, post-induction anesthesia, and post-anesthesia. Work is determined for each of the five components and summed to calculate total anesthesia work for the anesthesia code. The imputed value for the anesthesia code is compared to the building block estimate of work in order to assess whether, and if so, to what extent, the anesthesia code is not properly valued.

The most significant component of work for the anesthesia service is the intensity for the post-induction anesthesia time. The ASA thought that the RUC significantly misvalued this component in the second 5-Year Review. In addition, the ASA was dissatisfied that the RUC did not extend the analysis from the 19 high volume anesthesia codes reviewed by the RUC to all anesthesia codes.

In the CY 2007 PFS final rule with comment period, we addressed the issue of the work of anesthesia services under the third 5-Year Review of work.

As explained in that rule, we made very modest adjustments to the work of the 19 anesthesia codes surveyed and analyzed by the RUC in the second 5-Year Review of work. These adjustments were made recognizing that the work of the pre- and post-anesthesia service components as linked to certain E/M

services. Since we accepted the AMA RUC’s recommendations for increased work values for certain E/M codes for the third 5-Year Review of work, we recalculated the work of the 19 anesthesia services to incorporate these higher work values. The adjustment in work was reflected by increasing the anesthesia CF by less than 1 percent.

However, on the more significant issue of the valuation of work in the post-induction anesthesia period, we took no action. Rather, in the CY 2007 PFS final rule with comment period, we asked the RUC to review and consider this issue as part of the third 5-Year Review of work. We also asked the RUC to consider how increases in the work of pre- and post-anesthesia services could cause adjustments to the anesthesia services not specifically reviewed by the ASA and the RUC.

In January 2007, the ASA requested the AMA RUC to review the undervaluation of the work of the post-induction anesthesia period and to consider also an analytic approach, based on linear regression analysis, which could be used to evaluate the work of the entire anesthesia service. The linear regression model relates the work of the post-induction period time and the work of the entire anesthesia service to the base unit value for the anesthesia code. Under this model, the work of anesthesia services is undervalued by approximately 34 percent.

The RUC established an anesthesia workgroup to examine this proposal. The workgroup discussed this proposal extensively at its two teleconferences, prior to the April RUC meeting, and at the April RUC meeting itself. In May 2007, the AMA RUC, based on the analyses and recommendations of its workgroup, submitted a recommendation to CMS for a 32 percent increase in the work of anesthesia services.

The workgroup approved the ASA’s use of the linear regression model to value only the work of the post-induction period time. In contrast to the ASA proposal, the workgroup

considered an analytic approach different from the regression model developed by the ASA. This approach is

based on a building block approach that could be used to evaluate the work of all anesthesia service components other

than the pos-induction period time. For example, for pre-anesthesia time, the methodology is as shown in Table 11.

TABLE 11.—PRE-ANESTHESIA TIME

All Anesthesia codes with 3 base units .....	linked to the work of 99201.
All Anesthesia codes with 4 base units .....	linked to the blend of work for 99201 and 99202.
All Anesthesia codes with 5 to 15 base units .....	linked to the work of 99202.
All Anesthesia codes with 16 to 30 base units .....	linked to the work of 99252.

Note: The source of the link for work is the pre-anesthesia valuation from the 19 surveyed anesthesia codes whose base units varied from 3 units to 25 units.

Similar approaches are used for each anesthesia component: preparation time, induction period time, and post-anesthesia time. Systematically, codes with lower anesthesia base unit values have lower work values for each component of the building block approach than do codes with higher anesthesia base unit values. For the given building block component, the work value of that component is the same for all anesthesia services that have the same base unit value.

According to the workgroup's revised methodology which is extended from the 19 surveyed codes to all 271 anesthesia codes, the work of anesthesia services is undervalued by approximately 32 percent. Thus, based on the acceptance of the workgroup and the RUC's recommendation, an adjustment of approximately 25 percent would be applied to the anesthesia CF.

Increases in the work of anesthesia services would have to be offset by additional adjustments to the PFS BN adjuster for work. We estimate that the increase in the anesthesia CF would result in an additional 1.0 percent increase in the BN adjuster for work.

Other adjustments also affect the anesthesia CF. For example, an increase in anesthesia work may have implications for PE because indirect PEs are allocated based on the sum of work and direct PEs. When we ran the PE RVU program, there was no increase in the aggregate anesthesia PEs. Thus, no adjustment is being made to the PE share of the anesthesia service or to the anesthesia CF for this component.

We are proposing to accept the RUC's recommendation and increase the work of anesthesia services by 32 percent.

Due to the proposed work RVU changes for the codes listed in Table 10 and the proposed increases in the work of anesthesia services, we are proposing to revise the work adjuster to maintain budget neutrality. Based upon the increases, the proposed revised work adjuster is approximately 0.8816, which is discussed further in the impact section of this proposed rule.

## 6. Reporting of Cardiac Rehabilitation Services

For CY 2008, we are proposing to assign a status indicator of "I" (invalid for Medicare purposes, Medicare recognizes another code for the billing of this service) to the current CPT codes for cardiac rehabilitation services, CPT codes 93797, *Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)*, and 93798, *Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)*. (There is no definition of "per session.") Therefore, to clarify the coding and payment for these services, we propose to establish two new Level II HCPCS codes that we believe are more appropriate for specifically reporting cardiac rehabilitation services under the PFS. The proposed HCPCS codes are: Gxxx1, *Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour)*, and Gxxx2, *Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)*. We believe the new codes that use a per hour descriptor will more accurately measure the services being provided and facilitate proper coding and payment. The current RVUs associated with CPT codes 93797 and 93798 will be crosswalked to HCPCS Codes Gxxx1 and Gxxx2, respectively, because 1 hour of service was assumed in establishing the current RVUs.

### F. Part B Drug Payment

#### 1. Average Sales Price (ASP) Issues

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

Medicare Part B covers a limited number of prescription drugs and biologicals. For the purposes of this proposed rule, the term "drugs" will hereafter refer to both drugs and biologicals, unless otherwise specified. Medicare Part B covered drugs not paid on a cost or prospective payment basis

generally fall into the following three categories:

- Drugs furnished incident to a physician's service.
- DME drugs.
- Drugs specifically covered by statute (certain immunosuppressive drugs, for example).

Beginning in CY 2005, the vast majority of Medicare Part B drugs not paid on a cost or prospective payment basis are paid under the ASP methodology. The ASP methodology is based on data submitted to us quarterly by manufacturers. In addition to the payment for the drug, Medicare currently pays a furnishing fee for blood clotting factors, a dispensing fee for inhalation drugs, and a supplying fee to pharmacies for certain Part B drugs.

In January 2006, the drug coverage available to Medicare beneficiaries expanded with the implementation of Medicare Part D. The Medicare Part D program does not change Medicare Part B drug coverage.

In this section, we discuss proposed changes and issues related to the determination of the payment amounts for covered Part B drugs and furnishing blood clotting factor. This section also discusses proposed changes to how manufacturers calculate and report ASP data to us.

#### a. ASP Payment

Section 303(c) of the MMA amended Title XVIII of the Act by adding section 1847A. This section revised the payment methodology for the vast majority of drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005. The ASP reporting requirements are set forth in section 1927(b) of the Act. Manufacturers must submit ASP data by 11-digit National Drug Code (NDC) to us quarterly. The manufacturers' submissions are due to us not later than 30 days after the last day of each calendar quarter. The methodology for developing Medicare drug payment allowances based on the manufacturers' submitted ASP data is specified in 42 CFR, part 414, subpart K.

We update the Part B drug payment amounts quarterly based on the data we receive.

In this section of the preamble, we discuss our intent to establish further guidance regarding certain aspects of the calculation of manufacturers' ASP data, and seek comments on issues related to bundled price concessions.

Further information on manufacturers' submission of ASP data for Medicare Part B drugs and biologicals is contained in prior rulemaking documents and other guidance accessible on the CMS Web page at (<http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>).

Specifically refer to the April 6, 2004 ASP interim final rule with comment period (IFC) (69 FR 17935) and the CY 2007 PFS final rule with comment period (71 FR 69624), which finalized the ASP calculation and reporting requirements of the April 6, 2004 IFC, and the Frequently Asked Questions available on the Web page.

#### b. Bundled Price Concessions

In the CY 2007 PFS proposed rule and final rule with comment period, we solicited and responded to comments regarding the issue of how to allocate price concessions across drugs that are sold under bundling arrangements for purposes of calculating the ASP. We did not establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of the ASP calculation in the CY 2007 PFS final rule with comment period. In the absence of specific guidance, we maintained existing guidance that manufacturers may make reasonable assumptions in its calculation of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices. Our intent in not being prescriptive in this area in the CY 2007 PFS final rule with comment period was to allow manufacturers the flexibility to adopt a methodology with regard to the treatment of bundled price concessions in the ASP calculation that, based on their particular circumstances, will best ensure the accuracy of the ASP calculation and not create inappropriate financial incentives. We also stated that we would be closely monitoring this issue and may provide more specific guidance in the future if we determine it is warranted. In addition, we encouraged stakeholders and the public to relay additional information or concerns to us on this issue. We specifically noted that MedPAC would be studying this issue, and that we looked forward to its work in this area.

In its January 2007 Report to Congress, "Impact of Changes in Medicare Payments for Part B Drugs", MedPAC discusses the issue of how to allocate bundled price concessions for purposes of calculating the ASP, noting that "some manufacturers offer provider discounts for one of their products contingent on purchases of one or more other products." The full report is posted on the MedPAC's Web site at ([http://www.medpac.gov/publications/congressional\\_reports/Jan07\\_PartB\\_mandated\\_report.pdf](http://www.medpac.gov/publications/congressional_reports/Jan07_PartB_mandated_report.pdf)). MedPAC's report illustrates the potential effects that certain methods for allocating bundled price concessions may have on Medicare payment rates, physicians' ability to choose a product based on clinical factors, and market availability of products. MedPAC notes that:

Bundling arrangements take many forms. For example, some bundling arrangements may include only Part B drugs while others may include both Part B drugs and other products. Similarly, price concessions may be structured in numerous ways. For example, a discount on one or more drugs may be contingent on the purchase of other drugs or on meeting an aggregate expenditure target for a group of products. CMS's policy on reporting discounts may need to change over time to reflect changing market practices but that should not slow down action in this area. [MedPAC. 2007. *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs*. Washington, DC: MedPAC: page 8]

In its report, MedPAC discusses two alternative approaches for allocating bundled price concessions. According to MedPAC, one option would be to require manufacturers to allocate bundled discounts in proportion to the sales of each drug sold under the bundled arrangement. For example, Drug A and Drug B are sold under a bundled arrangement and have a combined bundled discount equal to \$200,000 on total sales of \$1 million. If Drug A has sales of \$600,000, the manufacturer would allocate 60 percent of the bundled discount to that drug when calculating ASP. Forty percent of the bundled discount would be allocated to Drug B. MedPAC states that this approach would parallel bundling requirements under Medicaid and would be simpler to administer. However, MedPAC notes that this method might not capture contingent discounts.

The other approach discussed by MedPAC would be to require manufacturers to allocate bundled discounts to reflect the contingencies in the contract. That is, manufacturers would allocate any additional (or increased) discount to the sales of the

drug (or drugs) that the discount is meant to increase. This approach would result in an ASP that more accurately reflects the transaction price of drugs when a discount for one drug or drugs is contingent in whole or in part on the purchase of another drug. For example, if a greater discount on the purchase price of Drug A is contingent on the purchase (or purchases) of Drug B, this additional discount would be allocated to sales of Drug B in the calculation of ASP.

In its discussion of bundling, MedPAC states that the goal should be to ensure that ASP reflects the average transaction price for drugs. To that end, MedPAC recommends that the Secretary clarify the ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. Further, MedPAC states that we should ensure that the reporting requirements for allocating discounts are clear and that they can be implemented by manufacturers in a timely fashion.

In the December 22, 2006 Medicaid Program: Prescription Drugs proposed rule (71 FR 77176), for purposes of calculating the average manufacturer price (AMP), we proposed that, the discounts associated with a bundled sale would be allocated proportionately according to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts would be proportionately allocated across all of the drugs in the bundle. For AMP purposes, a bundled sale would mean an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit NDC level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside of the bundled arrangement. In the December 22, 2006 Medicaid Program: Prescription Drugs proposed rule, we further proposed that the AMP should be adjusted for bundled sales by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations. The aggregate discount is allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. Where

discounts are offered on multiple products in a bundle, the aggregated value of all of the discounts should be proportionately allocated across all of the drugs in the bundle.

We received many comments on the many aspects of the December 22, 2006 Medicaid: Prescription Drugs proposed rule. However, our review of those comments and development of the final AMP calculation policies and rule are not complete, and therefore, we will respond to those comments in future rulemaking.

In the CY 2007 PFS final rule with comment period, we stated that we may provide more specific guidance on bundled price concessions in the future if we determine it is warranted. In light of MedPAC's recommendation that we clarify the ASP reporting requirements for bundled products and our discussion of bundled price concessions in the CY 2007 PFS rulemaking, we believe specific guidance in the ASP context is warranted to provide for greater consistency in ASP reporting across manufacturers and enhancing the accuracy of the ASP payment system. We find MedPAC's suggestion to not defer further guidance in this area compelling with respect to the potential that manufacturers may make differing assumptions in the absence of specific guidance on how to allocate bundled price concessions in the context of ASP.

As we noted in the CY 2007 PFS final rule with comment period, there is a potential for great variation in the structure of bundling arrangements and in the characteristics of drugs included in those arrangements. Thus, we believe that, in establishing a specific methodology for allocating bundled price concessions for purposes of calculating ASP, we should seek to balance the desirability of a consistent methodology across manufacturers' ASP calculations with the potential complexity that may be introduced by the designated approach. Our intention in proposing to adopt a specified approach for allocating bundled price concessions in the ASP context is to avoid greater computational complexity than necessary at this time primarily because it is unknown whether applicable data may be adequately known at quarterly reporting intervals for manufacturers to appropriately reflect the contingencies in purchasing contracts within their ASP calculations at the 11-digit NDC level.

In addition, we believe that it is appropriate at this time to propose a specified method for treating bundled price concessions in the calculation of ASP which is consistent with our proposed approach for treating such

discounts for purposes of the AMP calculation. Furthermore, because section 1847A(d) of the Act, as discussed elsewhere in this section, permits substitution of 103 percent of the AMP for the ASP-based payment limit in certain instances, we believe incorporating appropriate consistencies across the calculations of ASP and AMP, as allowable by statute, is rational. Although we are proceeding cautiously with such potential substitutions, we believe appropriate consistencies across the calculations of ASP and AMP will result in a lower potential for error and more accurate calculations of both prices.

