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Department of Health and Human Services

Centers for Medicare & Medicaid Services

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 cardiothoracic 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 Index (PCI).	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

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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, 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/.

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 ¹ / HCPCS code	Mod	Descriptor	2007 work RVU	Requested work RVU	RUC REC	CMS proposal (agree/ disagree)	2008 Proposed work RVU ²
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 ¹ / HCPCS code	Mod	Descriptor	2007 work RVU	Requested work RVU	RUC REC	CMS proposal (agree/ disagree)	2008 Proposed work RVU ²
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

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² 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 adjustor for work. We estimate that the increase in the anesthesia CF would result in an additional 1.0 percent increase in the BN adjustor 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 adjustor to maintain budget neutrality. Based upon the increases, the proposed revised work adjustor 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). 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 the 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.

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. 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](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

requirements prior to being eligible to bill the Medicare program.

While this change limits the retrospective payments that an IDTF may obtain from Medicare program, we believe that this approach is consistent with our existing requirements for those providers that require a State survey prior to being enrolled as specified in § 489.13 and the requirements followed by DMEPOS suppliers as established in section 1834(j)(1) of the Act and § 424.57(b)(2). Moreover, this change would ensure that we are able to verify that an IDTF meets all program requirements at the time of filing, including the performance standards outlined in § 410.33(g) before payment for service occurs.

We are also proposing a new performance standard at § 410.33(g)(15), which states, "Does not share space, equipment, or staff or sublease its operations to another individual or organization." We believe that it is inappropriate for a fixed-base (physical site) IDTF to commingle office space, staff, and equipment, and that commingling office space, staff and equipment or subleases its fixed-base (physical site) operation to another individual or organization constitutes a significant risk to the Medicare program because it prohibits CMS or our contractors from ensuring that each fixed-base (physical site) IDTF establishes and maintains Medicare billing privileges consistent with the provisions at § 424.500 and each IDTF meets and maintains all performance standards and other requirements under § 410.33. While we believe that this new performance standard should only apply to fixed-base (physical site) IDTF locations, we are seeking public comments on establishing a similar requirement for mobile IDTFs. This proposed standard, in conjunction with the existing IDTF performance standard three (concerning appropriate sites for an IDTF), expands the interpretation of these standards to state that a motel, or hotel is not an appropriate site for an IDTF. While we initially believed that this new performance standard should apply to only fixed-based (physical site) locations, we also believe it should apply to mobile IDTFs, but we are seeking public comment on establishing this requirement.

We believe that allowing fixed-base (physical site) IDTFs to commingle office space (including waiting rooms), staff (including supervising physicians, nonphysician personnel, or receptionists), or equipment through subleasing agreements may allow an IDTF to circumvent Medicare enrollment and billing requirements.

These types of arrangements also raise concerns because they may implicate the physician self-referral prohibition and the anti-kickback prohibition.

J. Expiration of MMA Section 413 Provisions for Physician Scarcity Areas (PSAs)

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

Section 413(a) of the MMA added a new section 1833(u) to the Act. That section provided a 5 percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs) for physicians' services furnished on or after January 1, 2005, and before January 1, 2008. Specifically, section 1833(u) of the Act provided for payment of an additional 5 percent of the payment amount for services furnished by primary care physicians in a primary care scarcity area and by non-primary care physicians in a specialist care scarcity area.

Because the provisions of section 1833(u) of the Act do not apply to services furnished after January 1, 2008, we are providing notification that these 5 percent incentive payments will no longer be made for services furnished on or after January 1, 2008.

K. Comprehensive Outpatient Rehabilitation Facility (CORF) Issues

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

Section 4541(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA), related to prospective payment for outpatient rehabilitation services, established section 1832(a)(2)(E) of the Act for all comprehensive outpatient rehabilitation facility (CORF) services, not just rehabilitation services of outpatient physical therapy services (including outpatient speech-language pathology (SLP) services), and outpatient occupational therapy services. The BBA also amended sections 1833 and 1834 of the Act to provide that all CORF services (as defined under section 1861(cc)(1) of the Act) furnished on or after January 1, 1999 would no longer be paid on a "reasonable cost" basis but instead would be paid based on the applicable fee schedule amount (or if less, based on the actual charge for the services). Where there is no applicable fee schedule amount, payment would be based on a comparable service or, if less, the CORF's actual charge for the service. Specifically, section 1834(k)(1)(B) of the

Act states that the payment basis for outpatient physical therapy services (including outpatient SLP services), outpatient occupational therapy services, and all other CORF services provided on or after January 1, 1999 will be 80 percent of the lesser of: (i) The actual charge for the services; or (ii) the applicable fee schedule amount. The term "applicable fee schedule amount" is defined under section 1834(k)(3) of the Act to mean, for services furnished in a year, the payment amount determined under the PFS established under section 1848 of the Act for such services for the year "or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies."

In the CY 1999 PFS final rule (63 FR 58860), we stated that we would base payment for a CORF service on the PFS amount for the service when the PFS established a payment amount for such service. We further explained that we would use the higher PFS amount applicable to services furnished in a nonfacility setting, rather than the facility payment amount, because no separate payment will be made for facility costs. The nonfacility payment rate includes, along with any physician work and MP RVUs, the PE RVUs representing nonfacility resources necessary for the physician to perform each service in the office setting, including both direct and indirect PE inputs, such as the costs of clinical labor, disposable supplies, personnel salaries, equipment, and overhead expenses. The facility payment rate is based primarily on the physician work and MP RVUs, although it contains RVUs for the indirect PE RVUs related to the primary providing specialties, but does not include the costs of the direct PE inputs (that is, clinical labor, disposable supplies, and equipment) that are utilized when the service is provided in the physician office or nonfacility setting. Payment at the higher nonfacility payment rate was already in place prior to CY 1999 for physical therapy, occupational therapy, and speech-language pathology (SLP) services provided in the physician's office and for the services of physical therapists (PTs) and occupational therapists (OTs) in private practice. Effective with the CY 1999 PFS final rule, we used the PFS nonfacility amount to make payment for outpatient Part B physical therapy, occupational therapy, and SLP services furnished in provider settings, including outpatient hospitals, SNFs, providers of outpatient

physical therapy (OPT) and SLP services, also known as rehabilitation agencies, CORFs, and home health agencies (HHAs) (for non-homebound patients), as discussed in the CY 1999 PFS final rule (63 FR 58860). Similarly, we used the PFS nonfacility amount for all other CORF services when the PFS established a payment amount for such service.

In addition, in CY 1999, we established a fee schedule amount under the PFS for nursing services delivered within a CORF, and created a new HCPCS code (G0128) for such services. We defined this code as direct face-to-face skilled nursing services delivered to a CORF patient by a registered nurse (RN) as part of a rehabilitative therapy plan of treatment, billable in 10-minute intervals provided the initial interval is longer than 5 minutes. We stated that the HCPCS code G0128 could be used for RN services that are not included in the work or PE of another therapy or physician service. The CORF conditions of participation at § 485.58 provide that CORF services must be provided by personnel that meet the qualifications set forth in § 485.70. Sections 485.70(b) and (h) require, respectively, that as a condition of coverage of service a licensed practical nurse (LPN) be licensed as a LPN or vocational nurse by the State of practice, and that an RN be a graduate of an approved school of nursing and licensed as an RN by the State of practice. In creating the HCPCS code G0128 for CORF nursing services, we determined that a condition of coverage for the service is that it be furnished by an individual who meets the personnel requirements for an RN because we believe only an RN possesses the necessary training to provide the clinical nursing services that are medically necessary and appropriate for CORF patients as they relate to the therapy plan of treatment.

Finally, in the CY 1999 PFS final rule (63 FR 58860), we explained that we interpret section 1834(k)(3) of the Act, defining the term “applicable fee schedule amount,” as requiring us to use the payment amount established by an existing fee schedule other than the PFS when the PFS does not establish a payment amount for the CORF service. Specifically, we stated that we would use the existing fee schedules for prosthetic and orthotic devices, DME and supplies, and drugs and biologicals for covered prosthetics and orthotics devices, durable medical equipment (DME) and supplies, and drugs and biologicals, respectively, provided by CORFs. Covered DME, orthotic and prosthetic devices, and supplies

provided by a CORF are paid under the DMEPOS fee schedule.

Drugs and biologicals that are not considered to be self-administered are specified as CORF services at section 1861(cc)(1)(F) of the Act. However, as discussed in section II.K.7., we believe that drugs and biologicals provided to CORF patients are not appropriately provided as part of a rehabilitation plan of treatment and, as such, we propose to remove drugs and biologicals from the scope of CORF services as defined at § 410.100. In addition, because we believe it is appropriate for pneumococcal, influenza, and hepatitis B vaccines to be administered to CORF patients in the CORF setting, even though such vaccines fall outside the scope of CORF services, we propose to revise the conditions of participation at § 485.51(a) to permit CORFs to provide to their patients pneumococcal, influenza, and hepatitis B vaccines in addition to CORF services.

Because the regulations under 42 CFR parts 410 and 413 were never updated to reflect the change in CORF payment methodology from a “reasonable cost” basis to 80 percent if the lesser of a payment amount under an existing fee schedule or the CORF’s actual charge, we are proposing to add a new subpart M to 42 CFR Part 414 to reflect the change in CORF payment methodology. In addition, we propose to revise the following sections of the Medicare regulations to clarify the CORF benefit.

1. Requirements for Coverage of CORF services—Plan of Treatment (§ 410.105(c))

In accordance with section 1861(cc)(1) of the Act, requiring that CORF services be furnished “under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician,” § 410.105(c) provides that CORF services as defined under § 410.100 are covered only if furnished under a written plan of treatment. Specifically, the plan of treatment must: (1) Be established and signed by a physician prior to the commencement of treatment in the CORF setting; and (2) Indicate the diagnosis and anticipated rehabilitation goals, and prescribe the type, amount, frequency, and duration of the services to be furnished. We interpret these provisions as requiring that the services furnished under the plan of treatment must relate directly to the rehabilitation of injured, disabled, or sick patients. Services provided in the CORF setting that do not relate directly to such rehabilitation goals are not covered as CORF services.

We propose to revise § 410.105(c) to clarify our policy that CORF services are covered only if they relate directly to the rehabilitation of injured, disabled, or sick patients. We believe our policy is consistent with the statutory requirements under section 1861(cc) of the Act. Section 1861(cc)(1) of the Act specifies that CORF services must be furnished under a plan of treatment. Section 1861(cc)(1)(H) of the Act further states that “other items and services” are considered CORF services only if “medically necessary for the rehabilitation of the patient.” We believe the implication of this limitation for “other items of services” is that all other CORF services (that is, those listed under sections 1861(cc)(1)(A) through (G) of the Act) also must be necessary for the rehabilitation of the patient. In addition, we note that section 1861(cc)(2)(A) of the Act specifies that a CORF facility is a facility “primarily engaged in providing * * * diagnostic, therapeutic, and restorative services to outpatients *for the rehabilitation of injured, disabled, or sick persons*” (emphasis added). We believe this requirement further signals the Congress’s intent that the services provided in a CORF setting be covered as CORF services only if such services relate directly to the rehabilitation of the patient.

2. Included Services (§ 410.100)

Section 410.100 establishes the services that are covered under the CORF services benefit, consistent with section 1861(cc)(1) of the Act. Because of the change in payment methodology from that based on cost to payment under the PFS and other existing fee schedules beginning in CY 1999, this section does not reflect our current payment policies. Therefore, we propose to clarify our payment policy in the introductory paragraph of this section by including a cross-reference to proposed § 414.1101, which sets forth the payment methodology for CORF services, including identifying the applicable fee schedule for each CORF service. In addition, we propose to revise our definitions of physician services to reflect the change in payment methodology for CORF services. We also propose to revise the definitions of physician services, respiratory therapy services, social and psychological services, and nursing services to ensure that these definitions include only those services appropriately provided by qualified nonphysician and physician personnel and related to the rehabilitation plan of treatment established under § 410.105(c). In addition, we propose

revisions to the definition of supplies, equipment, and appliances to conform to the statutory provision at section 1861(cc)(1)(G) of the Act. Finally, we propose to remove the provision for drugs and biologicals. Although vaccines are not included in the definition of CORF services at section 1861(cc)(1) and § 410.100, we propose to make revisions to the CORF conditions of participation at § 485.51 to reflect current coverage and payment policy for vaccines provided in the CORF setting.

3. Physician services (§ 410.100(a))

Section 410.100(a) defines the physician services included within the scope of CORF services. Specifically, those services of a CORF physician described as administrative in nature are considered CORF services, to the exclusion of diagnostic and therapeutic services, which are physician services under section 1861(q) of the Act and separately billable as physician services under 42 CFR part 414, subpart B. Section 1861(cc)(1) of the Act excludes from the definition of CORF services any item or service that, if furnished to an inpatient of a hospital, would be excluded under section 1861(b) of the Act. Section 1861(b)(4) of the Act excludes from the definition of "inpatient hospital services" the "medical or surgical services provided by a physician," which would include the diagnostic and therapeutic services of a physician. Consequently, diagnostic and therapeutic services provided in the CORF setting by a physician are not considered CORF services. In contrast, because those services of a CORF physician that are of an administrative nature are not "medical" services, such services are included in the definition of CORF services.

In accordance with section 1861(cc)(2)(B)(i) of the Act and § 485.70(a)(1), the CORF physician must be either a medical doctor (MD) or a Doctor of Osteopathy (DO); and the conditions of participation at § 485.70(a)(2) and (3) further require that the physician have training or experience in the medical management of patients requiring rehabilitation services. The conditions of participation at § 485.58(a)(1)(i) also require the CORF facility physician to provide, in accordance with accepted principles of medical practice, medical direction, medical supervision, medical care services and consultation. We are proposing to revise § 410.100(a) to clarify that only those physician services required and provided by the CORF facility physician that are administrative in nature are considered

CORF services, whereas diagnostic and therapeutic services provided by a physician to CORF patients are considered physician services under section 1861(q) of that Act. Specifically, we propose to define CORF physician services as those services provided by a CORF facility physician that are administrative in nature, such as consultation with and medical supervision of nonphysician staff, patient case review conferences, utilization review, and the review of the therapy plan of treatment, as appropriate.

Services provided to a CORF patient by the CORF facility physician or other physician that are not administrative in nature but that are diagnostic or therapeutic services are considered physician services under section 1861(q) of the Act. Where these services are covered, they are separately payable to the physician as physician services under the PFS at the nonfacility payment amount. The physician bills the carrier in the same manner as if the services were provided in the physician office setting and notes the CORF as the place of service.

In addition, § 410.100(a) currently provides that physician services included within the definition of CORF services are reimbursed on a reasonable cost basis under part 413, and that physician services to CORF patients not included within the definition of CORF services but billed as physician services are paid by the carrier on a reasonable charge basis subject to the provisions of subpart E of part 405 of this chapter. This description of the payment methodology for physician services provided in the CORF setting under § 410.100(a) is inconsistent with the payment methodology set forth under section 1834(k)(1) of the Act for CORF services and section 1848 of the Act for physician services, as well as the preamble discussion in the CY 1999 PFS final rule (63 FR 58860). In the CY 1999 PFS final rule, we stated that we would base payment for diagnostic and therapeutic physician services provided to individuals in the CORF setting on the PFS amount for the services. Therefore, we are proposing to revise § 410.100(a) to remove the reference to reasonable cost-based payments for CORF physician services and the reference to reasonable charge based payments for non-CORF physician services. In place of these references, we propose to revise § 410.100(a) to add a reference to 42 CFR part 414, subpart B, setting forth the payment methodology for non-CORF physician services.

4. Clarifications of CORF Respiratory Therapy Services

Section 1861(cc)(1)(B) of the Act states that CORF services include respiratory therapy services along with physical therapy, occupational therapy, and SLP services. Because respiratory therapists (RTs) are not recognized as independent practitioners in the Act or regulations, and respiratory therapy services do not have a statutory benefit category except as specified in the CORF services benefit at section 1861(cc)(1)(B) of the Act, separate payment is not made for services provided by RTs. Instead, RTs are most often employed in physician offices and in facility settings, such as hospitals and SNFs, where payment is made to the RT employer.

The description of CORF respiratory therapy services currently includes some services that should be provided by a physician, and not an RT, and thus are inappropriate to include in a respiratory therapy plan of care. Therefore, we are proposing to remove these services from the description of CORF respiratory therapy services under § 410.100(e), and to limit these services to those provided by RTs under a respiratory therapy plan of treatment. Section 410.105(c) requires a physician, and not the RT, to provide the clinical diagnosis; establish and sign the respiratory therapy plan of treatment for each patient that includes the type, amount, frequency and duration of the services to be furnished; and indicate the diagnosis and the patient's rehabilitation goals. The physician must also recertify this plan for medical necessity every 60 days or sooner if appropriate. However, the description of respiratory therapy services under § 410.100(e) includes these services, as well as other services that under current clinical standards should not be provided by RTs, but rather should be entrusted to the physician.

Therefore, we are proposing to revise § 410.100(e) to limit respiratory therapy services to those services appropriately provided to CORF patients by RTs under a physician-established respiratory therapy plan of treatment in accordance with current medical and clinical standards. Specifically, we propose to remove from the definition of CORF respiratory therapy services the services of establishing the medical and therapy-related diagnosis and the provision of E/M services because these services are provided by the physician, as necessary, to establish the respiratory therapy plan of treatment. These services may be provided by either the CORF facility physician, as CORF

physician services or as non-CORF physician services, or by the patient's referring physician, as appropriate. We also propose to remove diagnostic tests from the description of CORF respiratory therapy services since diagnostic tests are covered under the physician services benefit category at section 1861(s)(2)(C) of the Act when provided by the physician to a CORF patient, and accordingly are separately billable by the physician under the PFS as previously discussed.

In addition to RTs, we note that the conditions of participation also recognize respiratory therapy technicians as CORF personnel; however, during the CY 1999 PFS rulemaking to recognize the 1997 BBA payment requirements, we did not include services performed by respiratory therapy technicians because we believed that current medical standards for skilled respiratory therapy services provided to patients in the CORF setting required the educational requirements possessed by RTs. This determination to only recognize the services of RTs, and not those provided by respiratory therapy technicians in carrying out the therapy plan of treatment was further supported in the CY 2002 and CY 2003 rulemaking (66 FR 55311 and 67 FR 79999), when we developed and discussed G-codes for certain CORF respiratory therapy services and specifically recognized the RT as the appropriate level of personnel to provide these CORF services. These G-codes were created to differentiate between the CORF services provided under a respiratory therapy plan of treatment from those services provided under physical and occupational therapy plans of treatment by PTs and OTs, respectively, under benefit sections 1861(p) and (g) of the Act in the 97XXX CPT code series. Because physical and occupational therapy services are subject to the therapy caps, the services provided under a CORF respiratory therapy plan of treatment needed to be identified by procedure codes specific to these services so as not to be attributed to the therapy caps. The three HCPCS codes G0237, G0238, and G0239 are specific to services provided under the respiratory therapy treatment plan and, as such, are not designated as subject to the therapy caps. We are proposing to revise the description of respiratory therapy services to remove those services appropriately provided by the physician establishing the respiratory therapy plan of treatment. In addition, we have determined that a condition of coverage for the respiratory therapy service is that it be provided by

an individual meeting the educational and training level of the RT, rather than the RT technician. For these reasons, we will accept comments on the service description at § 410.100(e), and the personnel qualifications at § 485.70(j) and (k) for a respiratory therapist and a respiratory therapy technician, respectively.

5. Social and Psychological Services

In accordance with section 1861(cc)(1)(D) of the Act, social and psychological services are included within the definition of CORF services under § 410.100(h) and (i), respectively. In addition, § 485.58 specifies that the CORF must provide a coordinated rehabilitation program that includes, at a minimum, social or psychological services, along with physical therapy services and physician services, and that these services must be consistent with the therapy plan of treatment.

Currently, the description of social work services considered CORF services under § 410.100(h) includes (1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility; (2) casework services to assist in resolving social and emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and (3) assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care. The current description of CORF psychological services under § 410.100(h) includes: (1) Assessment diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation; (2) Psychological evaluations of the individual's response to and rate of progression under the treatment plan; and (3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment. We believe the current definitions of CORF social and psychological services are too broad. As discussed above in this section, we propose to revise § 410.105 to clarify our policy that CORF services are covered only if they are provided under the rehabilitation plan of treatment and relate directly to the rehabilitation of the patient. As such, we are concerned that the current descriptions of CORF social and psychological services may be misconstrued to include social and psychological services for the treatment of mental illness, which we believe is

outside the scope of coverage for CORF social and psychological services because these services do not relate directly to a rehabilitation plan of treatment and the associated rehabilitation goals.

In addition, we believe it unnecessary to distinguish between CORF social services and CORF psychological services given their similarities, and therefore, we propose to merge the two definitions into a single definition of CORF social and psychological services. As noted at section 1861(cc)(2)(B) of the Act, we believe that CORFs are required to provide either social services or psychological services, and not both types of services. We believe that merging the regulations at § 410.100(h) and (i) into a single definition of CORF social and psychological services is warranted to clarify the similarities between them.

Therefore, we are proposing to clarify the description of social and psychological services at § 410.100(h) to include only those services that address the patient's response and adjustment to the treatment plan; rate of improvement and progress towards the rehabilitation goals, or other services as they directly relate to the physical therapy, occupational therapy, SLP, or respiratory therapy plan of treatment. In addition, we propose to change the heading at § 410.100(h) from "social services" to "social and psychological services," and to eliminate the separate definition for psychological services under § 410.100(i).

Because we are proposing to revise the description of social and psychological services in § 410.100(h), we are interested in receiving comments concerning the CORF personnel qualifications in the conditions of participation at § 485.70(l) and (g) for social workers and psychologists, respectively, and comments relating to the appropriate CPT codes to represent these CORF services.

Due to the specificity of the purpose of CORF social and psychological services requiring these covered services to directly relate to the patient's rehabilitation treatment plan, we are inviting comments on which CPT codes would be appropriate for CORF social and psychological services. We believe that the procedure codes for health and behavior assessment and treatment, represented by CPT codes 96150 through 96154, specific to the patient's physical health problems, best describe the social and psychological services required in the CORF setting.

6. Nursing Care Services

Because the PFS does not contain a CPT code for nursing services, we established in the CY 1999 PFS final rule a new HCPCS code (G0128) for direct face-to-face skilled nursing services delivered to a CORF patient by an RN as part of a rehabilitative therapy plan of treatment. In the CORF conditions of participation at § 485.70(b) and (h), qualified personnel for nursing services include an LPN or vocational nurse and an RN, respectively. However, when the HCPCS code G0128 was created for CORF nursing services we determined that a condition for coverage is that the nursing service be provided by an individual meeting the qualifications of an RN, rather than the LPN, for CORF clinical nursing services as they relate, or are part of, the therapy plan of treatment. Because we established coverage for CORF nursing services only when provided by an RN, we are proposing to revise new § 410.100(i) (that is, the current § 410.100(j) is redesignated as § 410.100(i)) to specifically reflect this coverage decision. Consequently, in addition to the above proposal, we are also asking for comments on the appropriateness of the personnel qualification standards at § 485.79(b) and (h) for the LPN and for the RN, respectively.

7. Drugs and Biologicals

Section 410.100(k) currently provides that drugs and biologicals included within the definition of CORF services includes drugs and biologicals that are prescribed by a physician and administered by a physician or a CORF RN and not otherwise excluded from Medicare Part B payment under section § 410.29 (relating to self-administered drugs). In addition, in accordance with § 410.105(c), drugs and biologicals administered to a CORF patient will be covered as CORF services only if included as part of the rehabilitation plan of treatment. However, we are unable to identify any physician prescribed drugs or biologicals that are not self-administered that would be appropriately provided under a patient's rehabilitation treatment plan.

In addition, we are concerned about duplicate payment for drugs and biologicals provided to CORF patients in the CORF setting. Drugs and biologicals provided to CORF patients by CORF physicians or RNs under the supervision of a physician are considered services and supplies furnished incident to a physician's professional services under section 1861(s)(2)(A) of the Act, and therefore,

may be paid to the physician in accordance with section 1847(A) of the Act. Physicians bill the carrier for such incident to services. If such drugs and biologicals also considered CORF services, the CORF could submit a claim for the same drugs and biologicals to the fiscal intermediary for payment. If physicians and CORFs each were able to bill for drugs and biologicals that are provided in the CORF setting, we believe there is a risk of duplicative payments for the same drugs and biologicals—one payment to the CORF and one payment to the physician by the carrier. Such duplicative billing would be difficult for us to detect given that CORFs bill the fiscal intermediary for CORF services while physicians bill the carrier for physician services.

While we recognize that drugs and biologicals are enumerated as CORF services at section 1861(cc)(1) of the Act, we do not believe that drugs and biologicals are appropriately provided under rehabilitation therapy plans of treatment. Therefore, we propose to remove § 410.100(k).

We invite comments on this proposal. We are especially interested in receiving comments on the appropriateness of including drugs and biologicals under a CORF patient's rehabilitation plan of treatment.

8. Supplies and DME

Payment for supplies and DME as part of CORF services is specified at § 410.100(l) as “[s]upplies, appliances and equipment” and includes nonreusable supplies, medical equipment and appliances, and DME as defined in § 410.38 (except for renal dialysis systems), is a CORF covered service when provided for the patient's use outside the CORF whether purchased or rented, and is paid under the DMEPOS fee schedule. We believe that the provision at § 410.100(l) is too broad, out of date, and inconsistent with current terminology used for covered services or items. The CORF provision at section 1861(cc)(1)(G) of the Act applies only to supplies and DME, yet the regulatory provision also encompasses medical equipment and appliances. Because we believe the requirements of § 410.100(l) are inconsistent with those of section 1861(cc)(1)(G) of the Act, we are proposing to revise both the title and description at new § 410.100(k) (that is, the current § 410.100(l) is redesignated as § 410.100(k)) by deleting reference to medical equipment and appliances to reflect the CORF statutory provision by including only the items specified under section 1861(cc)(1)(G) of the Act. We also note that DME, as well as

prosthetics, orthotics, and supplies, provided in the CORF setting requires the CORF's participation in the competitive bidding, where applicable, in accordance with 42 CFR part 414 subpart F.

9. Clarifications and Payment Updates for Other CORF Services

Section 4078 in the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) (OBRA) amended section 1861(cc)(1) of the Act to provide that there is no requirement that any item or service furnished by a CORF in connection with physical therapy, occupational therapy, and speech pathology services under the plan of treatment be furnished at a single fixed location; however, such items and services are covered as CORF services only if payment is not otherwise made under Medicare. We note that such items and services may be covered under the Medicare home health benefit established under sections 1861(g), (m), and (p) of the Act. Accordingly, physical therapy, occupational therapy, and SLP services provided in the home are not covered as CORF services if such services and related items are covered under the Medicare home health benefit. Because the CORF regulations were not revised to reflect these changes in coverage and payment methodology, we propose to do so now.

Therefore, we are proposing to clarify the regulations at new § 410.100(l) (that is, the current § 410.100(m) is redesignated as § 410.100(l)) and § 410.105(b)(3) to reflect these requirements.

In § 410.105(b)(3), we propose to clarify that physical therapy, occupational therapy and SLP services can be furnished in the patient's home when payment for these therapy services is not otherwise made under the Medicare home health benefit.

In addition, we propose to revise § 410.100(l) to clarify that the patient must be present during the home environment evaluation that is performed by the PT, OT or speech-language pathologist, as appropriate, because we believe that the patient's presence is necessary to fully evaluate the potential impact of the home situation on the patient's rehabilitation goals.

10. Cost-Based Payment (§ 413.1)

Section 413.1(a)(2)(iv) currently provides for cost-based payment for CORF services, which reflects the payment methodology provided for under section 1833(a) of the Act, requiring payment on the basis of the lesser of the provider's reasonable costs

or customary charges. As discussed above, this payment methodology is inconsistent with section 1834(k) of the Act, requiring that the payment basis for outpatient physical therapy services (including outpatient SLP services), outpatient occupational therapy services, and all other CORF services provided on or after January 1, 1999 be 80 percent of the lesser of: (i) The actual charge for the services; or (ii) the applicable fee schedule amount. Therefore, we are proposing to remove § 413.1(a)(2)(iv) to clarify that cost-based payment is not applicable to services provided in the CORF setting. We are also proposing to remove § 413.1(a)(2)(vi) for OPTs or rehabilitation agencies as referenced at section 1861(p) of the Act, because these providers were also affected by the same payment changes required by the 1997 BBA for physical therapy, occupational therapy, and SLP services effective for CY 1999.

11. Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

We are proposing to establish a new regulatory subpart M at 42 CFR Part 414 to specify the payment methodology for comprehensive outpatient rehabilitation services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act. Specifically, this proposed subpart would identify and describe how payment is determined for services included as CORF services under § 410.100.

Proposed § 414.1100 sets forth the basis and scope for payment for CORF services. Proposed § 414.1101 sets forth the payment methodology for CORF services, including identifying the applicable fee schedule for each type of CORF service identified in § 410.100.

Section 1834(k)(1)(B) of the Act provides that the payment basis for CORF services is 80 percent of the lesser of: (i) The actual charge for the services; or (ii) the applicable fee schedule amount. The term "applicable fee schedule amount" is defined under section 1834(k)(3) of the Act to mean, for services furnished in a year, the payment amount determined under the PFS established under section 1848 of the Act for such services for the year "or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies." Accordingly, we propose at new § 414.1101(a) to base payment for a CORF service on 80 percent of the lesser of the actual charge or the PFS amount

for the service when the PFS establishes a payment amount for such service. Payment for CORF services under the PFS is made for physical therapy, occupational therapy, SLP, and respiratory therapy services, as well as the related nursing and social and psychological services. In the CY 1999 PFS final rule (63 FR 58860), we explained that we interpret section 1834(k)(3) of the Act, defining the term "applicable fee schedule amount," as requiring us to use the payment amount established by an existing fee schedule other than the PFS when the PFS does not establish a payment amount for the CORF service. Therefore, we propose at new § 414.1101(c) that we use the existing fee schedules for prosthetic and orthotic devices, DME and supplies for covered DMEPOS provided by CORFs. Specifically, we propose that payment for covered DME, orthotic and prosthetic devices and supplies provided by a CORF be based on the lesser of 80 percent of actual charges or the payment amount established under the DMEPOS fee schedule under sections 1834 and 1847 of the Act and in 42 CFR part 414, subparts D and F. Finally, we propose at new § 414.1101(d) that if there is no fee schedule amount established for a CORF service, payment shall be based on the lesser of 80 percent of actual charges or the amount determined under the fee schedule established for a comparable service, as specified by the Secretary.