Although ASP and AMP serve similar, but not identical, purposes, differences between these calculations provide rationale for, and in some instances may require, minor differences between Medicaid and Medicare proposed regulations. For example, the Medicaid proposed rule proposes a definition of "bundled sales" whereas we believe "bundled arrangement" is more appropriate for purposes of the ASP context because, for ASP purposes, "bundling" is most applicable in the context of price concessions. Furthermore, based on our experience with manufacturers' ASP reporting, we believe other refinements are appropriate for purposes of ASP. We believe these differences are necessary to clarify certain aspects of a consistent approach for treatment of bundling, and will not result in significant policy differences on how bundling is addressed in the context of AMP and in the context of ASP.

Therefore, for purposes of calculating the ASP (beginning with the reporting period for the first calendar quarter of 2008 and thereafter), we propose that the manufacturer must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement to ensure that the ASP is adjusted for bundled arrangements as defined in the definition of bundled arrangement we are proposing at § 414.802. For bundled arrangement, where multiple drugs are discounted, the aggregate value of all the discounts would be proportionately allocated across all of the drugs sold under the bundled arrangement. We propose that a bundled arrangement, for ASP purposes, would mean an arrangement, regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example,

the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement. We propose to define bundled arrangement at § 414.802, and to specify in proposed § 414.804(a)(2)(iii) that all price concessions on drugs sold under a bundled arrangement must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement.

In making this proposal, we seek to establish a method for treating bundled price concessions for purposes of ASP that is consistent with the method proposed for AMP calculations while addressing existing program differences. We believe an overall consistent methodology for addressing bundling in both contexts will reduce the burden and the likelihood of errors for manufacturers calculating and reporting the ASP. We also believe that our proposed approach balances the need to provide clarification of how bundled price concessions are to be treated for purposes of calculating the ASP so that there is greater consistency across calculations of ASP with concerns that a more complex approach would present complicated implementation and monitoring challenges, as discussed by MedPAC and in our response to comments in the CY 2007 PFS final rule with comment period.

As discussed previously in this section of the preamble, we propose to establish a method for the treatment of bundled price concessions that is appropriately consistent with proposed Medicaid policy for bundled sales, and we intend to remain consistent with the final policy adopted in the Medicaid final rule on this issue, as appropriate. However, we note that the final Medicaid AMP final rule is still under development, and the Medicaid policies on bundled sales may ultimately differ from our discussion of the topic in this section of the preamble. Because of the timing of the two proposed rules, the policy we ultimately adopt in this final rule may reflect the final Medicaid policy on bundled sales, but only to the extent that it is appropriate for ASP and the public has had the opportunity to comment on how the final Medicaid policy for bundled sales, if appropriately adopted for ASP purposes, would affect the calculation of ASP.

We note that the comment period on the Medicaid proposed rule is closed. Therefore, comments received in response to this proposed rule on the topic of bundled sales for purposes of AMP will be considered untimely for the purposes of the Medicaid final rule and outside of the scope of this rulemaking.

We are soliciting comments on our proposed approach for requiring manufacturers to allocate the total value of all price concessions on all drugs sold under a bundled arrangement proportionately according to the dollar value of the units of each drug sold under the bundled arrangement for purposes of the calculation of ASP, and on our proposal to specify the method for treatment of bundling in the ASP context that is appropriately consistent with the treatment of bundling in the AMP context. We are specifically soliciting comments on how our proposed approach for treatment of bundled price concessions for purposes of calculating ASP may impact the estimation of lagged price concessions, whether manufacturers believe additional guidance on this topic is needed, and the nature of the potential additional guidance. Further, we are soliciting comments on potential alternative approaches for the treatment of bundled price concessions that are appropriate for the calculation of ASP, including the alternative approach discussed by MedPAC in its recent report as noted previously in this section of the preamble. In addition, we seek comments on how our proposed approach or an alternative approach would result in clear reporting requirements for allocating discounts that can be implemented by manufacturers in a timely fashion.

#### c. Clotting Factor Furnishing Fee

Section 303(e)(1) of the MMA added section 1842(o)(5) of the Act which requires the Secretary, beginning in CY 2005, to pay a furnishing fee, in an amount the Secretary determines to be appropriate, to hemophilia treatment centers and homecare companies for the items and services associated with the furnishing of blood clotting factor. Section 1842(o)(5)(C) of the Act specifies that the furnishing fee for clotting factor for CY 2006 and subsequent years will be equal to the fee for the previous year increased by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending with June of the previous year. In the CY 2007 PFS final rule with comment period, we announced that the furnishing fee for CY 2007 is \$0.152 per unit clotting

factor based on the percentage increase in the CPI of 4.1 percent for the 12-month period ending June 2006.

The CPI data for the 12-month period ending in June 2007 is not yet available. In the CY 2008 PFS final rule with comment period, we will include the actual figure for the percent change in the CPI for medical care for the 12 month period ending June 2007, and the updated furnishing fee for CY 2008 calculated based on that figure.

In the CY 2006 and CY 2007 PFS proposed and final rules, as well as in this proposed rule, we have included a discussion of the annual update of the blood clotting factor furnishing fee as specified in section 1842(o)(5)(C) of the Act. Because the update is based on the percentage increase in the CPI for medical care for the 12-month period ending with June of the previous year and the Bureau of Labor Statistics releases the applicable CPI data after our proposed rule is published, we are not able to include the actual updated furnishing fee in the CY 2006 through CY 2008 proposed rules. Rather, we announced in these proposed rules that we intended to include the actual figure for the percent change in the applicable CPI, and the updated furnishing fee calculated based on that figure in the associated final rule. Given the timing of the availability of the applicable data and our timeframe for preparing proposed rules, this process is unavoidable and likely to remain unchanged in the future. We believe that including a discussion of the furnishing fee update in annual rulemaking does not provide an advantage over other means of announcing this information, so long as the current statutory update methodology continues in effect. We believe that the public's need for information and adequate notice regarding the updated furnishing fee can be better met by issuing program instructions which will eliminate the discussion of the furnishing fee update annually in rulemaking. In addition, by communicating the updated furnishing fee in program instruction, the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure can be announced more timely than when included as part of the PFS final rulemaking process. Because the furnishing fee update process is statutorily determined and is based on an index which is not affected by administrative discretion or public comment, we do not believe a subregulatory means of communicating the update will adversely affect stakeholders or the public. Therefore,

for CY 2009 and thereafter until such time as the update methodology may be modified, we propose to announce the blood clotting furnishing fee using applicable program instructions and posting on the CMS Web site. We are soliciting comments on our proposal to announce the updated furnishing fees via program instructions.

#### d. Widely Available Market Prices (WAMP) and AMP Threshold

Section 1847A(d)(1) of the Act states that "the Inspector General of HHS shall conduct studies, which may include surveys to determine the widely available market prices (WAMP) of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate." Section 1847A(d)(2) of the Act states that, "Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the ASP under this section for drugs and biologicals with—

- The widely available market price (WAMP) for these drugs and biologicals (if any); and
- The AMP (as determined under section 1927(k)(1) of the Act for such drugs and biologicals."

Section 1847A(d)(3)(A) of the Act states that, "The Secretary may disregard the ASP for a drug or biological that exceeds the WAMP or the AMP for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B))." The applicable threshold is specified as 5 percent for CY 2005. For CY 2006 and subsequent years, section 1847A(d)(3)(B) of the Act establishes that the applicable threshold is "the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the WAMP or the AMP, or both." In CY 2006 and CY 2007, we specified an applicable threshold percentage of 5 percent for both the WAMP and AMP. We based this decision on the limited data available to support a change in the current threshold percentage.

For CY 2008, we propose to specify an applicable threshold percentage of 5 percent for the WAMP and the AMP. At present, the OIG is continuing its comparison of both the WAMP and the AMP. Furthermore, information on how recent changes to the calculation of the AMP may affect the comparison of AMP to ASP is not available at this time. Since we do not have data that suggest another level is more appropriate at this time, we believe that continuing the 5 percent applicable threshold percentage

for both the WAMP and AMP is appropriate for CY 2008.

As we noted in the CY 2007 PFS final rule with comment period (71 FR 69680), we understand that there are complicated operational issues associated with potential payment substitutions. We will continue to proceed cautiously in this area and provide stakeholders, particularly manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions regarding such, including the opportunity to provide input with regard to the processes for substituting the WAMP or the AMP for the ASP. As part of our approach, we intend to develop a better understanding of the issues that may be related to certain drugs for which the WAMP and AMP may be lower than the ASP over time.

We welcome comments on our proposal to continue the applicable threshold at 5 percent for both the WAMP and AMP for CY 2008.

## 2. Competitive Acquisition Program (CAP) Issues

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

In this section, we discuss the impact of new legislation on administrative and operational aspects of the CAP. Topics include the implementation of a post-payment review process and the corresponding changes to claims processing procedures. In subsequent subsections, we also seek comments regarding changes to other operational aspects of the CAP.

This proposed rule will also be used to discuss comments related to transporting CAP drugs and the administrative burden of the CAP submitted in response to the Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Final Rule with Comment Period published in the July 6, 2005 **Federal Register** (hereinafter referred to as the July 6, 2005 IFC). We are addressing these comments in this proposed rule because we plan to ask for additional comments on these areas to explore areas that might be developed in future rulemaking efforts. In the upcoming PFS final rule with comment, we intend to finalize the portions of the July 6, 2005 IFC that were not finalized in the CY 2006 PFS final rule with comment period. We also will respond to the other timely comments we received on the July 6, 2005 IFC that we have not responded to previously.

This proposed rule implements conforming changes to the CAP

regulations to reflect provisions of section 108 of the MIEA–TRHCA that made changes to the payment process of the CAP for Part B Drugs. Section 303(d) of the MMA required the implementation of a CAP for certain Medicare Part B drugs and biologicals not paid on a cost or PPS basis. The provisions for acquiring and billing drugs under the CAP were described in the Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B proposed rule and July 6, 2005 IFC (70 FR 10746 and 70 FR 39022, respectively), and certain provisions were finalized in the CY 2006 PFS final rule with comment period (70 FR 70116). We specified a single CAP drug category to include a defined list of drugs furnished incident to a physician's service.

The program began on July 1, 2006. At that time, physicians were given a choice between obtaining these drugs from vendors selected through a competitive bidding process and approved by CMS, or directly purchasing these drugs and being paid under the ASP system.

### a. MMA Operational Provisions

Prior to the enactment of the MIEA–TRHCA, section 1847B(a)(3)(A) of the Act set forth specific requirements that have a direct impact on the administrative and operational parameters for instituting a CAP. This section of the statute requires the following:

(1) Approved CAP vendors bill the Medicare program for the drug or biological supplied, and collect any applicable deductibles and coinsurance from the Medicare beneficiary. (For purposes of the preamble, the term "approved CAP vendor" means the term "contractor" as referred to in the statute.)

(2) Any applicable deductible and coinsurance may not be collected unless the drug was administered to the beneficiary. (For purposes of the preamble, the term "drug" refers to drugs and biologicals furnished under the CAP, unless the context specifies otherwise.)

(3) Medicare can make payments only to the approved CAP vendor, and these payments are conditioned upon the administration of the drug.

Section 108 of the MIEA–TRHCA amended this third element.

### b. MIEA–TRHCA

Section 108 of the MIEA–TRHCA made changes to the CAP payment methodology. Section 108(a)(1) of the MIEA–TRHCA amended section 1847B(a)(3)(A)(iii) of the Act by adding

new language that requires that payment for drugs and biologicals shall be made upon receipt of a claim for a drug or biological supplied for administration to a beneficiary. This statutory change took effect on April 1, 2007.

Section 108(a)(2) of the MIEA–TRHCA requires the Secretary to establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological only if the drug or biological has been administered to a beneficiary. The Secretary shall recoup, offset, or collect any overpayments determined by the Secretary under this process.

Section 108(b) of the MIEA–TRHCA states that nothing in this section shall be construed as requiring the conduct of any additional competition under section 1847B(b)(1) of the Act; or requiring an additional physician election process.

Section 108(c) of the MIEA–TRHCA states that the amendments of this section apply to payments for drugs and biologicals supplied (1) on or after April 1, 2007, and (2) on or after July 1, 2006 and before April 1, 2007, for claims that are unpaid as of April 1, 2007.

### c. CAP Claims Processing

In the July 6, 2005 IFC (70 FR 39042), we initially implemented a claims processing system that enables selected approved CAP vendors to bill the Medicare program directly, and to bill the Medicare beneficiary and his or her third party payer after verification that the physician has administered the drug. When a participating CAP physician elects to join the program, he or she must agree to obtain all drugs on the CAP list from the approved CAP vendor, with only a few exceptions. For example in furnish as written (FAW) situations (that is, where a beneficiary needs a particular formulation of a drug not available from the approved CAP vendor) the participating CAP physician would be allowed to obtain that drug outside of the CAP. In the case of Medicare Secondary Payer (MSP) (that is, where a Medicare beneficiary may have another payer primary to Medicare), the participating CAP physicians must obtain physician administered drugs from entities approved by the primary plan and bill the primary payer. Detailed MSP instructions have been issued by CMS that allow payment to the physician under the ASP methodology in this situation.

Claims processing procedures for the approved CAP vendor and the participating CAP physician, which

remain largely unchanged under the new statutory provision, are as follows: Once a shipment is received from the approved CAP vendor, the participating CAP physician stores the drug until the date of drug administration. When the drug is administered to the beneficiary, the participating CAP physician places the prescription order number for each drug administered on the claim form submitted to his or her regular Part B carrier. Similarly, when the approved CAP vendor bills Medicare for the drug it shipped to the participating CAP physician, it places the relevant prescription order number on the claim form submitted to the designated carrier. The use of the prescription order number on both the participating CAP physician's claim and the approved CAP vendor's claim is intended to verify drug administration to the beneficiary. The participating CAP physician's claim and the approved CAP vendor's claim are matched in the Medicare claims processing system so that drug administration can be verified and payment to the approved CAP vendor can be made.

#### d. Required Changes to CAP Claims Processing

As originally implemented, the claims matching process described above was completed before payment was made. However, as of April 1, 2007, section 108 of the MIEA-TRHCA requires payment to be made to the CAP vendor for claims upon receipt. The statute also requires us to establish a post-payment review process to assure that payment is made for a drug only if the drug has been administered to a beneficiary. We are also charged with recouping, offsetting, or collecting any overpayments found. The statute also authorizes us to conduct post-payment review using statistical sampling and to implement the post-payment review process by program instruction or otherwise. We implemented the necessary changes to our claims processing system and initiated the post-payment review process on April 1, 2007 via instructions to the CAP designated claims processing contractor and questions and answers posted on the CMS competitive bidding Web site at [http://www.cms.hhs.gov/CompetitiveAcquisforBios/15\\_Approved\\_Vendor.asp#TopOfPage](http://www.cms.hhs.gov/CompetitiveAcquisforBios/15_Approved_Vendor.asp#TopOfPage).

The post-payment review process uses statistical sampling to determine whether drugs were administered and if they were medically necessary. All Medicare claims are subject to medical necessity determinations; however, under the changes required by the MIEA-TRHCA, CAP claims may not all

be reviewed for medical necessity before they are paid. Therefore, the post-payment review includes verification of drug administration and a medical necessity review of a statistically valid sample of CAP claims. We note that in conducting the post-payment review, we will continue to monitor for fraud, waste, and abuse. All CAP transactions will remain eligible for review for medical necessity and verification of administration. We also anticipate that the post-payment review process will provide CMS with additional opportunities to monitor for the appropriate payment of drugs furnished under this program.

As part of the post-payment review process, the CAP-designated carrier will use the CMS claims processing system to look for a match between the CAP prescription order number on the participating CAP physician's claim and the same prescription order number on the approved CAP vendor's claim to track drug administration on a dose-by-dose basis. If the CAP designated carrier is able to find a match between the two claims, this assists the carrier in determining that the beneficiary did receive the drug being billed for. The participating CAP physician claim may also contain information on any determination of medical necessity and coverage made by the local carrier.

To conduct post-payment review of claims, we may also ask for documentation of administration from the approved CAP vendor and for medical records from the participating CAP physician for any claim that is identified for review. While it is standard practice for Medicare providers to be required to submit medical records to assist in claims review, we reserve the right to also specifically request any other records that verify the administration of a CAP drug. Furthermore, we want to make it very clear to the participating CAP physician at the time he or she elects to join the program that he or she may be asked to supply medical records for post-payment review. Therefore, we are proposing to revise § 414.908(a)(3)(xi) and the physician election agreement form to make clear that medical records and certain information may be requested from CAP physician during the post-payment review process. The procedures being used to verify valid claims and ensure proper payment for drugs supplied under the CAP are based on established post-payment review processes used in other parts of the Medicare program. The request for medical records as part of the claims payment process during CAP post-payment review is intended to work in

conjunction with Item 12 on the Health Insurance Claim Form CMS-1500 which, when signed by a beneficiary, authorizes the release of "any medical information necessary to process a claim."

When a claim is selected for review we notify the approved CAP vendor and request its records to verify administration. We also notify the approved CAP vendor that we will be requesting medical records from the participating CAP physician and ask for his or her help in obtaining them. If the medical record is not received within 30 days, the claim is denied because we will not have sufficient information to verify drug administration and medical necessity. This review process is similar to those used elsewhere in the Medicare program such as clinical laboratory payment review or payment of radiology services. It is also consistent with our practice in reviewing claims for postoperative treatment. For example, if post-operative services have been provided by two physicians, and payment was denied to one physician, and that physician appeals, the Medicare contractor may request medical records from the other physician that treated the beneficiary to document that there was no overlap in the services provided by each physician. If the contractor does not receive the medical record of the other physician within a specified amount of time the appeal would be denied because there was no way to document the services provided. A similar process is used when durable medical equipment (DME) is provided through third party suppliers. In these cases, the physician ordering the DME is required to provide the supplier medical records to support the necessity of the equipment he or she ordered. If the supplier does not obtain the records, then payment is denied.

As we specified in the CAP IFC (70 FR 39038), the local carrier's medical review policies and coverage determinations will continue to apply in the CAP. Under our previous claims processing methodology the local carrier made the coverage determination on the drug ordered by the participating CAP physician and provided by the approved CAP vendor as part of the claim matching process prior to payment of the approved CAP vendor's claim. Under the new methodology, the drug claim will be paid upon receipt unless the local carrier has already made a coverage or medical necessity determination on the drug, and the match has already occurred showing that the drug claim should be denied. As part of the post-payment review process, the CAP designated carrier will

check the CMS central claims processing system to determine whether the local carrier has made a coverage or medical necessity determination on the CAP drug indicated on the participating CAP physician's drug administration claim. If so, the CAP designated carrier will reflect this decision in its post-payment review of the claim. If the local carrier has not reviewed the drug administration portion of the participating CAP physician's claim as of the date that the designated carrier processes the approved CAP vendor's drug claim, the CAP designated carrier will use the local carrier's coverage determination policies when conducting medical review of the claim.

#### e. Provisions for Collection of Beneficiary Coinsurance

In the CY 2006 PFS final rule with comment period, we specified § 414.914(h)(1) that subsequent to receipt of final payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies. If a balance remains after the supplemental insurer pays their share of the bill, or if there is no supplemental insurance, the approved CAP vendor may bill the beneficiary for the balance. In prior practice, a match in the claims system between the participating CAP physician's drug administration claim and the approved CAP vendor's drug claim and the subsequent payment by Medicare was used to indicate that the beneficiary received the drug. We also allowed voluntary information exchanges between the approved CAP vendor and the participating CAP physician's office have also been used to verify CAP drug administration. Additionally, we note that under the CAP regulations, the participating CAP physician has a responsibility to notify the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered.

Because section 108 of the MIEA-TRHCA requires the payment of CAP claims upon receipt, payment of a claim by Medicare may occur before administration of the drug has been verified. However, section 1847B(a)(3)(A)(ii) of the Act, which states that deductible and coinsurance shall not be collected unless the drug or biological is administered, remains unchanged. Thus, because we have interpreted this provision as requiring verification of administration prior to the collection of applicable cost sharing amounts, the requirement for verification of administration similarly

remains unchanged. However, because of the statutory change of section 108(a)(1) of the MIEA-TRHCA and its resulting impact on our claims processing methodology, the claims processing system no longer provides a way for CMS to verify administration on the approved CAP vendor's behalf before the approved CAP vendor collects coinsurance from the beneficiary or the supplemental insurer. Verification of CAP drug administration is also conducted in the post-payment review process. The approved CAP vendor is expected to make information available to verify administration for post-payment review as necessary.

We believe that an approved CAP vendor can verify whether a CAP drug was administered in a variety of ways. For example, an approved CAP vendor may enter into a voluntary agreement with a participating CAP physician to exchange such information as described in the CY 2006 PFS final rule with comment period (70 FR 70251). However, if a participating CAP physician is unwilling to enter into a voluntary agreement to verify administration, the approved CAP vendor may verify that the drug was administered by contacting the participating CAP physician's office to request verbal confirmation. In such an instance, the approved CAP vendor is expected to document the verbal confirmation of CAP drug administration, the identities of individuals who exchanged the information and the date and time that the information was obtained. In addition to verifying administration through contact with the physician's office, we also suggest that the approved CAP vendor place a statement on beneficiaries' bills informing them of the statutory requirement and suggesting that they contact their participating CAP physician to verify that they received the dose of the drug for which they are being billed prior to paying any cost sharing amount.

For the reasons described above in this section, we believe that the verification of CAP drug administration remains a required element of the CAP and we are proposing to clarify § 414.906(a)(6) by specifying that all of the following elements shall be required to document the verification of CAP drug administration:

- Beneficiary's name.
- Health insurance number.
- Expected date of administration.
- Actual date of administration.
- Identity of the participating CAP physician.
- Prescription order number.

- Identity of the individuals who supply and receive the information.
- Dosage supplied.
- Dosage administered.

Also, as a result of changes mandated by section 108(a)(1) of the MIEA-TRHCA, we propose to revise § 414.914(h)(1) to remove the reference to "final payment by Medicare" and revise this language to state, "payment by Medicare." The original language was written to indicate that an approved CAP vendor could not bill a beneficiary's supplemental insurer for applicable amounts of cost sharing until the CAP drug claim had matched the corresponding physician's drug administration claim. Under the post-payment review process, the final payment would not occur until a statistical review of the claims was complete, a process that may take several months. Removing the word final from this section of the regulation will clarify that the approved CAP vendor may bill the supplemental insurer immediately after the designated CAP carrier makes the initial payment on a CAP drug claim. Under our current regulations, the approved CAP vendor may also bill the beneficiary if drug administration is verified by the participating CAP physician. This provision remains unchanged.

Under the revised CAP claims payment process, the approved CAP vendor will bill Medicare for the CAP drug that has been provided. In most cases Medicare will pay the claim upon receipt. If the beneficiary has a supplemental insurance policy, and the supplemental insurer has a crossover agreement with Medicare, the claim automatically will cross over to the supplemental insurer for payment. The supplemental insurer will pay its share. Upon receipt of payment from the supplemental insurer the approved CAP vendor may bill the beneficiary for any residual amount. For beneficiaries who do not have a supplemental insurance policy, the approved CAP vendor may bill the beneficiary after payment by Medicare.

However, in either case, the approved CAP vendor may not collect any coinsurance owed from the beneficiary or his or her supplemental insurer unless it has verified that the drug was administered. If the approved CAP vendor believes that the drug was administered but later learns that it was not, the approved CAP vendor must refund any coinsurance collected to the beneficiary and his or her supplemental insurer, as applicable. In addition, in § 414.914(i)(2), we are proposing that the approved CAP vendor must promptly refund any payment made by

CMS if the vendor has been paid for drugs that were not administered. We are proposing that promptly is defined as 2 weeks so that the approved CAP vendor would have 2 weeks from the date that they were notified that they had been paid for a drug that had not been administered to the beneficiary to refund any payment for the claim made to the designated carrier and refund any cost sharing collected to the beneficiary and his or her supplemental insurer.

#### f. Approved CAP Vendor Appeals for Denied Drug Claims

In the March 4, 2005 proposed rule (70 FR 10757 through 10758) and the July 6, 2005 IFC (70 FR 39054 through 39057), we discussed the development of the CAP dispute resolution process and the limited applicability of the traditional Medicare fee for service appeals process to an approved CAP vendor's dispute of CAP drugs claims that are denied by the CAP designated carrier. We stated that the approved CAP vendor could file appeals as a Medicare supplier consistent with the rules at 42 CFR Part 405, Subpart I. For the purposes of the appeals regulations at Part 405, Subpart I, we indicated that a local carrier's initial determination of the participating CAP physician's drug administration claim was an initial determination regarding payment of the approved CAP vendor's drug claim. Thus, the approved CAP vendor was to be considered a party to any redetermination of the drug administration claim by the local carrier. In addition, the approved CAP vendor would be considered a party to an initial determination on the claim for payment for the drug product the approved CAP vendor filed with the designated carrier. We also specified that appeals of either initial determination would be filed with the local carrier. We stated that the local carrier, rather than the designated carrier, possessed all information necessary to adjudicate an appeal in this situation. Such information included local coverage decisions, medical necessity determinations, and information regarding payment of drug administration claims. A dispute resolution process was set forth in § 414.916.

Under our initial implementation of the provision that authorized CAP, this alternative approach, which provided party status to the approved CAP vendor on the participating CAP physician's drug administration claim, was necessary because an approved CAP vendor was not permitted to receive payment for a CAP drug until the corresponding drug administration

claim was submitted by a participating CAP physician, the approved CAP vendor's claim and the participating CAP physician's claim were matched in the system and the approved CAP vendor's claim was authorized for payment.

However, changes to the claims processing requirements and the addition of a post-payment review process required by section 108(a)(2) of the MIEA-TRHCA (discussed above in this section) eliminates the approved CAP vendor's dependency on a participating CAP physician's filing of a drug administration claim before the approved CAP vendor may be paid for a CAP drug. Accordingly, there is no longer a need to afford party status to the approved CAP vendor for the drug administration claim submitted by the participating CAP physician. Instead, under the TRHCA legislation, the approved CAP vendor's drug claim may be paid by the designated carrier once received. This determination made on the claim constitutes an initial determination as defined in § 405.924. The approved CAP vendor is considered a party to this initial determination, and thus, may request a redetermination and subsequent appeals consistent with the process established under 42 CFR Part 405, Subpart I.

The changes proposed to CAP claims processing in this proposed rule that conform to the TRHCA legislation result in two scenarios that create appeals rights for the approved CAP vendor with respect to their drug product claim: (1) Prepayment denials of the approved CAP vendor's claim made by the designated carrier (based on information from the local carrier that the payment for the drug should be denied as excluded or non-covered); and (2) post-payment denials by the designated carrier based on the post-payment review process established under TRHCA.

Therefore, we are proposing the following clarifications regarding the CAP appeals process for an approved CAP vendor's denied drug claims:

- For prepayment denials, the approved CAP vendor, as a supplier, has a direct right to appeal the initial determination made by the designated carrier on its drug product claim. The local carrier will conduct the redetermination on prepayment denials. We acknowledge that this process differs from a traditional fee-for-service appeal since the redetermination will not be conducted by the contractor that issued the initial determination. However, we believe the local carrier is the most appropriate entity to review the prepayment denial since it is most

familiar with the relevant coverage policies for that jurisdiction.

- For the postpayment review process, if the designated carrier selects the drug claim for review, this constitutes a reopening of the initial determination. If the designated carrier cannot verify administration or cannot determine that the drug is covered or medically reasonable and necessary, the designated carrier issues a revised determination to deny coverage of the drug product claim. The designated carrier then determines whether an overpayment exists, and if so, seeks recovery of the overpayment. The approved CAP vendor, as a supplier, would then have the right to request a redetermination of the revised coverage determination, and the overpayment assessment. The designated carrier will process the redetermination.

#### g. Definition of Exigent Circumstances

Sections 1847B(a)(1)(A)(ii) and 1847B(a)(5)(A)(ii) of the Act require that each physician be given the opportunity annually to elect to obtain drugs and biologicals through the CAP and to select an approved CAP vendor. Section 1847B(a)(5)(A)(i) of the Act allows for selection of another approved CAP vendor more frequently than annually in exigent circumstances as defined by CMS.

In the CY 2006 PFS final rule with comment period (70 FR 70258), we stated that participating CAP physicians would have the option of changing approved CAP vendors or opting out of the CAP program on an annual basis. We also provided the circumstances, as specified in § 414.908(a)(2), under which a participating CAP physician may choose a different approved CAP vendor mid-year or opt-out of the CAP. These circumstances are: (1) If the selected approved CAP vendor ceases to participate in the CAP; (2) if the participating CAP physician leaves the group practice that had selected the approved CAP vendor; (3) if the participating CAP physician relocates to another competitive acquisition area (if multiple CAP competitive areas are developed) or, (4) for other exigent circumstances defined by CMS. We also identified a separate exigent circumstance relating to instances in which an approved CAP vendor declines to ship CAP drugs (when the conditions of § 414.914(h) are met) in § 414.908(a)(5). We noted that in all these cases, while there is only one drug category for CAP, the participating CAP physician would be allowed to opt-out of the CAP altogether.