As discussed in sections II.K.7. and II.K.12., we propose to remove drugs and biologicals from the scope of CORF services as defined under § 410.100. Therefore, we propose not to include payment for drugs and biologicals under § 414.1101.

As discussed in section II.K.3., physician services included within the definition of CORF services under § 410.100(a) are limited to those services of a CORF physician described as administrative in nature, to the exclusion of diagnostic and therapeutic services which are considered separately billable physician services. Medicare generally does not permit providers to separately bill for their administrative costs; rather, such costs typically are subsumed in the payment amounts for covered medical services and items furnished to Medicare beneficiaries. Under the PFS these costs are included in the payment amount as part of the indirect practice expenses that are reflected in the PE RVUs for each service and also captured as part of the post-visit work RVU component. Similarly, we believe payment to CORFs for the administrative duties of a CORF physician, required as a condition of

participation at § 485.58(a), such as participating in patient case review conferences is subsumed within PFS payments to CORFs for physical therapy, occupational therapy, SLP, and respiratory therapy services, and the related nursing, and social and psychological services. Generally, administrative costs associated with the provision of such services is incorporated into payment amounts established under the PFS through the PE RVUs representing the resources necessary to perform each service in the physician office or nonfacility setting. Therefore, we believe it unnecessary to separately compensate CORFs for CORF physician services given that such services are administrative in nature, and propose at § 414.1001(b) not to separately pay CORFs for CORF physician services.

To ensure that CORFs are not paid twice for CORF services, we propose at new § 414.1101 to base payment for a CORF service on the applicable fee schedule amount only to the extent that payment for such service is not included in the payment amount for other CORF services. For example, under the PFS, disposable supplies generally are included in the PE RVUs representing the resources necessary to perform the service in the nonfacility setting, and thus are included in the payment amount for each service and cannot be billed separately.

Accordingly, under proposed § 414.1001(c) a CORF could not bill separately for supplies included in the PE RVU component of the payment amount established for a service under the PFS. However, we note that CORFs could bill separately for certain splint and cast supplies for the application of casts and strapping because these supplies have been removed from the payment amounts established under the PFS. These splint and cast supplies are currently paid using the HCPCS code series Q4001 through Q4051 which were established to make separate payment under section 1861(s)(5) of the Act for surgical dressings, and splint and cast materials. In the CORF setting, the splint and cast supplies may be applicable for certain cast/strapping application procedures in the CPT code series 29000 through 29750. We would note that Medicare makes separate payment for surgical dressings, which are also referenced at section 1861(s)(5) of the Act, only when used by the beneficiary in his or her home. No separate payment is made when these surgical dressings are used in the CORF setting; rather the dressings costs are bundled into the payment amount

established under the PFS for the provided services.

For CORF services based on the payment amount determined under the PFS, we propose at new § 414.1101(a)(2) to use the PFS amount applicable to services furnished in a nonfacility setting, with no separate payment made for facility costs. The nonfacility payment rate includes, along with any physician work and malpractice RVUs, the PE RVUs representing the resources necessary to perform each service in the nonfacility setting, such as overhead expenses and personnel salaries and the direct costs of clinical labor, disposable supplies, and equipment. In contrast, the facility payment rate is based primarily on the physician work and malpractice RVUs, as well as RVUs for indirect PE incurred by the physician, and does not include the cost of the direct PE associated with providing each service in the physician office or nonfacility setting. We propose to use the PFS nonfacility amount for CORF services in order to offset any costs of providing such services in the CORF setting.

12. Vaccines

Section 485.51(a) defines a CORF as a nonresidential facility that “is established and operated exclusively for the purpose of providing” rehabilitation services by or under the supervision of a physician. Because vaccines administered in the CORF setting are not rehabilitation services furnished under a plan of treatment relating directly to the rehabilitation of the patient (or, presumably, even medically necessary for the rehabilitation of the patient), in accordance with § 485.51(a), a CORF may not administer vaccines to its patients. However, we note that nothing in the Medicare statute would prohibit a CORF from providing pneumococcal, influenza, and hepatitis B vaccines to its patients provided the facility is “primarily engaged in providing * * * diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons” (section 1861(cc)(2)(A) of the Act). Accordingly, under the statute, such vaccines may be covered separately from the CORF services benefit under section 1861(s)(10) of the Act—defining the term “medical and other health services” to include the pneumococcal, influenza, and hepatitis B vaccines—provided the applicable conditions of coverage under § 410.58 and § 410.63 are met. In order to include coverage and payment for these vaccines when provided to CORF patients in the CORF setting, we propose to amend the CORF

conditions of participation at § 485.51 to permit CORFs to provide vaccines to their patients in addition to rehabilitation services. Such vaccines would be covered in the CORF setting provided the conditions of coverage under § 410.58 and § 410.63 are met. In accordance with sections 1833(a)(1) and 1842(o)(1) of the Act, payment for covered pneumococcal, influenza, and hepatitis B vaccines provided in the CORF setting is based on 95 percent of the average wholesale price (AWP).

We are interested in receiving comments on this proposal.

L. Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen (§ 414.930)

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

1. Background

a. Statutory Requirements

Section 1861(t)(2)(B)(ii)(I) of the Act lists three drug compendia that may be used in determining the medically-accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen. The three drug compendia listed are:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- American Medical Association Drug Evaluations (AMA-DE)
- United States Pharmacopoeia-Drug Information (USP-DI)

Section 1861(t)(2) of the Act provides the Secretary the authority to revise the list of compendia for determining medically-accepted indications for drugs. Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for our reference. (That is, AMA-DE is no longer in publication; USP-DI has been purchased by Thomson Micromedex and it is our understanding that the name “USP-DI” may not be used after 2007.)

Section 6001(f)(1) of the DRA amends both “sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of the Act by inserting ‘(or its successor publications)’ after ‘United States Pharmacopoeia-Drug Information.’” We interpret this DRA provision as explicitly authorizing the Secretary to continue recognition of the compendium currently known as USP-DI after its name change if the Secretary determines that it is in fact a successor publication rather than a substitute publication.

b. Requests To Amend the Compendia Listings

We received requests from the stakeholder community for recognition of additional compendia under the following authorities:

- Section 1861(t)(2)(B) of the Act which allows the Secretary to identify additional authoritative compendia; and
- Section 1873 of the Act which allows the Secretary to recognize a successor publication if one of the statutorily named compendia changes its name.

In contrast, others have suggested that the Secretary consider elimination of certain listed compendia. However, there is no established regulatory process by which the agency can currently accept and act definitively on such requests. In addition, there is currently no transparency about the criteria upon which we could base a decision. Therefore, we are seeking public input on this topic.

c. Technology Assessment of Drug Compendia Used to Determine Medically-Accepted Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen

We commissioned a technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ) on the currently listed compendia (AHFS and USP-DI), as well as other compendia (that is, National Comprehensive Cancer Network (NCCN), ClinPharm, DrugDex, Facts & Comparisons (F&C)) which might provide comparable information. AHRQ contracted the TA to the New England Medical Center (NEMC) and Duke Evidence-based Practice Centers (EPCs) and found little agreement in the evidence cited among drug compendia. In addition, the TA found little agreement between the EPC’s independent identification of evidence on 14 example off-label indications and evidence cited in the drug compendia. The TA can be found at <http://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=46>.

d. Medicare Evidence Development and Coverage Advisory Committee (MedCAC)

On March 30, 2006, the MedCAC (formerly the Medicare Coverage Advisory Committee (MCAC)) met in public session to advise CMS on the evidence about the desirable characteristics of compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy and the degree to which the currently listed and other

available compendia display those characteristics. All information on this MedCAC meeting can be found on the CMS Web site at <http://www.cms.hhs.gov/mcd/viewmcc.asp?where=index&mid=33>. The agenda included a presentation of the TA performed for AHRQ by staff of the NEMC and Duke EPCs, scheduled stakeholder presentations, as well as an opportunity to hear testimony from members of the audience. As is customary, the MedCAC panelists elicited additional information from the presenters and discussed the evidence in preparation for a formal vote.

The MedCAC identified the following desirable characteristics:

- Extensive breadth of listings.
- Quick throughput from application for inclusion to listing.
- Detailed description of the evidence reviewed for every individual listing.
- Use of pre-specified published criteria for weighing evidence.
- Use of prescribed published process for making recommendations.
- Publicly transparent process for evaluating therapies.
- Explicit “Not recommended” listing when validated evidence is appropriate.
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies.
- Explicit “Equivocal” listing when validated evidence is equivocal.
- Process for public identification and notification of potential conflicts of interest of the compendia’s parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

The MedCAC concluded that none of the compendia fully display the desirable characteristics. The voting results can be viewed at the same Web site provided previously for the MedCAC meeting. In addition the MedCAC noted significant variability among the compendia. There was no agreement among the panel members that any particular predetermined number of compendia was desirable.

Participants in the meeting also discussed the clinical usefulness of drug compendia in the treatment of cancer. It was reported that oncologists do not rely on compendia when making treatment decisions, relying instead on published treatment guidelines, clinical trial protocols, or consultation with peers.

Prior to this proposed rule, we received and reviewed unsolicited comments from professional societies regarding additions and deletions to the listing of compendia for purposes of

section 1861(t) of the Act. We believe that the notice and comment period of this proposed rule will provide the opportunity for the public to present its concerns regarding this process. We encourage all interested parties to submit their comments via the process mentioned in the **SUPPLEMENTARY INFORMATION** section of this proposed rule.

2. Process for Determining Changes to the Compendia List

A compendium for the purpose of this section is defined as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment. A compendium: (1) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; (2) is indexed by drug or biological; (3) differs from a disease treatment guideline, which is indexed by disease. We believe that the use of compendia to determine medically-accepted indications of drugs and biologicals in the manner specified in section 1861(t)(2)(B)(ii)(I) of the Act is more efficiently accomplished if the information contained is organized by the drug or biological and if the listings are comprehensive.

We propose to create a process incorporating public notice and comment to receive and make determinations regarding requests for changes to the list of compendia used to determine medically-accepted indications for drugs and biologicals used in anti-cancer treatment as described in section 1861(t)(2)(B)(ii)(I) of the Act. Requests may be for addition or deletion of a compendium from the list.

We will use the following process to receive and make determinations regarding requests for changes to the list of compendia:

- For the purposes of this section, the notice may be accomplished by posting the information on the CMS Web site. This does not preclude us from using other reasonable means at our discretion. We believe this will facilitate a timely and efficient consideration of requests.

- We will issue annually a notice for requests to revise the list of compendia. This notice will be published and will specify a 30-day time period within which we will accept any external requests that are complete, as defined in this section. To allow sufficient time for

the public to be notified, we will begin the acceptance process for external requests no sooner than 45 days after publication of the notice. We believe that this will enhance the administrative efficiency of this process without placing a significant burden on the public.

- We will publish a listing of the timely complete request(s) received and allow the public 30 days to submit comments on the request(s). The listing will identify the requestor and the requested addition or deletion to the list of compendia.

- A complete request must include the following:

- + The full name and contact information (including the mailing address, e-mail address, and telephone number) of the requestor. If the requestor is not an individual person, the information shall identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.

- + Full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

- + A complete written copy of the compendium that is the subject of the request. If the complete compendium is available electronically, it may be submitted electronically in place of hard copy. If the compendium is available online, the requestor may provide us with electronic access by furnishing at no cost to the Federal government sufficient accounts for the purposes and duration of the review of the application in place of hard copy.

- + The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium.

- + Detailed, specific documentation that the compendium that is the subject of the request does or does not comply with the conditions of this rule. Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed; therefore, they will not be accepted.

- + A request may have only a single compendium as its subject. This will provide greater clarity on the scope of the agency’s review of a given request. A requestor may submit multiple requests, each requesting a different action.

- + Requests must be in writing as opposed to verbal.

- Requests may be submitted in two ways (no duplicates please). Electronic

submissions are encouraged to facilitate administrative efficiency. We will, in our solicitation of requests, identify the electronic address to be used for submissions. Hard copy requests can be sent to the Centers for Medicare & Medicaid Services, Coverage and Analysis Group, Mailstop C1-09-06, 7500 Security Boulevard, Baltimore, MD, 21244. Please allow sufficient time for hard copies to be received prior to the close of the solicitation period. We may internally generate a request to change the list of compendia at any time. We believe that this preserves the agency's ability to act quickly if we determine that urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

- We will consider a compendium's attainment of the MedCAC-recommended desirable characteristics of compendia, listed above in this section, in reviewing requests. We may consider additional reasonable factors in making a determination. (For example, we may consider factors that are likely to impact the compendium's suitability for this use, such as a change in ownership or affiliation, the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. We may consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians or both in choosing among treatment options.)

- We will also consider a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

- We may, at our discretion, combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in our review of requests.

- We will publish our decision within 120 days after the close of the public comment period.

- For each compendium that we determine should be included on the list, the publisher or its designee must notify CMS, within 45 days from the publication date of each new edition or revision of the compendium, that a new edition or version is available. This will ensure that we have the most current information for each compendium. This may be provided electronically or via online access. We believe that this is necessary to permit us to efficiently ensure that the listed compendia continue to meet the conditions set forth in this rule.

- In addition to the annual process, we may generate a request for changes to the list of compendia at any time.

M. Physician Self-Referral Provisions

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

1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Medicare rules currently prohibit the markup of the technical component of certain diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity (§ 414.50). In addition, Medicare program instructions restrict who may bill for the professional component (the interpretation) of diagnostic tests (CMS Pub. 100-04, Chapter 1, 30.2.9.1).

In the CY 2007 PFS proposed rule (71 FR 48982), we stated that recent changes to our rules on reassignment concerning the right to receive Medicare payment may have led to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred under a contractual arrangement. In addition, we expressed concern about the existence of certain arrangements that we believe are not within the intended purpose of the physician self-referral rules, which permit physician group practices to bill for certain services furnished by a contractor physician in a "centralized building." We also expressed concern that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program (71 FR 49054).

In the CY 2007 PFS proposed rule (71 FR 48982), we proposed to amend § 424.80 to provide that if the TC of a diagnostic test (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act) is billed by a physician or medical group (the "billing entity") under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity, less the applicable deductibles

and coinsurance, may not exceed the lowest of the following amounts:

- The physician or other supplier's net charge to the billing physician or medical group.
- The billing physician's or medical group's actual charge.
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

We also proposed that, to bill for the TC, the billing entity would be required to perform the interpretation. In addition, we considered imposing certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test. We stated that we were considering the following conditions (which currently appear in manual provisions and are known as the purchased interpretation rules):

- The test must be ordered by a physician who is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation.
- The physician or medical group performing the interpretation does not see the patient.
- The physician or medical group billing for the interpretation must have performed the TC of the test.

We stated that, although we welcomed comments on all aspects of our proposals, we were particularly interested in receiving comments on whether: diagnostic imaging tests should be excepted from any of our proposed provisions; the proposal in whole or in part should apply only to pathology services; any of the proposed provisions should apply to services performed on the premises of the billing entity and if so, how to define the premises appropriately. We also requested comments as to whether an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement, and if so, how to determine the correct amount that should be billed to the Medicare program.

For our physician self-referral rules, we proposed to modify the definition of "centralized building" at § 411.351 to require a centralized building to consist of at least 350 square feet. We further proposed that the proposed minimum square footage requirement would not apply to space owned or rented in a building in which no more than three group practices own or lease space in the "same building," as defined at § 411.351 (that is, in a building with the same street address) and share the same

“physician in the group practice” (as defined at § 411.351). We also proposed that a centralized building must contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services (DHS) that are performed in the space in order to meet the definition of a centralized building. We solicited comments as to whether a centralized building should have a minimum square foot requirement, and if so, whether the minimum should be 350 square feet or an amount more or less than that. In addition, we sought comments regarding whether there should be an exception to any minimum square foot requirement, and if so, the circumstances under which an exception should apply.

For our proposal that the centralized building permanently contain the necessary equipment to perform substantially all of the DHS that is furnished in the centralized building, we sought comments on whether this test should be imposed, and whether at least 90 percent or some other minimum percentage or measurement would be appropriate. We stated that we were also considering whether to require that, for space to qualify as a centralized building, the group practice must employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. Finally, we sought comments on whether a group practice should be allowed to maintain a centralized building in a State different from the State(s) in which it has an office that meets the criteria in § 411.355(b)(2)(i), and if so, whether space that is located in a different State must be within a certain number of miles from an office of the group practice that meets the criteria in § 411.355(b)(2)(i) in order to qualify as a centralized building.

We received numerous comments on these proposals. As a result, we did not finalize our proposals in the CY 2007 PFS final rule with comment period. Based on the comments received and other information that we considered, we are proposing to impose an anti-markup provision on the TC and PC of diagnostic tests. We would apply the anti-markup provision irrespective of whether the billing physician or medical group outright purchases the PC or the TC, or whether the physician or other supplier performing the TC or PC reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity). To prevent gaming, whereby the performing physician's or other

supplier's net charge to the billing entity is inflated to cover the cost of equipment or space that is leased to the performing physician or other supplier, we would define “net charge” as exclusive of any amount that takes into consideration such charges. For example, consider the following hypothetical:

- The fee schedule amount for the PC of a particular diagnostic test is \$100.
- Performing Physician A rents office space and equipment from Group B for \$50 per test interpretation performed.
- Physician A charges Group B \$100 per test. In this example, pursuant to our proposal, Physician A's charge of \$100 would be deemed to take into account the \$50 rental fee imposed by Group B (simply by virtue of the rental arrangement). Therefore, Group B would not be allowed to bill the full fee schedule amount of \$100, but rather, would be limited to the lesser of Physician A's net charge determined exclusive of the amount that is deemed to have taken into consideration the lease expense, that is \$50, or Group B's actual charge for the PC. We are also concerned that overutilization of diagnostic tests could continue despite our proposal to apply an anti-markup provision to TCs that are reassigned to, or outright purchased by, group practices. That is, our proposal in the CY 2007 PFS proposed rule to impose an anti-markup provision would not have addressed the situation in which the TC is performed by a part-time or leased employee of the group practice in a centralized building, and the group neither receives a reassignment from the employee technician (if the technician is not able to bill for the TC in his or her own right), nor purchases the TC outright from the technician. Therefore, we are proposing to apply an anti-markup provision to TCs that are performed in a centralized building, and are seeking comments on whether we should have such a provision and, if so, how we should effect such a provision (for example, through amending the definition of “centralized building” or through some other means. We would except the anti-markup provision for PCs ordered by independent laboratories because we do not believe that PCs ordered by independent laboratories pose a significant risk of program abuse because the independent lab is not ordering the TC. In States where the corporate practice of medicine doctrine is in effect, independent labs that are organized as corporations are prevented from hiring physicians as employees to perform PCs of diagnostic tests.

In addition, we are proposing in § 414.50 that—(1) The PC of a purchased test be subject to an anti-markup provision; (2) the anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity; (3) the performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity; and (4) the anti-markup provision not apply to independent labs that have not ordered the TC.

At this time, we are not proposing to make changes to the definition of “centralized building” (with the one possible exception noted below in this section). We believe that changes to the definition may be unnecessary in light of our proposals for an anti-markup provision on the TC and PC of diagnostic tests (although if we decide to impose an anti-markup for TCs performed by technicians in a centralized building, we may accomplish that through amending the definition of “centralized building”). If an anti-markup provision is finalized, we may evaluate at a later time whether to make any revisions to the definition of “centralized building.” We also are not proposing to adopt the purchased test interpretation rules in the context of reassignments because this provision may be unnecessary if we impose an anti-markup provision and because the purchased test interpretation rules may be problematic for multi-specialty group practices. Finally, in the CY 2007 PFS proposed rule, we proposed that, in order to bill for the TC of the diagnostic test, the billing physician or medical group must directly perform the PC. However, we believe this provision may be unnecessary if we impose an anti-markup provision and also would be problematic for independent labs that cannot employ physicians due to corporate practice of medicine restrictions.

2. Burden of Proof

We are proposing to add § 411.353(g) to clarify that, consistent with our policy with respect to claims denials, in any appeal of a denial of payment for a DHS that was made on the basis that the service was furnished pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral. That is, the burden of proof is not on CMS or our contractors to establish that the service was furnished pursuant to a prohibited referral.

3. In-Office Ancillary Services Exception

One of the most important exceptions to the physician self-referral prohibition, applicable to services furnished by group practices and sole practitioners, is the in-office ancillary services exception. Section 1877(b)(2) of the Act sets forth an exception for certain services (other than durable medical equipment and parenteral and enteral nutrients) that are provided ancillary to medical services provided by a physician or group practice and that meet certain conditions. The in-office ancillary services exception is codified in § 411.355(b).

Among other things, the exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services, including some services unrelated to the furnishing of DHS. The exception provides additional flexibility for patients seen by a physician in a group practice by allowing these patients to receive a test or procedure in another building in space owned or leased on a full-time, exclusive basis by a group practice (that is, a "centralized building" as defined at § 411.351).

The in-office ancillary services exception does not contain certain requirements that are found in other compensation exceptions. For example, the exception for personal service arrangements in § 411.357(d), like many of the compensation exceptions, requires that compensation be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. These requirements are not present in the in-office ancillary services exception. Also, under the "special rule for productivity bonuses and profit shares" in § 411.352(i), a physician in a group practice may receive a share of profits or a productivity bonus for referred ancillary services, provided that the payment is not directly related to the volume or value of referrals.

We believe that the Congress included an exception for in-office ancillary services to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under

such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited.

However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice. For example, pathology services may be furnished in a building that is not physically close to any of the group practice's other offices, and the professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship with the group practice (in some cases, the technical component of the pathology services is furnished by laboratory technologists who are employed by an entity unrelated to the group practice). In other words, the core members of the group practice and their staff are never physically present in the contractor pathologist's office. Similarly, the contractor pathologists do not participate in any group practice activities; they attend no meetings (except for phone calls about individual patients), and do not obtain retirement or health benefits from the group practice. In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS.

Even in the case of ancillary services furnished in the same building, there may be very little interaction between the physicians who treat patients and the staff that provide the ancillary services. For example, an entity with its own staff located in a large medical office building next to a hospital may furnish an array of diagnostic services, including clinical laboratory services and radiology services, to patients of physicians who practice in the building and own either the equipment or the entity.

Comments received on the Phase I and Phase II physician self-referral rules (66 FR 856 and 69 FR 16055, respectively) stated that the in-office ancillary services exception is susceptible to abuse. For example, in response to the 1998 physician self-referral proposed rule (66 FR 892), a commenter asserted that the Congress did not intend for a group practice to have multiple centralized office locations, except for the provision of clinical laboratory services. This sentiment was reiterated in response to the Phase I final rule when several commenters objected to the decision to allow group practices to have more than one centralized facility (69 FR 16075).

In response to Phase II, we received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices. In addition, we have been informed by a number of physician specialists that the in-office ancillary services exception enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist.

In the CY 2007 PFS proposed rule (71 FR 48982), we stated our intent to address certain types of potentially abusive arrangements in which group practice physicians make a referral for a DHS to a specialist who is an independent contractor of the group practice. The specialist then performs the service for the group practice in a "centralized building" and reassigns his or her right to Medicare payment to the group (which then bills Medicare at a profit).

Comments received on the CY 2007 PFS proposed rule stated that, although our proposal addressed potential abuses arising from referrals to independent contractors who perform services in a centralized building, it failed to address abusive arrangements within the physician's office. Our review of industry trade articles and discussions with trade associations has heightened our awareness of the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices. "Turn-key" operations, such as the arrangements described in this section for in-office laboratories and other ventures, are being marketed to physicians over the internet.

At this time, we decline to issue a specific proposal for amending the in-office ancillary services exception. Rather, we are soliciting comments as to whether changes are necessary and, if so, what changes should be made. We are interested in receiving comments on: (1) Whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists;

and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

4. Obstetrical Malpractice Insurance Subsidies

We are concerned that our exception for obstetrical malpractice insurance subsidies is unnecessarily restrictive; that is, that our exception does not allow for certain obstetrical malpractice insurance subsidies that may be provided without a risk of program or patient abuse. The exception in § 411.357(r) incorporates by reference the conditions in the anti-kickback safe harbor in § 1001.952(o). We have received accounts, through advisory opinion requests and anecdotally, of patient difficulty obtaining obstetrical care in some communities in States in which obstetrical malpractice insurance premiums are relatively high. We have also been informed that obstetricians have left these States for other practice locations where obstetrical malpractice insurance premiums are less expensive, requiring patients to drive long distances to receive obstetrical care. We are seeking comments describing such problems and recommendations for how the exception should be changed without creating a risk of program or patient abuse. For example, the exception requires that the physician practice in a primary care HPSA and that 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA or a medically-underserved area or be part of a medically-underserved population. We are interested in whether the exception would more effectively ensure beneficiary access to obstetrical care without risking program abuse if any of the requirements were changed. In addition, to the extent possible, we would like to establish bright-line requirements in the exception.

We are proposing to revise the exception in § 411.357(r) to specifically list the conditions that we believe are appropriate to safeguard against program or patient abuse when remuneration is provided by a hospital to a physician in the form of an obstetrical malpractice insurance subsidy. As noted previously, the current exception incorporates the conditions in the anti-kickback safe harbor in § 1001.952(o). We are seeking comments with respect to requirements, such as the following, that would be appropriate to include in the exception for obstetrical malpractice insurance subsidies:

- A requirement for a written agreement between the parties.
 - Physician certification (or, in subsequent years, actual data indicating) that a specified percent of the physician's obstetrical patients treated under the coverage of the subsidized malpractice insurance will either reside in a HPSA or medically-underserved area or be part of a medically-underserved population.
 - Location of the entity making the malpractice insurance premium subsidy payment.
 - Location of the medical practice of the physician receiving the malpractice insurance subsidy payment.
 - A requirement that the payment not be conditioned on the physician making referrals to, or otherwise generating business for, the entity.
 - No restriction on the physician establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity.
 - A requirement that the amount of the payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the physician.
 - A requirement that the physician must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.
 - A requirement that the insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.
- In addition, we would include the requirement that the arrangement not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission (which is a requirement of our other compensation exceptions issued under our authority under section 1877(b)(4) of the Act).

5. Unit-of-Service (Per-Click) Payments in Space and Equipment Leases

Section 1877(e)(1) of the Act provides an exception to the prohibition of physician referrals for space and equipment leases, provided that certain requirements are met. Among the requirements, which are incorporated in our regulations in § 411.357(a) and (b), are that the lease be commercially reasonable even if no referrals were made between the parties, and that the rental charges be set in advance, be consistent with market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated

between the parties. The statute also requires that the lease arrangement meet such other requirements as the Secretary may impose by regulation as needed to safeguard against program or patient abuse. We are concerned with lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for DHS. Such arrangements could take the form of a physician leasing equipment that he or she owns to a hospital, and receiving a per-use (per-click) fee each time a patient is referred by the physician-owner to the hospital for the use of the equipment. We are also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For example, if a physician rents an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital, the physician benefits financially and the arrangement could provide an incentive for overutilization or other program abuse.

In the 1998 proposed rule (63 FR 1714), we noted that we had been asked about situations in which a physician rents equipment (such as a magnetic resonance imaging (MRI) machine) to an entity that furnishes a DHS, such as a hospital, with the physician receiving rental payments on a per-click basis (that is, total rental payments increase each time the machine is used). We stated that we believed that this arrangement would not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements were typical and complied with the fair market value and other requirements included under the rental exception. However, we added that, because a physician's compensation under this exception may not reflect the volume or value of the physician's own referrals, the rental payments may not reflect per-click payments for patients who are referred for the service by the lessor physician.

In the Phase I rulemaking, we stated that we were substantially revising the proposed rule with respect to "the volume or value standard." We stated:

Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at

inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. (66 FR 876)

After reconsidering the issue, we are proposing that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee, and we would disallow such per-click payments, using our authority under section 1877(e)(1) of the Act, even if the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee.

Finally, we are soliciting comments on whether, using our authority under section 1877(e)(1) of the Act, we should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

6. Period of Disallowance for Noncompliant Financial Relationships

In response to the Phase II interim final rule with comment period (69 FR 16054), we received several comments that questioned what the period would be for which the physician could not refer DHS to the entity and the entity could not bill Medicare for the situation in which a financial arrangement between a referring physician and an entity failed to satisfy the requirements of an exception to the general prohibition on self-referrals.

At this time, we are not making proposals for prescribing the period of disallowance for various types of noncompliance, but rather are seeking comments on how we might, to the extent practicable, set forth the period of disallowance for arrangements that implicate, but fail to satisfy the requirements of, one or more of the various exceptions. As a general matter, we believe that the statute contemplates that the period of disallowance should begin with the date that a financial arrangement failed to comply with the statute and the regulations and end with the date that the arrangement came into compliance or ended. However, in some instances it may not be clear when a financial arrangement has ended. For example, where an entity leases space to a physician at a rental price that is substantially below fair market value, it may raise the inference that the below market rent was in exchange for future referrals, including referrals made

beyond the expiration of the lease. We are seeking comment whether, with respect to types of noncompliance for which it is not clear when a financial relationship ended, we should always employ a case-by-case approach, or deem certain types of financial relationships to continue for a prescribed period of time.

We are also soliciting comment as to whether we should allow the period of disallowance to terminate where the parties have returned, or paid back the value of, the consideration. For example, if we were to impose a period of disallowance for a prescribed period of time because it would not be clear when a noncompliant compensation arrangement ended, we might allow the parties to terminate the period of disqualification sooner than the prescribed period if the prohibited compensation were returned. We caution that we do not envision allowing such an option where the parties knew or, in our judgment, reasonably should have known that the arrangement did not satisfy the requirements of an exception.

We are also seeking comment as to whether we should impose a period of disqualification from using an exception where an arrangement has failed to satisfy the requirements of that exception. For example, suppose non-monetary compensation is given by an entity to a physician that greatly exceeds the permissible limit prescribed in § 411.357(k). In addition to whatever period of disallowance that would apply, we are considering whether the parties should be disqualified, for a period of time, from relying on this exception. For example, if an entity gives a piece of equipment to a physician that has a fair market value of \$900, we may—

- Prohibit one or both of the parties from relying on this exception for a period of time;
- Require the parties to “spend down” in order to use the exception again (for example, if the permissible year limit is \$300 (not taking into account adjustment for inflation) and the parties exceeded this limit by \$600, the parties would be precluded from using the exception during the next 2 years (not taking into account adjustment for inflation); or
- Require the physician to return or pay back the value of the excess compensation in order for one or both of the parties to use the exception again.