The CAP became operational on July 1, 2006. Since that time, we have been

contacted by a few participating CAP physicians requesting that they be permitted to cancel their election agreement. Some of these requests have come from physician practices that misunderstood the program but found the program structure workable after further education about the CAP. Other requests have come from participating CAP physicians who identified significant concerns within the first few weeks of their participation that could not be resolved through provider education. When we initially implemented the CAP, we believed that most issues raised by participating CAP physicians would relate to quality and service issues that could be resolved through the approved CAP vendor's grievance process and the dispute resolution process conducted by the designated carrier. However, our experience with the initial operation of the CAP has demonstrated that there may be other business reasons a practice might wish to leave the program that are unrelated to the approved CAP vendor's performance. Examples of these include a demonstration of financial hardship due to participation in the CAP, the practice's inability to update its billing system despite a good faith effort, or that the practice relied on misleading information about the program from outside sources when making the decision to participate. Therefore, while we continue to believe that opportunities for leaving the CAP outside the annual election process should be limited because the CAP was designed as a program that physicians would make a decision to participate in on an annual basis, consistent with section 1847B(a)(5)(A) of the Act, we are proposing to define an additional exigent circumstance for opting out of the CAP. Under this proposed exigent circumstances exception, a participating CAP physician would be able to submit a written request to terminate his or her CAP physician election agreement within 30 days of its effective date, and CMS would grant such a request if the participating CAP physician could demonstrate that remaining in the CAP would be a significant burden.

The participating CAP physician would be required to submit a written request to terminate his or her participation in the CAP, along with a reason for the request to leave the CAP, within 30 days of the effective date of the election agreement. Examples of a significant burden include, but are not limited to the following: A demonstration of financial hardship due to participation in the CAP, the practice's inability to update its billing

system despite a good faith effort, or that the practice relied on misleading information about the program from outside sources when making the decision to participate and has proof of receiving such information. The request would be sent to the CAP-designated carrier under the dispute resolution process, and within 1 business day the designated carrier would determine whether the request was related to the service provided by the approved CAP vendor. If so, the CAP designated carrier would refer the participating CAP physician to his or her approved CAP vendor's grievance process to further determine whether any appropriate and reasonable steps could be taken to resolve the issue the participating CAP physician had identified. The approved CAP vendor would have 2 business days to respond to the participating CAP physician's concern, consistent with our regulations at § 414.914(f)(5). If the approved CAP vendor was unable to identify a solution, consistent with the CAP statute, regulations, contracts and guidance, and acceptable to the physician, for resolving the issue, the participating CAP physician would be referred back to the CAP designated carrier for assistance under the dispute resolution process.

We propose that the participating CAP physician's request would be handled under the dispute resolution process because procedures and defined time frames for handling participating CAP physician and approved CAP vendor complaints are already developed under the CAP dispute resolution process. If the designated carrier did not believe the participating CAP physician's request was related to an issue that could be resolved by the approved CAP vendor, then the designated carrier would seek to resolve any other issues raised by the physician in the request to terminate CAP participation. The designated carrier would conduct an investigation into the physician's request to terminate his or her CAP election agreement and attempt to resolve any issues. If the designated carrier is unable to resolve the situation to the physician's satisfaction, within 2 business days, the designated carrier can either make a recommendation to CMS that the physician be permitted to terminate his or her CAP election agreement or request a 2-day extension to continue an attempt to resolve the issue. We believe that 4 business days would be sufficient to conclude this process because it would give the carrier time to gather information from other affected parties, such as the participating CAP physician's carrier,

but still prepare a speedy summary of the issues involved in the physician's request. After the 2-day or 4-day period, as applicable, the designated carrier would forward the physician's request, along with its recommendation, to CMS. We would then review the recommendation and make a final decision within 2 business days of the date we received the request.

If we agree that the participating CAP physician has demonstrated that remaining in the CAP is a significant burden, we would allow that physician to terminate his or her participation in the program. We would inform the CAP-designated carrier of its decision and the decision would be communicated to the participating CAP physician in writing by the designated carrier. As part of this process, the physician's termination date for his or her CAP election agreement would be determined and communicated to the all parties involved, including the physician's local carrier. If we do not believe that the physician has demonstrated a significant burden, we would not allow the physician to terminate his or her participation in the CAP. We would inform the physician of such a decision and would include a recommendation for corrective action (such as education), and the right to request reconsideration as specified in § 414.917.

If we agree to terminate the participating CAP physician's CAP election agreement, the physician would be required to cooperate in any post-payment review and appeals of claims for drugs that the approved CAP vendor had already provided to the physician and been paid for. The physician would also have to make arrangements with the approved CAP vendor for the return of any unused drugs that had not been administered to the beneficiary prior to the effective date of the physician's termination from the CAP. If the approved CAP vendor has inadvertently billed CMS for drugs that had not been administered to a beneficiary, the vendor would be required to correct the claim and return any overpayment.

#### h. Transporting CAP drugs

Although section 1847B(b)(4)(E) of the Act provides for the shipment of CAP drugs to settings other than a participating CAP physician's office under certain conditions, we did not propose to implement the CAP in alternative settings. In the July 6, 2005 IFC, we described both comments that supported the idea of allowing participating CAP physicians to transport drugs to multiple office locations and comments that raised

concerns about the risk of damaging a drug that has not been kept under appropriate conditions while being transported.

As stated in § 414.906(a)(4), we implemented the CAP with a restriction that CAP drugs should be shipped directly to the location where they will be administered. However, we were aware that physicians may desire to administer drugs in alternative settings, especially in a home. We sought comment on how this could be accommodated under the CAP in a way that addresses the concerns about product integrity and damage to the approved CAP vendors' property expressed by the potential vendors.

Several comments submitted in response to the July 6, 2005 IFC suggested either narrowing or removing the restriction on transporting drugs to other locations. Commenters believed that physicians were knowledgeable about drug stability and handling, and therefore, were capable of assuming this responsibility. Other commenters pointed out that transporting the drug to another office location may allow for flexibility in scheduling patient visits. It would allow practices with satellite operations that are not open every business day to receive shipments of CAP drugs at another practice location and then to administer the drugs in the satellite office.

These comments and our experience with the CAP thus far, have caused us to consider changing our position. Therefore in this proposed rule, we are seeking comment on the potential feasibility of narrowing the restriction on transporting CAP drugs where this is permitted by State law and other applicable laws and regulations. We are asking commenters to consider how such a policy could be constructed so that the approved CAP vendor could retain control over how drugs that it owns are handled (we remind commenters that CAP drugs are the approved CAP vendor's property until they have been administered). We welcome comments on other issues that we should take into account as we consider the possibility of future changes to the regulation so that CAP drugs may be transported from one approved CAP physician's practice location to another office location that is listed on the physician's CAP election agreement form. We also welcome comments on how to structure requirements so that drugs are not subjected to conditions that will jeopardize their integrity, stability or sterility while being transported and steps to keep transportation activities consistent with all applicable laws and

regulations. We are also seeking comments on whether any agreement allowing participating CAP physicians to transport CAP drugs to alternate practice locations should be voluntary, meaning that approved CAP vendors would not be required to offer such an agreement and physicians who participate in the CAP would not be required to accept such an offer. Finally, we are seeking comments on whether the agreement should be documented in writing, and whether it is necessary to create any restrictions on which CAP drugs could be transported. Again, we remind potential commenters that we are not making a specific proposal at this time, but we will use any information we receive to structure a future proposal, in the event we make one.

#### i. Alternatives to the CAP Prescription Order Number

We received a number of comments that we responded to in the July 6, 2005 IFC (70 FR 39043 and 39049,) about the administrative burden that the CAP ordering and claims payment process imposes upon participating CAP physicians; specifically, activities associated with using and tracking the prescription order number were mentioned. In response to the IFC, we have received additional comments on this issue. After the close of the comment period we also received an inquiry from the current approved CAP vendor about the potential length of the CAP prescription order number and whether it could present a burden to participating CAP physicians. A 30-byte field is currently available on the electronic claim form for prescription numbers; however, it is not necessary for the prescription order number to be 30 bytes long. To meet national electronic standards for the automated transfer of certain health care data mandated by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA), Medicare claims that are submitted electronically must use a specific data format. Within this framework, the CAP prescription order number is captured in Loop 2410, REF02 (REF01=XZ) of the ANSI 4010A1 electronic claims transaction. This segment is designed to capture the assigned prescription number. The requirements for developing the CAP prescription order number are as follows: the first 9 characters are the approved CAP vendor's ID and the HCPCS code of the drug that is being billed for; the approved CAP vendor sets the remaining characters. Typically, 15 or

fewer total characters have been used by the approved CAP vendor.

Each prescription order number is unique to a dose of a CAP drug that is being shipped for administration to a particular beneficiary. The approved CAP vendor is responsible for generating the prescription order number, and as stated in the July 6, 2005 IFC (70 FR 39042), each dose of a CAP drug is required to have a separate prescription order number to facilitate claim matching and approved CAP vendor payment. Although the CAP prescription order number on the approved CAP vendor's claim is no longer matched to the prescription order number on the participating CAP physician's claim prior to claims payment, the prescription order is still used to track each dose of a drug that is shipped by the approved CAP vendor to the participating CAP physician and administered to the beneficiary. Prior to paying the approved CAP vendor's claim for a drug the CAP designated carrier uses the prescription order number to check the claims processing system to ascertain whether the local carrier has adjudicated the drug administration claim. If so, the CAP designated carrier will look to see whether the local carrier determined that the CAP drug administered by the participating CAP physician is covered and is medically necessary. If the participating CAP physician's local carrier has not made a determination on the physician's claim and the CAP drug claim, the designated carrier will pay the approved CAP vendor's claim upon receipt and use the CAP prescription order number to help verify drug administration on a post-payment basis.

The prescription order number accompanies each dose of drug that is sent to a participating CAP physician. After the drug is administered, the *participating CAP* physician's drug administration claim is submitted with a no-pay line containing the prescription order number. The approved CAP vendor's claim for the CAP drug also contains the prescription order number.

Under the claims matching system used when the CAP was implemented, the prescription order number was used to match an approved CAP vendor's CAP drug claim to the participating CAP physician's drug administration claim in the claims processing system prior to payment. The presence of a drug administration claim with a matching prescription order number indicated that the drug on the corresponding approved CAP vendor's claim had been administered and a successful match

allowed the approved CAP vendor to be paid for that claim.

At this time, section 108(a)(2) of the MIEA-TRHCA requires us to make payment upon receipt of an approved CAP vendor's drug claim and then to conduct a post-payment review of claims. As stated in the MIEA-TRHCA, the post-payment review process is intended to "assure that payment is made only for a drug or biological \* \* \* if the drug or biological has been administered to a beneficiary." Under this new process, the prescription order number is still used to establish that the drug that is being billed for by the approved CAP vendor has been administered by the participating CAP physician and that the vendor's claim is payable. Situations such as the frequency of recurring cyclic drug treatment regimens, the possibility of temporary interruption to these regimens, and the lack of agreement between the approved CAP vendor's anticipated day of service and the actual date that the drug is administered make the use of an aid to assist accurate tracking of CAP drugs desirable. We believe that the prescription order remains an appropriate and necessary tool to track the administration of a specific dose of a drug and for the accurate execution of the post-payment review process.

Although we believe that the use of the prescription order number is necessary to facilitate accurate review of CAP claims, we are aware that it may be considered an inconvenience by some potential CAP-participating physicians and approved CAP vendors. Therefore, we are seeking comment on alternative methods that could be used to accurately track the administration of specific doses of drugs in order to meet the requirements stated in section 108(a)(2) of the MIEA-TRHCA. We are not proposing to implement such a change at this time, but would like to receive comments on other methods that could be used to track CAP drug administration on a dose by dose basis. We may propose a change in future rulemaking.

#### j. Prefilled Syringes

In the July 6, 2005 IFC (70 FR 39061), we described public comments that stated that participating CAP physicians could not vouch for the quality of products that were opened by an approved CAP vendor for repackaging, for mixing the drug with other drugs or injectable fluids (admixture), or for removing a part of the contents to supply the exact dose for a beneficiary. Several commenters recommended that approved CAP vendors deliver their

products in the same form in which they are received from the manufacturer, without opening packaging or containers, mixing or reconstituting vials, or repackaging. Specifically, the commenters were concerned about the capabilities of individuals who mix the drug, as well as shipping conditions, storage, and stability.

We responded by stating that the CAP is not intended to require approved CAP vendors to perform pharmacy admixture services, (for example, to furnish reconstituted or otherwise mixed drugs repackaged in IV bags, syringes, or other containers that are ready to be administered to a patient) when furnishing CAP drugs. Admixture services for injectable drugs require specialized staff, training, and equipment, and these services are subject to standards such as United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding—Sterile Preparations. These requirements have significant impact on drug shipping, storage, and stability requirements, as well as system cost and complexity. As stated in § 414.906(a)(4), the approved CAP vendor must deliver "CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer."

Since issuing the July 6, 2005 IFC, we have become aware that bevacizumab (Avastin®) is being used for the treatment of exudative age-related macular degeneration (wet AMD) in very small doses. Although this is an off-label use, it is gaining acceptance among ophthalmologists who treat wet AMD and this use has been the subject of several carriers' local coverage determinations. Bevacizumab is considerably less expensive than certain other drugs used in the treatment of wet AMD.

The smallest commercially available package of bevacizumab is a 100mg single use vial, while a dose used to treat wet AMD is approximately 1mg. Some local carriers who have issued coverage instructions for the use of bevacizumab in the treatment of wet AMD allow physicians to obtain these small doses of drug from a pharmacy that is capable of preparing sterile products. We expect to issue instructions that will allow participating CAP physicians to use the furnish as written option, as appropriate, and to obtain small doses of bevacizumab outside of the CAP in prefilled syringes if their local carrier's coverage determinations allow such a practice

and it is consistent with applicable laws and regulations. We believe that this approach will minimize the waste associated with using a 100mg single use vial for the treatment of wet AMD and will increase the flexibility for participating CAP physicians by making an alternative quantity of this drug available to participating CAP physicians whose carriers have applicable policies.

However, this option is not available in all areas. Therefore, we are considering reassessing our policy on the use of prefilled syringes to determine whether it would be feasible to make the option of using prefilled syringes supplied by an approved CAP vendor available to all physicians who participate in the CAP, rather than requiring physicians to go outside the CAP in order to obtain CAP drugs in prefilled syringes. We are seeking comments on whether allowing approved CAP vendors to repack CAP drugs in certain situations may be beneficial to beneficiaries, the program, and to the physicians who participate in it. We are not proposing to make a change to our regulations at this time, but we are seeking additional information that might allow us to consider making such a change in the future.

In considering whether to propose a change to our regulations in the future, we seek comments on whether approved CAP vendors are likely to be pharmacies or have access to pharmacy services with trained personnel and facilities for the small scale preparation of sterile drug products in response to a specific prescription order for a specific patient. At this time there is no specific requirement for approved CAP vendors to be pharmacies. Also, please note we are describing a specialized pharmacy function; we are not contemplating manufacturing of drug products under this program.

We are also seeking comments on whether an approved CAP vendor should be given an opportunity to supply bevacizumab under the CAP if it is repackaged in a patient-specific dose consistent with applicable state laws and regulations upon request from a participating CAP physician. Furthermore, we are seeking comments on whether this sort of activity should be restricted to bevacizumab, or possibly phased-in for other CAP drugs. If we were to apply this sort of policy to other CAP drugs, we would also have to determine how phasing-in might occur, which drugs it should apply to and whether the preparation of admixtures (including the preparation of sterile syringes, minibags, and mixing

of drugs and solutions intended for intravenous administration) should be allowed as well.

We also seek comments on how this sort of service could be limited to participating CAP physicians who voluntarily agree to use it, and whether such an agreement should be made in writing between the approved CAP vendor and the participating CAP physician. We also seek comment on how such a program could be structured so that the service and staff engaged in providing the service would be required to meet all applicable laws (including Stark, Anti-kickback, and State pharmacy laws, as well as regulations for the preparation of sterile products, (including standards for product integrity and sterility). We also seek comments on whether the cost of preparing such product would be included in the CAP vendor's bid price. Finally, we seek comments on whether any other important elements should be evaluated if we consider changing CAP policy on prefilled syringes in the future.

#### k. Contractual Provisions

Section 1847B of the Act is generally silent on the subject of disputes surrounding the delivery of drugs and the denial of drug claims. However, section 1847B(b)(2)(A)(ii)(II) of the Act states that a grievance process is a quality and service requirement expected of approved CAP vendors. In the July 6, 2005 IFC (70 FR 39055 through 39058), we described the process for the resolution of approved CAP vendors' claims denials and the resolution of participating CAP physicians' drug quality and service complaints. We encouraged participating CAP physicians, beneficiaries, approved CAP vendors, and the designated carrier to use informal communication as a first step to resolve service-related administration issues. However, we recognized that certain disputes would require a more structured approach, and therefore, we established processes under § 414.916 and § 414.917.

Suspension and termination from the CAP were the only remedies described under the CAP dispute resolution processes. Having gained some experience with the CAP, we believe that having an intermediate level of remedy is desirable in order to bridge the gap between taking no action and suspension or termination of an approved CAP vendor for less serious but persistent problems.

We believe that additional contractual obligations, such as additional reporting requirements could be useful,

particularly if they provide an opportunity for the approved CAP vendor to come into compliance using objective goals and a set timeline. Therefore, we are seeking comments on what types of potential contractual provisions that could be used to encourage approved CAP vendors to comply with CAP requirements for less serious violations, such as missing reporting deadlines, or participation in inappropriate promotional strategies. Given that the CAP statute does not provide for the imposition of sanctions such as withholding payment or imposing other types of monetary penalties, we believe that building appropriate provisions into the approved CAP vendor's contract to address noncompliance or expanding the approved vendor's code of conduct by proposing more specific CMS requirements could be appropriate approaches. We are requesting comments on what type of contractual provisions would be suitable, for example, requests for specific or targeted reporting and monitoring activities in response to specific violations, etc. We are also looking for comments on whether an approved CAP vendor's code of conduct could be used to address these types of less serious situations and how that could be accomplished. Finally, we invite comments on whether the CAP physician election agreement should be revised to include provisions to address participating CAP physicians' noncompliance with CAP rules or the CAP election agreement. We will use any information that we receive on these issues to possibly develop a future proposal.

#### *G. Issues Related to the Clinical Laboratory Fee Schedule*

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

##### 1. Date of Service for the Technical Component of Physician Pathology Services (§ 414.510)

In the CY 2007 PFS final rule with comment period (71 FR 69787), we added § 414.510 for the date of service of a clinical diagnostic laboratory test that uses a stored specimen. Generally, our policy states the date the specimen is collected is the date of service for claims review and adjudication. However, for a laboratory test that uses a stored specimen, the date of service is the date the specimen was obtained from the storage for a specimen that is stored for more than 30 days before

testing. Specimens stored 30 days or less have a date of service of the date the test was performed only if—

(a) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(b) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(c) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(d) The results of the test do not guide treatment provided during the hospital stay; and

(e) The test was reasonable and medically necessary for the treatment of an illness.

In addition, § 414.510(b)(3) specifies the conditions for the date of service for a chemosensitivity test.

When we added § 414.510, we indicated the provision applies to clinical diagnostic laboratory tests. For outpatients, clinical diagnostic laboratory tests are paid under the Medicare Part B clinical laboratory fee schedule. Upon further review, we believe the provision should also apply to the technical component (TC) of physician pathology services. In practice, the collection date for both clinical laboratory services and the TC of physician pathology services is similar. Therefore, we believe § 414.510 should apply to both types of services. This will improve claims processing and adjudication in relation to the clarity of dates of service, accuracy of payment, and detection of duplicate services. For outpatients, the TC of physician pathology services can be paid under the PFS or the hospital OPPS. As a result, for § 414.510, we are proposing to revise the section heading and introductory sentence to specify the provision applies to both clinical laboratory and pathology specimens. We are also revising § 415.130(d) to include a reference to § 414.510.

##### 2. New Clinical Diagnostic Laboratory Test (§ 414.508)

###### a. Background

In the CY 2007 PFS final rule with comment period (71 FR 69701), we adopted a new subpart G under part 414 that implemented section 942(b) of the MMA requiring that we establish procedures for determining the basis for, and amount of payment for any clinical diagnostic laboratory test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 ("new tests").

Under § 414.508, we use one of two bases for payment to establish a payment amount for a new test. Under § 414.508(a), the first basis, called "crosswalking," is used if a new test is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. If we use crosswalking, we assign the new test code the local fee schedule amounts and national limitation amount (NLA) of the existing test code or codes. If we crosswalk to multiple existing test codes, we determine the local fee schedule amounts and NLA based on a blend of payment amounts for the existing test codes. For example, we may pay based on 75 percent of the payment amounts for one existing test code and 25 percent of the payment amounts for another existing test code.

The second basis for payment is "gapfilling." Under § 414.508(b), we use gapfilling when no comparable existing test is available. We instruct each Medicare carrier to determine a carrier-specific amount for use in the 1st year that the new code is effective. The sources of information that these carriers examine in determining carrier-specific amounts include:

- Charges for the test and routine discounts to charges;
- Resources required to perform the test;
- Payment amounts determined by other payers; and
- Charges, payment amounts, and resources required for other tests that may be comparable (although not similar enough to justify crosswalking) or otherwise relevant.

After the first year, the carrier-specific amounts are used to calculate the NLA for subsequent years. Under § 414.508(b)(2), the test code is paid at the NLA, rather than the lesser of the NLA and the carrier-specific amounts.

In the CY 2007 PFS final rule with comment period, we also explained that we notify our carriers when to use the gapfill method described with a program instruction which lists the specific new test code and the timeframes to establish carrier-specific amounts. Contractors are required to establish carrier-specific amounts on or before March 31 of the year. Contractors may revise their payment amounts, if necessary, on or before September 1 of the year. In this manner, a carrier may revise its carrier-specific amount based on additional information during the 1st year.

In the CY 2007 PFS final rule with comment period (71 FR 69702), we also described the timeframes for determining the amount of and basis for payment for new tests. Under 45 CFR

§ 162.1003, a code for a new test may be developed either by the AMA's CPT Editorial Panel, which maintains and distributes the CPT codes, or HHS, which maintains and distributes the HCPCS codes. The codes to be included in the upcoming year's fee schedule (effective January 1) are available as early as May. We then list the new clinical laboratory tests codes on our Web site, usually in June, along with registration information for the public meeting.

The public meeting is held no sooner than 30 days after we announce the meeting in the **Federal Register**. The public meeting is typically held in July. In September, we post our proposed determination of the basis for payment for each new code. We also seek public comment on these proposed determinations of the basis for payment. The updated clinical laboratory fee schedule is prepared in October for release to our contractors during the first week in November. Our contractors have many information system steps to complete during the months of November and December so that the updated clinical laboratory fee schedule is ready to pay claims effective January 1 of the following calendar year.

In response to the CY 2007 PFS proposed rule, we received several comments regarding the level of detail of information presented during the public meeting process. We responded that we did not believe that opportunities for information gathering on new tests have been fully utilized within the public meeting process and that payment recommendations from the public have sometimes lacked charge, cost, and clinically detailed information for the new clinical laboratory tests. We also stated that when soliciting public input for the meeting we would recommend that all participants in the public meeting consultation process strive for transparency and try to provide as much supporting information as possible to assist us in evaluating their recommendations.

We also received some comments that suggested that the method used by contractors to determine their price for gapfilled tests should be more specific. We responded that we would engage in discussions with our carrier contractors and laboratory industry representatives to explore their experiences with the gapfill process. We also agreed to host a forum to listen to suggestions from the public.

We have discussed these issues with our contractors. We also plan to solicit comments on the gapfill process in the clinical laboratory public meeting

scheduled on July 16, 2007. Although we encourage the public to suggest improvements to our gapfilling process at the upcoming clinical laboratory public meeting, we recommend that interested parties also submit written comments on the proposed changes for the gapfilling process contained in this rule. Written comments will be considered in the final rule to the extent that these comments relate to the issues discussed in this proposed rule.

Discussions with our contractors and other interested parties revealed the length of time we allow for a contractor to establish a carrier-specific amount may sometimes be insufficient for obtaining additional sources and data on a new test. However, our contractors and other interested parties were also concerned that if procedures and determinations were permitted to extend over too long a time frame, the uncertainty of the final payment amount would be detrimental for laboratories, practitioners, and patients for incorporating new technology tests and improving patient care.

In addition, in response to the CY 2007 PFS proposed rule, a commenter requested that we establish a formal review, or reconsideration process of a payment amount determination. In response to the comment, we revised § 414.508(b)(3) to provide that if we gapfill a test, but determine after the 1st year of gapfilling that carrier-specific gapfilled amounts will not pay for the test appropriately, in the 2nd year we may use the crosswalk basis to establish fees for the test. We also stated that we expected to solicit comments on a potential reconsideration process in a future rulemaking.

At § 414.509, we are proposing a reconsideration process for determining the basis for and amount of payment for any new test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008. We have strived to balance additional opportunities for public input against the necessity for establishing final fees for new clinical laboratory test codes.

Section 1833(h)(8)(A) of the Act provides broad authority to develop through regulation procedures for the method for determining the basis for and amount of payment for new tests. We believe that we have authority under section 1833(h)(8)(A) of the Act to establish procedures under which we may reconsider the basis for and amount of payment for a new test. Furthermore, under section 1833(h)(8)(D) of the Act, the Secretary may convene such other public meetings to receive public comments on payment amounts for new tests as the Secretary deems appropriate.

We note that, under both section 1833(h)(8)(B)(v) of the Act and § 414.506(d)(2), the Secretary must make available to the public a list of "final determinations." We do not believe that these provisions preclude us from reconsidering our final determinations. It is not unusual for us to provide for discretionary reopening or reconsideration of final agency action. For example, under § 405.1885, we may reopen a final agency determination regarding payment to a provider of services.

#### b. Basis for Payment

Under our existing procedures for determining the basis for payment of a new test, either to crosswalk or gapfill, we receive comments on the appropriate basis for payment for a new test both at the public meeting in July and after we announce our proposed determinations in September. In November, we post our determination for the basis for payment for the new test on the CMS Web site. This determination of the basis for payment is final, except in the case of a gapfilled test for which we later determine that gapfilling is not appropriate under § 414.508(b)(3).

We are proposing to create a reconsideration process for determinations of the basis, either crosswalking or gapfilling, for payment of a new clinical diagnostic laboratory test. Consistent with our existing process, we would make a determination using the information gathered from the public meeting process and post a determination of the basis for payment, either to crosswalk or gapfill, on the CMS Web site, likely in November. Under § 414.508, claims would be paid using this basis to calculate fees beginning January 1. We would accept written comments on this basis determination for 60 days after we posted the determination on the CMS Web site. If a commenter recommended that we switch from gapfilling to crosswalking for a new code, the commenter would also have the opportunity to recommend the code or codes to which to crosswalk the new test code.

In addition, those members of the public who submitted a written comment within the 60-day comment period would also have the opportunity to present their comment orally at the next clinical laboratory public meeting and hear other comments during the public meeting.

After considering the comments received and the information of the public meeting, we would post our decision as to whether we elected to reconsider our determination of the

basis for payment. If we elect to reconsider the basis for payment, we would post our determination as to whether we would change of the basis for payment on the CMS Web site on or before January 1 of the next year. Our decision regarding the basis for payment would be final and not subject to further reconsideration.

If we change our prior determination of the basis for payment, the new determination would be effective the following January 1. We would not reopen or otherwise reprocess claims with dates of service prior to the effective date of the revised determination.

We note that, under our proposed reconsideration processes (for both the basis for payment and amount of payment), we would make two separate decisions. First, we would decide whether to reconsider our prior determination. If we elect to reconsider our prior determination, we would then determine whether we should change our prior determination.

#### c. Amount of Payment

##### i. Crosswalking

Under our existing procedures, commenters recommend the code or codes to which to crosswalk a new clinical laboratory test both at the public meeting in July and during the comment period after we issue our proposed determination in September. We consider the appropriate basis for payment and the amount of payment at the same time. Therefore, commenters that recommend crosswalking as the basis for payment for a new test also make recommendations concerning the code or codes to which to crosswalk the new test. In November, we post the code or codes to which we will crosswalk the test and the payment amount for the test on the CMS Web site. This determination is final.

We are proposing to create a reconsideration process under which we may reevaluate the code or codes and their corresponding fees to which we crosswalk a new test's fees. After we posted our determination of the code or codes to which the test would be crosswalked on the CMS Web site, we would pay claims on the basis of this determination beginning January 1. We would accept written comments on the crosswalked code or codes and the resulting amount of payment for the new code for 60 days after we posted the determination on the CMS Web site. In addition, a commenter, who had submitted a written comment within the 60-day comment period, would also be given the opportunity to present their

comment orally at the next public meeting.

After considering the comments received and the information of the public meeting, we would post our decision as to whether we had elected to reconsider our determination of the crosswalked code or codes and the resulting amount of payment. If we elect to reconsider the amount of payment and had determined that we should revise the amount of payment, we would post a new determination of the code or codes to which we would crosswalk the test on or before January 1 of the next year. Our decision regarding the amount of payment would be final and not subject to further reconsideration.

If we change our prior determination of the amount of payment, the new determination would be effective the following January 1. We would not reopen or otherwise reprocess claims with dates of service prior to the effective date of the revised determination.

As discussed in section II.G.2.b., we may also change the basis for payment for a new test as the result of reconsideration. If we change the basis for payment from gapfilling to crosswalking, we would also determine the code or codes to which we would crosswalk the test. Because we believe it is important to establish final payment amounts within a reasonable amount of time, we are proposing that these determinations of crosswalked payment amounts would not be subject to reconsideration.

##### ii. Gapfilling

As discussed in this preamble and in accordance with § 414.508(b), after we determine that gapfilling will be the basis for payment for a new clinical diagnostic laboratory test, we instruct our contractors to determine carrier-specific gapfill amounts by April 1 and finalize carrier-specific amounts by September 30. We include the determinations of carrier-specific amounts and the NLA for the new test code in the clinical laboratory fee schedule the following November when we post our payment determinations on the CMS Web site. Except in the case of a gapfilled test for which we determine that gapfilling was not appropriate under § 414.508(b)(3), these determinations are final.