7. Ownership or Investment Interest in Retirement Plans

In the 1998 proposed rule (63 FR 1708), we noted that we had received

questions concerning whether stock options and other nonvested interests (such as an interest in retirement funds that vests after a certain number of years worked) in an entity constitutes ownership in that entity. We replied that it was our view that options and nonvested interests are inchoate or partial ownership interests that qualify as “ownership” for purposes of the physician self-referral law. In response to a comment to the 1998 proposed rule, however, we stated in the Phase I final rule with comment period that we were withdrawing the statement in the 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest for purposes of section 1877 of the Act and that, instead, we would consider contributions (including employer contributions) to retirement plans to be part of an employee’s overall compensation arrangement with his or her employer (66 FR 870). As part of the Phase I rule, we promulgated § 411.354(b)(3)(i), which excludes “[a]n interest in a retirement plan” from the definition of ownership and investment interests. We made no changes to this provision in Phase II (69 FR 16054).

We received a comment in response to the Phase II interim final rule (69 FR 16054) concerning the exclusion from an ownership or investment interest for retirement plans as specified in § 411.354(b)(3)(i). The commenter stated that, contrary to our intent, some physicians are using retirement plans to purchase DHS entities to which they refer patients for DHS. We agree with the commenter that it was not our intent to exclude from the definition of an ownership or investment interest an interest in a DHS entity that results from a physician’s (or family member’s) participation in a retirement plan that purchases an interest in that DHS entity. That is, where a physician has an interest in a retirement plan offered by Entity A, through the physician’s (or an immediate family member’s) employment with Entity A, we intended to except from the definition of ownership or investment interests any interest the physician would have in Entity A by virtue of his or her interest in the retirement plan; we did not intend to exclude from the definition of ownership or investment interests any interest the physician may have in Entity B through the retirement plan’s purchase of an interest in Entity B.

Accordingly we are proposing to revise § 411.354(b)(3)(i) to provide that ownership and investment interests do not include an interest in a retirement plan offered by the entity to the physician or immediate family member

as a result of the physician's or immediate family member's employment with the entity.

8. "Set in Advance" and Percentage-Based Compensation Arrangements

Several of the compensation exceptions in section 1877 of the Act require that the compensation be "set in advance" (or "fixed in advance"). This requirement has been carried over in our regulations implementing those statutory exceptions, and we have also included a "set in advance" requirement in some of our regulatory exceptions (that is, exceptions promulgated pursuant to our authority in section 1877(b)(4) of the Act to create additional exceptions that pose no risk of program or patient abuse). In § 411.354(d), Special Rules on Compensation, we state that compensation will be considered "set in advance" if the aggregate compensation, a time-based or per unit-of-service-based amount, or a specific formula for calculating the compensation, is set forth in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. Under Phase I (66 FR 959), the last sentence of § 411.354(d)(1) read,

Percentage compensation arrangements do not constitute compensation that is 'set in advance' in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

We had explained in that rule, in response to a public comment, that "[p]ercentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections or expenses, is not fixed in advance" (66 FR 878). Following publication of the Phase I rule, however, we received anecdotal accounts about contracts for physician services under which payment was calculated based on a percentage of the revenue raised by a physician's own professional services. Therefore, we delayed the effective date of the final sentence of § 411.354(d)(1) through four **Federal Register** notices, to allow us to revise the provision "to avoid unnecessarily disrupting existing contractual arrangements for physician services" (68 FR 74491, December 24, 2003; 68 FR 20347, April 25, 2003; 67 FR 70322, November 22, 2002; 66 FR 60154 and 60155, December 3, 2001).

In the Phase II interim final rule with comment period, in the section on physician compensation, we explained that percentage compensation arrangements were of particular concern

to academic medical centers and to hospitals "which argued that percentage compensation is commonplace in their physician compensation arrangements" (69 FR 16068). We were persuaded that our original position was overly restrictive, and accordingly, we deleted the last sentence in § 411.354(d)(1) and clarified that the specific formula must be set forth in sufficient detail before the furnishing of the items or services and the formula may not be modified within the time period in any manner that reflects the volume or value of referrals or any other business generated between the parties.

Despite our intent that percentage compensation arrangements could be used only for compensating physicians for the physician services they perform, it has come to our attention that percentage compensation arrangements are being used for the provision of other services and items, such as equipment and office space that is leased on the basis of a percentage of the revenues raised by the equipment or in the medical office space. We are concerned that percentage compensation arrangements in the context of equipment and office space rentals are potentially abusive. We note that section 1877(e)(1)(A)(vi) of the Act, with respect to office space rentals, and section 1877(e)(1)(B)(vi) of the Act, with respect to equipment rentals, allow us to impose requirements on office space and equipment rental arrangements as needed to protect against program or patient abuse. Although we are concerned primarily with percentage compensation arrangements in the context of equipment and office space rentals, we believe there is the potential for percentage compensation to be utilized in other areas as well. Therefore, relying on our authority in sections 1877(e)(1)(A)(vi), 1877(e)(1)(B)(vi), and 1877(b)(4) of the Act, we are proposing to clarify that percentage compensation arrangements: (1) May be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided).

9. Stand in the Shoes

Commenters to the Phase I final rule with comment period proposed that we permit physicians to stand in the shoes of their group practices, thereby requiring analysis of certain indirect compensation arrangements as direct

compensation arrangements. In the Phase II interim final rule, we solicited comments on this issue, and we may be addressing this issue in an upcoming final rule. In this proposed rule, we are focusing on the DHS entity side of physician-DHS entity financial relationships. We propose to amend § 411.354(c) to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls. For example, a hospital would stand in the shoes of a medical foundation that it owns or controls (such as where the hospital is the sole member of a non-profit corporation). Thus, if a hospital owns or controls a medical foundation that contracts with a physician to provide physician services at a clinic owned by the medical foundation, the hospital would stand in the shoes of the medical foundation, and would be deemed to have a direct compensation relationship with the contractor physician.

We believe that it is necessary to collapse the type of relationship discussed above to safeguard against program abuse by parties who endeavor to avoid the application of the physician self-referral requirements by simply inserting an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician. We are soliciting comments as to whether and how we would employ a stand in the shoes approach for the type of relationship discussed above, as well as for other types of financial relationships. In submitting comments, commenters should be mindful that we finalize (or may already have finalized) a provision that treats physicians as standing on the shoes of their group practices or other physician practices.

10. Alternative Criteria for Satisfying Certain Exceptions

We received several comments in response to the Phase II rulemaking that asserted that even innocent and trivial violations of the physician self-referral statute may result in huge penalties to an entity that submits claims to Medicare. For example, the failure of a hospital to obtain a signature on a lease or a personal services arrangement with a physician could result in the hospital being required to make repayment for all services for which it billed Medicare as a result of prohibited referrals from the physician. One commenter stated that we should exercise our discretion

in pursuing minor violations and the failure to meet the procedural requirements of an exception (such as obtaining all required signatures prior to commencement of the agreement for personal services) and technical violations. Another commenter stated that we should consider adding an exception that would permit physicians to refer for DHS, and entities to submit and receive payment for DHS, if, in our sole discretion, we determined that there was no abuse. The commenter suggested that such an exception be available only after (1) receipt by the entity of a favorable advisory opinion, or (2) a voluntary disclosure by the entity or upon audit or investigation by the government.

Although we do not have discretion to waive violations of the physician self-referral statute, we are considering whether to amend certain of the exceptions that appear in § 411.355 through § 411.357 to provide an alternate method for satisfying the exception. We caution that our proposal is intended to address only inadvertent, violations in which an agreement fails to satisfy the procedural of "form" requirements of an exception of the statute or regulations. We do not intend to apply the alternative method for compliance to other requirements such as compensation that is fair market value, not related to volume or value of referrals, or set in advance. What we have in mind, for example, is a situation in which parties are missing a signature but every other requirement of the exception for personal service arrangements is satisfied. In such a case, provided that there is full disclosure, the missing signature is inadvertent, and other conditions for alternative compliance described here are satisfied, the alternative method for compliance would be met and the parties would comply with the exception.

The alternative method for compliance with the physician self-referral prohibition would provide that, if an arrangement does not meet all of the existing prescribed criteria of an exception, the arrangement nevertheless would meet the exception if: (1) The facts and circumstances of the arrangement are self-disclosed by the parties to us; (2) we determine that the arrangement satisfied all but the prescribed procedural or "form" requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS; (3) the failure to meet all the prescribed criteria of the exception was inadvertent; (4) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the

prescribed criteria of the exception were not met (consistent with other exceptions, we would apply the same knowledge standard as that applicable under the False Claims Act; (5) the parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship between or among them; (6) the arrangement did not pose a risk of program or patient abuse; (7) no more than a set amount of time had passed since the time of the original noncompliance with the prescribed criteria; and (8) the arrangement at issue is not the subject of an ongoing Federal investigation or other proceeding (including, but not limited to, an enforcement matter). We would consider there to be an "inadvertent" failure to meet all of the prescribed criteria in an exception only where there was an innocent or unintentional mistake. We would rely on our authority under section 1877(b)(4) of the Act to implement an alternative compliance policy, and we would include requirements that are contained in all exceptions that we promulgate under that authority (including, but not limited to, the requirement that the arrangement not violate the anti-kickback statute).

We believe that if we were to adopt an alternative compliance method policy for certain exceptions, with the criteria specified above, the determination of whether an arrangement meets the terms of an exception despite not meeting all of the prescribed criteria of an exception should be at our sole discretion and not subject to further administrative or judicial review. We caution that we would retain the discretion as to *whether* to make such a determination; parties would have no right to receive such a determination and no time period by which we would be required to issue a determination. We further caution that, because we would retain sole authority to determine that an arrangement that failed to satisfy all of the prescribed procedural or "form" criteria of an exception that meets the conditions for the alternative method of compliance, and because of the proposed requirements that: (1) The failure to meet all of the prescribed criteria of the exception was inadvertent; and (2) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met, parties to an arrangement

would not be able to refer or bill for DHS with the knowledge that the arrangement did not comply with all of the prescribed criteria of an exception and then later claim in response to an enforcement action that they believed that their conduct was proper because, in their view, the arrangement would have met the criteria for the alternative method for compliance with the prescribed criteria of an exception. In fact, if our proposal were to be adopted and a DHS entity were to submit a claim for Medicare payment with the knowledge that its financial relationship with the referring physician (or his or her immediate family member) did not meet the prescribed criteria of any exception, and did so in advance of any determination from us that the arrangement met the alternative method of compliance, it could be found liable under the False Claims Act.

We are especially interested in comments regarding: whether we should adopt an alternative compliance method policy, and if so, the exceptions for which the policy should be applicable; the conditions that must be met in order to obtain a favorable determination that an arrangement that does not meet all of the prescribed criteria of an exception nevertheless satisfies the alternative method of compliance with the exception; the manner (for example, advisory opinion) for making such a determination; the length of time during which the alternative method option would be available (that is, the length of time that a party would have to discover that an arrangement was out of compliance with the prescribed criteria of an exception and seek protection under the alternative compliance method policy); and, whether, having received a favorable determination that an arrangement satisfied the alternative method of compliance (essentially, that the arrangement was deemed to have met the prescribed criteria of an exception), an entity should be precluded for a period of time from receiving another favorable determination with respect to an arrangement that (1) failed to meet the prescribed criteria of the same exception (or similar criteria of another exception) and (2) that was entered into after the date the arrangement that received the favorable determination was entered into by the entity. We are also interested in comments as to whether each eligible exception should specify which criterion or criteria an arrangement can fail to meet and nevertheless still qualify under the alternative method criteria as satisfying the exception (for

example, specifying in several exceptions that an arrangement that is missing a signature can nevertheless qualify for the alternative compliance method), or whether, in addition to or in lieu thereof, we should provide that an arrangement may qualify for the alternative compliance method if we make a determination that the arrangement substantially complied with the prescribed criteria and met all of the other alternative criteria. We are specifically seeking comment on what, if any, additional requirements or standards should be met where an arrangement fails to satisfy a procedural of "form" requirement of an exception. For example, we would like comments on whether we should require other documentary proof of the parties' intent to contract (through memoranda, electronic mail, or otherwise) in the case where the parties failed to obtain a necessary signature to effect the contractual arrangement.

We reiterate that we do not have the authority to waive violations of the physician self-referral statute or regulations. We do not mean to suggest that, for financial relationships that implicate the general prohibition, anything less than full compliance with one or more of the exceptions is sufficient; rather, we are proposing to provide additional and alternative criteria for some of the exceptions themselves so that some arrangements that otherwise would be noncompliant as a result of an inadvertent mistake might satisfy an exception. In effect, we are merely proposing to expand the scope of some exceptions to provide more flexibility.

Finally, we note that our proposal for an alternative compliance method policy is intended to complement, and not replace, the provisions in § 411.353(f) for certain arrangements involving temporary noncompliance. Among other requirements, in order to qualify for protection under § 411.353(f), the financial relationship between the entity and the referring physician must have been in compliance with an exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant, and the financial relationship must have fallen out of compliance due to reasons beyond the control of the entity. In addition, claims are payable only for DHS rendered during a maximum of 90 consecutive calendar days following the date on which the financial relationship became noncompliant; the exception may be used by an entity only once every 3 years for the same referring physician; and the exception may not be

used for temporary noncompliance with the exception for nonmonetary compensation or medical staff incidental benefits.

11. Services Furnished "Under Arrangements"

Our physician self-referral rules prohibit a physician from making referrals for DHS to an entity with which the physician (or an immediate family member) has a financial relationship, and prohibits the entity from billing Medicare for the DHS, unless an exception applies. In the 1998 proposed rule, we stated that we had received questions about which entities are the relevant ones for purposes of the prohibition on referrals, given that some entities only bill for services, whereas others actually directly "furnish" the services. We noted that, for example, in an "under arrangements" situation, a hospital, rural primary care hospital, SNF, HHA, or hospice program contracts with a separate provider to furnish services to the hospital's, SNF's, or other contracting entity's patients, for which the hospital, SNF or other contracting entity ultimately bills. Sections 1832, 1835(b)(1), 1861(e), and 1861(w)(1) of the Act and § 413.65(i) provide for Medicare payment to providers for services furnished "under arrangements." The Internet-Only Manual (IOM) manual 100-01, Medicare General Information, Eligibility and Entitlement Manual, Pub. 100-01, at Chapter 5, section 10.3 requires that the provider must exercise professional responsibility over an arranged-for service, using the same quality controls as applied to services furnished by the provider's salaried employees. Under § 413.65(i), a provider-based hospital department may not provide all of its services under arrangements. Therefore, a hospital department may not contract out all of its patient care services.

We stated in the 1998 proposed rule that, absent an exception, the referral prohibition applies to a physician's DHS referrals to any entity that directly furnishes DHS to Medicare or Medicaid patients. We stated that a physician can have an incentive to overutilize services if he or she has a financial relationship with the entity that directly furnishes DHS, even if this is not the entity ultimately billing for the services. In these situations, the physician can potentially recognize a profit from each referral based on the fact that the DHS will, in essence, be sold to the entity that bills (63 FR 1707). Notwithstanding our statements in the 1998 proposed rule, we have interpreted the definition of "entity" at § 411.351 as including only the person or entity that bills

Medicare for the DHS, and not the person or entity that performs the DHS (where the person or entity performing the DHS is not the person or entity billing for it).

We continue to have concerns with services provided under arrangements to hospitals and other providers. We believe that the risk of overutilization that we identified in the 1998 proposed rule has continued, particularly with hospital outpatient services for which Medicare pays on a per-service basis. That is, we pay a hospital separately for each clinical laboratory test, for each therapy service, and for the vast majority of radiology and other imaging services. We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly. There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished by the joint venture were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by hospitals.

We are also concerned that the services furnished under arrangements to a hospital are furnished in a less medically-intensive setting than the hospital, but billed at higher outpatient hospital PPS rates, which not only costs the Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance. Often, physician specialists who order services for their hospital patients set up joint ventures, frequently including as an owner a hospital to which the physicians refer patients. The joint venture often owns an entity that furnishes medically less intensive services than a hospital, such as an ASC, an IDTF, or a physician office. The entity may even be located in a hospital building in space leased by the hospital to the joint venture, whether owned by physicians alone or with the hospital. It appears that the use of these arrangements may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries.

We believe that more and more procedures are being performed as arranged for hospital services. The provider community is well aware that, effective for services furnished on or after January 1, 2008, Medicare may pay more for all hospital outpatient surgical procedures than for the same procedures billed by ASCs under the

revised ASC payment system required by section 626(b) of the MMA. (In the CY 2007 OPPTS/ASC proposed rule (71 FR 49635), we proposed that payment for an ASC surgical procedure would be made at 62 percent of the payment for the same procedure under the OPPTS (71 FR 49656).)

After the close of the Phase II comment period, the Medicare Payment Advisory Commission (MedPAC), in its March 2005 Report to Congress, recommended that the Secretary “should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services.” Specifically, MedPAC wrote:

Physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to higher use of services. Prohibiting these arrangements should help ensure that referrals are based on clinical, rather than financial, considerations. It would also help ensure that competition among health care facilities is based on quality and cost, rather than financial arrangements with entities owned by physicians who refer patients to the facility.

(See http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf, at page 170.)

We agree with the concerns of MedPAC and a commenter to the Phase II interim final rule that arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing DHS but do not submit claims, raise significant concerns under the fraud and abuse laws. We believe such arrangements to be contrary to the plain intent of the physician self-referral law. Arrangements so structured are particularly problematic because referrals by physician-owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making.

We are attempting to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. We note that some of the arrangements described by MedPAC are subject to the physician self-referral prohibition and more may become subject to the physician self-referral prohibition through provisions we may implement in the upcoming Phase III final rule.

Although MedPAC recommended that the definition of physician ownership subject to the physician self-referral prohibition be expanded to include any entity that derives a substantial proportion of its revenue from a provider of DHS, we are proposing what we believe is a more straightforward approach to addressing the issue. That is, we propose to revise our definition of entity at § 411.351 so that a DHS entity includes both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. Our proposal is not meant to exclude any persons or entities that presently are considered to be DHS entities. (In this regard, we note that we propose to reorganize and delete some of the material in the current definition and are seeking comment on our proposed changes to the regulatory text.) Although we believe our proposed approach is sufficient to address abusive arrangements, we solicit comments on whether we should implement the MedPAC approach, either in some combination with our proposed approach or instead of our proposed approach. We would be particularly interested in comments related to what should constitute a “substantial” proportion of revenue derived from providing DHS.

N. Beneficiary Signature for Ambulance Transport Services

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

Section 424.36 requires that a beneficiary's signature must appear on all claims submitted for Medicare services, unless the beneficiary has died, or another exception applies. For example, if a beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on the beneficiary's behalf by another individual listed in § 424.36(b). Ambulance suppliers and providers have stated that, in emergency situations, it is impossible or impractical for ambulance providers or suppliers to obtain a beneficiary's or other authorized person's signature on a claim to properly bill Medicare for ambulance transport services because: (1) Many beneficiaries are incapable of signing claims due to their medical condition at the time of transport; and (2) another person authorized to sign the claim under § 424.36(b) is not available, or is unwilling to sign the claim at the time of transport; and (3) if an individual listed in § 424.36(b) is not available or willing to sign a claim on

behalf of the beneficiary at the time of transport, it is impractical later to locate the beneficiary (or the beneficiary's authorized representative) to obtain a signature on the claim form before submitting it to Medicare for payment.

We are sympathetic to the concerns of ambulance providers and suppliers insofar as emergency transport services are involved. Therefore, at § 424.36, we are proposing that, for emergency ambulance transport services, where the ambulance provider or supplier documents that the beneficiary was physically or mentally incapable of signing a claim form at the time the service was provided and that none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign a claim on behalf of the beneficiary, the ambulance provider or supplier may submit the claim without a beneficiary signature. Such claim submission would be permitted only if: (1) The beneficiary was physically or mentally incapable of signing the claim form at the time the service was provided; (2) none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign the claim form on behalf of the beneficiary at the time the service was provided; and (3) the ambulance provider or supplier maintains in its files for a period of at least 4 years from the date of service certain documentation. Required documentation would include: (1) A signed contemporaneous statement, made by an ambulance employee present during the trip to the receiving facility, that the beneficiary was physically or mentally incapable of signing a claim form and that none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign the claim form on behalf of the beneficiary at the time the service was provided; (2) the date and time the beneficiary was transported, and the name and location of the facility where the beneficiary was received; and (3) a signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the time and date that the beneficiary was received by that facility.

For non-emergency ambulance transport services, the ambulance provider or supplier would continue to be required to obtain a beneficiary's signature on a claim form (or the signature of someone who is authorized to sign on behalf of the beneficiary under § 424.36(b)(1) through (5) prior to submitting claims to Medicare.

O. Update to Fee Schedules for Class III DME for CYs 2007 and 2008

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

1. Background

a. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Classifications

Under § 414.210, for Medicare payment purposes, fee schedules are determined for the following classes of equipment and devices:

- Inexpensive or routinely purchased items as specified in § 414.220.
- Items requiring frequent and substantial servicing, as specified in § 414.222.
- Certain customized items, as specified in § 414.224.
- Oxygen and oxygen equipment, as specified in § 414.226.
- Prosthetic and orthotic devices, as specified in § 414.228.
- Other DME (capped rental items), as specified in § 414.229.
- Transcutaneous electric nerve stimulators (TENS), as specified in § 414.232.

We designate the items in each class of equipment or device through our program instructions.

Under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c), the Food and Drug Administration (FDA) must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness; class III devices typically posing the greatest risk. Devices are to be classified into class I if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness. General controls apply to all medical devices and include provisions that relate to adulteration, misbranding, device registration and listing, notification, including repair, replacement, or refund, records and reports, and good manufacturing practices. Examples of class I devices are canes and crutches.

Class II devices are those for which general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, development and dissemination of

guidelines, recommendations, and any other appropriate action the FDA deems necessary (section 513(a)(1)(B) of the act). Examples of class II devices are blood glucose test systems and infusion pumps.

Class III devices are those for which there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Class III devices paid in accordance with the DME fee schedule payment methodology include osteogenesis or bone growth stimulators, implantable infusion pumps, and stair-climbing wheelchairs (standard power wheelchair function only). This is not an inclusive list of class III devices. The Medicare DMEPOS suppliers should specify on the Medicare claim form whether the device furnished to a beneficiary is a class III device as described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)(C)).

b. DMEPOS Payment

Section 302(b)(1) of the MMA amended section 1847 of the Act to require the Secretary to establish and implement competitive acquisition programs for the furnishing under Medicare Part B of certain types of DMEPOS. Section 1847(a)(2)(A) of the Act provides that devices determined by the FDA to be class III devices under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) cannot be included in the competitive acquisition programs. As part of the transition to competitive acquisition, the Congress mandated in sections 1847(a)(14)(G) through (I) of the Act that the fee schedule amounts for DME, other than class III devices, be frozen at 2003 levels through 2008.

For class III devices, section 1834(a)(14)(G)(i) of the Act mandates that an annual update factor based on the percentage change in the consumer price index for urban customers (CPI-U) be applied to the fee schedule amounts for CYs 2004 through 2006. Section 1834(a)(14)(H)(i) of the Act, as added by section 302 of the MMA, gives the Secretary discretion in determining the appropriate fee schedule update percentage for CY 2007 for DME which are class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)(C)).¹ Specifically, for

¹ Section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act has been codified as 21 U.S.C.

2007, the 2006 fee schedule amounts for class III devices are to be updated by the percentage change determined to be appropriate by the Secretary, taking into account recommendations contained in a report of the Comptroller General of the United States under section 302(c)(1)(B) of the MMA. Also mandated by section 1834(a)(14)(I)(i) of the Act, for 2008, the 2007 fee schedule amounts for class III devices are to be increased by an annual factor based on the percentage change in the CPI-U, as applied to the 2007 payment amount determined after application of the percentage change under section 1834(a)(14)(H)(i) of the Act.

As stated above, section 1834(a)(14)(H)(i) of the Act mandated that the Secretary take into account recommendations by the Comptroller General of the United States, who is the head of the Government Accountability Office (GAO), when determining the appropriate update percentage for class III devices for 2007. On March 1, 2006, the GAO published a report, "Class III Devices do not Warrant a Distinct Annual Payment Update" (GAO-06-62). The GAO concluded in that report, "because the initial payment rates for all classes of devices on the Medicare DME fee schedule are based on retail prices or an equivalent measure, they account for the costs of class III and similar class II devices in a consistent manner. Distinct updates for two different classes of devices are unwarranted." The GAO recommended that the Secretary establish a uniform payment update to the DME fee schedule for 2007 for class II and class III devices.

In the May 1, 2006 **Federal Register**, we published the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues proposed rule (71 FR 25660). We solicited comments on how to determine the appropriate fee schedule percentage change for class III devices for 2007 and 2008. We stated that we would consider the comments received in conjunction with the recommendations in the GAO report in determining the appropriate update percentage for these devices for 2007 and 2008.

A majority of the submitted public comments indicated that the GAO report was flawed since it did not recommend a specific update factor or take into account changes over time in the costs of producing, supplying and

360c(a)(1)(C). Accordingly, we believe that the reference to 21 U.S.C. 360(c)(1)(C) in sections 1834(a)(14)(G)(i), (H)(i), and (I)(i) of the Act is a scrivener's error.

servicing class III devices. Several commenters recommended that we continue to use the CPI-U to adjust fee schedule amounts for class III devices, but offered no substantive information that would otherwise support a distinct update factor for class III devices. Another commenter recommended that the class III proposal be included in a separate rulemaking procedure because it is not related to competitive acquisition.

2. Proposed Update to Fee Schedule

We believe that the GAO has done a thorough job in reviewing Medicare payment rules and methods and issues associated with the costs of furnishing class III devices. Accordingly, we agree with the finding in the report that the costs of furnishing class II and class III DME devices have been factored into the fee schedule amounts calculated for these devices. We also agree with the GAO recommendation that a uniform payment update be established to the DME fee schedule for 2007 for class II and class III devices. For class II devices, the MMA provided for a zero percent payment update from 2004 through 2008. Accordingly, for 2007, we are proposing a zero percent update for class III devices. Also, in accordance with the MMA, we are proposing to use the percent change in the CPI-U to update the class III device 2007 fee schedule amounts for 2008.

P. Discussion of Chiropractic Services Demonstration

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

In the CY 2006 PFS final rule with comment period (70 FR 70266) and the CY 2007 PFS final rule with comment period (71 FR 69707), we included a discussion of the 2-year chiropractic services demonstration that ended on March 31, 2007. This demonstration was authorized by section 651 of the MMA to evaluate the feasibility and advisability of covering chiropractic services under Medicare. These services extended beyond the current coverage for manipulation to care for neuromusculoskeletal conditions typical among eligible beneficiaries, and covered diagnostic and other services that a chiropractor was legally authorized to perform by the State or jurisdiction in which the treatment was provided. The demonstration was conducted in four sites, two rural and two urban. The demonstration was required to be budget neutral as the statute requires the Secretary to ensure

that the aggregate payment made under the Medicare program does not exceed the amount which would be paid in the absence of the demonstration.

Ensuring budget neutrality requires that the Secretary develop a strategy for recouping funds should the demonstration result in costs higher than those that would occur in the absence of the demonstration. As we stated in the CY 2006 and CY 2007 PFS final rules with comment period, we would make adjustments to the chiropractor fees under the Medicare PFS to recover aggregate payments under the demonstration in excess of the amount estimated to yield budget neutrality. We will assess budget neutrality by determining the change in costs based on a pre- and post-comparison of aggregate payments and the rate of change for specific diagnoses that were treated by chiropractors and physicians in the demonstration sites and control sites. Because the aggregate payments under the expanded chiropractor services may have an impact on other Medicare expenditures, we will not limit our analysis to reviewing only chiropractor claims.

Any needed reduction to chiropractor fees under the PFS would be made in the CY 2010 and CY 2011 physician fee schedules as it will take approximately 2 years after the demonstration ends to complete the claims analysis. If we determine that the adjustment for BN is greater than 2 percent of spending for the chiropractor fee schedule codes (comprised of the 3 currently covered CPT codes 98940, 98941, and 98942), we would implement the adjustment over a 2-year period. However, if the adjustment is less than 2 percent of spending under the chiropractor fee schedule codes, we would implement the adjustment over a 1-year period. We will include the detailed analysis of budget neutrality and the proposed offset during the CY 2009 PFS rulemaking process.

Q. Technical Corrections

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

1. Particular Services Excluded From Coverage (§ 411.15(a))

Prior to January 1, 2005, Medicare did not pay for routine physical examinations or checkups. Section 1862(a)(7) of the Act states that routine physical checkups are excluded services. This exclusion is described in § 411.15(a), Particular services excluded from coverage. In addition, we had interpreted section 1862(a)(1)(A) of the

Act to exclude coverage for cardiovascular disease screening tests and diabetes screening tests. This section provides that items or services must be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member as stated in § 411.15(k). Since preventative services are not provided for diagnosis or treatment of illness, injury, or malformation, we determined that these services are not reasonable and necessary within the meaning of the statute.

Effective January 1, 2005, Part B coverage was expanded to include an initial preventative physical examination (IPPE) for certain individuals. Our regulations governing the IPPEs are primarily set forth in § 410.16. Additional conforming changes were made at that time to § 411.15 to reflect this expansion in coverage.

Sections 612 and 613 of the MMA added coverage under Part B for cardiovascular disease screening tests and diabetes screening tests, effective for services furnished on or after January 1, 2005, subject to certain eligibility and other limitations. These provisions were implemented in the CY 2005 PFS final rule with comment period (69 FR 66236). Those rules are codified in § 410.17 and § 410.18, respectively. However, at the time we neglected to make additional conforming changes to § 411.15 to reflect this expansion in coverage.

To conform the regulations to the MMA provisions, we are proposing a technical correction to the provisions in § 411.15 by specifying additional exceptions to provide payment for cardiovascular disease screening tests and diabetes screening tests that meet the eligibility limitation and the conditions for coverage that we specified under § 410.17, Cardiovascular Disease Screening Tests, and § 410.18, Diabetes Screening Tests.

2. Medical Nutrition Therapy (MNT) (§ 410.132)

In the CY 2006 PFS final rule with comment period (70 FR 70160), we added individual medical nutrition therapy, as represented by HCPCS codes G0270, 97802 and 97803, to the list of telehealth services. We are making a technical correction to § 410.132(a) to conform the regulations to include an exception for services provided at § 410.78. This revised paragraph reads as follows:

“(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT services provided by a registered

dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Except as provided at § 410.78, services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally-accepted dietary or nutritional protocols.”

3. Payment Exception: Pediatric Patient Mix (§ 413.184)

In the CY 2006 PFS final rule with comment period (70 FR 70214), we revised § 413.180 through § 413.192 regarding criteria and the application procedures for requesting an exception to the ESRD composite rate payment. As part of the revisions we intended to amend the section heading of § 413.184 to reflect that, as specified in the statute, this exception only pertains to a pediatric ESRD facility. However, this change was not made. Therefore, we are proposing to revise the section heading of § 413.184 to read as follows: “Payment exception: Pediatric patient mix.”

4. Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§ 410.32(a)(1))

Section 1861(r)(5) of the Act was amended by section 4513(a) of the BBA to allow Medicare payment for a chiropractor’s manual manipulation of the spine to correct subluxation, without requiring the subluxation to be demonstrated by an x-ray. The BBA provision was effective for services furnished on or after January 1, 2000. Prior to this statutory change, the subluxation was required to be demonstrated by an x-ray. Because chiropractors are limited by statute with respect to the services they can provide under Medicare, it had been necessary to create an exception to the requirement that diagnostic services (including x-rays) must be ordered by the treating physician as provided in § 410.32(a). This exception, which permits a physician who is not a treating physician to order and receive payment for an x-ray that is used by a chiropractor, is specified in § 410.32(a)(1).

We revised § 410.22 to reflect the BBA change in the CY 2000 PFS final rule (64 FR 59439). (Note: § 410.22 was redesignated as § 410.21 in the CY 2001 PFS final rule.) However, we neglected to remove the chiropractic exception at § 410.32 (a)(1). Because of the BBA change, which removed the requirement that subluxation must be demonstrated by an x-ray, the chiropractic exception is no longer warranted. We do not believe it would be necessary or

appropriate to continue to permit payment for an x-ray ordered by a non-treating physician when a chiropractor, not the ordering physician, will use that x-ray. Therefore, we are proposing to revise § 410.32 by removing paragraph (a)(1) and by redesignating paragraphs (a)(2) and (a)(3) as (a)(1) and (a)(2), respectively.

R. The Percentage Change in the Medicare Economic Index (MEI)

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

The Medicare Economic Index (MEI) is authorized by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes.

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians’ services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has CY 2000 base year weights, is comprised of two broad categories: (1) Physician’s own time; and (2) physician’s PE.

The physician’s own time component represents the net income portion of business receipts and primarily reflects the input of the physician’s own time into the production of physicians’ services in physicians’ offices. This category consists of two subcomponents: (1) Wages and salaries; and (2) fringe benefits.

The physician’s PE category represents nonphysician inputs used in the production of services in physicians’ offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician’s PE component also includes the following categories of nonlabor inputs: office expense; medical materials and supplies; professional liability insurance; medical equipment; prescription drugs; and other expenses. The components are adjusted to reflect productivity growth in physicians’ offices by the 10-year moving average of productivity in the private nonfarm business sector. Table 14 presents a listing of the MEI cost categories with the associated weights.

TABLE 14.—MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES AND WEIGHTS

Expenditure category	2000 Expense weight
Physician Compensation	52.466
Wages and Salaries	42.730
Benefits	9.735
Practice Expense	47.534
Nonphysician Compensation	18.653
Nonphysician wages	13.808
Prof/Tech Wages ..	5.887
Manager Wages	3.333
Clerical Wages	3.892
Services Wages	0.696
Employee Benefits	4.845
Other Practice Expense	18.129
Office Expenses	12.209
Prof. Liability Insurance	3.865
Medical equipment	2.055
Drugs and Supplies	4.319
Medical material and supplies	2.011
Prescription Drugs	2.308
Other Expenses	6.433
All Other	6.433

Beginning in April 2007, with their March 2007 publication, the Bureau of Labor Statistics (BLS) will discontinue production and publication of the white collar occupation employment cost index (ECI) series.

The white collar benefit ECI for private workers has been used as the price proxy for nonphysician benefits in the MEI. There is no other comparable, published series that is a suitable replacement for the white collar benefit ECI. Consequently, Global Insight, Inc. (GII) and CMS jointly developed a composite series which is composed of four published ECI series and weighted by November 2004 National Industry—Specific Occupational Employment and Wage Estimates for NAICS 6211, Office of Physicians. Global Insight Inc. is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Table 15 lists the four ECI series and corresponding weights used to construct the new composite benefit index. We are proposing to replace the ECI white collar benefit series with this composite benefit index effective for the CY 2008 MEI update.

TABLE 15.—CMS COMPOSITE PRICE INDEX FOR NON-PHYSICIAN EMPLOYEE BENEFITS

ECI series	Weight
Benefits, Private, Professional, Scientific, Technical	59.0

TABLE 15.—CMS COMPOSITE PRICE INDEX FOR NON-PHYSICIAN EMPLOYEE BENEFITS

ECI series	Weight
Benefits, Private, Management, Business, Financial	6.3
Benefits, Private, Office & Administrative Support	32.6
Benefits, Private, Service Occupations	2.1

We compared the historical 4-quarter moving average percent changes of the MEI using the ECI white collar benefit index and the proposed ECI composite benefit series and in the 5 most recent calendar years, the difference in the overall MEI update is no greater than 0.1 percentage point. This analysis shows that the new composite benefit index would be expected to have little material impact on the aggregate MEI updates; and therefore, we believe the use of this composite benefit index is the most technically accurate index for capturing nonphysician benefits price pressures.

Although we have not done so in the past, we believe it would be beneficial to publish a preliminary estimate of the expected MEI update. For CY 2008, the forecasted increase in the MEI is 1.9 percent, which includes a forecasted 1.5 percent productivity offset based on the 10-year moving average of multifactor productivity. This forecast is based on GII's 1st quarter 2007 forecast of the MEI market basket. The final update will be based on historical data through 2nd quarter 2007.

S. Other Issues

1. Recalls and Replacement Devices

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

Recently, there has been a recall of 73,000 implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) because of a faulty capacitor that can cause the batteries to deplete sooner than expected. (See the FDA Web site at www.fda.gov/cdrh/news for Questions and Answers posted April 20, 2007 on this recall). This follows upon the recall of thousands of ICDs and pacemakers in CY 2004 and CY 2005. These recalls raise issues both with regard to the additional costs of replacement devices and with regard to the additional physicians' services and diagnostic tests that beneficiaries who have these devices often need.

For outpatient hospital costs of the replacement devices, effective for services furnished on or after January 1, 2007, we reduce the ambulatory payment classification (APC) payment we make to hospitals when the hospital receives a replacement device without cost or with full credit for the device.

We also proposed a reduction to Medicare payment for inpatient hospital services in the FY 2008 IPPS proposed rule (72 FR 26479). This proposed rule would reduce payments for hospital inpatients when hospitals use a recalled or replacement device at no cost or with partial credit.

While these regulations address hospital payment for the devices involved, there are also costs associated with physician monitoring of patients treated with recalled devices. Specifically, the manufacturer of the devices that have been most recently recalled recommends that patients with the recalled device consult with their physicians in each case and, in some cases, begin a routine of monthly evaluations. We would expect that not only could extra visits to physicians' offices or hospital outpatient departments be necessary, but additional diagnostic tests may also be needed to care for the beneficiaries who have the recalled devices. Thus, even when immediate replacement of the device is not required, we are concerned that the potential greater costs to Medicare and to the beneficiary for these unforeseen extra services may be substantial and burdensome.

We will be actively assessing ways to identify the additional health care costs and Medicare expenditures associated with device recall actions and exploring what actions would be appropriate in the case of these additional monitoring and related expenses as they relate to both the hospital outpatient and physician payment systems. We welcome public comments on this issue to inform our future review and analyses.

2. Therapy Standards and Requirements

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

a. Revisions to Personnel Qualification Standards for Therapy Services

In the CY 2005 PFS final rule with comment period (69 FR 66354), we amended § 410.59, § 410.60, and § 410.62 to refer to the qualifications for physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists at § 484.4, which sets the

personnel qualifications required under the HHA Conditions of Participation.

Section 484.4 contains requirements for persons furnishing services in HHAs that include physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), occupational therapy assistants (OTAs) and speech-language pathologists (SLPs). The CY 2005 PFS final rule with comment period clarified that the personnel qualifications in § 484.4 are applicable to all outpatient PT, OT, and SLP services "in order to create consistent requirements for therapists and therapy assistants" (69 FR 66345).

We propose to update the personnel qualifications in § 484.4 for PTs, PTAs, OTs, and OTAs. We also propose to revise the qualifications for SLPs to remove a reference to audiologists in the definition for speech-language pathologists because a speech-language pathologist would not have a Certificate of Clinical Competence in audiology, as implied by the regulation, unless that person was dually qualified as an audiologist. Otherwise, we are not proposing to update the qualifications for SLPs because we believe the qualifications in § 484.4 are currently appropriate and address the issues of continuing education and internationally trained SLPs.

We are proposing these changes for the following several reasons.

- The current regulations at § 484.4 contain outdated terminology relating to several of the relevant professional organizations.
- The standards that now exist in the fields of physical therapy and occupational therapy have changed since a substantial portion of these qualification requirements were developed.
- Some of the current qualification requirements do not address individuals who have been trained outside of the United States, or refer to outdated requirements.
- These revisions would have the benefit of establishing consistent standards across provider/supplier lines.

Although all States license PTs, some States have no licensing provisions for PTAs, OTs, OTAs, and SLPs. In particular, the qualifications for PTAs vary widely among States. According to the Federation of State Boards of Physical Therapy Web site (accessed on March 29, 2007), the "Number of states that grandfathered PTAs prior to regulation = 41." Under the title "What method does your state use to regulate PTAs?" the field contains the word "Licensed," or "Certified", or is blank. Therefore, we believe PTAs who have

been licensed and practicing for many years may not meet the current education requirements in § 484.4. We believe the same is true of occupational therapy assistants who obtained their training prior to application of the requirements of the certification examination for Certified Occupational Therapy Assistant (COTA) developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). Additionally, we believe some States permitted licensure or certification of PTs and OTs without successful completion of a curriculum in physical therapy or occupational therapy after 1977 (the date currently specified under the “grandfather clause” in § 484.4 before which a practicing PT or OT need not have completed a curriculum in physical therapy or occupational therapy). We believe there may also be licensed or certified PTAs and OTAs who do not meet the educational requirements in § 484.4.

Therefore, we believe it would be appropriate to broaden the current grandfathering clauses for practicing PTs, OTs, PTAs, and OTAs. We propose to revise our requirements to recognize PTs, OTs, PTAs, or OTAs who meet their respective State qualifications (or have received State recognition as PTs, OTs, PTAs or OTAs) before January 1, 2008. Individuals who furnish physical or occupational therapy services but have not met State qualifications (or received State recognition as PTs, OTs, PTAs and OTAs) before January 1, 2008, would be required to meet the updated qualifications in § 484.4.

We are not proposing to change the current grandfathering provisions relating to the qualifications for PTs, OTs, PTAs, and OTAs furnishing services under the Home Health PPS or the Hospice PPS because the current regulations in § 484.4 (that is, occupational therapist (paragraph (c)), OTA (paragraph (b)), physical therapist (paragraph (c) or (d)), or PTA (paragraph (2)) have applied to those settings consistently for almost 20 years. We do not expect that there are therapists furnishing services in a HHA or hospice that do not meet either the current or proposed revised qualifications. Therefore, we will retain the current grandfathering clauses for personnel providing services in those settings before 1977. We would not apply to Home Health and Hospice settings the proposed new grandfathering clause that would permit those qualified professionals who are licensed, certified, registered or otherwise regulated by a State and are furnishing services in other settings before January

1, 2008 to continue providing services without updating their education to meet the new requirements.

We are seeking comment on appropriate grandfathering provisions relating to qualifications of therapists and assistants to assure that skilled therapists and assistants with comparable and appropriate education and training treat Medicare beneficiaries in all settings. We propose these grandfathering provisions to § 409.16, § 409.23, § 410.43, § 410.59, § 410.60, § 482.56, § 485.70, § 485.705, § 491.9.

The proposed revised personnel qualifications in § 484.4 for therapists and assistants must address minimum requirements for the provision of therapy services by qualified personnel who have attained the skills of therapists with education and training in the specific discipline in which they are practicing, but who are not licensed. Also, for therapists and assistants trained outside the United States or trained by the United States military, we want to consider developing standards comparable to those applied to therapists and assistants trained in the United States. By “comparable” we mean that we would refer to and base our standard on a process whereby it is determined (either by the State or by another credentialing authority such as the NBCOT) that the education, training, or testing standards obtained outside the United States or in the military are so similar as to be substantially indistinguishable from standards applied to those who meet the qualifications for therapists and assistants trained in the United States. However, we note that we intend to establish standards comparable to those we establish for PTs, OTs, PTAs, OTAs, and speech-language pathologists, and not to recognize as qualified therapists or therapy assistants individuals trained in other disciplines for purposes of furnishing PT, OT, or SLP services to Medicare beneficiaries. It is not our intention to modify the policy that requires physical therapy, occupational therapy, and SLP services furnished incident to a physician's service to meet all the standards and conditions (except licensure) that apply to therapists, as this policy is based on the section 1862(a)(20) of the Act. Rather, it is our intention to assure that Medicare payment is made only for physical therapy, occupational therapy, and SLP services provided by personnel who meet qualifications, including consistent and appropriate education and training relevant to the discipline, so that they are adequately prepared to safely and effectively treat Medicare beneficiaries.

In this proposal, we refer to persons who are licensed, certified, and otherwise regulated by a State. We interpret “otherwise regulated” to mean that, while a State may not regulate a profession by granting a license or certifying educational or training credentials, it may nevertheless regulate the practice of a profession by application of certain other requirements. For example the use of the title physical therapy assistant might be limited to those who have passed a course for PTAs in a State-approved college, even when the State does not grant graduates a license or certificate to practice. By “otherwise regulated,” we do not mean to refer to State regulations that are generally applicable to all health care or other professionals regarding, for example, business practices, employment or hygiene. Rather, we mean to refer to the specific qualifications one must have in order to practice within a particular discipline or use a particular title.

We propose to require that OT's beginning their practice after January 1, 2008, must be licensed, certified, registered or otherwise regulated as an OT, and have graduated from an occupational therapist curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association (AOTA), and also have successfully completed the certification examination developed and administered by the NBCOT. By “successfully completed” we mean the individual must perform sufficiently well on the exam to receive (or be eligible to receive) certification. For services incident to a physician's or nonphysician practitioner's service where the licensure requirement does not apply, the education requirements continue to apply.

We propose that after January 1, 2008, OTAs must be licensed, certified, registered or otherwise regulated as an OTA and have graduated from an OTA curriculum accredited by the nationally recognized organization for accreditation of occupational therapists, the ACOTE of the AOTA, and successfully completed the certification examination for Certified Occupational Therapy Assistant (COTA) developed and administered by the NBCOT.

We are proposing that OTs who are educated outside the United States or by the U.S. Military— (1) Be graduates of an occupational therapy curriculum accredited by the World Federation of Occupational Therapists (WFOT); (2) have successfully completed the NBCOT International Occupational Therapy Eligibility Determination

(IOTED) review; and (3) have successfully completed the certification examination for Registered Occupational Therapist. We propose to adopt similar standards for OTAs (but with an OTA curriculum) and seek comments on qualifications for internationally educated occupational therapy assistants.

For PTs, we propose the therapist must be licensed as a physical therapist by the State in which practicing and accredited by the Commission on Accreditation in Physical Therapy Education (CAPTE) based on American Physical Therapy Association (APTA) guidelines. When the licensure requirement is not applicable (that is, for services furnished incident to the services of physicians and NPPs), we propose to require that PTs must have been accredited by the CAPTE. We seek comment on qualifications for PTs that include a curriculum and a national examination each approved by the APTA.

We propose that licensure or certification, registration or other regulation by the State in which services are furnished would be required for PTAs under our regulations. We also propose that PTAs be accredited by the CAPTE. We seek comment on appropriate qualifications for PTAs.

b. Application of Consistent Therapy Standards

(1) Personnel Qualifications

We believe therapy services should be provided according to the same standards and policies in all settings, to the extent possible and consistent with statute. For example, personnel qualifications for therapists and assistants should apply equally to all settings in which Medicare pays for physical therapy, occupational therapy and SLP services. Therefore, we propose to revise our regulations to cross-reference the personnel qualifications for therapists in § 484.4 to the personnel requirements for PTs, OTs, PTAs, OTAs, and SLPs in the following sections:

- § 409.10 and § 409.16 (Inpatient hospital services and inpatient critical access hospital services).
- § 409.23 (Posthospital SNF care).
- § 410.43 (Partial hospitalization services).
- § 410.59 (Outpatient occupational therapy services).
- § 410.60 (Outpatient physical therapy services).
- § 410.62 (Outpatient SLP services).
- § 418.92 (Hospice).
- § 482.56 (Optional hospital services, Rehabilitation services).
- § 485.70 (Specialized providers).

- § 485.705 (Clinics, Rehabilitation agencies, Public health agencies).
- § 491.9 (Rural health clinics and Federally qualified health centers (FQHCs)).

We also welcome comments on whether the personnel qualifications at § 484.4 should be made applicable in other settings.

It is our intention that when Medicare policies describe physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants and speech-language pathologists, the qualifications for those professions would be the same in all settings, without exception.

(2) Application of Consistent Therapy Standards

In tandem with cross-referencing Part A and Part B therapy personnel requirements in the regulations, we believe it would be appropriate to clarify our policies to improve consistency in the standards and conditions for Part A and Part B therapy services. Many, but not all, of the policies described for therapy services in Part B settings are also appropriate to Part A settings.

In § 409.17, we propose to clarify that hospital services include physical therapy, occupational therapy and SLP. We propose to add regulations for inpatient hospital services to include a plan of treatment for therapy services consistent with the plan required for outpatient therapy services. We invite comment on PT, OT, and SLP plan of treatment policies that are appropriately applied to all therapy services, whether provided under Medicare Part A or B.

Since inpatient hospital services are always provided under the care of a physician, we believe that the physician's review and certification of the therapy plan of treatment is implied by the physician's review and approval of a facility plan that includes therapy services and, therefore, we are not proposing additional therapy certification requirements for the hospital setting.

c. Outpatient Therapy Certification Requirements

The signature of a physician or NPP in the medical record indicating approval of the plan of care for outpatient therapy services certifies the initial need for therapy services furnished under Part B. For other covered medical and health services furnished by providers and suppliers of outpatient services, certification is required only once, either at the beginning or at the end of a series of visits. Recertification is not required for

most health services. In 1988, in an attempt to control the expanding utilization of therapy services, we added a 30-day recertification requirement for outpatient therapy services to our regulation at § 424.24. This requires that a physician certifies a plan of care for 30 days, regardless of the appropriate length of treatment. To continue treatment past 30 days, the physician is required to recertify the plan. After many years of experience with the current recertification requirements, we now believe that requiring recertification at 30-day intervals may not always provide sufficient flexibility to the physician to order the correct amount of therapy for the patient's needs. In some cases, it may impact utilization by encouraging reevaluations at intervals based on certification timing, rather than on necessity. Since the 30-day recertification requirement was initiated in 1988, many other means of ensuring appropriate utilization of therapy services have been developed. Medicare policies have been clarified to define skilled services, reasonable and necessary services, and appropriate documentation. Payments for therapy services are now limited by annual per beneficiary caps, and there are many local medical review policies and system edits to monitor extended treatment. Therapy services are now identified as such on claims, making it easier to analyze and review overutilization of services. Three studies on utilization of therapy services are published and available to medical reviewers and providers or suppliers of services to help identify typical episodes of care. Taken together, these changes may have improved appropriate utilization and limit errors in billing for therapy services, as evidenced in the Improper Medicare Fee-for-Service Payment Report of May 2007.

In 2004 and again in 2006, we engaged a contractor to perform an extensive analysis of the utilization of therapy services. The analyses indicated that the 30-day recertification requirement has not had the anticipated impact on utilization of services and does not serve to limit therapy services payments. About 70 percent of episodes are completed before the first 30-day recertification interval. Although CORFs have a 60-day recertification period, and SNFs and ORFs have 30-day recertification periods, the average number of treatment days is similar in these settings. This suggests that the interval of the recertification requirement does not affect professional decisions regarding the duration of treatment. In fact, contrary to the pattern

expected if certification impacted duration of treatment, the number of physical therapy treatment days is higher in a SNF (30-day recertification interval) than in a CORF (60-day recertification interval).

For these reasons, we do not believe there is a continued need for recertification at the 30-day interval. We propose that review of the plan of care continue to be required at certification and recertification. Since the plan of care may be established by a nurse practitioner, a clinical nurse specialist, or a physician assistant (nonphysician practitioners) as well as a physician, we propose to modify the language in § 410.61 to include those professionals among those who shall review the plan. Since the certification and recertification of the plan requires a signature, we propose to remove the current redundant requirement at § 410.61(e) to date and sign a review at the same time as the plan is certified.

We propose to change the plan of treatment recertification schedule in § 424.24. Currently, the physician must initially certify a plan of treatment at the time the plan is established or as soon thereafter as possible. If the need for treatment continues beyond 30 days, the plan of treatment must be recertified every 30 days until discharge. We propose that the physician (or NPP, as appropriate) would continue to review and certify the initial plan of care as soon as possible, but that the certification would apply for an episode length based on the patient's needs, not to exceed 90 days and would be recertified every 90 days thereafter. Payment would continue to be denied if services were provided without a certified plan of care. Overutilization of services would continue to be monitored, as it is now, by Medicare contractors based on data analysis assisted by system edits.

We believe adjusting the first recertification interval from 30 to 90 days would allow the physician to approve a plan of care that represents the clinically appropriate length of treatment, discourage routine 30-day plans, encourage professional determination of an appropriate length of treatment at the time of the initial certification, protect the patient's access to needed treatment when the certifying physician or NPP is not available at the 30-day interval, reduce the administrative burden on providers, suppliers, physicians, NPPs and Medicare contractors, and provide an appropriate timeline for monitoring the necessity of continuing therapy services. Therefore, we are proposing to amend

§ 424.24 to require recertification every 90 days after beginning treatment.

We propose to revise § 424.24 to remove reference to a certification "statement" and to require that the continuing need for therapy services be documented in the medical record, for example, the plan of treatment. Since each plan must include the duration of treatment, the current requirement for an estimate of how much longer the services will be needed is proposed to be omitted as redundant.

We propose to continue to review the utilization of therapy services to assess any changes in practice that might be related to the proposed changes in our regulations regarding certification of a plan of care for an appropriate length of treatment. After 2 years, if we determine that there are changes in practice that suggest inappropriate utilization of therapy services based on the certification timing, we will consider whether to reinstate the 30-day recertification requirement.

3. Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission from the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals

[If you choose to comment on issues in this section, please include the caption "PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES" at the beginning of your comments.]

a. Legislative History

Section 101 of the MMA amended title XVIII of the Act to establish a voluntary prescription drug benefit program. Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA-PD), and other Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and dispensing pharmacy and pharmacist. This would include information about eligibility, benefits (including drugs included in the applicable formulary, any tiered formulary structure and any requirements for prior authorization), the drug being prescribed or dispensed and other drugs listed in the medication history, as well as the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed. The MMA directed the

Secretary to issue uniform standards for the electronic transmission of such data.

There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, would be required to comply with any applicable final standards that are in effect.

Section 1860D-4(e) of the Act required the Secretary to conduct a pilot project to test initial standards recognized under section 1860D-4(e)(A) of the Act, prior to issuing the final standards in accordance with section 1860D-4(e)(D) of the Act. Initial standards were recognized by the Secretary in 2005 and then tested in a pilot project during CY 2006. The MMA created an exception to the requirement for pilot testing of standards where, after consultation with the National Committee on Vital and Health Statistics (NCVHS), the Secretary determined that there already was adequate industry experience with the standard(s). Such "foundation standards" were recognized and adopted through notice and comment rulemaking as final standards without pilot testing.

Based upon the evaluation of the pilot project, and not later than April 1, 2008, the Secretary is required to issue final uniform standards. These final standards must be effective not later than 1 year after the date of their issuance.

For a complete discussion of the statutory bases for the e-prescribing portions of this proposed rule and the statutory requirements at section 1860D-4 of the Act, please refer to the "Background" section of the E-Prescribing and the Prescription Drug Program proposed rule published in the February 4, 2005 **Federal Register** (70 FR 6256).

b. Regulatory History

i. Foundation Standards

After consulting with the NCVHS, the Secretary found that there was adequate industry experience with several potential e-prescribing standards. Upon adoption through notice and comment rulemaking, these standards were called "foundation" standards, because they would be the first set of final standards adopted for an electronic prescription drug program. Three standards were adopted in the E-Prescribing and the Prescription Drug Program final rule

published in the November 7, 2005 **Federal Register** (70 FR 67568).

The foundation standards are as follows:

- For the exchange of eligibility information between prescribers and Part D sponsors: ASC X12N-270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 transaction).

- For the exchange of eligibility information between dispensers and Part D sponsors: The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard, September 1999, Implementation Guide Version 5, Release 1 (Version 5.1) for NCPDP Data Record in the Detail Data Record (hereafter referred to as the NCPDP Telecommunication Standard).

- For the exchange of new prescriptions, changes, renewals, cancellations and certain other transactions between prescribers and dispensers: NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as NCPDP SCRIPT Standard).

ii. Exemption to Foundation Standard Requirements for Computer-Generated Facsimiles

The November 7, 2005 final rule included an exemption for entities that transmit prescriptions or prescription-related information by means of computer-generated facsimile (faxes) from the requirement to use the adopted NCPDP SCRIPT standard. “Electronic media” was already defined by the HIPAA, so e-prescribing utilized the same definition. As a result, faxes that were generated by a prescriber’s/dispenser’s computer and sent to a provider’s/dispenser’s fax machine which prints out a hard copy of the original computer-generated fax (that is, “computer-generated” faxes) fell within the definition of “electronic media” for e-prescribing. Absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. Comments received from the health care industry indicated that this would cause computer-generated faxers

to revert to paper prescribing. As the Secretary believed that prescribers/dispensers using computer fax capabilities would eventually migrate to fully functional e-prescribing, possibly at the same time as they implemented electronic health record (EHR) systems, the November 7, 2005 final rule exempted entities transmitting computer-generated faxes from having to comply with the NCPDP SCRIPT standard.

c. Proposal of Elimination of Exemption

We propose to revise § 423.160(a)(3)(i) to eliminate the computer-generated facsimiles (faxes) exemption to the NCPDP SCRIPT Standard for the communication of prescription or certain prescription-related information between prescribers and dispensers for the transactions listed at § 423.160(b)(1)(i) through (xii). In the November 7, 2005 final rule (70 FR 67571), we explained that faxes generated by one computer and electronically transmitted to another computer or fax machine would be included under the e-prescribing definition of electronic media. This computer-generated fax technology is used in some e-prescribing software products and under the definition of electronic media, providers and dispensers who utilize these products would be required to comply with adopted e-prescribing standards. Our discussion of computer-generated faxing distinguished between cases where the prescriber’s/dispenser’s software has the ability to generate SCRIPT transactions, but the feature is not activated because the prescriber has not activated the feature on their software, and other cases where software (such as a word processing program) is used that creates and sends a fax that results in a paper prescription or response at the receiving end, but does not have true e-prescribing (electronic data interchange using the SCRIPT standard) capabilities.

We believed that requiring prescribers/dispensers who already use electronic media to e-prescribe to modify or change their software and hardware products to be compliant with the foundation standards would likely result in their simply reverting to paper prescribing and would be counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing. Also, we believed that prescribers and dispensers would begin to migrate to true e-prescribing in time, and therefore, adopted an exemption that permitted prescribers and dispensers to continue to use computer-generated faxes for transmitting certain prescriptions and

prescription-related information. However, at the same time we encouraged all prescribers and dispensers using fax technology to move as quickly as possible to computer-to-computer data interchange via the NCPDP SCRIPT standard.

Since January 2006, we have seen little reduction in the use of computer-generated fax technology. Based on data provided to CMS by SureScripts, which operates the Pharmacy Health Information Exchange, the largest network to link electronic communications between pharmacies and physicians, serving more than 95 percent of all pharmacies and all major physician technology vendors in the United States, it estimates that of the 150,000 prescribers now using software that is capable of generating SCRIPT transactions, only 15 percent are doing so. The remaining 85 percent are still generating paper faxes. The costs to convert to e-prescribing using NCPDP SCRIPT for these prescribers would in most cases be included in the annual maintenance fee they pay their software vendor. However, the cost of conversion for prescribers using e-prescribing software that cannot generate SCRIPT transactions would be higher, as these prescribers would have to purchase and install other software products. Therefore, we are specifically soliciting comments on the impact to providers and pharmacies.

Pharmacy implementation of e-prescribing is considerably more widespread. SureScripts reports that all chain drug stores and 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions. Independent pharmacies are less likely to perceive a return on investment for e-prescribing due to low numbers of practices seeking to move to e-prescribing using the SCRIPT transaction.

Since computer-generated faxing retains some of the disadvantages of paper prescribing (for example, the administrative cost of keying the prescription into the pharmacy system and the related potential for data entry errors that may impact patient safety), we believe it is important to take steps to encourage prescribers and dispensers to move toward use of the SCRIPT standard.

One concrete step we could take to increase the use of the SCRIPT transaction would be to eliminate the exemption for computer-generated faxing. This would move prescribers and dispensers using this technology to upgrade to software products or to new versions of the products they currently use, that would enable electronic

transmission of SCRIPT transactions. Because this requirement would fall on prescribers that already use e-prescribing software, it would increase the number of SCRIPT transactions fairly significantly in a relatively short time period, and this could in turn create a “tipping point” that could create an economic incentive for independent pharmacies to adopt software to begin to exchange SCRIPT transactions with their prescriber partners.

Therefore, we propose to eliminate the computer-generated fax exemption for all provider/dispenser transactions. We anticipate having this change effective 1 year after the effective date of the CY 2008 PFS final rule. This will provide notice to prescribers and dispensers seeking to implement or upgrade e-prescribing software to look for products and upgrades that are capable of generating and receiving NCPDP SCRIPT transactions. It also affords current e-prescribers time to work with their trading partners to eventually eliminate computer to fax machine transactions.