We are proposing to provide for a reconsideration process for gapfilled payment amounts. Under this process, by April 30, we would post the carrier-specific amounts on the CMS Web site. Interested parties would submit written comments to CMS on the carrier-

specific amounts within 60 days from the date of posting the carrier-specific amounts. In addition, those commenters, who had submitted a written comment within the 60-day comment period, would be given the opportunity to present their comments orally at the next clinical laboratory public meeting.

Carriers would finalize carrier-specific amounts by September 30 and we would set the NLA be at the median of the carrier-specific amounts. However, based on the comments received, we would evaluate whether we should reconsider the carrier-specific amounts and NLA. If we elected not to reconsider the carrier-specific amounts and the NLA, we would post the carrier-specific amounts and NLA on the CMS Web site on or before January 1 of the next year. These amounts would be based on the carrier-specific amounts and NLA we had posted in September. Payment for the test would be made at the NLA on January 1 of the next year. This determination would be final and not subject to further reconsideration.

If we elect to reconsider the carrier-specific amounts and decide to revise our prior determination, we would adjust the NLA based on comments received. We would post the revised NLA on the CMS Web site and payment for the test would be made at the NLA beginning January 1. This determination would be final and not subject to further reconsideration.

We are also proposing that, if we change the basis of payment from crosswalking to gapfilling as the result of a reconsideration, the new gapfilled payment amount would be subject to reconsideration under proposed § 414.509(b)(2). Unlike a crosswalked test, the payment amount for a gapfilled test is not established when we determine the basis for payment because it takes approximately 9 months for our contractors to establish carrier-specific amounts. Thus providing for reconsideration of gapfilled payment amounts would not lengthen the period of time it would take to determine a final payment amount.

In addition, we are proposing to amend § 414.508(b)(3) to provide that § 414.508(b)(3) applies to new tests for which a new or substantially revised HCPCS code assigned on or before December 31, 2007. We believe that the more comprehensive reconsideration procedures we are proposing should apply to new or substantially revised HCPCS codes assigned after December 31, 2007.

#### d. Jurisdiction for Reconsideration Decisions

We are proposing that jurisdiction for reconsideration would rest exclusively with the Secretary. A decision whether to reconsider a determination would be committed to the discretion of the Secretary. Accordingly, a refusal to reconsider an initial determination would not be subject to administrative or judicial review. We recognize that parties dissatisfied with an initial determination as to the amount of payment for a particular claim for laboratory services may appeal the initial determination under part 405, subpart I of our regulations. Under our proposal, a party could challenge under part 405, subpart I a determination regarding the amount of payment for a new test—regardless of whether the amount of payment was established as the result of a reconsideration—but a party could not challenge a decision not to reconsider.

#### 3. Technical Revisions

We are also proposing technical revisions to § 414.502, § 414.506, and § 414.508. Under section 1833(h)(8)(A) of the Act, the term “new tests” is defined as any clinical diagnostic laboratory test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005. However, our regulations do not define the term “new test.” Therefore, we are proposing to define the term “new test” under § 414.502 using the statutory definition. In addition, under § 414.506 and § 414.508, we are proposing to replace references to “new clinical diagnostic laboratory test that is assigned a new or substantially revised code on or after January 1, 2005” with references to “new test.”

#### *H. Proposed Provisions Related to Payment for Renal Dialysis Services Furnished by End-Stage Renal Disease (ESRD) Facilities*

[If you choose to comment on issues in this section, please include the caption “ESRD PROVISIONS” at the beginning of your comments.]

Since August 1, 1983, payment for dialysis services furnished by ESRD facilities has been based on a composite rate payment system that provides a fixed, prospectively determined amount per dialysis treatment, adjusted for geographic differences in area wage levels. In accordance with section 1881(b)(7) of the Act, separate composite rates have been established for hospital-based and independent ESRD facilities. The composite rate is designed to cover a package of goods

and services needed to furnish dialysis treatments that include, but not be limited to, certain routinely provided drugs, laboratory tests, supplies, and equipment. Unless specifically included in the composite rate, other injectable drugs and laboratory tests medically necessary for the care of the dialysis patient are separately billable. The base composite rates per treatment, effective on August 1, 1983, were \$123 for independent ESRD facilities and \$127 for hospital-based ESRD facilities. The Congress has enacted a number of adjustments to the composite rate since that time. The current 2007 base composite rates are \$132.49 for independent ESRD facilities and \$136.68 for hospital-based ESRD facilities.

Section 623 of the MMA amended section 1881 of the Act to require changes to the composite rate payment methodology, as well as to the pricing methodology for separately billable drugs and biologicals furnished by ESRD facilities.

Section 1881(b)(12) of the Act, as added by the MMA, required the establishment of a basic case-mix adjusted prospective payment system (PPS) that would include the services comprising the composite rate and an add-on to the composite rate component for the difference between current payments for separately billed drugs and the revised drug pricing specified in the statute. In addition, section 1881(b)(12) of the Act required that the composite rate be adjusted for a limited number of patient characteristics (case-mix) and section 1881(b)(12)(D) of the Act gave the Secretary discretion to revise the wage indices and the urban and rural definitions used to develop them. Finally, section 1881(b)(12)(E) of the Act imposed a budget neutrality requirement, so that aggregate payments under the basic case-mix adjusted composite payment system for 2005 would equal the aggregate payments that would have been made for the same period if section 1881(b)(12) of the Act did not apply.

Before January 1, 2005, payment to both independent and hospital-based facilities for the anti-anemia drug, erythropoietin (EPO) was established under section 1881(b)(11) of the Act at \$10.00 per 1,000 units. For independent ESRD facilities, payment for all other separately billable drugs and biologicals was based on the lower of actual charges or 95 percent of the average wholesale price (AWP). Hospital-based ESRD facilities were paid based on the reasonable cost methodology for separately billed drugs and biologicals (other than EPO) furnished to dialysis

patients. Changes to the payment methodology for separately billed ESRD drugs and biologicals that were established by the MMA and were effective January 1, 2005 are described in sections II.H.1. and II.H.2. These changes affected payments in both CY 2005 and CY 2006.

In addition, section 623(f)(1) of the MMA directs the Secretary to submit a Report to Congress detailing a bundled PPS for services furnished by ESRD facilities to Medicare beneficiaries. The bundled PPS would be a different way of paying for ESRD services since it will include not only composite rate services, but would also include separately billable drugs (including EPO), laboratory tests, and other separately billable items into one PPS payment rate. We expect to release the REPORT TO CONGRESS this summer.

#### 1. CY 2005 Revisions

In the CY 2005 PFS final rule with comment period (69 FR 66319 through 66334), we implemented section 1881(b) of the Act, as amended by section 623 of the MMA, and revised payments to ESRD facilities. These revisions were effective January 1, 2005, included implementation of a case-mix adjusted payment system that incorporated services that comprise the composite rate; an update of 1.6 percent to the composite rate component of the payment system; and a drug add-on of 8.7 percent to the composite rate for the difference between current payments for separately billable drugs and payments based on the revised drug pricing for 2005 which used acquisition costs. The CY 2005 PFS final rule with comment period also implemented case-mix adjustments to the composite rate for a limited number of patient characteristics (that is, age, low body mass index (BMI), and body surface area (BSA)), effective April 1, 2005.

In addition, to implement section 1881(b)(13) of the Act, we revised payments for drugs billed separately by independent ESRD facilities, paying for the top 10 ESRD drugs based on acquisition costs (as determined by the OIG) and for other separately billed drugs at the average sales price +6 percent (hereafter referred to as ASP+6 percent). Hospital-based ESRD facilities continued to receive cost-based payments for all separately billable drugs and biologicals except for EPO which was paid based on average acquisition costs.

#### 2. CY 2006 Revisions

In the CY 2006 PFS final rule with comment period (70 FR 70161), we implemented additional revisions to

payments to ESRD facilities under section 623 of the MMA. For CY 2006, we further revised the drug payment methodology applicable to drugs furnished by ESRD facilities. All separately billed drugs and biologicals furnished by both hospital-based and independent ESRD facilities are now paid based on ASP+6 percent.

We recalculated the 2005 drug add-on adjustment to reflect the difference in payments between the pre-MMA AWP pricing and the revised pricing based on ASP+6 percent. The recalculation did not affect the actual add-on adjustment applied to payments in 2005, but provided an estimate of what the adjustment would have been had the 2006 payment methodology been in effect in 2005. The drug add-on adjustment was then updated to reflect the expected growth in expenditures for separately billable drugs in CY 2006.

As of January 1, 2006, we also implemented a revised geographic adjustment authorized by section 1881(b)(12) of the Act. As part of that change, we—

- Revised the labor market areas to incorporate the new CBSA designations established by the Office of Management and Budget (OMB);
- Eliminated the wage index ceiling and reduced the floor to 0.8500; and
- Revised the labor portion of the composite rate to which the geographic adjustment is applied.

We also provided a 4-year transition from the previous wage-adjusted composite rates to the current wage-adjusted rates. For CY 2006, only 25 percent of the payment is based on the revised geographic adjustments, and the remaining 75 percent of payment is based on the old metropolitan statistical area-based (MSA-based) payments.

In addition, section 5106 of the DRA provided for a 1.6 percent update to the composite rate component of the basic case-mix adjusted payment system, effective January 1, 2006. As a result, the base composite rate was increased to \$130.40 for independent ESRD facilities and \$134.53 for hospital-based facilities. For 2006, the drug add-on adjustment (including the growth update) was 14.5 percent.

#### 3. CY 2007 Updates

In the CY 2007 PFS final rule with comment period (71 FR 69681), we implemented the following updates to the basic case-mix adjusted payment system:

- An update to the wage index adjustments to reflect the latest hospital wage data, including a BN adjustment of 1.052818 to the wage index for CY 2007.

- A method to annually calculate the growth update to the drug add-on adjustment required by section 1881(b)(12) of the Act, as well as growth update to the drug add-on adjustment of 0.5 percent for CY 2007. Therefore, effective January 1, 2007 the drug add-on adjustment was increased to 15.1 percent.

In addition, section 103 of the MIEA—TRHCA established a 1.6 percent update to the composite rate portion of the payment system, effective April 1, 2007. Therefore, the current base composite rate is \$132.49 for independent facilities and \$136.68 for hospital-based facilities. Also, the effect of this increase in the composite rate portion of the payment system was a reduction in the drug add-on adjustment to 14.9 percent, effective April 1, 2007. Since the statutory increase only applied to the composite rate, this adjustment to the drug add-on percent was needed to maintain the drug add-on amount constant.

#### 4. Provisions of This Proposed Rule

For CY 2008, we are proposing the following updates to the composite rate payment system:

- A growth update to the drug add-on adjustment to the composite rates; and
- An update to the wage adjustment to reflect the latest available wage data, and a revised budget neutrality adjustment.

##### a. Proposed Growth Update to the Drug Add-on Adjustment to the Composite Rates

Section 623(d) of the MMA added section 1881(b)(12)(B)(ii) of the Act which required the establishment of an add-on to the composite rate to account for changes in the drug payment methodology stemming from enactment of the MMA. Section 1881(b)(12)(c) of the Act provides that the drug add-on must reflect the difference in aggregate payments between the revised drug payment methodology for separately billable ESRD drugs and the AWP payment methodology. In 2005, we generally paid for ESRD drugs based on average acquisition costs. Thus the difference from AWP pricing was calculated using acquisition costs. However, in 2006 when we moved to ASP pricing for ESRD drugs, we recalculated the difference from AWP pricing using ASP prices.

In addition, section 1881(b)(12)(F) of the Act requires that, beginning in CY 2006, we establish an annual update to the drug add-on to reflect estimated growth in expenditures for separately billable drugs and biologicals furnished by ESRD facilities. This growth update applies only to the drug add-on portion

of the case-mix adjusted payment system.

The CY 2007 drug add-on adjustment to the composite rate is 14.9 percent. The drug add-on adjustment for CY 2007 incorporates an inflation adjustment of 0.5 percent. This computation is explained in detail in the CY 2007 PFS final rule with comment period (71 FR 69682 through 69684). We note that the drug add-on adjustment of 15.1 percent that was published in the CY 2007 PFS final rule with comment period did not account for the 1.6 percent update to the composite rate portion of the basic case-mix adjustment payment system that was subsequently enacted by the MIEA-TRHCA, effective April 1, 2007. Since we compute the drug add-on adjustment as a percentage of the weighted average base composite rate, the drug add-on percentage was decreased to account for the higher composite payment rate resulting in a 14.9 percent add-on adjustment beginning April 1, 2007. This adjustment was necessary to ensure that the total drug add-on dollars remained constant.

(i) Estimating Growth in Expenditures for Drugs and Biologicals for CY 2008

Section 1881(b)(12)(F) of the Act specifies that the drug update must reflect "the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable \* \* \*" By referring to "expenditures", we believe the statute contemplates that the update would account for both increases in drug prices, as well as increases in utilization of those drugs.

In the CY 2007 PFS final rule with comment period (71 FR 69682), we established a methodology for annually estimating the growth in ESRD drugs and biological expenditures that uses the Producer Price Index (PPI) for pharmaceuticals as a proxy for pricing growth in conjunction with 2 years of ESRD drug data to estimate per patient utilization growth.

For CY 2008, we are proposing to continue using this methodology to update the drug add-on adjustment. As we indicated in the CY 2007 PFS final rule with comment period, we believe the PPI is a reasonable measure of drug pricing growth, and when used in conjunction with an estimate of per patient growth in drug utilization, this measure provides a simple and accurate approach to updating the drug add-on that could be readily used in subsequent years. Moreover, using the PPI significantly reduces any data bias that is inherent in using historical drug

expenditure data that do not reflect current drug payment methodologies.

Therefore, we established a mechanism for estimating the annual growth in expenditures for ESRD drugs and biologicals using the PPI for prescription drugs as a measure of price increases in conjunction with 2 years of historical data as a basis for estimating utilization growth at the per patient level.