We now believe that, with the additional phase-in period allotted to allow for this transition, with improved and more readily available standards-based e-prescribing products, and the apparent ability of e-prescribing networks to now identify which prescribers and dispensers are capable of making SCRIPT enabled transactions and which use this information to facilitate successful SCRIPT enabled transactions, this elimination of the exemption for computer-generated faxing will encourage e-prescribers and dispensers to move as quickly as possible to use of the SCRIPT standard with what we perceive to be minimal impact.

We are soliciting comments on the impact of the proposed elimination of this exemption, including the total number of affected practices and pharmacies and the time required for them to implement SCRIPT-enabled software. Specifically, we are soliciting information regarding the number of practices that currently use legacy versions of software that are not capable of generating SCRIPT transactions and the amount of lead time they would need to comply. We are also soliciting comments regarding the extent to which eliminating the exemption would cause entities using fax technology to revert to paper prescribing rather than update current software.

T. Division B of the Tax Relief and Health Care Act of 2006—Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432) (MIEA-TRHCA)

In addition to the provisions of the MIEA-TRHCA discussed in section II.B. (GPCIs), additional provisions of the MIEA-TRHCA are discussed in this section of the proposed rule.

1. Section 101(b)—Physician Quality Reporting Initiative (PQRI)

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 101(b): PQRI” at the beginning of your comments.]

a. Background

Section 101(b) of the MIEA-TRHCA amended section 1848 of the Act by adding subsection (k). Section 1848(k)(1) of the Act requires the Secretary to implement a system for the reporting by eligible professionals of data on quality measures as described in section 1848(k)(2) of the Act. As specified in section 1848(k)(3)(B) of the Act, for the purpose of the quality reporting system, eligible professionals include physicians, other practitioners as described in section 1842(b)(18)(C) of the Act, physical and occupational therapists, and qualified speech-language pathologists. Section 101(c) of the MIEA-TRHCA authorizes “Transitional Bonus Incentive Payments for Quality Reporting” in 2007, specifically for satisfactory reporting of quality data, as defined by section 101(c)(2) of the MIEA-TRHCA. We have named this quality reporting system for 2007, including the 2007 bonus payment, the “Physician Quality Reporting Initiative (PQRI)” for ease of reference.

For 2007, section 1848(k)(2)(A)(i) of the Act, as added by the MIEA-TRHCA, provides that the quality measures for the PQRI shall be the physician quality measures published as 2007 Physician Voluntary Reporting Program (PVRP) quality measures on the CMS Web site as of the date of enactment of this subsection, except as may be changed based on the results of a consensus-based process in January 2007. The 2007 PVRP quality measures consist of the 66 measures that we had identified and posted on the CMS Web site on December 5, 2006 (see “Transition from 2006 PVRP” below in this section). The statute also allowed for additional quality measures to be added to the original set as the result of a consensus-based process in January 2007. As allowed under the statute, and based on actions approved at the AQA Alliance

(formerly the Ambulatory Care Quality Alliance) meeting on January 22, 2007, 8 quality measures were added to the 66 measures identified and originally posted to the CMS Web site on December 5, 2006. The final result is 74 “2007 PQRI Quality Measures.” A list and description of these 74 measures is available for download from the PQRI Measures/Codes page of the PQRI section of the CMS Web site at www.cms.hhs.gov/PQRI.

Although section 1848(k)(2)(A)(ii) of the Act does not allow for any further additions to or deletions from the 2007 PQRI Quality Measures after January 2007, the statute does allow modifications or refinements (such as code additions, corrections, or revisions) to the detailed specifications for the 2007 PQRI quality measures until the beginning date of the reporting period (that is, July 1, 2007). After this date, no further revisions to the specifications for 2007 PQRI measures are allowed by section 1848(k) of the Act. The specifications for the 2007 PQRI quality measures are available as a download from the Measures/Codes page of the PQRI section of the CMS Web site at <http://www.cms.hhs.gov/pqri>. Additional materials containing information on the 2007 PQRI, including but not limited to the calculation of eligibility for and amount of bonus payment for satisfactory reporting, are also available on this section of the CMS Web site.

Section 1848(k)(2)(B) of the Act requires that the Secretary publish in the **Federal Register** not later than August 15, 2007, proposed quality measures that would be appropriate for eligible professionals to use to submit data to the Secretary in 2008. The final 2008 PQRI quality measures must be determined and published by November 15, 2007, as specified in section 1848(k)(2)(B) of the Act as amended by the MIEA-TRHCA.

b. MIEA-TRHCA Requirements for Measures Included in the 2008 PQRI

(i) Overview of MIEA-TRHCA Requirements for 2008 PQRI Quality Measures

Section 1848(k)(2)(B)(i) of the Act requires, “for purposes of reporting data on quality measures for covered professional services furnished during 2008, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and

that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of EHRs and electronic prescribing technology.”

Section 1848(k)(2)(B)(ii) of the Act requires, that “[n]ot later than August 15, 2007, the Secretary shall publish in the **Federal Register** a proposed set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008. The Secretary shall provide for a period of public comment on such set of measures.”

In examining the statutory requirements of section 1848(k)(2)(B)(i) of the Act, we believe that the requirement that measures be endorsed or adopted by a consensus organization applies to each measure that would be included in the measures set for submitting quality data on covered professional services furnished during 2008. Likewise, the requirement for measures to have been developed using a consensus-based process (as identified by the Secretary) applies to each measure. By contrast, we do not interpret the provision requiring inclusion of measures submitted by a specialty to apply to each measure. Rather, we believe this requirement means that in endorsing or adopting measures, a consensus organization must include in its consideration process at least some measures submitted by one physician or organization representing a particular specialty. Similarly, we interpret the requirement that 2008 measures include structural measures, such as the use of EHRs and electronic prescribing technology, to mean that the 2008 measure set must include at least 2 structural measures.

In examining sections 1848(k)(2)(B)(ii) through (iii) of the Act, we believe that the Secretary is given broad discretion to determine which quality measures meet the statutory requirements and are appropriate for inclusion in the final set of measures for 2008. We do not interpret the Act to require that all measures that meet the basic requirements of section 1848(k)(2)(B)(i) of the Act must be included in the 2008 set of quality measures.

We discuss in the following section the statutory requirements for consensus organizations and the use of a consensus-based process for developing quality measures as they relate to the requirements for the set of measures for 2008 in the context of other applicable Federal law and policy. We also discuss the policies used in proposing the initial

set of quality measures for eligible professionals for use in 2008 and the policies we propose to apply in publishing the final set.

(ii) Consensus Organizations and Consensus-Based Process for Developing Measures

The MIEA–TRHCA requires that measures used for 2008 be identified by the Secretary as having been endorsed or adopted by a consensus organization and having been developed through the use of a consensus-based process. We believe that these requirements should be interpreted in the context of the National Institute of Standards and Technology Act (NISTA) (15 U.S.C. 271 et seq.) as amended by the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) (NTTAA) and implemented by OMB Circular No. A–119 (OMB A–119) dated February 10, 1998.

Per the NTTAA, except when it is inconsistent with applicable law or otherwise impractical, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies and shall also participate with such bodies in the development of technical standards when such participation is in the public interest and compatible with the agency and departmental missions, authorities, priorities, and budget resources.

OMB A–119 provides specific policy guidance to agencies on the appropriate interpretation of agency responsibilities under the NTTAA. Specifically, OMB A–119 establishes as government-wide policy that agencies “must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical.” OMB A–119 explains that in determining whether use of existing voluntary consensus standards in its regulatory and procurement activities is otherwise impractical, “‘Impractical’ includes circumstances in which such use would fail to serve the agency’s program needs; would be infeasible; would be inadequate, ineffectual, inefficient, or inconsistent with agency mission; or would impose more burdens, or be less useful, than the use of another standard.”

OMB A–119 further provides that “voluntary consensus standards” are standards developed or adopted by voluntary consensus standards bodies. OMB A–119 defines “voluntary consensus standards body” as

maintaining the following attributes: (1) Openness; (2) Balance of interest; (3) Due process; (4) An appeals process; (5) Consensus; which is defined as general agreement, but not necessarily unanimity, and also includes a process for attempting to resolve objections by interested parties. The process requires that, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons for the disposition, and the consensus body members are given an opportunity to change their votes after reviewing the comments. Voluntary consensus standards must include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available to all interested parties on a nondiscriminatory, royalty-free, or reasonable royalty basis.

Other types of standards, that are distinct from voluntary consensus standards include the following: (1) Industry standards, company standards, non-consensus standards, or de facto standards which are developed in the private sector but not in the full consensus process of a voluntary consensus standards body; (2) Government-unique standards which are developed by the government for its own uses; (3) Standards mandated by statute such as those contained in the United States Pharmacopeia and the National Formulary, as referenced in 21 U.S.C. 351.

The term “technical standards” under 12(d)(4) of the NTTAA, means “performance-based or design-specific technical specifications and related management systems practices”. When healthcare quality measures are used in a regulatory framework such as contemplated for the 2008 PQRI quality measures under the MIEA–TRHCA, we believe that such measures constitute “technical standards” as used in the NTTAA and that NTTAA applies to such measures.

Two consensus organizations are referenced in MIEA–TRHCA: the National Quality Forum (NQF) and the AQA. The NQF has a formal organizational structure and established processes that are intentionally designed to comply with the NTTAA and OMB A–119. Membership is open and includes physicians and other providers, hospital organizations, purchasers, researchers, payers, and employers. In achieving its determination of whether or not to endorse a standard, the NQF uses a formal process that consists of five principal steps that follow a project’s conceptualization, prioritization, and

planning. The steps are: (1) Consensus Standard Development; (2) Widespread Review; (3) Member Voting and Member Council Approval; (4) Board of Directors Action; and (5) Evaluation that includes an appeals process. The NQF meets the NTTAA requirements for a voluntary consensus standards body within the meaning of the NTTAA and its endorsed healthcare quality measures constitute voluntary consensus standards within the meaning of NTTAA.

The AQA, also referenced in section 1848(k)(2) of the Act as a consensus organization for the purpose of identifying measures that have successfully completed review by a consensus organization, utilizes certain essential practices of a voluntary consensus standards body under NTTAA and the OMB A-119 relating to openness, balance of interest, and consensus. Of particular note is the breadth of formal participation among stakeholders that have an interest in healthcare quality measures dealing with physician care. Participants at AQA may vote without limitation as to which stakeholder category into which they may fall. Voting participation, for example, includes physicians, other providers, purchasers, payers, consumers, accrediting organizations, and employers. However, the AQA does not have a defined organizational structure intended to meet the requirements of the NTTAA and the OMB A-119 and has no formal due process or appeals structure. Therefore, the AQA does not meet the requirements of the NTTAA for a "voluntary consensus standards body".

By citing AQA as an example of an acceptable consensus organization, section 1848(k)(2)(B) of the Act establishes that AQA adoption satisfies the requirement of section 1848(k)(2)(B) of the Act that PQRI quality measures be adopted or endorsed by a consensus organization. We believe it follows that the Congress did not intend to require all 2008 quality measures under section 1848(k)(2)(B) of the Act to meet the requirements to be considered voluntary consensus standards under the NTTAA. However, by giving NQF and AQA as examples of consensus organizations, we believe the Congress intended that consensus organizations should, in the context of section 1848(k)(2)(B) of the Act, have a breadth of stakeholder involvement and voting participation substantially comparable to that of the NQF or AQA.

Inasmuch as we are unaware of any other organizations that engage in endorsement or adoption of healthcare quality measures for physician services that have the level of openness, balance

of interest, and consensus based on voting participation, that is comparable to NQF or AQA, we propose to limit measures for inclusion as 2008 PQRI to measures that are endorsed or adopted by NQF or AQA. However, as elaborated in the policies we set forth below in this section, we invite comment as to other consensus organizations that may have a comparable level of consensus organization characteristics.

Given the overlap of NQF and AQA as consensus organizations under the MIEA-TRHCA, it is important to distinguish their roles. As currently established, the principal purpose of AQA for physician quality measures is to select among NQF endorsed measures for coordinated implementation. Unlike NQF, AQA is not established to serve as a "voluntary consensus standards body" under NTTAA. Therefore, the AQA is not established as an alternative or substitute for NQF endorsement processes as an entity organized to comply with the NTTAA and OMB A-119 requirements for a voluntary consensus standards body. However, during a time of rapid physician quality measures development and implementation, it is impractical to delay implementation of physician quality measures until the formal processes of NQF are completed. Therefore, AQA has been able to facilitate incorporation of new measures into the quality reporting system by providing consensus review acceptable under MIEA-TRHCA for implementation of a measure prior to actual NQF endorsement. In the event of a determination by NQF to decline endorsement of a particular measure after it had been adopted by AQA, we anticipate that AQA would withdraw its adoption of such a measure.

Turning to the requirement of a consensus-based process for developing quality measures, we propose to interpret this requirement in light of the NTTAA and the importance of broad consensus for health care quality measures used for regulatory purposes. In this context we will outline the process of health care quality measurement development and distinguish basic development steps from the completion of a consensus-based development process as required under MIEA-TRHCA.

Many organizations are involved in the development of health care quality measures including physician organizations, health care providers, Federal agencies, accreditation organizations, disease-focused not-for-profit organizations, research organizations, and health plans. The basic development processes of leading

health care quality measure developers generally use standardized methods that include identification of a quality goal or gap, literature and evidence review, expert and technical evaluation, specification development, testing, organizational review, and that may include public comment.

In the framework of the NTTAA, upon completion of the basic development work, healthcare quality measures do not constitute voluntary consensus standards, even though they may have utilized consensus as a mechanism of achieving agreement among the developer's participants or within the developer's organizational structure. Rather, to achieve the status as a voluntary consensus standard under NTTAA, the measure must go through the additional development that occurs through the broader consensus process of consensus endorsement. During this process, based on the need to achieve agreement, quality measures are often modified in order to achieve the necessary broad consensus.

Consistent with this in concept but without proposing that 2008 PQRI measures be limited to those meeting the definition of a voluntary consensus standard under NTTAA, we interpret "consensus-based process for developing measures" as used in MIEA-TRHCA to encompass not only the basic development work of the formal measure developer, but also to include the achievement of consensus among stakeholders in the health care system based on at least a level of openness, balance of interest, and consensus reflected in the structures and processes of the NQF and AQA as of the date of enactment of MIEA-TRHCA and the date of publication of this proposed rule.

Based on the considerations previously discussed, we propose to apply the following policies in identifying measures that meet the MIEA-TRHCA requirements for having used a consensus-based process for development and the requirement for having been endorsed or adopted by a consensus organization such as the NQF or AQA, and that are appropriate for inclusion as 2008 measures:

(1) We interpret "a consensus-based development process" as meaning that in addition to the measure development, the measure has achieved adoption or endorsement by a consensus organization having at least the basic characteristics of the AQA as a consensus organization as of December 2006, when the MIEA-TRHCA incorporating reference to AQA was passed and signed into law. Those basic characteristics include a comparable

level of openness, balance of interest, and consensus based on voting participation. As discussed above and further clarified in points (3) and (5), we do not interpret “consensus-based development process” per section 1848(k)(2)(B) of the Act to require that the consensus organization or process meet all of the criteria of the NTTAA and OMB A–119 definition of a voluntary consensus standards body.

(2) “Voluntary consensus standard” is interpreted to mean a voluntary consensus standard that has been endorsed as such by a consensus organization that meets the requirements of the NTTAA, as implemented by OMB A–119, for a voluntary consensus standards body.

(3) Where there are available quality measures, and some of these measures meet the definition of “voluntary consensus standards” while others do not, those measures that meet the definition of “voluntary consensus standards” are preferred to other measures not meeting the requirements of the NTTAA.

(4) In view of the preference for voluntary consensus standards, if a measure has been specifically considered by NQF for possible endorsement but NQF has declined to endorse it as of November 15, 2007, we propose not to include it in the final set of 2008 PQRI Quality Measures.

(5) Although the AQA does not meet the requirements of the NTTAA for a voluntary consensus standards body, it is a consensus organization per section 1848(k)(2)(B) of the Act. In circumstances where no voluntary consensus standard (NQF-endorsed) measure is available, a quality measure that has been adopted by the AQA (or another consensus organization with comparable consensus-organization characteristics, will meet the requirements of MIEA–TRHCA is we determine that it is appropriate for eligible professionals to use to submit data.

(6) We are unaware of other consensus organizations that are comparable to the NQF in terms of meeting the formal requirements of the

NTTAA or of organizations other than AQA that do not strictly meet the requirements of the NISTA as amended by the NTTAA but that feature the breadth of stakeholder involvement in the consensus process necessary to meet the intent of the MIEA–TRHCA.

However, the MIEA–TRHCA does not limit consensus organizations to the NQF or the AQA, nor restrict the field of potential consensus organizations. The MIEA–TRHCA, thereby, maintains flexibility in potential sources of measure consensus review, which is, like having multiple sources of measure development, key to maintaining a robust marketplace for development and review of quality measures.

(7) The basic steps for developing the physician level measures may be carried out by a variety of different organizations. We do not interpret the MIEA–TRHCA to place special restrictions on the type or make up of the organizations carrying out this basic development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of physician quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards.

(8) The policies we propose are based on the preference as articulated in NTTAA and OMB A–119 for “voluntary consensus standards” to government standards, and a preference for quality measures that have achieved broad consensus among stakeholders in the health care system. However, the MIEA–TRHCA does not require that quality measures meet the NTTAA or OMB A–119 definition of “voluntary consensus standards” in order to be used for PQRI. Thus, though we prefer to use quality measures meeting the NTTAA and OMB A–119 criteria for voluntary consensus standards, neither this CMS preference nor the NTTAA or OMB A–119 preclude CMS from selecting measures for PQRI based upon a lesser degree of consensus when necessary to meet CMS’ program needs as determined by the Secretary.

c. Proposed 2008 PQRI Quality Measures

The identified measures we propose for 2008 would be made final as of the effective date of the final rule, and no changes (no additions or deletions of measures) will be made after that date. However, as was done for 2007, we may make modifications or refinements, such as code additions, corrections, or revisions, to the detailed specifications for the 2008 measures until the beginning of the reporting period. Such specification modifications may be made through the last day preceding the beginning of the reporting period. The 2008 measures specifications will be available on the PQRI section of the CMS Web site at <http://www.cms.hhs.gov/pqri> when they are sufficiently developed or finalized but in no event later than December 31, 2007. These detailed specifications will include instructions for reporting and identify the circumstances in which each measure is applicable.

For 2008, we propose PQRI Quality measures selected from measures listed in Tables 16 through 22, which fall into 7 broad categories as set forth below in this section. We welcome comments on the implications of including any given measure or measures proposed herein in the final 2008 PQRI quality measures.

(i) Measures Selected From the 2007 PQRI Quality Measures

We propose to retain and include in the final 2008 PQRI measures the following 2007 PQRI measures in Table 16 contingent on NQF endorsement of each such included measure by November 15, 2007. All 2007 PQRI measures have been considered or are under consideration for endorsement under NQF projects. Those 2007 PQRI measures that have been declined for endorsement are not included in the list of proposed measures for 2008. The measures in Table 16 include measures submitted by specialties, in compliance with section 1848(k)(2)(B) of the Act, for example, the measures for diabetic retinopathy (ophthalmology).

TABLE 16.—2007 PQRI MEASURES

Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus.

Low Density Lipoprotein Control in Type 1 or 2 Diabetes Mellitus.

High Blood Pressure Control in Type 1 or 2 Diabetes Mellitus.

Screening for Future Fall Risk.

Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).

Oral Antiplatelet Therapy Prescribed for Patients with Coronary Artery Disease.

Beta-blocker Therapy for Coronary Artery Disease Patients with Prior Myocardial Infarction (MI).

Heart Failure: Beta-blocker Therapy for Left Ventricular Systolic Dysfunction.

Antidepressant Medication During Acute Phase for Patients with New Episode of Major Depression.

TABLE 16.—2007 PQRI MEASURES—Continued

Medication Reconciliation.
 Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.
 Characterization of Urinary Incontinence in Women Aged 65 Years and Older.
 Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older.
 Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.
 Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.
 Asthma: Pharmacologic Therapy.
 Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports.
 Stroke and Stroke Rehabilitation: Carotid Imaging Reports.
 Primary Open Angle Glaucoma: Optic Nerve Evaluation.
 Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.
 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care.
 Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician.
 Perioperative Care: Selection of Prophylactic Antibiotic—First or Second Generation Cephalosporin.
 Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures).
 Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (when indicated in All patients).
 Osteoporosis: Management Following Fracture.
 Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture.
 Aspirin at Arrival for Acute Myocardial Infarction (AMI).
 Electrocardiogram Performed for Non-Traumatic Chest Pain.
 Electrocardiogram Performed for Syncope.
 Vital Signs for Community-Acquired Bacterial Pneumonia.
 Assessment of Oxygen Saturation for Community-Acquired Bacterial Pneumonia.
 Assessment of Mental Status for Community-Acquired Bacterial Pneumonia.
 Empiric Antibiotic for Community-Acquired Bacterial Pneumonia.
 Asthma Assessment.
 Perioperative Care: Timing of Prophylactic Antibiotics—Administering Physician.
 Stroke and Stroke Rehabilitation: Deep Vein Thrombosis Prophylaxis (DVT) for Ischemic Stroke or Intracranial Hemorrhage.
 Stroke and Stroke Rehabilitation: Discharged on Antiplatelet Therapy.
 Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge.
 Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered.
 Stroke and Stroke Rehabilitation: Screening for Dysphagia.
 Stroke and Stroke Rehabilitation: Consideration of Rehabilitation Services.
 Dialysis Dose in End Stage Renal Disease (ESRD) Patients.
 Hematocrit Level in ESRD Patients.
 Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.
 Osteoporosis: Pharmacologic Therapy.
 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG) Surgery.
 Preoperative Beta-blocker in Patients with Isolated Coronary Artery Bypass Graft (CABG) Surgery.
 Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).
 Appropriate Treatment for Children with Upper Respiratory Infection (URI).
 Appropriate Testing for Children with Pharyngitis.
 Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow.
 Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy.
 Multiple Myeloma: Treatment with Bisphosphonates.
 Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry.
 Hormonal Therapy for Stage IC–III ER/PR Positive Breast Cancer.
 Chemotherapy for Stage III Colon Cancer Patients.
 Plan for Chemotherapy Documented Before Chemotherapy Administered.
 Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery.
 Advance Care Plan.

Please note that measures specifications for 2007 PQRI measures may be updated or modified during the NQF endorsement process or may otherwise be modified prior to 2008. The 2008 PQRI measure specifications for any given measure may, therefore, be different from specifications for the same measure used for 2007. All specifications for 2008 measures must be obtained from the specifications document for 2008 measures, which will be available on the CMS PQRI Web site on or before December 31, 2007.

(ii) AMA–PCPI Measures

We propose to include measures in the final 2008 PQRI selected from those listed in Table 17 that are currently under development via the AMA–Physicians Consortium for Performance Improvement (PCPI) provided that they achieve NQF endorsement or AQA adoption by November 15, 2007. We propose to select from among these measures based upon development completion in a sufficiently timely manner that implementation for 2008

would be practical, their importance in relation to quality goals, their meaningfulness as measures of quality, their utility in the PQRI program such as through augmenting the scope of services provided by eligible practitioners to which PQRI measures apply, the degree to which they meet the needs of the Medicare program, and their functionality in terms of their ability to be collected and calculated in the PQRI program.

TABLE 17.—AMA/PCPI MEASURES

Prevention of Ventilator-Associated Pneumonia—Head elevation.

TABLE 17.—AMA/PCPI MEASURES—Continued

Stress Ulcer Disease (SUD) Prophylaxis in Ventilated patients.
 Prevention of Catheter-Related Bloodstream Infections in Ventilated patients—Catheter Insertion Protocol.
 Perioperative Temperature Management for Surgical Procedures Under General Anesthesia.
 Assessment of Thromboembolic Risk Factors in patients with Atrial Fibrillation.
 Chronic Anticoagulation in patients with Atrial Fibrillation.
 Monthly INR Measurements in patients with Atrial Fibrillation.
 GFR Calculation in patients with Chronic Kidney Disease (CKD).
 Blood Pressure Measurement in patients with CKD.
 Plan of Care for patients with CKD and Elevated Blood Pressure.
 ACE Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy in patients with CKD.
 Calcium, Phosphorus and Intact Parathyroid Hormone Measurement in patients with CKD.
 Lipid Profile in patients with CKD.
 Hemoglobin Monitoring in patients with CKD.
 Erythropoietin Overuse in patients with CKD and normal Hemoglobin.
 Influenza Vaccination in patients with End Stage Renal Disease (ESRD).
 Vascular Access for patients Undergoing Hemodialysis.
 Permanent Catheter Vascular Access for patients Receiving Hemodialysis.
 Plan of Care for ESRD patients with Anemia.
 Plan of Care for Inadequate Hemodialysis in ESRD patients.
 Plan of Care for Inadequate Peritoneal Dialysis.
 Assessment of GERD Symptoms in Patients Receiving Chronic Medication for GERD.
 Testing of patients with Chronic Hepatitis C (HCV) for Hepatitis C Viremia.
 Initial Hepatitis C RNA Testing.
 HCV Genotype Testing Prior to Therapy.
 Consideration for Antiviral Therapy in HCV Patients.
 HCV RNA Testing at Week 12 of Therapy.
 Hepatitis A and B Vaccination in patients with HCV.
 Counseling patients with HCV Regarding Use of Alcohol.
 Counseling of patients Regarding Use of Contraception Prior to Starting Antiviral Therapy.
 Patients who have Major Depression Disorder who meet DSM IV Criteria.
 Patients who have Major Depression Disorder who are assessed for suicide risks.
 Patients with Osteoarthritis who receive Anti-Inflammatory or Analgesia Medication.
 Patients with Osteoarthritis who have an assessment of their pain and function.
 Patients with Acute Otitis Externa (AOE) or Otitis Media with Effusion (OME) who receive Topical Therapy.
 Patients with AOE/OME who have a pain assessment.
 Patients with AOE/OME who are inappropriately prescribed antimicrobials.
 Patients with AOE/OME who have an assessment of tympanic membrane mobility.
 Patients with AOE/OME who undergo hearing testing.
 Patients with AOE/OME who inappropriately receive antihistamines/decongestants.
 Patients with AOE/OME who inappropriately receive systemic antimicrobials.
 Patients with AOE/OME who inappropriately receive systemic steroids.
 Breast cancer patients who have a pT and pN category and histologic grade for their cancer.
 Colorectal cancer patients who have a pT and pN category and histologic grade for their cancer.
 Documentation of hydration status in Pediatric Patients with Acute Gastroenteritis (PAG).
 Weight measurement in patients with PAG.
 Recommendation of appropriate oral rehydration solution in PAG patients.
 Education parents of PAG patients.
 Perioperative Cardiac risk assessment (history).
 Perioperative Cardiac risk assessment (current symptoms).
 Perioperative Cardiac risk assessment (physical examination).
 Perioperative Cardiac risk assessment (electrocardiogram).
 Perioperative Cardiac risk assessment (continuation of Beta Blockers).
 Appropriate initial evaluation of patients with Prostate Cancer.
 Inappropriate use of Bone Scan for staging Low-Risk Prostate Cancer patients.
 Review of treatment options in patients with clinically localized Prostate Cancer.
 Adjuvant Hormonal therapy for High-risk Prostate Cancer patients.
 Three-dimensional radiotherapy for patients with Prostate Cancer

(iii) Nonphysician Measures Currently Under Development

We propose to include measures in the final 2008 PQRI quality measures selected from those listed in Table 18 that are currently under development by Quality Insights of Pennsylvania (under the Medicare Quality Improvement Organization (QIO) contract for the State of Pennsylvania) and that achieve NQF endorsement or AQA adoption by November 15, 2007. We propose to

select from among these measures based upon: Development completion in a sufficiently timely manner that implementation for 2008 would be practical; their importance in relation to quality goals; their meaningfulness as measures of quality; their utility in the PQRI program such as through augmenting the scope of services provided by eligible professionals to which PQRI measures apply; the degree to which they meet the needs of the

Medicare program and their functionality in terms of ability to be collected and calculated in the PQRI program.

TABLE 18.—QUALITY INSIGHTS OF PENNSYLVANIA NONPHYSICIAN MEASURES

Universal Weight Screening (BMI).
 Universal Weight Screening Follow-up (BMI).
 Universal Hypertension Screening.
 Universal Hypertension Screening Follow-up.

TABLE 18.—QUALITY INSIGHTS OF PENNSYLVANIA NONPHYSICIAN MEASURES—Continued

Universal Influenza Vaccine Screening and Counseling.
 Universal Documentation and Verification of Current Medications in the Medical Record.
 Screening for Clinical Depression.
 Screening for Cognitive Impairment.
 Patient Co-development of Treatment Plan.
 Patient Co-development of Plan of Care.
 Pain Assessment Prior to Initiation of Patient Treatment.

(iv) Structural Measures Currently Under Development

We propose to include measures in the final 2008 PQRI measures selected from the structural measures listed in Table 19 that are currently under development by Quality Insights of Pennsylvania (under the Medicare QIO contract for the State of Pennsylvania) and that achieve NQF endorsement or AQA adoption by November 15, 2007. These measures meet the requirement of section 1848 (k)(2)(B)(i) of the Act that the quality reporting system for 2008 include structural measures.

TABLE 19.—QUALITY INSIGHTS OF PENNSYLVANIA STRUCTURAL MEASURES

HIT—Adoption/Use of E-Prescribing
 HIT—Adoption/Use of Health Information Technology (Electronic Health Records)

(v) Additional AQA Starter-Set Measures

We propose to include measures in the final 2008 PQRI measures selected from the AQA starter set that were not included in the 2007 PQRI quality measures but that are relevant to Medicare beneficiaries. Specifications necessary for PQRI reporting of these measures will be completed for such measures by November 15, 2007, and posted on the CMS Web site. Each of the AQA starter-set measures that is identified in Table 20 we propose to include in the 2008 PQRI quality measures provided it retains NQF endorsement and AQA adoption as of November 15, 2007.

TABLE 20.—ADDITIONAL AQA STARTER-SET MEASURES

Dilated eye exam in diabetic patient.
 Beta-Blocker Therapy (persistent for 6 months or more)—Post MI.
 Screening Mammography.
 Colorectal Cancer Screening.
 Inquiry regarding Tobacco Use.
 Advising Smokers to Quit.

(vi) Other NQF-Endorsed Measures

We propose to include in the final 2008 PQRI measures other measures endorsed by the NQF that were not included in the 2007 PQRI quality measures but that are relevant to Medicare beneficiaries, address overuse/misuse of pharmacologic therapy, and that expand the specialty applicability and patient population. Specifications necessary for PQRI reporting of these measures will be completed for such measures by November 15, 2007, and posted on the CMS Web site. We propose to include in the 2008 PQRI quality measures each of the NQF-endorsed measures identified in Table 21 provided it retains NQF endorsement as of November 15, 2007.

TABLE 21.—OTHER NQF-ENDORSED MEASURES

Inappropriate antibiotic treatment for adults with acute bronchitis.
 Disease Modifying Anti-rheumatic Drug Therapy in Rheumatoid Arthritis.
 Angiotensin Converting Enzyme Inhibitor (ACE) or Angiotensin Receptor Blocker (ARB) Therapy for patients with coronary artery disease and diabetes and/or left ventricular systolic dysfunction (LSDV).
 Urine screening for microalbumin or medical attention for nephropathy in diabetic patients.
 Annual Therapeutic monitoring for patients on the following persistent medications:
 • Angiotensin Converting Enzyme Inhibitor (ACE)/Angiotensin Receptor Blocker (ARB);
 • Digoxin;
 • Diuretics;
 • Anticonvulsants; and
 • Statins.
 Influenza vaccination for patients ≥ 50 years old.
 Pneumonia vaccination for patients 65 years and older.

(vii) Podiatric Measures

We propose to include measures in the final 2008 PQRI quality measures selected from those listed in Table 22 that are currently under development by the American Podiatric Medical Association and that achieve NQF endorsement or AQA adoption by November 15, 2007. We propose to select from among these measures based upon development completion of the measures in a sufficiently timely manner that implementation for 2008 would be practical.

TABLE 22.—PODIATRIC MEASURES

Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation.

TABLE 22.—PODIATRIC MEASURES—Continued

Diabetic Foot and Ankle Care, Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement.
 Diabetic Foot and Ankle Care, Ulcer Prevention: Evaluation of Footwear.

d. Addressing a Mechanism for Submission of Data on Quality Measures Via a Medical Registry or Electronic Health Record

Section 1848(k)(4) of the Act, as amended by the MIEA—TRHCA, requires that “as part of the publication of proposed and final quality measures for 2008 under clauses (i) and (iii) of paragraph (2)(B), the Secretary shall address a mechanism whereby an eligible professional may provide data

on quality measures through an appropriate medical registry”.

A medical registry, which is also often referred to as a “clinical registry” or “clinical data registry”, henceforth “registry”, may be broadly defined as a file of documents containing uniform information about a defined population of individual persons or events, collected using an observational study design in a systematic way, in order to serve a predetermined scientific, clinical, or policy purpose. It is generally agreed that clinical data registries are one potential means to measure and report physician and other eligible professionals’ performance for purposes of quality improvement, public reporting, quality based payment, continuous certification, and credentialing. Other possible uses of

data collected by a registry include satisfying requirements for maintenance of professional or specialty board certification status, and ongoing improvement of professional performance.

The MIEA–TRHCA lists the Society of Thoracic Surgeons (STS) National Database registry as an example of a registry. The STS registry collects outcomes and quality data on cardiac surgeries. The data output provides an analysis of the participant's adult cardiac surgery outcomes, resulting in a benchmarking of each participant's data against regional and national outcomes. The STS registry currently collects data on two PQRI quality measures that have been adapted from existing STS measures. These two measures are: Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG) Surgery; and Pre-operative Beta-blocker in Patient with Isolated Coronary Artery Bypass Graft (CABG) Surgery.

To be eligible for the incentive payment under MIEA–TRHCA, cardiac and thoracic surgeons who report data to the STS registry will in 2007 and 2008 still find it necessary under PQRI to report quality data with reference to those same measures through the claims process. To avoid duplication of data submission and to support the use of registries, generally, we believe that it would be desirable to establish a mechanism whereby the quality data relevant to PQRI measures could be reported from the registries, on behalf of eligible professionals.

At this point, it is unclear which registries currently collect or plan to collect data for PQRI quality measures and which approach or approaches should be utilized to allow registries to report quality data to PQRI. For this reason, in 2008, we anticipate evaluating and testing the mechanisms to use registries for the reporting of PQRI quality data. We plan to use the results of this evaluation and testing to determine whether and how to implement the use of registries for the reporting of quality data in the future.

In concept, we anticipate that upon implementation of registry-based quality data reporting, eligible professionals would be able to provide data on PQRI quality measures through an appropriate medical registry by authorizing or instructing the registry to submit data on their behalf. Thus, the registry would act as a data submission vendor for the eligible professional. A "data submission vendor" is defined as an entity that has permission from the eligible professional to provide medical registry data to the Quality Reporting System developed per the statute. The

registry, acting as such a data submission vendor, would submit data to the CMS clinical data warehouse component of the Quality Reporting System, using a CMS-specified record layout based on the quality measures' specifications as published by CMS. For purposes of this proposed rule, the term, "CMS clinical data warehouse," is defined as a clinical data warehouse designated by CMS.

For 2008, we expect to explore at least the five different data submission options described below, and to test in CY 2008 one or more of these options. There are several data formats and analytical options that we see as potentially available to fulfill the objectives of registry inclusion in PQRI. These options vary with regard to whether individual beneficiary-level data is submitted by the registry, as well as to the number and type of data elements needed from the registry.

Option 1: Registries provide the quality-data codes required for a particular PQRI measure plus beneficiary/service identifier information needed to link the registry data to Medicare Part B claims. The beneficiary/service identifiers would be used to pull in the denominator data by CMS. All non-registry analytics payment information and diagnosis would come from claims. Reporting/performing rates would be calculated from the registry-submitted data.

Examples of data elements needed from a registry are:

- Beneficiary HIC Number
- Beneficiary Date of Birth
- Date of Service
- NPI and Tax ID
- CPT category II and G codes and modifiers

• Clinical data elements required to compute the appropriate CPT category II codes, G codes and modifiers

Option 2: Registries provide the quality codes and diagnosis codes. We would use claims to capture the payment information at the NPI/Tax ID level. The beneficiary-specific information is de-identified. All PQRI reporting and performance calculations would be performed using registry data. Payment information would be extracted from Medicare claims. The registries would be required to add data elements to the database to allow collection of appropriate codes.

Examples of data elements needed from a registry:

- Beneficiary/procedure level data (ICD–9 and CPT codes)
- HCPCS codes (G-codes and CPT category II codes and modifiers)
- NPI and Tax ID

Option 3: Registries calculate the reporting and performance rates for Medicare beneficiaries only, and submit these rates to CMS (that is, aggregate information by NPI within a Tax ID). We assume no beneficiary-level information will be shared. Registries would be required to add data elements to the database to allow collection of appropriate quality-data codes or clinical data needed to compute the quality-data codes. Registries would be required to perform the necessary calculations to be able to submit completed numerator/denominators for both reporting and performance rates.

Option 4: Registries provide all of the claims data elements as submitted using the Part B claims process. We perform all rate calculations.

Examples of data elements needed from a registry include the following:

- Line Item TIN
- Line Item Individual NPI
- Line Item Group NPI
- Claim Beneficiary Claim Account Number (CAN)
- Claim Beneficiary Identification Code (BIC)
- Claim Date of Birth
- Line Item First Expense Date
- Line Item Last Expense Date
- Line Item Diagnosis Code
- Line Item HCPCS (HCPCS Level 1, CPT Category I, CPT Category II, HCPCS Level 2 G Codes)
- Line Item Initial Modifier Code
- Line Item Secondary Modifier Code
- Claim CMS Claims Processing Date
- Claim Overall Allowable Charges
- Line Item Allowable Charges
- Claim Gender
- Claim Carrier Number
- Claim Control Number
- Claim Final Action Status
- Claim Carrier Claim Receipt Date
- Claim Payment Denial Code
- Line Item Procedure Indicator Code
- Line Item Carrier Locality Code
- Line Item Provider State Code
- Line Item Place of Service
- Line Processing Indicator Code

Option 5: Registry data dump for Medicare beneficiaries *only*; for all information in the registry for the service period of interest. There is an assumption that the registry is able to submit either: (1) the ICD–9, HCPCS, and CPT category II codes and exclusions as stated in the measures specifications; or (2) supply the clinical information needed for CMS to make those judgments (eligibility and quality of care). We would be required to use a series of linkage algorithms to attempt to connect the registry data with the matching claims.

Examples for linkage of registry data to the corresponding Medicare Part B claims include some combination of:

- Beneficiary-level identifiers: HIC (or SSN), DOB, gender
- Procedure-level identifiers: date of service (or procedure date)
- Provider identifiers: NPI, Tax ID, or even UPIN

For CMS to maintain compliance with applicable statutes, including but not limited to HIPAA, the registry must maintain compliance with HIPAA requirements for processing, storing, and transmitting data. To be considered an appropriate registry from which we can accept and process data for the purposes of calculating PQRI measures, a registry must also comply with the Consolidated Health Informatics Initiative (CHI) standards adopted by the Federal government, and therefore, applicable to the HHS. A description of the CHI, including its purpose, Federal member agencies, and the specific standards adopted by the Federal government, is available on the HHS Office of the National Coordinator for Health Information Technology (ONC) Web site at <http://www.hhs.gov/healthit/chiinitiative.html>.

Upon determination of the preferred option and conclusion of the testing phase for registry-based reporting to PQRI, we anticipate that all necessary information and instructions will be made available on the PQRI section of the CMS Web site at <http://www.cms.hhs.gov/pqri>. This information will include at a minimum:

- (a) The exact data elements needed and the CMS-specified record layout for transmitting the data to the CMS clinical data warehouse; and
- (b) a detailed description of the proposed CMS infrastructure for accepting registry-based submission of PQRI quality data, including, but not limited to, electronic data exchange specifications, and applicable processes for authenticating registry users for access to the warehouse submission interface.

We anticipate requesting that registries interested in participating in the testing of the registry-based quality data submission mechanism will be invited to self-nominate via a simple process that will be published on the PQRI section of the CMS Web site, and via one or more additional CMS communication venues, in the fourth quarter of 2007. We propose and expect to begin testing with the registries in the first quarter of 2008.

We plan to select for testing, from the self nominees, a group of registries that are HIPAA and CHI compliant and technically capable of interfacing with the CMS clinical warehouse electronic data exchange interface (EDI). The number of registries selected for testing may be all that are technically capable

or may need to be limited to some or all of those that already contain key minimum data elements on at least a test basis, depending on the number of registries falling into these categories and on the actual level of complexity and effort required for the testing from the CMS data infrastructure.

(Experience with other initiatives has suggested that some data submission vendors and their software are more easily interfaced and tested with the CMS data warehouse EDI than others.)

We invite comments on these plans for evaluation and testing mechanisms for registry-based quality-data reporting to PQRI with reference to the 5 data submission options described. We also invite comments on appropriate validation methodologies for reporting and performance rates.

In addition to the testing of registry-based submission of quality data, CMS is considering for 2008 the feasibility and utility of accepting clinical quality data submitted from EHRs. For 2008, we plan to consider accepting EHR-extracted clinical data for a limited number of ambulatory-care PQRI measures for which data may also be submitted under the current Doctors Office Quality-Information Technology (DOQ-IT) Project. The listing of and specifications for DOQ-IT ambulatory-care measures are available at <http://www.qualitynet.org>, under the subsidiary headings Physician Offices, Doctors Office Quality Information Technology (DOQ-IT), Ambulatory-Care Measures. If implemented in 2008, the EHR-based submission of PQRI/DOQ-IT overlapping ambulatory-care measures would serve as an alternative method to claims-based reporting of submitting quality data for those measures, not a required method.

2. Section 110—Reporting of Anemia Quality Indicators (§ 414.707(b))

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 110: ANEMIA QUALITY INDICATORS” at the beginning of your comments.]

Medicare Part B provides payment for certain drugs used to treat anemia.

Anemia is common in cancer patients and may be caused by the cancer itself or by various anti-cancer treatments, including chemotherapy, radiation therapy and surgical therapy. Anemia occurs when the number of red blood cells is reduced by an anti-cancer treatment. This happens due to the effect of chemotherapy or radiation therapy on the bone marrow, wherein red blood cells are produced by dividing precursor cells. This chemotherapy effect is commonly referred to as “bone

marrow suppression.” Anemia may also result from blood loss in association with surgical therapy for the cancer.

Anemia adversely impacts the quality of life for beneficiaries being treated for cancer. Fatigue and reduced performance capacity are the side effects of anemia that cancer patients report as the most disabling and contributing to poor quality of life. The treatment of anemia in cancer patients commonly includes the use of drugs, specifically erythropoiesis stimulating agents (ESAs) such as recombinant erythropoietin and darbepoietin. Although other pharmacologic interventions are available, ESAs have received the greatest attention. Notably, recent research has raised concerns that these drugs may be associated with significant adverse effects including a higher risk of mortality in some populations, possibly related to the amount of drug administered.

In 2006, we implemented a revised ESA claims monitoring policy based on the last hemoglobin or hematocrit value from the preceding month on Medicare claims for payment of ESAs administered to beneficiaries with anemia due to ESRD receiving dialysis treatments in facilities. For many years prior, we have required the reporting of these red blood cell indicators by ESRD facilities to ensure that the beneficiaries' anemia was addressed.

Section 110 of the MIEA-TRHCA amends section 1842 of the Act by adding a new subsection (u) that reads as follows: “Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.” Section 110 of the MIEA-TRHCA requires such reporting for drugs furnished on or after January 1, 2008. In addition, subsection (b) directs the Secretary to use the rulemaking process under section 1848 of the Act to address the implementation of this requirement.

By requiring the reporting of the anemia quality indicators in cancer patients undergoing treatment for anemia, we will facilitate assessment of the quality of care for this condition. We will use the information reported to help determine the prevalence and severity of anemia associated with cancer therapy, the clinical and hematologic responses to the institution of anti-anemia therapy, and the outcomes associated with various doses of anti-anemia therapy.

While not specifically addressing other indications, the recent research on the adverse effects of ESAs in patients with cancer does raise concerns as to whether patients receiving ESAs for other conditions, such as in the treatment of HIV–AIDS and for some surgical patients, are also at higher risk. While not required by this statute, we are requesting public comment on the potential of expanding this regulation to include all uses of ESAs.

3. Section 104—Extension of Treatment of Certain Physician Pathology Services Under Medicare

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 104: PHYSICIAN PATHOLOGY SERVICES” at the beginning of your comments.]

The TC of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist will interpret. (In contrast, the pathologist’s interpretation of the slide is the PC service. If this service is furnished by the hospital pathologist for a hospital patient, it is separately billable. If the independent laboratory’s pathologist furnishes the PC service, it is usually billed with the TC service as a combined service.)

In the CY 2000 PFS final rule, we stated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to hospital patients. Before that provision, any independent laboratory could bill the carrier under the PFS for the TC of physician pathology services for hospital patients. As stated in the CY 2000 PFS final rule, this policy has contributed to the Medicare program paying twice for the TC service, first through the inpatient prospective payment rate to the hospital where the patient is an inpatient and again to the independent laboratory that bills the carrier, instead of the hospital, for the TC service.

Therefore, in the CY 2000 PFS final rule, in § 415.130 we specified that for services furnished on or after January 1, 2001, the carriers would no longer pay claims to the independent laboratory under the PFS for the TC of physician pathology services for hospital patients.

Ordinarily, the provisions in the PFS final rule are implemented in the following year. However, in this case, the change to § 415.130 was delayed one year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements. Moreover, our full implementation of § 415.130 was further delayed through CY 2006.

In the CY 2007 PFS final rule with comment period (71 FR 69700), we announced that beginning January 1, 2007, we would no longer allow the carriers to pay the independent laboratory for the TC of physician pathology services to hospital patients. In effect, we would be implementing the provisions of the CY 2000 PFS final rule whose implementation had been delayed by section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA) and section 732 of the MMA.

Subsequent to publication of the CY 2007 PFS final rule with comment period, the MIEA–TRHCA was enacted. Section 104 of the MIEA–TRHCA provided for an additional 1 year extension to allow carriers to continue to pay independent laboratories under the PFS for the TC portion of physician pathology services furnished to patients of a covered hospital.

Consistent with this legislative change we are amending § 415.130(d) to reflect that for services furnished after December 31, 2007, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

4. Section 201—Extension of Therapy Cap Exception Process

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 201: THERAPY CAPS” at the beginning of your comments.]

Section 1833(g)(1) of the Act applies an annual per beneficiary combined cap beginning January 1, 1999, on outpatient physical therapy and speech-language pathology services, and a similar separate cap on outpatient occupational therapy services. These caps apply to expenses incurred for the respective therapy services under Medicare Part B, with the exception of outpatient hospital services. The caps were implemented from January 1, 1999 through December 31, 1999, from September 1, 2003 through December 7, 2003, and beginning January 1, 2006 (with an exception process). In CY 2000 through CY 2002, and from December 8, 2003 through December 31, 2005, the Congress placed moratoria on implementation of the caps. Section 1833(g)(2) of the Act provides that, for CY 1999 through CY 2001, the caps were \$1500, and for the calendar years after 2001, the caps are equal to the preceding year’s cap increased by the percentage increase in the Medicare Economic Index (MEI) (except that if an increase for a year is not a multiple of

\$10, it is rounded to the nearest multiple of \$10).

Section 5107(a) of the DRA required the Secretary to develop an exceptions process for the therapy caps effective for expenses incurred during CY 2006. Details of the CY 2006 exceptions process were published in a manual change on February 13, 2006 (CR4364 consists of Transmittal 855, Transmittal 47, and Transmittal 140). Section 201 of the MIEA–TRHCA extended the exceptions process to apply for expenses incurred through December 31, 2007. Therapy cap exception policies for 2007 were specified in Change Request 5478 which consists of three transmittals with current numbers of—

- Transmittal 1145CP, Pub. 100–04;
- Transmittal 63BP, Pub. 100–02; and
- Transmittal 181PI, Pub. 100–08.

The transmittals are incorporated into the Internet Only Manuals available at <http://www.cms.hhs.gov/Manuals> and are also available on our Web site at <http://www.cms.hhs.gov/Transmittals/>.

In accordance with the statute as amended by the MIEA–TRHCA, we will continue to implement therapy caps, but the exceptions process will no longer be applicable, for expenses incurred beginning on January 1, 2008. The dollar amount of the therapy caps in CY 2008 will be the CY 2007 rate (\$1,780) increased by the percentage increase in the MEI.

As noted previously in this section, under current law therapy caps will continue to apply to expenses incurred for therapy services after December 31, 2007, with one exception. That is, the therapy caps will remain inapplicable to expenses incurred for therapy services furnished in the outpatient hospital setting as provided in section 1833(g) of the Act.

5. Section 101(d)—Physician Assistance and Quality Initiative (PAQI) Fund

[If you choose to comment on issues in this section, please include the caption “TRHCA—SECTION 101(d): PAQI” at the beginning of your comments.]

Section 1848(1) of the Act, as added by section 101(d) of the MIEA–TRHCA requires the Secretary to establish a Physician Assistance and Quality Initiative Fund (PAQI) which shall be available for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the PFS CF. The provision makes available \$1.35 billion to the Fund for services furnished during 2008. Specifically, the provision directs the Secretary to provide for expenditures from the Fund

in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire \$1.35 billion for payment for physicians' services furnished during CY 2008. The provision also requires that if expenditures from the Fund are applied to, or otherwise affect, a conversion factor for a year, the conversion factor for a subsequent year shall be computed as if the adjustment to the conversion factor had never occurred.

As the legislation indicates, this Fund can be used to either buy down the negative update to the fee schedule or for quality improvement initiatives. We believe it is essential that Medicare continue to encourage improvement in the efficiency and quality of health care delivered to Medicare beneficiaries. Therefore, we are proposing that the \$1.35 billion be used to fund bonus payments to be made during 2009 for physician reporting of measures during 2008. Specifically, we propose that the physician quality initiative for 2008 be structured and implemented in the same manner as the 2007 PQRI with regard to the professionals eligible to participate in the program, reporting quality measures via claims submission, and the standards for satisfactory reporting. If, as discussed in section II.T.1 of this proposed rule, we determine that a quality measure reporting mechanism based on EHRs can be effectively implemented in 2008, we would plan to also offer eligible professionals the option of reporting quality measures via such EHR-based mechanism based in lieu of claims-based reporting. If the EHR-based reporting mechanism is implemented for 2008, we would expect to apply to professionals opting to report via that mechanism the same standards for satisfactory reporting as are applicable to professionals reporting quality measures via claims.

The differences between 2007 and 2008 that we currently anticipate are noted below in this section. As we monitor the implementation of the 2007 PQRI and possibly make refinements to the 2007 program, we anticipate that such refinements would also apply under the 2008 program. Such refinements, should they be needed, will be noted with guidance linked from the CMS quality reporting Web site at http://www.cms.hhs.gov/PQRI/01_Overview.asp#TopOfPage.

As with the 2007 PQRI, we are proposing that eligible professionals who successfully report a designated set of quality measures in 2008 may earn a bonus payment of a percentage of total allowed charges for covered Medicare services, subject to a cap based on the volume of quality reporting. In contrast

to 2007, we propose that physicians could report applicable measures for services furnished from January 1, 2008 through December 31, 2008, and allowed charges during such period would be the basis for calculating the bonus payments. We propose that the 2008 measures that we finalize in the PFS final rule would apply for 2008. We also propose to estimate all of the bonus payments that would be payable to physicians using the same method as the one used for reporting during 2007 and to calculate the amount of the bonus payment, after the close of 2008 reporting period. Given that we are proposing to use the PAQI Fund for the 2008 PQRI program, we also propose that the bonus payments to individual physicians be subject to an aggregate cap of \$1.35 billion. Because we are proposing to scale aggregate payments to physicians in a manner such that Medicare would pay \$1.35 billion during 2009 for measures reported for services furnished during 2008, we are unable to provide an exact percentage for the bonus payment at this time. However, we anticipate that the bonus payments will be approximately 1.5 percent of allowed charges for participating professionals (and we do not expect that the ultimate percentage amount will exceed 2 percent).

Medicare payment systems need to encourage reliable, high quality and efficient care, rather than making payment simply based on the quantity of services provided and resources consumed. This approach allows CMS to fully expend the \$1.35 billion fund and further the goal of improving quality and efficiency by utilizing the infrastructure that both physicians and Medicare have invested in for the 2007 PQRI. We believe implementing this Fund through an extension of the PQRI program is the best way to ensure physicians get the greatest benefit from the Fund's resources while ensuring that the Fund is being used to increase quality and efficiency of care for Medicare beneficiaries.

We recognize that there is an alternative approach to using this fund. That is, the \$1.35 billion could be used in some manner to reduce the update to the PFS of -9.9 percent that is projected for 2008. However, there are fundamental legal and operational problems with this approach that make it not feasible. The \$1.35 billion is a fixed dollar amount. Once the amount is reached, there is no authority to pay any more than that amount. Medicare is an entitlement program that covers medically necessary services for eligible beneficiaries, but such coverage is not limited to a fixed dollar amount for a

year. While we estimate that the \$1.35 billion would reduce the negative update by approximately two percentage points, actual spending could be above or below the estimate. To insure that we do not exceed the Fund amount, we would have to estimate an amount to reduce the update by that is low enough to ensure the \$1.35 billion funding cap is not exceeded. While this approach might reduce the 2008 negative update, it could still leave money in the Fund, and we would be faced with the same problem of how to spend such remaining funds in the future. Therefore, as previously stated, we believe the best use of the Fund is to apply it to extend PQRI into 2008.

6. Section 108—Payment Process Under the Competitive Acquisition Program (CAP)

[If you choose to comment on issues in this section, please include the caption "TRHCA—SECTION 108: CAP" at the beginning of your comments.]

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 which 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.

Section 108(a)(2) of the MIEA-TRHCA required 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, Construction, 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.

III. Fee Schedule for Payment of Ambulance Services Update for CY 2007; Ambulance Inflation Factor Update for CY 2008; and Proposed Revisions to the Publication of the Ambulance Fee Schedule (§ 414.620)

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

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the following levels of service:

For Ground—

- Basic Life Support (BLS)
- Advanced Life Support, Level 1 (ALS1)

(ALS1)

- Advanced Life Support, Level 2 (ALS2)

(ALS2)

- Specialty Care Transport (SCT)
- Paramedic ALS Intercept (PI)

For Air—

- Fixed Wing Air Ambulance (FW)
- Rotary Wing Air Ambulance (RW)

A. History of Medicare Ambulance Services

1. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations as specified in § 410.40. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

3. Transition to National Fee Schedule

The national fee schedule for ambulance services was phased in over a 5-year transitional period beginning April 1, 2002, as specified in § 414.615. As of January 1, 2006, the total payment amount for air ambulance providers and suppliers is based on 100 percent of the national ambulance fee schedule. In accordance with section 414 of the MMA, we added § 414.617 which specifies that for ambulance services furnished during the period July 1, 2004, through December 31, 2009, the ground ambulance base rate is subject to a floor amount, which is determined by establishing nine fee schedules based on each of the nine census divisions and using the same methodology as was used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is lower than or equal to the national ground base rate, then it is not used, and the national fee schedule amount applies for all providers and suppliers in the census division. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the fee schedule portion of the base rate for that census division is equal to a blend of the national rate and the regional rate through CY 2009. Thus, as of January 1, 2007, the total payment amount for ground ambulance providers and suppliers is based on either 100 percent of the national ambulance fee schedule amount, or a combination of 80 percent of the national ambulance fee schedule and 20 percent of the regional ambulance fee schedule.

B. Ambulance Inflation Factor (AIF) During the Transition Period

As we noted in the previous section, the national fee schedule for ambulance services was phased in over a 5-year transition period beginning April 1, 2002, as specified in § 414.615. During

the transition period, the ambulance inflation factor (AIF) was applied separately to both the fee schedule portion of the blended payment amount (regardless of whether a national or regional fee schedule applied) and to the supplier's reasonable charge or provider's reasonable cost portion of the blended payment amount, respectively, for each ambulance provider or supplier. Then, the two amounts were added together to determine the total payment amount for each provider or supplier.

C. Ambulance Inflation Factor (AIF) for CY 2008

Section 1834(l)(3)(B) of the Act provides the basis for updating payment amounts for ambulance services. Section 414.610(f) specifies that certain components of the ambulance fee schedule are updated by the AIF annually, based on the consumer price index for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year. At this time, the CPI-U for the 12-month period ending with June 2007 is not available. We will announce the AIF for CY 2008 in the final rule which will be published in the **Federal Register** later this year. In addition, as set forth in Section III.D., we propose to announce the AIF for CY 2009 and subsequent years via CMS instruction and on the CMS Web site.

D. Proposed Revisions to the Publication of the Ambulance Fee Schedule (§ 414.620)

Currently, section 414.620 specifies that changes in payment rates resulting from incorporation of the AIF will be announced by notice in the **Federal Register** without opportunity for prior comment. We believe it is unnecessary to undertake notice and comment rulemaking to update the AIF because the statute and regulations specify the methods of computation of annual inflation updates, and we have no discretion in that matter. Thus, the annual AIF notice does not change or establish policy, but merely applies the update methods specified in the statute and regulations.

By mid-July of each year, we have the CPI-U for the 12-month period ending with June of such year. Therefore, we know what the AIF for the upcoming calendar year will be by mid-July of each year. However, the AIF is not published by CMS until November because § 414.620 currently states that the AIF will be announced in the **Federal Register**. Each document published in the **Federal Register** requires scheduling and a thorough

review by CMS, HHS, and OMB prior to publication. Therefore, even though we know the AIF by mid-July of each year, the final rule announcing the AIF is not published until November. This publication timeframe does not allow Medicare contractors the optimal amount of time to update their systems so that they can effectuate the proper payment on Medicare ambulance claims timely. In addition, it does not provide an optimal amount of time for either the Medicare contractors or the ambulance industry to take advantage of testing practices to make sure that the update is working properly as implemented. We believe that announcing the AIF via CMS instructions and on the CMS Web site would enable the AIF to be released earlier in the calendar year, allowing the Medicare contractors to test their data systems, and to timely effectuate and provide accurate payments on Medicare ambulance claims.

Therefore, we are proposing to revise § 414.620 to state that we will announce the AIF via CMS instruction and on the CMS Web site and to remove the language that states that we will announce the AIF by notice in the **Federal Register**.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Section 410.33 Independent diagnostic testing facility

Section 410.33(g)(2) states that an independent diagnostic testing facility (IDTF) should provide complete and accurate information on its Medicare

enrollment application. In addition, an IDTF is required to notify its designated fee-for-service contractor within 30 days of any changes in ownership, location, general supervision, and any adverse legal actions. The notification must be made on the Medicare enrollment application. All of the changes to the enrollment application must be reported within 90 days.

The aforementioned requirements are not new. The burden associated with completing the Medicare enrollment application is currently approved under OMB control number 0938-0685. The collection has an expiration date of April 30, 2009.

Section 410.33(g)(6) states the comprehensive liability insurance requirements for IDTFs. Specifically, § 410.33(g)(6)(1) states that must have a comprehensive insurance policy or notify the CMS designated contractor, in writing, of any policy changes or cancellations. The burden associated with this requirement is the time and effort necessary to draft and submit the written notification to the CMS designated contractor. While this requirement is subject to the PRA, we believe it is exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6). This information will be collected on a case-by-case basis.

Section 410.33(g)(8) requires an IDTF to answer, document, maintain documentation of beneficiaries questions, and responses to beneficiary complaints at the physical site of the IDTF. Sections 410.33(g)(8)(i) through (iii) list the minimum amount of documentation needed to comply with this requirement. The burden associated with these requirements is the time and effort associated with responding to beneficiary questions and complaints, documenting the actions taken in response to the questions and complaints, and maintaining the documentation. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). The burden associated with documenting and maintaining the documentation of the corrective actions is a usual and customary business practice. The time, effort, and financial resources necessary to comply this information collection requirement would be incurred by persons in the normal course of their activities (for example, in compiling and maintaining business records) is not subject to the PRA.

Section 414.707 Basis of payment

Section 414.707(c) states that effective January 1, 2008, each request for payment for anti-anemia drugs

furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's most recent hemoglobin or hematocrit level. The burden associated with this requirement is the time and effort associated with obtaining the most recent hemoglobin or hematocrit levels and documenting it on the request for payment. The requirement and its associated burden are not subject to the PRA under 5 CFR 1320.3(h)(5). The interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens is not subject to the PRA.

Section 414.914 Term of contract

Section 414.914(h) states that the approved CAP vendor must verify drug administration prior to the collection of any applicable cost sharing amount. As part of the verification process, § 414.914(h)(1) through (2) lists the documentation that is required as part of the verification process. Section 414.914(h)(3) states that the approved CAP vendor must provide this information to CMS or the beneficiary upon request.