As discussed in detail below in this section, we are proposing to estimate growth in per patient utilization of drugs for CY 2008 by using historical drug expenditure data from CY 2005 and CY 2006. However, we are proposing to use only drug expenditures data from independent ESRD facilities because we are unable to determine utilization change in hospital-based dialysis facilities due to the changes in payment methodology for these types of dialysis facilities from 2005 to 2006. In 2005, payments to hospital-based facilities were based on cost (or a percentage of charges), whereas payments to hospital-based facilities in 2006 were based on ASP+6 percent. Because of the cost payment methodology, the "drug unit" fields on the 2005 hospital-based ESRD facility bills were not used for payment purposes, and therefore, the data were not accurately reported on those bills. As such, we are unable to accurately isolate the per unit payment differential for hospital-based ESRD facility drug expenditures between 2005 (cost payments) and 2006 (ASP payments) for purposes of estimating the residual utilization change between years. We considered applying the price differential factor for independent ESRD facilities between 2005 and 2006 to the ESRD hospital-based facility data, but the result was a negative utilization growth. Because we have no way of accurately determining what portion of the change in drug expenditures for hospital-based facilities between 2005 and 2006 is attributable to price versus utilization, we do not believe it would be appropriate to assume that the same price differential applicable to independent ESRD facility data would be indicative of the price change for hospital-based facilities between 2005 and 2006 where expenditures moved from cost-based to fee schedule payments. Given that the drug expenditure data for hospital-based ESRD facilities only represent about 9 percent of the total ESRD drug data, and we can more accurately measure the price difference between 2005 and 2006 for the independent ESRD facility expenditure data, we believe the best option would be to exclude the hospital-

based ESRD facility data from the computation of utilization growth between 2005 and 2006. Under this option, we would impute the same utilization growth for hospital-based ESRD facilities as estimated for independent ESRD facilities.

(ii) Estimating Growth in Per Patient Drug Utilization

To isolate and project the growth in per patient utilization of ESRD drugs for CY 2008, we need to remove the enrollment and price growth components from the historical drug expenditure data and consider the residual utilization growth. As discussed previously in this section, we propose to use independent ESRD facility drug expenditure data from CY 2005 and CY 2006 to estimate per patient utilization growth for CY 2008.

We first needed to estimate the total drug expenditures for independent ESRD facilities. For this proposed rule, we used the final CY 2005 ESRD claims data and the latest available CY 2006 ESRD facility claims, updated through December 31, 2006 (that is, claims with dates of service from January 1 through December 31, 2006, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2006). For the CY 2008 PFS final rule, we plan to use more updated CY 2006 claims with dates of service for the same time period. This updated CY 2006 data file will include claims that are received, processed, paid, and passed to the National Claims History File as of June 30, 2007.

While the December 2006 update of CY 2006 claims used in this proposed rule is the most recently available claims data, we recognize that it is not a fully complete year as claims with dates of service towards the end of the year have not all been processed. To more accurately estimate the update to the drug add-on, we need aggregate drug expenditures. Based on an analysis of the 2005 claims data, we inflated the CY 2006 drug expenditures to estimate the June 30, 2007 update of the 2006 claims file. We used the relationship between the December 2005 and the June 2006 versions of 2005 claims to estimate the more complete 2006 claims that will be available in June 2007. We applied that ratio to the 2006 claims data from the December 2006 claims file. We did this separately for EPO, the other top ten separately billable drugs, and the remaining separately billable drugs for independent and hospital-based ESRD facilities. All components were then combined to estimate aggregate CY 2006 ESRD drug expenditures. The net adjustment to the CY 2006 claims data

was an increase of 12 percent to the 2006 expenditure data. This adjustment allows us to more accurately compare the 2005 and 2006 data to estimate utilization growth.

The next step is to remove the enrollment and price growth components from that total. As discussed previously in this section, in developing the per patient utilization growth for this proposed rule, we limited our analysis to the latest 2 years of available independent ESRD facility drug data (that is, 2005 and 2006). We believe that per patient utilization growth between these years would be a better proxy for future growth, as it best represents current utilization trends.

To calculate the per patient utilization growth, we removed the enrollment component by using the growth in enrollment data between 2005 and 2006. This was approximately 3 percent. To remove the price effect we calculated the weighted difference between 2005 average acquisition price (AAP) and 2006 ASP pricing for the original top ten drugs for which we had average acquisition prices. We weighted the differences by 2006 independent ESRD facility drug expenditure data. Table 12 shows the 2006 weights for each of the top ten ESRD drugs billed by independent ESRD facilities.

This process led to an overall 3 percent reduction in price between 2005 and 2006.

TABLE 12.—CY 2006 DRUG WEIGHTS FOR INDEPENDENT FACILITIES

Independent drugs	2006 Weights (percent)
EPO .....	75.2
Paricalcitol .....	11.6
Sodium-ferric-glut .....	2.9
Iron-sucrose .....	5.6
Levocarnitine .....	0.3
Doxercalciferol .....	3.1
Calcitriol .....	0.1
Iron-dextran .....	0.0
Vancomycin .....	0.1
Alteplase .....	0.9

After removing the enrollment and price effects from the expenditure data, the residual growth would reflect the per patient utilization growth. To do this, we divided the product of the enrollment growth of 3 percent (1.03) and the price reduction of 3 percent (1.00 - 0.03 = 0.97) into the total drug expenditure change between 2005 and 2006 of -0.2 percent (1.00 - 0.00 = 1.00). The result is a utilization factor equal to 1.00(1.00/(1.03 \* 0.97) = 1.00).

We observed no growth in per patient utilization of drugs between 2005 and

2006. Therefore, we are projecting no growth in per patient utilization for all ESRD facilities in CY 2008.

b. Applying the Proposed Growth Update to the Drug Add-on Adjustment

In CY 2006, we applied the projected growth update percentage to the total amount of drug add-on dollars established for CY 2005 to come up with a dollar amount for the CY 2006 growth update. In addition, we projected the growth in dialysis treatments for CY 2006 based on the projected growth in ESRD enrollment. We divided the projected total dialysis treatments for CY 2006 into the projected dollar amount of the CY 2006 growth to develop the per treatment growth update amount. This growth update amount, combined with the CY 2005 per treatment drug add-on amount, resulted in an average drug add-on amount per treatment of \$18.88 (or a 14.5 percent adjustment to the composite rate) for CY 2006.

In the CY 2007 PFS final rule with comment period (71 FR 69684), we revised our update methodology by applying the growth update to the per treatment drug add-on amount. That is, for CY 2007, we applied the growth update factor of 4.03 percent to the \$18.88 per treatment drug add-on amount for an updated amount of \$19.64 per treatment (71 FR 69684).

For CY 2008, we are proposing to update the per treatment drug add-on amount of \$19.64 established in CY 2007 and convert the update to an adjustment factor as specified in section 1881(b)(12)(F) of the Act. As explained in the CY 2007 PFS proposed rule (71 FR 49007) and adopted in the CY 2007 PFS final rule with comment period (71 FR 69683), we believe this approach is more accurate than using an estimate of growth in treatments to determine the per treatment add-on adjustment each year.

c. Proposed Update to the Drug Add-on Adjustment

As discussed previously in this section, we estimate no growth in per patient utilization of ESRD drugs for CY 2008. Using the projected CY 2008 PPI for prescription drugs of 3.66 percent, we are projecting that the combined growth in per patient utilization and pricing for CY 2008 would result in an update equal to 3.66 percent (1.0 \* 1.0366 = 1.0366). This update factor would be applied to the CY 2007 average per treatment drug add-on amount of \$19.64 (reflecting a 14.9 percent adjustment in CY 2007), resulting in a proposed weighted average increase to the composite rate of

\$0.72 for CY 2008 or a 0.5 percent increase in the CY 2007 drug add-on percentage. Thus, the total proposed drug add-on adjustment to the composite rate for CY 2008, including the growth update, would be 15.5 percent (1.149 \* 1.005 = 1.155).

We propose to continue to use this method to estimate the growth update to the drug add-on component of the case-mix adjusted payment system until we have at least 3 years worth of ASP-based historical drug expenditure data that could be used to conduct a trend analysis to estimate the growth in drug expenditures. Given the time lag in the availability of ASP drug expenditure data, we expect that the earliest we could consider using trend analysis to update the drug add-on adjustment would be CY 2010. We intend to reevaluate our methodology for estimating the growth update at that time.

d. Proposed Update to the Geographic Adjustments to the Composite Rates

Section 1881(b)(12)(D) of the Act, as amended by section 623(d) of the MMA, gave the Secretary the authority to revise the wage indexes previously applied to the ESRD composite rates. The wage indexes are calculated for each urban and rural area. The purpose of the wage index is to adjust the composite rates for differing wage levels covering the areas in which ESRD facilities are located.

(i) Updates to Core-Based Statistical Area (CBSA) Definitions

In the CY 2006 PFS final rule with comment period (70 FR 70167), we announced our adoption of the OMB's CBSA-based geographic area designations to develop revised urban/rural definitions and corresponding wage index values for purposes of calculating ESRD composite rates. OMB's CBSA-based geographic area designations were described in OMB Bulletin 03-04, originally issued June 6, 2003, and available online at [www.whitehouse.gov/omb/bulletins/b03-04.html](http://www.whitehouse.gov/omb/bulletins/b03-04.html). In addition, OMB published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We wish to clarify that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage data used to determine the current ESRD wage index. The OMB bulletins may be accessed online at <http://www.whitehouse.gov/omb/bulletins/index.html>.

(ii) Updated Wage Index Values

In the CY 2007 PFS final rule with comment period (71 FR 69685), we stated that we intend to update the ESRD wage index values annually. Current ESRD wage index values for CY 2007 were developed from FY 2003 wage and employment data obtained from the Medicare hospital cost reports. The ESRD wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that is unadjusted for occupational mix.

The methodology for calculating the CY 2006 ESRD wage index values was described in the CY 2006 PFS final rule with comment period (70 FR 70168). We propose to use the same methodology for CY 2008, with the exception that FY 2004 hospital data will be used to develop the CY 2008 wage index values. For a detailed description of the development of the proposed CY 2008 wage index values based on FY 2004 hospital data, see the FY 2008 "Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2008 Rates" proposed rule (72 FR 24680). Section III G. (Computation of the Proposed FY 2008 Unadjusted Wage Index) of the preamble to that proposed rule describes the cost report schedules, line items, data elements, adjustments, and wage index computations. The wage index data affecting ESRD composite rates for each urban and rural locale may also be accessed on the CMS Web site at <http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp>

The wage data are located in the section entitled, "FY 2008 Proposed Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-reclassified Wage Index by CBSA".

(A) Third Year of the Transition

In the CY 2006 PFS final rule with comment period (70 FR 70169), we indicated that we would apply a 4-year transition period to mitigate the impact on composite rates resulting from our adoption of CBSA-based geographic designations. Beginning January 1, 2006, during each year of the transition, an ESRD facility's wage-adjusted composite rate (that is, without regard to any case-mix adjustments) will be a blend of its old MSA-based wage-adjusted payment rate and its new CBSA-based wage adjusted payment rate for the transition year involved. For each transition year, the share of the blended wage-adjusted base payment rate that is derived from the MSA-based and CBSA-based wage index values is shown in Table 13. In CY 2006, the first year of the transition, we implemented a 75/25 blend. In CY 2007, the second year of the transition, we implemented a 50/50 blend. Consistent with the transition blends announced in the CY 2006 PFS final rule with comment period (70 FR 70170), we are proposing a 25/75 blend between an ESRD facility's MSA-based composite rate, and its CY 2008 CBSA-based rate reflecting its revised wage index values.

In CY 2006, we also eliminated the wage index cap of 1.30, and stated that we would implement a gradual reduction in the wage index floor of 0.90. Prior to January 1, 2006, the wage

indexes were restricted to values no less than 0.90 and no greater than 1.30, meaning that payments to facilities in areas where labor costs fell below 90 percent of the national average, or exceeded 130 percent of that average, were not adjusted beyond the 90 percent or 130 percent level. Although we stated that the ESRD wage index values should not be constrained by the application of floors and ceilings, we also expressed concern that the immediate elimination of the floor could adversely affect ESRD beneficiary access to care. Therefore, we reduced the floor to 0.85 in CY 2006, and to 0.80 in CY 2007.

For CY 2008, we are proposing to reduce the wage index floor to 0.75. As we stated in the CY 2006 PFS final rule with comment period (70 FR 70169 through 70170), we intended to reassess the continuing need for a wage index floor in CY 2008 and CY 2009. For the third year of the transition, we believe that a reduction to 0.75 is appropriate as we continue to reassess the need for a wage index floor for future years. We believe that a gradual reduction to the wage index floor is needed to ensure patient access to dialysis in areas that have low wage index values, especially Puerto Rico, where payments would decrease significantly if the floor was eliminated.

The proposed wage index floors, caps, and blended shares of the composite rates applicable to all ESRD facilities during CY 2008 through CY 2009 are shown in Table 13. They are identical to the values shown in Table 4 of the CY 2007 PFS final rule with comment period (71 FR 69686) for the applicable years.

TABLE 13.—WAGE INDEX TRANSITION BLEND

CY payment	Floor	None	Ceiling	Old MSA (percent)	New CBSA (percent)
2006	0.85	None	.....	75	25
2007	0.80	None	.....	50	50
2008	*0.75	None	.....	25	75
2009	Reassess	None	.....	0	100

\*Each wage index floor is multiplied by a BN adjustment factor. For CY 2008, the BN adjustment is 1.054955 resulting in an actual wage index floor of 0.7912.

An example of how the wage-adjusted composite rates would be blended during CY 2008 and the additional subsequent transition year follows.

*Example:* An ESRD facility has a wage-adjusted composite rate (without regard to any case-mix adjustments) of \$135.00 per treatment in CY 2007. Using CBSA-based geographic area designations, the facility's CY 2008 wage-adjusted composite rate, reflecting its wage index value would be \$145.00.

During the remaining 2 years of the 4-year transition period to the new CBSA based wage index values, this facility's blended rate through 2009 would be calculated as follows:

$$\begin{aligned} \text{CY 2008 } & 0.25 \times \$135.00 + 0.75 \times \$145.00 \\ & = \$142.50 \\ \text{CY 2009 } & 0 \times \$135.00 + 1.0 \times \$145.00 = \\ & = \$145.00 \end{aligned}$$

We note that this hypothetical example assumes that the calculated wage-adjusted composite rate of \$145.00

for CY 2008 does not change in CY 2009. In actuality, the wage-adjusted composite rate would change because of annual revisions to the wage index. However, the example serves only to demonstrate the effect on the composite rate of the CBSA-based wage index values which will be phased-in during the remaining 2 years of the transition period.

**(B) Wage Index Values for Areas With No Hospital Data**

In CY 2006, while adopting the CBSA designations, we identified a small number of ESRD facilities in both urban and rural geographic areas where there is no hospital wage data on which to base the calculations of the CY 2006 ESRD wage index values. Our CY 2006 policy and CY 2007 proposals for each area are discussed separately below in this section.

The first situation is rural Massachusetts. Because in CY 2006 we had not determined a reasonable proxy for rural data within Massachusetts, we used the prior year's acute care hospital wage index value for rural Massachusetts. For CY 2007, we continued to use this value and requested public input on an alternative methodology as described below in this section. We described an alternative methodology whereby we would impute a rural wage index value by using a simple average CBSA-based rural wage index value at the Census Division level.

The second situation involves Puerto Rico. Rural Puerto Rico is similar to rural Massachusetts in that there are no acute care hospitals, and therefore, no hospital data. However, for ESRD facilities in rural Puerto Rico, the CY 2007 ESRD wage index floor value (0.8000) was applied to rural Puerto Rico ESRD facilities. All areas in Puerto Rico that have a wage index are eligible for the ESRD wage index floor because they have wage index values that are below 0.8000. Accordingly, for CY 2007, we applied the ESRD wage index floor value to rural Puerto Rico.