The burden associated with the requirements in § 414.914(1) through (3) is the time and effort needed to verify the drug administration. When obtaining written verification, the CAP vendor must document the elements listed in § 414.914(h)(1)(i) through (vi). When obtaining verbal verification, the CAP vendor must document the elements listed in § 414.914(h)(2)(i) through (ii). We believe the requirements and their associated burden are not subject to the PRA; they are part of the CAP vendor's usual and customary business practices as stipulated under 5 CFR 1320.3(h)(5).

In addition, § 414.914(h)(3) imposes both recordkeeping and reporting requirements. We believe that the burden associated with the recordkeeping requirement imposed by § 414.914(h)(3) is not subject to the PRA under 5 CFR 1320.3(c)(4) because it would affect less than 10 persons.

The reporting requirement places burden on the CAP vendor to provide the information listed in § 414.914(h)(1) through (2) to a beneficiary upon request. We estimate that the CAP vendor will receive 72 requests per year from beneficiaries. We believe it will take 15 minutes per request for the vendor to provide this information to the beneficiary. The total annual burden associated with this requirement is 1080 minutes or 18 burden hours. However, we believe this information collection requirement and the associated burden is not subject to the PRA as defined in

5 CFR 1320.3(c)(4) because it would affect less than 10 persons.

Section 414.930 Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

Section 414.930(b) states the process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment. We will annually solicit requests for changes to the list of compendia. As stated in § 414.930(c)(1), we will review a complete written request that is submitted in writing, electronically, or via hard copy. A complete written request must contain the following information as stated in § 414.930(c)(1)(i) through (vi):

- Full name and contact information for the requestor;
- Full identification of the compendium in question;
- A complete written copy of the compendium in question;
- The specific action requested of CMS;
- Supporting documentation for the requested action;
- Address a single compendium per request.

Section 414.930(d) states that for each compendium that is determined by CMS to be included on the list, the publisher or its designee must notify CMS, within 45 days of any update or revision, that a new edition or version is available.

The burden associated with the requirements contained in § 414.930(b) through (d) is the time and effort required to draft and submit to CMS a complete written request for changes to the list of compendia. In addition, there is additional time and effort for each compendium that is determined by CMS to be included on the list; the publisher or its designee must furnish to CMS, within 45 days of listing and within 45 days of any update or revision, a written copy of the current edition or version of the compendia, including updates. While these requirements are subject to the PRA, we believe the burden is exempt under 5 CFR 1320.3(c)(4) because it would affect less than 10 persons or entities. There are currently only 6 compendia that could reasonably be expected to be the subject of a request, so 6 requests is a likely maximum.

Section 424.36 Signature Requirements

Section 424.36(a) requires the beneficiary's signature on a claim for payment of services unless the beneficiary has died or the provisions of

§ 424.36(b), (c), or (d) apply. Section 424.36(b) states that if the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed by one of the persons specified in § 424.36(b)(1) through (5). Proposed § 424.36(b)(6) states that, for emergency ambulance transport services, if certain conditions and documentation requirements are met, an ambulance provider or supplier would be permitted to sign the claim on behalf of the beneficiary. Specifically, § 424.36(b)(6)(ii)(A) through (C) lists the documentation that would be required, all of which would have to be maintained by the ambulance provider or supplier in its files for a period of at least 4 years from the date of service. An ambulance provider or supplier would be required to obtain a signed, contemporaneous statement from an ambulance employee present during transport of the patient that, at the time the service was provided, the beneficiary was physically or mentally incapable of signing the claim and that none of the other qualified persons listed in § 424.36(b)(1) through (5) were available or willing to sign the claim on behalf of the beneficiary.

The ambulance provider or supplier would also be required to maintain documentation of the date and time that the beneficiary was transported and the name and location of the facility that received the beneficiary. In addition, the ambulance provider or supplier would be required to obtain and maintain a signed contemporaneous statement from a representative of the facility that received the beneficiary. The statement would have to contain the name of the beneficiary and the date and time the beneficiary was received at the facility.

The burden associated with the recordkeeping requirements contained in § 424.36(b)(6) is the time and effort associated with drafting, obtaining, and maintaining written statements from both employees of the ambulance provider or supplier transporting the beneficiary and employees of the facility receiving the beneficiary. We estimate that approximately 9,000 ambulance providers or suppliers will comply with these requirements. We estimate that it will take no more than 5 minutes for each provider or supplier to comply with the recordkeeping requirements. Based on the best available data at this time, we estimate the total annual burden associated with the requirements in § 424.36(b)(6) to be 541,667 hours nationwide. The annual total number of burden hours was arrived at by multiplying 5 minutes by the total estimated number of emergency ambulance transports of

6,500,000. We note that the total number of burden hours may be overstated, because not every beneficiary who receives emergency ambulance transport services is unable to sign the claim. However, we also note that the 6.5 million figure for emergency transports is the estimated number of ALS1-emergency and BLS-emergency ambulance claims processed by Part B carriers, incurred in 2006 and processed through April 2007, and thus, does not include the number of emergency ambulance transport services billed to fiscal intermediaries by ambulance providers (this number is not available to us). In any event, we believe our proposal will benefit ambulance providers and suppliers by allowing them an alternative procedure for submitting claims to Medicare. In the absence of the proposed procedure for signing claims on behalf of beneficiaries for emergency ambulance transport services, ambulance suppliers and providers would be required to track down beneficiaries after the emergency transport services have been rendered, in an attempt to have the beneficiary sign the claim. Moreover, such attempts may prove fruitless, thereby preventing the ambulance suppliers and providers from submitting the claim to Medicare.

Additional Information Collection Requirements

This proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed rule also makes reference to several associated information collections that are not discussed in the regulation text. The following is a discussion of these collections, which have already received OMB approval.

Part B Drug Payment

Section II.F.1 of the preamble of this proposed rule discusses payment for Medicare Part B drugs and biologicals under the ASP methodology. Drug manufacturers are required to submit ASP data to us on a quarterly basis. As stated in section II.F.1.a. of the preamble, the ASP reporting requirements are set forth in section 1927(b) of the Act.

The collection of ASP data imposes a reporting requirement on the public. The burden associated with this requirement is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to calculate, record, and submit the required data to CMS. While the burden associated with this requirement is subject to the PRA, it is currently approved under OMB

control number 0938–0921, with an expiration date of May 31, 2009.

Competitive Acquisition Program (CAP)

In section II.F.2.c. of the preamble, we propose to revise the CAP physician election agreement. In conjunction with post-payment review process, we are revising the CAP physician election agreement to reflect the physician's obligation to provide medical records to assist with claims review. The CAP physician election agreement is currently approved under 0938–0955 with an expiration date of August 31, 2009. Under a separate notice, we will make the revised instrument available for public comment prior to submitting the revised information collection request to OMB for approval.

Section II.F.2.e. of the preamble discusses details of the CAP. Each year, physicians are given the option to elect to obtain Medicare Part B drugs and biologicals through the CAP. In addition, physicians are also given an opportunity to select an approved CAP vendor. The burden associated with these election requirements is the time and effort necessary for a physician to make an election and notify CMS. The burden associated with election requirements for participating in the CAP and selecting an approved CAP vendor is subject to the PRA. However, it is currently approved under OMB control numbers 0938–0955 and 0938–0987 with expiration dates of August 31, 2009 and April 30, 2009, respectively.

Section II.F.2.e. of the preamble also discusses the exigent circumstances exception for leaving the CAP outside of the annual election process. A physician may request a release from the CAP within the first 30 days of its participation if it can prove that staying in the program would impose a significant burden. Specifically, the physician must submit a release request to the CAP designated carrier.

While this burden is subject to the PRA, we believe it is exempt under 5 CFR 1320.3(h)(6). Facts or opinions collected from a single person or entity are not subject to the PRA. The aforementioned information collection request will be reviewed individually on a case-by-case basis.

Once the CAP-designated carrier receives a removal request, they are required to refer the physician to their approved CAP vendor. As part of the grievance process, the CAP vendor will try to work with the physician to address their concerns for participation in the program. Then, the CAP vendor

has 2 business days to address the physician's concerns. If the CAP vendor and the physician cannot resolve the outstanding issues within 2 business days, the CAP vendor may submit a request to CMS for an extension to allow for an additional 2 business days to resolve the physician's issues.

The burden associated with this requirement is the time and effort necessary to submit an extension request to CMS. While this burden is subject to the PRA, we currently have no way to quantify how many requests of this type we will receive. Requests from physicians will be reviewed by CAP vendors on an individual case-by-case basis. Similarly, requests for extensions from the CAP vendors will be reviewed individually, on a case-by-case basis. We will continue to monitor the process. If we believe that we will receive 10 or more requests, we will submit an information collection request to OMB.

Physician Quality Reporting Initiative (PQRI)

Section II.T.1.a. of the preamble discusses the background of the reporting initiative and provides information about the measures available to eligible professionals who choose to participate in PQRI. Section 1848(k)(1) of the Act requires the Secretary to implement a system for eligible professionals to submit data pertaining to certain quality measures. As stated in section II.T.1.a., eligible professionals, for the purpose of the quality reporting system, include physicians, other practitioners as described in section 1842(b)(18)(c) of the Act, physical and occupational therapists, and qualified speech-language pathologists. As also stated in section II.T.1.a., this is a voluntary initiative. Eligible professionals may choose whether to participate and, to the extent they satisfactorily submit data on quality measures applicable to covered professional services they furnish to Medicare beneficiaries, they can qualify to receive a bonus incentive payment.

Specifically, to qualify to receive a bonus incentive payment for satisfactory reporting of quality data on covered professional services furnished in 2007, an eligible professional must submit data on at least 1, 2, or 3 measures selected from the 74 PQRI 2007 quality measures. The minimum number of measures each professional must report to qualify for the bonus payment is determined by how many available

measures are applicable to the services that professional furnishes to Medicare beneficiaries. For a majority of the eligible professionals, three or more available measures will be applicable to their practice, and thus, the MIEA–TRHCA requires that they report on at least three measures at a rate of at least 80 percent for each of those three measures to meet statutory criteria for satisfactory reporting and qualify for the bonus payment. An eligible professional could meet the satisfactory reporting requirement, and thus be eligible for the bonus incentive payment, by reporting fewer than three measures only if his or her practice has fewer than three applicable measures available. The quality measures are posted and available for download on the CMS Web site at <http://www.cms.hhs.gov/pqri>.

The burden associated with this requirement is the time and effort associated with eligible professionals identifying applicable PQRI quality measures for which they can report the necessary information. In addition, they must gather the required information, select the appropriate quality-data codes, and include the appropriate quality-data codes on the claims they submit for payment.

In 2007, the PQRI will collect quality-data codes exclusively as additional (optional) line items on the existing HIPAA transaction 837–P and CMS Form 1500. There will be no new forms and no modifications to the existing transaction or form in support of 2007 PQRI. We also do not anticipate changes to the 837–P or CMS Form 1500 for 2008.

Because this is a voluntary program, it is impossible to estimate with any degree of accuracy how many eligible professionals will opt to participate in the PQRI in 2007. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. We estimate that the additional time required to put quality data codes on each claim is not a material increment to the time required to code the claim for payment. The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported.

TABLE 23.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Total annual burden (hours)
Preamble section II.F.1	0938–0921	120	480	17,760
Preamble section II.F.2.f	0938–0955	12	12	480
	0938–0987	10,000	10,000	20,000
§ 410.33	0938–0685	400,000	400,000	1,000,000
§ 424.36	0938–New	9,000	6,500,000	541,667
Total				1,579,907

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: William N. Parham, III, CMS–1385–P, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, [CMS–1385–P], carolyn_lovett@omb.eop.gov. Fax (202) 395–6974.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

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

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for proposed rules with economically significant effects (that is, a proposed rule that would have an annual effect on the economy of \$100 million or more in any one year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities). As indicated in more detail below in this regulatory impact analysis, we estimate that the PFS provisions included in this proposed rule will redistribute more than \$100 million in 1 year. We are considering this proposed rule to be economically significant because its provisions are estimated to result in an increase, decrease or aggregate redistribution of Medicare spending that will exceed \$100 million. Therefore, this proposed rule is a major rule and we have prepared a regulatory impact analysis.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year. (For further information, see the Small Business Administration’s regulation at 70 FR 72577, December 6, 2003.) Individuals and States are not included in the definition of a small entity. The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less

significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers, including IDTFs, are considered small businesses if they generate revenues of \$6.5 million or less. Approximately 95 percent of physicians are considered to be small entities. There are about 980,000 physicians, other practitioners and medical suppliers that receive Medicare payment under the PFS.

The CAP provides alternatives to physicians who do not wish to purchase drugs directly or collect coinsurance. The impact of the CAP provisions on an individual physician is dependent on whether the drugs they provide to Medicare beneficiaries are included in the list of CAP drugs, whether the physician chooses to obtain drugs administered to Medicare beneficiaries through the CAP. The proposed CAP provisions in this proposed rule will also have a potential impact on entities that are involved in the dispensing or distribution of drugs, plan to become approved CAP vendors, or are approved CAP vendors.

For purposes of the RFA, approximately 80 percent of clinical diagnostic laboratories are considered small businesses according to the Small Business Administration’s size standards. Ambulance providers and suppliers for purposes of the RFA are also considered to be small entities.

In addition, most ESRD facilities are considered small entities, either based on nonprofit status or by having revenues of \$31.5 million or less in any year. We consider a substantial number of entities to be affected if the proposed rule is estimated to impact more than 5 percent of the total number of small entities. Based on our analysis of the 930 nonprofit ESRD facilities considered small entities in accordance with the above definitions, we estimate that the combined impact of the proposed changes to payment for renal dialysis services included in this proposed rule would have a 0.8 percent increase in overall payments relative to current overall payments. The analysis

and discussion provided in this section, as well as elsewhere in this proposed rule, complies with the RFA requirements.

For the e-prescribing provisions, physician practices and independent pharmacies are considered small entities.

Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our initial regulatory flexibility analysis for the remaining provisions. Therefore, we are soliciting comments on our estimates and analysis of the impact of this proposed rule on those small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this proposed rule would have minimal impact on small hospitals located in rural areas. Of the 202 hospital-based ESRD facilities located in rural areas, only 40 are affiliated with hospitals with fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$120 million. This proposed rule will not mandate any requirements for State, local, or tribal governments. Medicare beneficiaries are considered to be part of the private sector for this purpose. A discussion concerning the impact of this rule on beneficiaries is found later in this section.

We have examined this proposed rule in accordance with Executive Order 13132 and have determined that this regulation would not have any significant impact on the rights, roles, or responsibilities of State, local, or tribal governments.

We have prepared the following analysis, which, together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures

we propose to use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we propose a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

A. RVU Impacts

1. Resource-Based Work and PE RVUs

Section 1848(c)(2)(B)(ii) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve BN. In the CY 2007 PFS final rule with comment period, the \$4 billion impact of changes in work RVUs resulting from the 5-Year Review required that a BN adjustment be made.

As discussed in section IV.D.3 of the CY 2007 PFS final rule with comment period (71 FR 69735), we carefully reviewed the comments received concerning the BN adjustment needed to offset the \$4 billion impact of changes in work RVUs resulting from the 5-Year Review. To meet the requirements set forth in section 1848(c)(2)(B)(ii)(II) of the Act, we implemented a BN adjuster of 0.8994 or 10.1 percent to be applied to the work RVUs.

Subsequent to the publication of the CY 2007 PFS final rule with comment period and the announcement of the 0.8994 BN adjustment to the work RVUs, the AMA RUC supplied work RVU recommendations on additional CPT codes from the 5-Year Review and recommendations for an increase in the work of anesthesia services. See Table 10 in Section II.E. for a listing of the RUC recommendations and CMS decisions on these additional codes reviewed for the 5-Year Review. As stated in the CY 2007 PFS final rule with comment period, these additional codes are still considered part of the 5-Year Review. The impact of these additional recommendations and increases in the work of anesthesia services on the BN adjustment must be accounted for by revising the current work adjuster of 0.8994. The proposed

revised work adjuster for 2008, based upon the proposed work RVUs for these additional CPT codes and proposed increases in the work of anesthesia services, is approximately 0.8816. Table 24 shows the specialty-level impact of the work and PE RVU changes.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2007 with proposed payment rates for CY 2008 using CY 2006 Medicare utilization for all years. We are using CY 2006 Medicare claims processed and paid through March 30, 2007, that we estimate are 98 percent complete. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown in Table 24. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 80 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Table 24 shows only the payment impact on PFS services. The following is an explanation of the information represented in Table 24. Note that Table 24 does not include the impact of the estimated CY 2008 update.

- Specialty: The physician specialty or type of practitioner/supplier.
- Allowed Charges: Allowed charges are the Medicare Fee Schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary.) These amounts have been summed across all services provided by physicians, practitioners, or suppliers with a specialty to arrive at the total allowed charges for the specialty.
- Impact of Work RVU Changes for additional proposed changes in work RVUs from the 5-Year Review.
- Impact of PE RVU changes. The impact is shown for both 2008 which is the second year of the 4-year transition using the new methodology and the fully implemented 2010 PE RVUs.
- Combined impact of the proposed work RVUs and PE RVUs for both 2008

and the fully implemented 2010 PE RVUs.

TABLE 24.—PROPOSED COMBINED TOTAL ALLOWED CHARGE IMPACT FOR WORK AND PRACTICE EXPENSE RVU CHANGES

Specialty	Impact of work RVU changes 2008 (percent)	Impact of PE RVU changes (percent)		Combined impact of PE and work changes* (percent)	
		2008 (PE trans. year 2)	2010 (PE full implement.)	2008 (PE trans. year 2)	2010 (PE full implement.)
TOTAL	0	0	0	0	0
ALLERGY/IMMUNOLOGY	0	1	2	1	3
ANESTHESIOLOGY	15	-1	-3	14	13
CARDIAC SURGERY	-1	-1	-2	-2	-3
CARDIOLOGY	-1	0	0	-1	-1
COLON AND RECTAL SURGERY	-1	1	2	0	1
CRITICAL CARE	-1	0	-1	-1	-2
DERMATOLOGY	-1	2	7	2	6
EMERGENCY MEDICINE	-1	0	-1	-2	-2
ENDOCRINOLOGY	-1	0	0	-1	-2
FAMILY PRACTICE	0	0	0	0	0
GASTROENTEROLOGY	-1	1	4	0	3
GENERAL PRACTICE	0	0	-1	0	-1
GENERAL SURGERY	-1	0	0	-1	-1
GERIATRICS	2	0	0	2	3
HAND SURGERY	-1	-1	-3	-2	-4
HEMATOLOGY/ONCOLOGY	-1	0	-1	-1	-2
INFECTIOUS DISEASE	-1	0	1	-1	0
INTERNAL MEDICINE	0	0	0	0	-1
INTERVENTIONAL RADIOLOGY	-1	-1	-4	-2	-4
NEPHROLOGY	-1	-1	-4	-2	-5
NEUROLOGY	-1	0	-1	-1	-2
NEUROSURGERY	-1	-1	-2	-2	-3
NUCLEAR MEDICINE	-1	4	13	4	12
OBSTETRICS/GYNECOLOGY	-1	0	-1	-1	-2
OPHTHALMOLOGY	2	-1	-3	1	-1
ORTHOPEDIC SURGERY	-1	-1	-2	-1	-2
OTOLARNGOLOGY	2	-1	-4	1	-2
PATHOLOGY	-1	-1	-3	-2	-4
PEDIATRICS	0	0	0	0	-1
PHYSICAL MEDICINE	0	-1	-2	-1	-2
PLASTIC SURGERY	-1	0	1	-1	0
PSYCHIATRY	-1	0	1	0	1
PULMONARY DISEASE	-1	0	1	-1	0
RADIATION ONCOLOGY	-1	0	1	0	1
RADIOLOGY	-1	1	2	0	1
RHEUMATOLOGY	-1	-1	-2	-2	-3
THORACIC SURGERY	-1	-1	-2	-2	-3
UROLOGY	-1	0	0	-1	-1
VASCULAR SURGERY	-1	0	-1	-1	-1
AUDIOLOGIST	26	-14	-43	12	-17
CHIROPRACTOR	-1	-1	-2	-2	-3
CLINICAL PSYCHOLOGIST	-1	-2	-6	-3	-7
CLINICAL SOCIAL WORKER	-1	-2	-5	-3	-6
NURSE ANESTHETIST	22	0	0	22	22
NURSE PRACTITIONER	1	0	1	2	2
OPTOMETRY	4	0	-1	4	3
ORAL/MAXILLOFACIAL SURGERY	-1	1	3	0	3
PHYSICAL/OCCUPATIONAL THERAPY	-1	1	4	1	4
PHYSICIAN ASSISTANT	-1	0	0	0	0
PODIATRY	-1	1	4	1	3
DIAGNOSTIC TESTING FACILITY	0	0	0	0	0
INDEPENDENT LABORATORY	0	3	9	3	9
PORTABLE X-RAY SUPPLIER	0	2	6	2	6

*Components may not sum to total due to rounding.

2. Adjustments for Payments for Imaging Services

Section 5102 of the Deficit Reduction Act of 2005 (Pub. L. 109-171) (DRA) exempts the estimated savings from the application of the OPSS-based payment limitation on PFS imaging services from the PFS BN requirement. We estimate that the combined impact of the current BN exemptions instituted by section 5102 of the DRA, the proposed addition of 6 codes to the list of services subject to the DRA OPSS cap (discussed in section II.E.1.), and the proposed payment revisions to OPSS cap amounts would result in no measurable changes in the specialty specific impacts of the DRA provisions with the exception of vascular surgery in CY 2008.

3. Combined Impact

Table 25 shows the specialty-level impact of the proposed work and PE RVU changes, section 5102 of the DRA (including the additional 6 services that were added to the list of services subject to the DRA OPSS cap and the proposed revision to OPSS payment amounts), and our most recent estimate (-9.9 percent) of the CY 2008 Medicare PFS update. Additionally, the impacts in this proposed rule reflect the use of updated physician time data from the AMA-RUC.

As indicated in Table 25, our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2007 with proposed payment rates for CY 2008 using CY 2006 Medicare utilization crosswalked to 2007 services. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown in Table 25. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides.

Table 25 shows only the payment impact on PFS services. The following is an explanation of the information represented in Table 25.

- Specialty: The physician specialty or type of practitioner/supplier.
- Allowed Charges: Allowed charges are the Medicare Fee Schedule amounts for covered services and include copayments and deductibles (which are the financial responsibility of the beneficiary.) These amounts have been summed across all services provided by physicians, practitioners, or suppliers

with a specialty to arrive at the total allowed charges for the specialty.

- Impact of the 2008 Work and PE RVU proposed changes using the methodology finalized in the CY 2007 PFS final rule with comment period and the revised data sources discussed in this proposed rule.

• Impact of section 5102 of the DRA: The CY 2008 percentage decrease in allowed charges attributed to section 5102 of the DRA with the proposed addition of six codes to the OPSS cap list.

- Combined impact of the proposed work and PE RVUs, section 5102 of the DRA and the proposed addition of six codes to the OPSS cap list, and the proposed revisions to OPSS payment amounts.

• CY 2008 Update: The percentage decrease in allowed charges attributed to the estimated CY 2008 PFS conversion factor update (-9.9 percent).

- Combined impact with CY 2008 update: The CY 2008 percentage decrease in allowed charges attributed to the impact of the work and PE RVU changes, section 5102 of the DRA (plus six proposed additions to OPSS cap list), and the proposed revisions to OPSS payment amounts, and the CY 2008 update.

TABLE 25.—COMBINED CY 2008 TOTAL ALLOWED CHARGE IMPACT FOR THE REMAINING 5-YEAR REVIEW OF WORK RVUS AND PRACTICE EXPENSE CHANGES, OPSS IMAGING CAP, AND THE CY 2008 UPDATE

Specialty	Allowed charges (mil)	Impact of work and PE RVU changes* (percent)	Impact of DRA 5102 (percent)	Combined impact RVU and DRA 5102** (percent)	CY 2008 update (percent)	Combined impact with CY 2008 update** (percent)
TOTAL	\$75,819	0	0	0	-10	-10
ALLERGY/IMMUNOLOGY	172	1	0	1	-10	-9
ANESTHESIOLOGY	1,600	14	0	14	-10	4
CARDIAC SURGERY	393	-2	0	-2	-10	-12
CARDIOLOGY	7,447	-1	0	-1	-10	-11
COLON AND RECTAL SURGERY	121	0	0	0	-10	-10
CRITICAL CARE	197	-1	0	-1	-10	-11
DERMATOLOGY	2,237	2	0	2	-10	-8
EMERGENCY MEDICINE	2,170	-2	0	-2	-10	-12
ENDOCRINOLOGY	347	-1	0	-1	-10	-11
FAMILY PRACTICE	5,011	0	0	0	-10	-10
GASTROENTEROLOGY	1,737	0	0	0	-10	-10
GENERAL PRACTICE	964	0	0	0	-10	-10
GENERAL SURGERY	2,282	-1	0	-1	-10	-11
GERIATRICS	145	2	0	2	-10	-8
HAND SURGERY	79	-2	0	-2	-10	-12
HEMATOLOGY/ONCOLOGY	1,905	-1	0	-1	-10	-11
INFECTIOUS DISEASE	499	-1	0	-1	-10	-11
INTERNAL MEDICINE	9,867	0	0	-1	-10	-11
INTERVENTIONAL RADIOLOGY	241	-2	0	-2	-10	-12
NEPHROLOGY	1,649	-2	0	-2	-10	-12
NEUROLOGY	1,385	-1	0	-1	-10	-11
NEUROSURGERY	568	-2	0	-2	-10	-12
NUCLEAR MEDICINE	77	4	0	4	-10	-6
OBSTETRICS/GYNECOLOGY	621	-1	0	-1	-10	-11
OPHTHALMOLOGY	4,642	1	0	1	-10	-9
ORTHOPEDIC SURGERY	3,221	-1	0	-1	-10	-11
OTOLARNGOLOGY	906	1	0	0	-10	-10

TABLE 25.—COMBINED CY 2008 TOTAL ALLOWED CHARGE IMPACT FOR THE REMAINING 5-YEAR REVIEW OF WORK RVUS AND PRACTICE EXPENSE CHANGES, OPPTS IMAGING CAP, AND THE CY 2008 UPDATE—Continued

Specialty	Allowed charges (mil)	Impact of work and PE RVU changes* (percent)	Impact of DRA 5102 (percent)	Combined impact RVU and DRA 5102** (percent)	CY 2008 update (percent)	Combined impact with CY 2008 update** (percent)
PATHOLOGY	939	-2	0	-2	-10	-12
PEDIATRICS	72	0	0	-1	-10	-11
PHYSICAL MEDICINE	775	-1	0	-1	-10	-11
PLASTIC SURGERY	268	-1	0	-1	-10	-11
PSYCHIATRY	1,076	0	0	0	-10	-10
PULMONARY DISEASE	1,679	-1	0	-1	-10	-11
RADIATION ONCOLOGY	1,599	0	0	0	-10	-10
RADIOLOGY	5,197	0	0	0	-10	-10
RHEUMATOLOGY	491	-2	0	-2	-10	-12
THORACIC SURGERY	432	-2	0	-2	-10	-12
UROLOGY	2,021	-1	0	0	-10	-10
VASCULAR SURGERY	634	-1	-1	-2	-10	-12
AUDIOLOGIST	31	12	0	12	-10	2
CHIROPRACTOR	717	-2	0	-2	-10	-12
CLINICAL PSYCHOLOGIST	521	-3	0	-3	-10	-13
CLINICAL SOCIAL WORKER	347	-3	0	-3	-10	-13
NURSE ANESTHETIST	605	22	0	22	-10	12
NURSE PRACTITIONER	783	2	0	2	-10	-8
OPTOMETRY	782	4	0	4	-10	-6
ORAL/MAXILLOFACIAL SURGERY	36	0	0	0	-10	-10
PHYSICAL/OCCUPATIONAL THERAPY	1,371	1	0	1	-10	-9
PHYSICIAN ASSISTANT	591	0	0	0	-10	-10
PODIATRY	1,554	1	0	1	-10	-9
DIAGNOSTIC TESTING FACILITY	1,162	0	0	0	-10	-10
INDEPENDENT LABORATORY	1,081	3	0	3	-10	-7
PORTABLE X-RAY SUPPLIER	80	2	0	2	-10	-8

* PE changes are CY 2008 second year transition changes. For fully implemented CY 2010 PE changes see Table 1.

** Components may not sum to total due to rounding.

Table 26 shows the estimated impact on total payments for selected high-volume procedures of all of the changes discussed previously. We selected these

procedures because they are the most commonly provided by a broad spectrum of physician specialties. There are separate columns that show the

change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE refer to Addendum A of this proposed rule.