The third situation involves an urban area in Hinesville, GA (CBSA 25980). As with the rural areas noted previously in this section, there are no available hospital wage index data as there are no urban hospitals within that CBSA. For CY 2007, we used a wage index value based on wage index values in all of the other urban areas within the same State to serve as a reasonable proxy for the urban areas without hospital wage index data. Specifically, for CY 2007, we used the average wage index value for all urban areas within the State of Georgia as the urban wage index for purposes of calculating the ESRD wage index value for Hinesville.

In CY 2007, we received no comments on maintaining the policies used in CY 2006 for establishing ESRD wage index values for rural and urban areas without hospitals, or an alternative approach for developing wage index values for rural areas without hospitals for CY 2007 and subsequent years. Therefore, for CY

2007, we maintained the policies used in CY 2006 for establishing ESRD wage index values for rural and urban areas without hospital data.

For CY 2007, the Home Health PPS (71 FR 65884 through 65905) adopted an alternative approach using the average wage index from all contiguous CBSAs to represent a reasonable proxy for the rural areas without hospital wage index data. Because we have used the same wage index value (from CY 2005) for rural Massachusetts for both, CY 2006 and CY 2007, we believe it is now appropriate to consider another methodology as a proxy for rural areas lacking hospital wage index data. We believe that use of contiguous areas is a valid proxy as it meets our criteria for imputing a wage index. This approach uses pre-floor, pre-reclassified hospital wage data, is easy to evaluate, can be updated from year-to-year, and uses the most local data available.

Therefore, in cases where there is a rural area without hospital wage data, we propose to use the average wage index from all contiguous CBSAs to represent a reasonable proxy for that rural area. As was the case in previous years, this proposed policy impacts rural Massachusetts.

In determining an imputed rural wage index, we interpret the term "contiguous" to mean sharing a border. For example, in the case of Massachusetts, the entire rural area consists of Dukes and Nantucket counties. We have determined that the borders of Dukes and Nantucket counties are "contiguous" with Barnstable and Bristol counties. Under the proposed methodology, the wage indexes for the counties of Barnstable (CBSA 12700, Barnstable Town, MA—(1.2539)) and Bristol (CBSA 39300, Providence-New Bedford-Fall River, RI—MA—(1.0783)) are averaged, resulting in an imputed rural wage index of 1.1665 for rural Massachusetts for CY 2008. While we believe that this policy could be readily applied to other rural areas that lack hospital wage data (possibly due to hospitals converting to a different provider type, such as a CAH, that does not submit the appropriate wage data), should a similar situation arise in the future, we may reexamine this policy.

As we stated previously in this section, rural Puerto Rico is similar to rural Massachusetts in that there are no acute care hospitals, and therefore, no hospital wage index data. However, for ESRD facilities in rural Puerto Rico we propose to use the proposed CY 2008 ESRD wage index floor value (0.7500) as a proxy for the hospital wage index data. Accordingly, all areas in Puerto Rico that have a wage index are eligible

for the ESRD wage index floor value because they have wage index values that are below 0.7500. We continue to believe that this approach is an appropriate proxy for rural Puerto Rico because it ensures a rural Puerto Rico wage index value consistent with all other areas in Puerto Rico. Thus, consistent with previous years, for CY 2008, we propose to continue to apply the ESRD wage index floor value (0.7500) to rural Puerto Rico.

We also propose the following approach with regard to an urban area lacking hospital wage index data, specifically, Hinesville, GA (CBSA 25980). Again, under CBSA designations there are no urban hospitals within that CBSA. For CY 2006 and CY 2007, we used all of the urban areas within the State to serve as a reasonable proxy for the urban area without specific hospital wage index data. Specifically, we used the average wage index value for all urban areas within the State of Georgia as the urban wage index for purposes of calculating the value for Hinesville for CY 2007.

We propose to continue this approach for urban areas without specific hospital wage index data. Specifically, for CY 2008, we are proposing to continue using this method for Hinesville, GA (CBSA 25980). Therefore, the wage index for urban CBSA (25980) Hinesville-Fort Stewart, GA is calculated as the average wage index of all urban areas in Georgia.

We solicit comments on these approaches to calculating the wage index values for areas without hospital wage index data for FY 2008 and subsequent years. We will also continue to evaluate existing hospital wage data and, possibly, wage data from other sources, such as the Bureau of Labor Statistics, to determine if other methodologies of imputing a wage index value where hospital wage data are not available may be feasible.

**(iii) Budget Neutrality (BN) Adjustment**

Section 1881 (b)(12)(E)(i) of the Act, as added by section 623(d) of the MMA, requires that any revisions to the ESRD composite rate payment system as a result of the MMA provision (including the geographic adjustment) be made in a budget neutral manner. This means that aggregate payments to ESRD facilities in CY 2007 should be the same as aggregate payments that would have been made if we had not made any changes to the geographic adjusters. We note that this BN adjustment only addresses the impact of changes in the geographic adjustments. A separate BN adjustment was developed for the case-mix adjustments, currently in effect. As

we are not proposing any changes to the case-mix measures for CY 2008, the current case-mix BN adjustment will remain in effect for CY 2008. For CY 2008, we again propose to apply a BN adjustment factor (1.054955) directly to the ESRD wage index values, as we did in CY 2007. As we explained in the CY 2007 PFS final rule with comment period (71 FR 69687 through 69688), we believe this is the simplest approach because it allows us to maintain our base composite rates during the transition from the current wage adjustments to the revised wage adjustments described previously in this section. Because the ESRD wage index is only applied to the labor-related portion of the composite rate, we computed the BN adjustment factor based on that proportion (53.711 percent).

To compute the proposed CY 2008 wage index BN adjustment factor (1.054955), we used the wage index values in Addenda G and H, 2006 outpatient claims (paid and processed as of December 31, 2006), and geographic location information for each facility which may be found through Dialysis Facility Compare Web page on the CMS Web site at <http://www.cms.hhs.gov/DialysisFacilityCompare/>.

Using treatment counts from the 2006 claims and facility-specific CY 2007 composite rates, we computed the estimated total dollar amount each ESRD provider would have received in CY 2007 (the 2nd year of the 4-year transition). The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2008. Next, we computed the estimated dollar amount that would have been paid to the same ESRD facilities using the proposed ESRD wage index for CY 2008 (the 3rd year of the 4-year transition). The total of these payments became the third year new amount of wage-adjusted composite rate expenditures for all ESRD facilities.

After comparing these two dollar amounts (target amount divided by 3rd year new amount), we calculated an adjustment factor that, when multiplied by the applicable CY 2008 ESRD wage index shown in Addenda G and H, will result in payments to each facility that will remain within the target amount of composite rate expenditures when totaled for all ESRD facilities. The proposed BN adjustment factor for the CY 2008 wage index is 1.054955.

To ensure BN, we also must apply the BN adjustment factor to the proposed wage index floor of 0.7500 which results in a proposed adjusted wage index floor

of 0.7912(0.7500 × 1.054955) for CY 2008.

#### (iv) ESRD Wage Index Tables

The proposed 2008 wage index tables are located in Addenda G and H.

#### *I. Independent Diagnostic Testing Facility (IDTF) Issues*

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

In the CY 2007 PFS final rule with comment period, we established 14 performance standards and several other provisions at § 410.33(g) associated with independent diagnostic testing facilities (IDTFs). In this proposed rule, we are clarifying our interpretation of several of the performance standards at § 410.33(g) to assist the public in understanding how we expect our designated contractors to implement these standards. In addition, we are proposing several new performance standards and other provisions associated with IDTFs.

#### 1. Proposed Revisions of Existing IDTF Performance Standards

##### a. § 410.33(g)(6)

The supplier standard at § 410.33(g)(6) states, "Has a comprehensive liability insurance policy in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. The policy must be carried by a nonrelative-owned company." We are proposing to revise this standard to read, "Has a comprehensive liability insurance policy in the amount of at least \$300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The policy must be carried by a nonrelative-owned company. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy changes or cancellations. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter." This proposed rule clarifies how we will verify whether an IDTF meets this standard to include the provision that IDTF suppliers are responsible for providing the contact information of an individual employed with the underwriter, who can verify coverage.

This proposed revision will not preclude the use of self insurance to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or our designated contractor can verify the policy and its coverage provisions with an independent underwriter.

We believe that we should be able to verify the issuance of a comprehensive liability insurance policy with an underwriter, as well as an insurance agent. This approach will allow our designated contractors to verify that a comprehensive liability insurance policy has been issued and is in effect at the time of enrollment and throughout the enrollment period. Moreover, since 90 days may pass before the underwriter receives notification the policy has been issued by the insurance agent or broker, we encourage IDTFs to obtain comprehensive liability insurance at least 90 days prior to filing its Medicare enrollment application. This will prevent delays in the enrollment process and will allow our designated contractors to verify the issuance of an IDTF's comprehensive liability insurance policy on the day an application is submitted for review.

As a result, at § 410.33(g)(6), we are proposing to revise this performance standard to include the requirement that an IDTF must list our designated contractor as a Certificate Holder on the policy. By listing our designated contractor as a Certificate Holder on the policy, our contractor will be able to verify coverage with the underwriter at the time of enrollment and as the need arises throughout the year.

Therefore, we are also proposing to revise § 410.33(g)(6) to state that it is the IDTF supplier's responsibility to: (1) Ensure that the insurance policy must remain in force at all times and provide coverage of at least \$300,000 per incident; and (2) promptly notify the CMS designated contractor in writing of any policy changes and cancellations.

##### b. § 410.33(g)(2)

Based on feedback that we received after the implementation of § 410.33(g)(2), we believe that several changes are necessary to ensure timely reporting of certain events and less frequent reporting of reportable events. Accordingly, we are proposing to change § 410.33(g)(2) from, "Provides complete and accurate information on its enrollment application. Any change in enrollment information must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change," to

“Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported within 30 calendar days of the change. All other reportable changes must be reported within 90 days.”

c. § 410.33(g)(8)

We are proposing to revise § 410.33(g)(8) from “Answer beneficiaries’ questions and respond to their complaints,” to, “Answer, document, and maintain documentation of beneficiaries’ questions and responses to their complaints at the physical site of the IDTF.” This change corrects an oversight in drafting of the initial performance standards for IDTFs. In the CY 2007 PFS final rule with comment period, we did not include a requirement for the documentation of the complaint process. Thus, by making this proposed change, we are proposing to require an IDTF to document its complaint process. We believe that this change is consistent with the established practice for durable medical equipment, prosthetics orthotics and supplies (DMEPOS) suppliers found in § 424.57(c)(19). To meet this revised standard, an IDTF would be responsible for maintaining the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

- The name, address, telephone number, and health insurance claim number of the beneficiary.
- A summary of the complaint; the date it was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.
- If an investigation was not conducted, the name of the person making the decision and the reason for the decision. For mobile IDTFs, this documentation would be stored at their home office.

d. § 410.33(b)(1)

At § 410.33(b)(1), we are proposing to delete, “The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations”. We believe that our earlier rulemaking effort had the unintended consequence of appearing to shift the overall administrative responsibility from owners or administrative staff

employed by an IDTF to the supervising physician. This was not our intent. Moreover, we believe that this requirement can be interpreted as being too restrictive as it is currently written and may convey responsibilities to a general supervising physician who may not have the administrative authority or knowledge to make these decisions. We are proposing to clarify and expand on our meaning of what constitutes three IDTF sites found at § 410.33(b)(1). We believe that limitation on sites applies to both fixed sites and mobile units. Accordingly, we believe that a physician providing general supervision as defined in § 410.32(b)(3)(i) can oversee a maximum of three sites (that is, fixed or mobile) where concurrent operations can be performed. For example, we believe that a physician providing general supervision could oversee up to three individual IDTF mobile units or three individual fixed location IDTFs, or a combination of both that total up to three separate places which can concurrently run diagnostic tests. This does not change the requirements found at § 410.32(b)(3) for direct and personal supervision.

2. Proposed New IDTF Standards

At § 410.33(i), we are proposing to add a provision to state that Medicare will establish an initial enrollment date for IDTFs. Currently, IDTFs can retroactively bill Medicare for services that are rendered before they submitted a Medicare enrollment application or were approved to participate in the Medicare program. This means an IDTF is allowed to bill Medicare for services rendered on dates prior to the date the IDTF was enrolled in the Medicare program. For example, if an IDTF submits a Medicare enrollment application in November 2007 and is enrolled in the Medicare program in December 2007, then a physician or supplier could retrospectively bill for services furnished to Medicare beneficiaries as far back as October 1, 2005; indeed, an IDTF may bill Medicare for services rendered up to 27 months prior to their Medicare enrollment date. This means that an IDTF in the example that is enrolled as meeting our program requirements in December 2007 may not have met those same requirements prior to the date of enrollment, even though the IDTF could bill Medicare and receive payments for services rendered up to 27 months prior to their enrolling in the Medicare program.

We are concerned that some IDTFs may bill Medicare for services when they do not meet all of the program requirements, including compliance

with the performance standards at § 410.33(g). Allowing an IDTF to bill Medicare for services furnished prior to being enrolled in the Medicare program, creates a significant risk for the Medicare program and its beneficiaries. Specifically, we believe that allowing an IDTF to bill for services furnished prior to enrolling in the Medicare program allows these facilities to potentially be reimbursed for services they are not qualified to perform or for which they otherwise may be precluded from billing to the Medicare program.

Since Medicare FFS contractors verify enrollment information at the time an enrollment application is filed, not for prior periods, we do not believe that it is appropriate to continue the practice of allowing IDTFs to bill the Medicare program for services rendered in periods prior to their enrollment in the Medicare program. Therefore, we are proposing to add § 410.33(i) to state that Medicare will establish an initial enrollment date for an IDTF that would be the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by FFS contractor; or (2) the date an IDTF first started rendering services at its new practice location. We also propose to define the “date of filing” as the date that the Medicare FFS contractor receives a signed provider enrollment application that the Medicare FFS contractor is able to process for approval. If the contractor rejects or denies and enrollment application, the new date of filing would be established when an IDTF submits a new enrollment application that the contractor is able to process for approval. Please note that we expect to implement a Web-based enrollment process known as the Provider Enrollment, Chain, and Ownership System (PECOS) process, to be known as PECOS Web, in most States during the 2007 calendar year. This internet enrollment process will permit IDTFs to complete and submit enrollment applications online. The date of filing for applications submitted through PECOS Web will be the date the Medicare FFS contractor receives all of the following: (1) A signed Certification Statement; (2) an electronic version of the enrollment application; and (3) a signature page that the Medicare FFS contractor processes to approval. Further, our proposed policy is consistent with current Medicare payment policy of precluding payment for services until the provider or supplier of service establishes that they meet enrollment and certification