TABLE 26.—IMPACT OF PROPOSED RULE AND ESTIMATED PHYSICIAN UPDATE ON PROPOSED 2008 PAYMENT FOR SELECTED PROCEDURES

CPT/ HCPCS	MOD	Description	Facility			Nonfacility		
			2007	Proposed 2008	Percent change	2007	Proposed 2008	Percent change
11721		Debride nail, 6 or more	\$28.80	\$24.92	-13	\$39.03	\$35.50	-9
17000		Destruct premalg lesion	44.72	41.64	-7	63.29	60.42	-5
27130		Total hip arthroplasty	1,360.52	1,199.16	-12	NA	NA	NA
27244		Treat thigh fracture	1,100.92	967.04	-12	NA	NA	NA
27447		Total knee arthroplasty	1,464.74	1,288.25	-12	NA	NA	NA
33533		CABG, arterial, single	1,908.52	1,664.76	-13	NA	NA	NA
35301		Rechanneling of artery	1,071.74	938.37	-12	NA	NA	NA
43239		Upper GI endoscopy, biopsy	155.00	140.98	-9	325.16	293.90	-10
66821		After cataract laser surgery	253.53	224.61	-11	270.97	239.63	-12
66984		Cataract surg w/iol, 1 stage	641.98	563.91	-12	NA	NA	NA
67210		Treatment of retinal lesion	556.34	491.54	-12	580.59	511.68	-12
71010		Chest x-ray	NA	NA	NA	26.15	22.87	-13
71010	26	Chest x-ray	8.72	7.85	-10	8.72	7.85	-10
77056		Mammogram, both breasts	NA	NA	NA	97.40	90.46	-7
77056	26	Mammogram, both breasts	41.31	37.55	-9	41.31	37.55	-9
77057		Mammogram, screening	NA	NA	NA	81.86	74.07	-10
77057	26	Mammogram, screening	33.35	30.38	-9	33.35	30.38	-9
77427		Radiation tx management, x5	176.22	159.07	-10	176.22	159.07	-10
78465	26	Heart image (3d), multiple	73.14	66.56	-9	73.14	66.56	-9
88305	26	Tissue exam by pathologist	37.90	32.77	-14	37.90	32.77	-14
90801		Psy dx interview	129.99	112.65	-13	145.15	131.76	-9
90862		Medication management	44.72	39.60	-11	50.40	46.76	-7
90935		Hemodialysis, one evaluation	67.46	59.05	-12	NA	NA	NA

TABLE 26.—IMPACT OF PROPOSED RULE AND ESTIMATED PHYSICIAN UPDATE ON PROPOSED 2008 PAYMENT FOR SELECTED PROCEDURES—Continued

CPT/ HCPCS	MOD	Description	Facility			Nonfacility		
			2007	Proposed 2008	Percent change	2007	Proposed 2008	Percent change
92012		Eye exam established pat	34.11	38.23	12	61.77	62.47	1
92014		Eye exam & treatment	55.71	59.39	7	91.33	91.14	0
92980		Insert intracoronary stent	795.85	721.61	-9	NA	NA	NA
93000		Electrocardiogram, complete	24.63	20.48	-17	24.63	20.48	-17
93010		Electrocardiogram report	8.34	7.51	-10	8.34	7.51	-10
93015		Cardiovascular stress test	104.22	92.51	-11	104.22	92.51	-11
93307	26	Echo exam of heart	46.99	42.33	-10	46.99	42.33	-10
93510	26	Left heart catheterization	242.92	215.73	-11	242.92	215.73	-11
98941		Chiropractic manipulation	28.80	25.60	-11	33.35	29.36	-12
99203		Office/outpatient visit, new	67.08	59.05	-12	91.71	81.58	-11
99213		Office/outpatient visit, est	42.07	37.55	-11	59.50	53.59	-10
99214		Office/outpatient visit, est	66.32	59.05	-11	90.20	80.56	-11
99222		Initial hospital care	119.00	105.48	-11	NA	NA	NA
99223		Initial hospital care	173.57	154.29	-11	NA	NA	NA
99231		Subsequent hospital care	35.62	31.75	-11	NA	NA	NA
99232		Subsequent hospital care	63.67	57.01	-10	NA	NA	NA
99233		Subsequent hospital care	90.95	81.24	-11	NA	NA	NA
99236		Observ/hosp same date	205.40	180.57	-12	NA	NA	NA
99239		Hospital discharge day	94.74	83.63	-12	NA	NA	NA
99243		Office consultation	93.23	83.29	-11	122.41	109.57	-10
99244		Office consultation	145.91	130.74	-10	179.26	160.43	-10
99253		Inpatient consultation	108.77	97.63	-10	NA	NA	NA
99254		Inpatient consultation	156.52	140.64	-10	NA	NA	NA
99283		Emergency dept visit	60.64	52.91	-13	NA	NA	NA
99284		Emergency dept visit	110.28	97.97	-11	NA	NA	NA
99291		Critical care, first hour	208.82	183.65	-12	256.19	224.95	-12
99292		Critical care, add'l 30 min	104.60	92.16	-12	114.45	100.70	-12
99348		Home visit, est patient	NA	NA	NA	66.32	58.03	-13
99350		Home visit, est patient	NA	NA	NA	150.83	131.42	-13
G0008		Admin influenza virus vac	NA	NA	NA	18.95	18.43	-3
G0317		ESRD related svcs 4+mo 20+yrs	283.09	246.45	-13	283.09	246.45	-13

B. Geographic Practice Cost Index Changes

Section 1848(e)(1)(A) of the Act requires that payments under the Medicare PFS vary among payment areas only to the extent that area costs vary as reflected by the area GPCIs. The GPCIs measure area cost differences in the three components of the PFS: Physician work; PEs (employee wages, rent, medical supplies, and equipment); and malpractice insurance. Section 1848(e)(1)(C) of the Act requires that GPCIs be reviewed and, if necessary, revised at least every 3 years. The first GPCI revision was implemented in 1993. The second revision was implemented in 1998, the next in 2001, and the last in 2005. In section II.C. of this proposed rule, we are proposing the next GPCI update. The proposed GPCI values are shown in Addendum E. These values reflect the expiration of the 1,000 floor on physician work as provided under section 102 of the MIEA-TRHCA. Section 1848(e)(1)(c) of the Act also requires that the GPCI revisions be phased-in equally over a 2-year period if more than 1 year has elapsed since the last adjustment.

An estimate of the overall effects of proposed GPCI changes on fee schedule area payments can be demonstrated by a comparison of area geographic adjustment factors (GAFs). The GAFs are a weighted composite of each area's work, PE, and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall area costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE, and malpractice expense RVUs for the service differ from those of the GAF. Addendum D shows the estimated effects of the revised GPCIs on area GAFs in descending order. The GAFs reflect the expiration of the 1,000 floor on physician work as provided under section 102 of the MIEA-TRHCA.

The effects of the 2008 transition year will be only one-half of the total amount of the revisions associated with the updated GPCI values. As required by law, the GPCIs would be phased in over a 2 year period. The total impact of the

GPCI revisions is shown in the 2009 GPCI values of Addendum E.

The most significant changes occur in 11 payment localities where the GAF moves up by 1 or more percent or down by more than 2 percent.

C. Telehealth

In section II.D of this rule, we are proposing to add neurobehavioral status exam as represented by HCPCS code 96116 to the list of telehealth services. To date, Medicare expenditures for telehealth services have been extremely low. For instance, in CY 2006, the total Medicare payment amount for telehealth services (including the originating site facility fee) was approximately \$2 million. Moreover, previous additions to the list of Medicare telehealth services have not resulted in a significant increase in Medicare program expenditures. For example, the psychiatric diagnostic interview examination (as described by CPT code 90801) was added to the list of Medicare telehealth services in CY 2003. The addition of CPT code 90801 resulted in an increase in Medicare payment amounts of approximately \$100,000 in CY 2006.

The neurobehavioral status exam (CPT code 96116) includes an initial assessment and evaluation of the mental status for a psychiatric patient. In this regard, the neurobehavioral status exam is similar to the psychiatric diagnostic interview examination (CPT code 90801). However, the utilization rate of psychiatric diagnostic interview examination is much greater than the neurobehavioral status exam. For instance, in CY 2006, the total allowed services for CPT code 90801 was approximately 1.3 million while total allowed services for neurobehavioral status exam in CY 2006 was approximately 105,000. Because utilization of neurobehavioral status exam is substantially less than the psychiatric diagnostic interview examination, we believe the budgetary impact of adding neurobehavioral status exam to the list of Medicare telehealth services will be even less than the previously added psychiatric diagnostic interview examination.

While we believe that addition of this service to the telehealth service list will enable more beneficiaries to access to these services, we do not anticipate that this proposed change will have a significant budgetary impact on the Medicare program.

D. Payment for Covered Outpatient Drugs and Biologicals

1. ASP Issues

The proposed changes discussed in section II.F.1. with respect to payment for covered outpatient drugs and biologicals, are estimated to have no impact on Medicare expenditures. However, we believe the changes will assist in clarifying existing policy with respect to ASP payment.

2. CAP Issues

This proposed rule describes a significant change in how CAP drug claims are paid due to the implementation of section 108(a)(2) of the MIEA-TRHCA. This rule also contains proposals and seeks comment on certain approaches to refining the CAP seek to improve service by improving compliance, increasing flexibility, and increasing choices available to participating CAP physicians. The proposed CAP provisions will also have a potential impact on entities that are involved in the dispensing or distribution of drugs, plan to become approved CAP vendors, or are approved CAP vendors. Changes associated with section 108(a)(2) of the MIEA-TRHCA, especially the provision for payment to vendors upon receipt of a claim, will almost certainly be

perceived as a positive step. Other changes which are proposed or are being contemplated seek to improve service by improving compliance, and increasing the services that an approved CAP vendor may offer to participating CAP physicians. At this time we anticipate these changes will result in no significant additional cost savings or increases associated with the CAP, relative to the ASP payment system.

E. Clinical Laboratory Fee Schedule issues

As discussed in section II.G. of this preamble, we have proposed two additions to § 410.508 for determining payment for a new clinical diagnostic laboratory paid under the Medicare Part B clinical laboratory fee schedule. These proposals will not increase or decrease payment amounts for existing clinical diagnostic laboratory tests because the payment amounts are not subject to these regulatory changes. For new tests, the proposals would primarily permit additional comment opportunity for establishing a payment amount for a new test but not result in an increase or decrease in payment amounts. Because any new laboratory tests to undergo a reconsideration request of a payment amount are unknown to us at the current time, we do not have any data to estimate the impact of our proposal to establish a reconsideration process. By improving the comment opportunities and timeframes for establishing payment amount for new tests, we expect less than five tests per year to undergo a subsequent reconsideration process with the resulting adjustments in payment amounts to be very modest if any.

F. Provisions Related to Payment for Renal Dialysis Services Furnished by End State Renal Disease (ESRD) Facilities

The ESRD-related provisions in this proposed rule are discussed in section II.H. To understand the impact of the proposed changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments under the current year (CY 2007 payments) to estimated payments under the revisions to the composite rate payment system (CY 2008 payments) as discussed in II.H. of this proposed rule. To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and proposed payments contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both

current 2006 payments and proposed 2007 payments.

ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). We also used the December 2006 update of CY 2006 National Claims History file as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. While the December 2006 update of the 2006 claims is not complete, we wanted to use the most recent data available, and plan to use an updated version of the 2006 claims file for the final rule. Due to data limitations, we are unable to estimate current and proposed payments for 168 of the 4,712 ESRD facilities that bill for ESRD dialysis treatments.

Table 27 shows the impact of this year's proposed changes to CY 2008 payments to hospital-based and independent ESRD facilities. The first column of Table 27 identifies the type of ESRD provider, the second column indicates the number of ESRD facilities for each type, and the third column indicates the number of dialysis treatments.

The fourth column shows the effect of the proposed change to the wage index floor as it affects the composite rate payments to ESRD facilities for CY 2008. The fourth column compares aggregate ESRD wage adjusted composite rate payments in the third year of the transition (CY 2008) using the CY 2008 wage index with a 0.80 floor compared to aggregate ESRD wage adjusted composite rate payments in the third year of the transition (CY 2008) using the CY 2008 wage index with a 0.75 floor. Note that the fourth column only includes the effect of the proposed change to the wage index floor and does not include the effects of other wage index changes, such as, moving from the second to third year of the transition and updated wage index values from CY 2007 to CY 2008.

The fifth column shows the effect of all proposed changes to the ESRD wage index for CY 2008 as it affects the composite rate payments to ESRD facilities. It is inclusive of the changes in the fourth column. The fifth column compares aggregate ESRD wage adjusted composite rate payments in the third year of the transition (CY 2008) to aggregate ESRD wage adjusted composite rate payments in the second year of the transition (CY 2007). In the third year of the transition (CY 2008), ESRD facilities receive 75 percent of the CBSA wage adjusted composite rate and

25 percent of the MSA wage adjusted composite rate. In the second year of the transition, ESRD facilities receive 50 percent of the CBSA wage adjusted composite rate and 50 percent of the MSA wage adjusted composite rate. The overall effect to all ESRD providers in aggregate is zero because the proposed CY 2008 ESRD wage index has been multiplied by a BN adjustment factor to comply with the statutory requirement that any wage index revisions be done in a manner that results in the same aggregate amount of expenditures as would have been made without any changes in the wage index. The decreases shown among census regions is primarily due to reducing the wage

index floor, as there were areas in these areas with wage index values below the proposed floor.

The sixth column shows the overall effect of the proposed changes in composite rate payments to ESRD providers. The overall effect is measured as the difference between the proposed CY 2008 payment with all changes as proposed in this rule and current CY 2007 payment. This payment amount is computed by multiplying the wage adjusted composite rate with the drug add-on for each provider times the number of dialysis treatments from the CY 2006 claims. The CY 2008 proposed payment is the transition year 3 wage-adjusted composite rate for each

provider (with the 15.5 percent drug add-on) times dialysis treatments from CY 2006 claims. The CY 2007 current payment is the transition year 2 wage-adjusted composite rate for each provider (with the current 14.9 percent drug add-on) times dialysis treatments from CY 2006 claims.

The overall impact to ESRD providers in aggregate is 0.5 percent. This increase corresponds to the proposed 0.5 percent increase to the drug add-on. The variation shown in column 6 is due to variation in changes in the wage index (column 5). All provider types receive the same 0.5 percent increase to the drug add-on.

TABLE 27.—IMPACT OF CY 2008 PROPOSED CHANGES IN PAYMENTS TO HOSPITAL-BASED AND INDEPENDENT ESRD FACILITIES

[Percent change in composite rate payments to ESRD facilities (both program and beneficiaries)]

ESRD provider	Number of facilities	Number of dialysis treatments (in millions)	Effect of changes in floor only ¹	Effect of changes in Wage Index ²	Overall effect ³
All Providers:	4,541	31.4	0.0	0.0	0.5
Independent	3,958	28.1	0.0	-0.1	0.5
Hospital-Based	583	3.3	0.0	0.5	1.0
By Facility Size:					
Less than 5000 treatments	1,821	5.4	-0.1	-0.2	0.3
5000 to 9999 treatments	1,805	13.0	0.0	0.0	0.6
Greater than 9999 treatments	915	13.0	0.0	0.1	0.6
Type of Ownership:					
Profit	3,611	25.6	0.0	-0.1	0.4
Nonprofit	930	5.9	0.0	0.3	0.8
By Geographic Location:					
Rural	1,227	6.5	-0.3	-0.5	0.0
Urban	3,314	25.0	0.1	0.1	0.6
By Region:					
New England	154	1.1	0.1	1.6	2.2
Middle Atlantic	549	4.0	0.1	0.4	1.0
East North Central	717	5.1	0.1	-0.7	-0.2
West North Central	343	1.7	0.0	-0.3	0.3
South Atlantic	1,023	7.3	0.0	0.1	0.6
East South Central	357	2.3	-0.3	-1.1	-0.6
West South Central	622	4.4	-0.1	-0.6	-0.1
Mountain	248	1.4	0.1	0.5	1.0
Pacific	498	3.9	0.1	1.3	1.8
Puerto Rico	30	0.4	-2.1	-3.1	-2.6

¹ This column only shows the effect of the proposed wage index floor changes on ESRD providers for CY 2008. Composite rate payments computed using the CY 2008 wage index with a 0.80 floor are compared to composite rate payments using the CY 2008 wage index with a 0.75 floor.

² This column shows the overall effect of wage index changes on ESRD providers. Composite rate payments computed using the current wage index are compared to composite rate payments using the CY 2008 wage index changes.

² This column shows the overall effect of wage index changes on ESRD providers. Composite rate payments computed using the current wage index are compared to composite rate payments using the CY 2008 wage index changes.

³ This column shows the percent change between CY 2008 and CY 2007 composite rate payments to ESRD facilities. The CY 2008 payments include the CY 2008 wage adjusted composite rate, and the 15.5 percent drug add-on times treatments. The CY 2007 payments to ESRD facilities includes the CY 2007 wage adjusted composite rate and the 14.9 percent drug add-on times treatments.

G. IDTF Changes

We believe that our proposals regarding IDTFs as discussed in section II.I. of this proposed rule would have no budgetary impact. However, we believe that these changes are necessary to ensure that only legitimate IDTFs are enrolled into the program. In addition, we believe that the proposed IDTF provisions contained in this rule will

help ensure that beneficiaries receive quality care. Therefore, we expect to have an impact on an unknown number of persons and entities who will be denied enrollment into the Medicare program.

H. CORF Issues

The revisions to the CORF regulations discussed in section II.K. update the regulations for consistency with the PFS

payment rules. These revisions will help to clarify payment for CORF services and are expected to have minimal impact on Medicare expenditures.

I. Compendia for Determination of Medically-Accepted Indications for Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

We anticipate that the proposals related to the compendia discussed in section II.L. of this proposed rule will have a negligible cost to the Medicare program. The proposed changes will enable CMS to respond quickly should changes in the number and quality of the compendia indicate a need to amend the list.

J. Physician Self-referral Provisions

We anticipate that our proposals in section II.M. of this proposed rule for the reassignment and anti-markup provisions, and the physician self-referral provisions would result in savings to the program by reducing overutilization and anti-competitive business arrangements. We cannot gauge with any certainty the extent of these savings to the Medicare program.

K. Beneficiary Signature for Ambulance Transport Services

We believe that our proposal in section II.N. of this proposed rule for allowing the ambulance provider or supplier to sign the claim on behalf of the beneficiary with respect to emergency transport services, provided that certain conditions are satisfied, will have no budget impact.

L. Update to Fee Schedules for Class III DME for CYs 2007 and 2008

In section II.O. of this proposed rule, we discuss the proposed update to the fee schedules for class III DME for CYs 2007 and 2008. Total allowed charges for class III devices in 2005 were \$71 million. Accordingly, with a zero percent increase for DME, other than class III devices, for 2005 and 2006 and with the proposed establishment of an update for 2007 of zero percent for class III devices, rather than 4.3 percent based on the CPI-U, this would result in a savings to the Medicare program of approximately \$2 million in FY 2007, \$4 million in FY 2008, \$4 million in FY 2009, \$5 million in FY 2010, \$5 million in FY 2011, and \$5 million in FY 2012.

M. Therapy Services

In section II.S.2., we proposed to change the certification the plan of care, for outpatient physical therapy, occupational therapy and speech-language pathology services from every 30 days to an appropriate length, based on the patient's needs, limited to 90 days. Analysis of Medicare claims data shows negative or no impact for this change. In most cases, the appropriate length of treatment will be less than 30

days. Certification of the appropriate length of treatment will discourage the practice of billing for re-evaluations prior to recertification regardless of need.

The 30-day recertification allows treatment under a plan of care for 30 days after initial certification, regardless of the appropriate length of treatment. The initial certification cannot assure that a physician reviews the plan or follows the patient's progress.

In 2004 and again in 2006, we received an extensive analysis of the utilization of therapy services. The analysis indicates that the recertification has no impact on utilization of services and does not limit payment. About 70 percent of episodes are completed before the first 30-day recertification interval. Although CORFs have a 60-day certification period, and SNFs and outpatient rehabilitation facilities (ORFs) have 30-day certification periods, the average number of treatment days is similar in these settings. Contrary to the pattern expected if certification impacted length of care, the number of physical therapy treatment days is higher in SNF than in CORF.

We propose to review the utilization of therapy services after a 2-year trial to assess any changes that might be related to certification of a plan of care for an appropriate length of treatment. At that time, if we determine that this change has caused an increase in inappropriate utilization, we will reconsider the 30-day certification requirement.

N. TRHCA 101(b) Physician Quality Reporting Initiative

As discussed in section II.T.1. of this proposed rule, the proposed 2008 PQRI measures satisfy the requirement of section 1848(k)(2)(B)(ii) of the Act that the Secretary publish in the **Federal Register** by August 15, 2007 a proposed set of measures that the Secretary determines would be appropriate for eligible professionals to use to submit data to the Secretary in 2008. We also expect to address registry-based data submission on a test basis in 2008. As discussed in section II.T.1. of this proposed rule, we will also explore and may offer an option in 2008 for reporting some of the 2008 PQRI measures via submission of clinical data extracted from EHRs. Although there may be some cost incurred for maintaining the measures and their associated code sets, and for expanding an existing clinical data warehouse to accommodate registry-based data submission, we do not anticipate a significant cost impact on the Medicare program.

O. TRHCA 101(d) Physician Assistance and Quality Initiative Fund

As discussed in section II.T.5. of this proposed rule, section 101(d) of the MIEA-TRHCA created the Physician Assistance and Quality Initiative Fund (PAQI) which provides \$1.35 billion for physician payment and quality improvement initiatives. The legislation directs the Secretary to provide for expenditures from the Fund in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire \$1.35 billion for payment for physician's services furnished during 2008.

P. TRHCA 110 Reporting of Anemia Quality Indicators

As discussed in section II.T.2. of this proposed rule, there are no program cost savings or increased expenditure associated with this proposed change; however, we expect that the regulation will have a positive impact on patient care.

Q. Proposed Elimination of Exemption From NCPDP SCRIPT Standard for Computer-Generated Facsimile Transmissions Under Medicare Part D

The proposed elimination of the exemption for computer-generated fax transactions under Medicare Part D is discussed in section II.S.3. of this proposed rule. E-prescribing is voluntary for providers and pharmacies. This proposal would affect only providers and pharmacies that already conduct e-prescribing using products that generate faxes rather than SCRIPT transactions.

We believe that providers and pharmacies that are now e-prescribing using products that generate faxes generally already possess the hardware necessary to e-prescribe. Many would need to obtain software upgrades to send and receive the SCRIPT transaction. This software will generally be available to providers through automatic version upgrades built into annual software vendor maintenance fees. However, providers currently using software that cannot be upgraded to generate SCRIPT transactions would need to purchase and install new e-prescribing software or revert to sending paper fax transactions to pharmacies.

Dispensers that currently e-prescribe but have not established the connectivity necessary to receive and send SCRIPT transactions would need to connect to a network, and may need to install software upgrades, which will generally be covered under annual fees. Because pharmacies customarily bear

the cost of transaction fees for the SCRIPT transactions they receive and send, these costs would increase as the rate of e-prescribing increases.

The proposed elimination of this exemption will have indirect benefits in that it will help to encourage e-prescribing using electronic data interchange, which will ultimately result in improved patient safety.

Because of the voluntary nature of e-prescribing for physicians and pharmacies, the relatively small number of entities currently e-prescribing, and the minimal nature of the anticipated costs, we believe this provision does not constitute a major rule for purposes of this analysis. However, we specifically solicit comments on the impact to providers and pharmacies.

R. Revisions to Payment Policies Under the Ambulance Fee Schedule and the Ambulance Inflation Factor Update for CY 2008

Ambulance providers and suppliers for purposes of the RFA are considered to be small entities. The proposal to remove the requirement that the AIF be published annually via **Federal Register** notice, as discussed in Section III. of this proposed rule has no monetary impact on small entities, or small businesses. It merely allows for the earlier dissemination of necessary information to the ambulance industry, the Medicare contractors, and the general public.

S. Alternatives Considered

This proposed rule contains a range of policies, including some provisions

related to specific MMA provisions. The preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our decisions and, where relevant, alternatives that were considered.

T. Impact on Beneficiaries

There are a number of changes made in this proposed rule that would have an effect on beneficiaries. In general, we believe these changes, particularly the implementation of the PQRI with its continuing focus on measuring, submitting, and analyzing quality data, will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

We do not believe that beneficiaries will experience drug access issues as a result of the proposed changes with respect to Part B drugs and CAP.

As explained in more detail subsequently in this section, the regulatory provisions may affect beneficiary liability in some cases. Most changes in aggregate beneficiary liability from a particular provision would be a function of the coinsurance (20 percent if applicable for the particular provision after the beneficiary has met the deductible) and the effect of the aggregate cost (savings) of the provision on the calculation of the Medicare Part B premium rate (generally 25 percent of the provision's cost or savings). In 2008, total cost sharing (coinsurance and deductible) per Part B enrollee associated with physician fee schedule services is estimated to be \$590. In

addition, the portion of the 2008 standard monthly Part B premium attributable to PFS services is estimated to be \$38.60.

To illustrate this point, as shown in Table 26, the 2007 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new), is 91.71 which means that currently a beneficiary is responsible for 20 percent of this amount, or 18.34. Based on this proposed rule, the 2008 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 26, is \$81.58 which means that, in 2008, the beneficiary coinsurance for this service would be \$16.32.

Proposed policies discussed in this rule that do affect overall spending, such as the proposed additions to the list of codes that are subject to section 5102 of the DRA imaging provisions, would similarly impact beneficiaries' coinsurance.

U. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 28, we have prepared an accounting statement showing the classification of the expenditures associated with this proposed rule. This estimate includes the incurred benefit impact associated with the estimated CY 2008 PFS update, shown in this proposed rule, based on the 2007 Trustees Report baseline. All estimated impacts are classified as transfers.

TABLE 28.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM CY 2007 TO CY 2008

Category	Transfers
Annualized Monetized Transfers	Estimated decrease in expenditures of \$ 5.9 billion.
From Whom To Whom?	Physicians, other practitioners and suppliers who receive payment under the Medicare Physician Fee Schedule; ESRD Medicare Providers; ambulance suppliers, DME suppliers, and Medicare suppliers billing for Part B drugs to Federal Government.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health Professionals, Medicare, Penalties,

Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

2. A new § 409.17 is added to read as follows:

§ 409.17 Physical therapy, occupational therapy, and speech-language pathology services.

(a) *General rules.* (1)(i) Except as specified in paragraph (a)(1)(ii) of this section, physical therapy, occupational therapy or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants or speech-language pathologists who meet the requirements specified in § 484.4 of this chapter.

(ii) Physical therapy, occupational therapy or speech-language pathology services may be furnished by qualified physical therapists, physical therapist

assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered or otherwise regulated as physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants by the State in which practicing before January 1, 2008 and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

(2) Physical therapy, occupational therapy or speech-language pathology services must be furnished under a plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan must be established before treatment begins by one of the following:

(1) A physician.

(2) A nurse practitioner, a clinical nurse specialist or a physician assistant.

(3) The physical therapist furnishing the physical therapy services.

(4) A speech-language pathologist furnishing the speech-language pathology services.

(5) An occupational therapist furnishing the occupational therapy services.

(c) *Content of the plan.* The plan must—

(1) Prescribe the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and

(2) Indicate the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan must be made in writing, incorporated immediately, and signed by one of the following:

(1) A physician.

(2) A nurse practitioner, clinical nurse specialist, or a physician assistant.

(3) The physical therapist furnishing the physical therapy services.

(4) The speech-language pathologist furnishing the speech-language pathology services.

(5) The occupational therapist furnishing the occupational therapy services.

(6) A registered professional nurse or a staff physician, in accordance with verbal orders from one the practitioners listed in paragraphs (1) through (5) of this section.

(e) *Review of the plan.* The physician, nurse practitioner, clinical nurse special or physician assistant reviews the plan as often as the individual's condition requires, but at least prior to certification.

Subpart C—Posthospital SNF Care

3. Section 409.23 is amended by adding paragraph (c) to read as follows:

§ 409.23 Physical, occupational, and speech therapy.

* * * * *

(c) Except as specified in paragraph (c)(1)(ii) of this section, physical therapy, occupational therapy or speech-language pathology services must be furnished—

(1)(i) By qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants or speech-language pathologists as defined in § 484.4; or

(ii) By qualified physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered or otherwise recognized by the State in which practicing before January 1, 2008 and continue to furnish Medicare physical therapy or occupational therapy services at least part time without an interruption in furnishing services of more than 2 years.

(2) In accordance with a plan of treatment that meets the requirements of § 409.16(b) through (e) of this part.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

4. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

Subpart B—Medical and Other Health Services

§ 410.32 [Amended]

5. Section 410.32 is amended by—

A. Removing paragraph (a)(1).

B. Redesignating paragraphs (a)(2) and (a)(3) as paragraphs (a)(1) and (a)(2).

6. Section 410.33 is amended by—

A. Removing the phrase, “and (h)” in the introductory text of paragraph (a)(2) and adding in its place, “and (i)”.

B. Revising paragraphs (b)(1), (g)(2), (g)(6), and (g)(8).

C. Adding paragraphs (g)(15) and (i).

The revisions and additions read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(b) * * *
(1) Each supervising physician must be limited to providing supervision to no more than three IDTF sites. This applies to both fixed sites and mobile

units where three concurrent operations are capable of performing tests.

* * * * *

(g) * * *

(2) 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 to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

* * * * *

(6) Have a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. 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. In addition, the IDTF must—

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least \$300,000 per incident;

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations; and

(iii) List the CMS designated contractor as a Certificate Holder on the policy.

* * * * *

(8) Answer, document, and maintain documentation of all beneficiaries' questions and responses to their complaints at the physical site of the IDTF. This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) 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.

(iii) 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.

* * * * *

(15) Does not share space, equipment, or staff or sublease its operations to another individual or organization.

* * * * *

(i) *Effective date of billing privileges.* The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a fee-for-service contractor;

(2) The date the IDTF first furnished services at its new practice location; or

(3) The filing date of the Medicare enrollment application or the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that it is able to process for approval.

7. Section 410.43 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 410.43 Partial hospitalization services: Conditions and exclusions.

(a) * * *

(3) * * *

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant—

(A) As specified in § 484.4 of this chapter; or

(B) Who has been licensed, certified, registered or otherwise recognized as an occupational therapist or occupational therapy assistant by the State in which practicing before January 1, 2008 and continues to furnish Medicare occupational therapy services at least part time without an interruption in furnishing services of more than 2 years.

* * * * *

8. Section 410.59 is amended by—

A. Removing the phrase “paragraph (a)(3)(iii)” in the introductory text to paragraph (a) and adding the phrase, “paragraphs (a)(3)(iii) and (iv)” in its place.

B. Adding a new paragraph (a)(3)(iv). The addition reads as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(3) * * *

(iv) By qualified occupational therapists or appropriately supervised occupational therapy assistants who meet the qualifications in § 484.4 of this chapter or who have been licensed, certified, registered or otherwise recognized by the State in which practicing before January 1, 2008 and continue to furnish Medicare occupational therapy services at least part time without an interruption in furnishing services of more than 2 years;

* * * * *

9. Section 410.60 is amended by—
A. Removing the phrase “paragraph (a)(3)(iii)” in the introductory text to paragraph (a) and adding the phrase, “paragraphs (a)(3)(iii) and (iv)” in its place.

B. Adding a new paragraph (a)(3)(iv). The addition reads as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(3) * * *

(iv) By qualified physical therapists or appropriately supervised physical therapist assistants who meet the qualifications in § 484.4 of this chapter or who have been licensed, certified, registered or otherwise recognized by the State in which practicing before January 1, 2008 and continue to furnish Medicare physical therapy services at least part time without an interruption in furnishing services of more than 2 years;

* * * * *

10. Section 410.61 is amended by revising paragraph (e)(1) to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

* * * * *

(e) * * *

(1) The physician, nurse practitioner, clinical nurse specialist or physician's assistant reviews the plan as often as the individual's condition requires, but at least at every certification and recertification.

* * * * *

11. Section 410.78 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management, end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site), individual medical nutrition therapy, and neurobehavioral status exam furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

12. Section 410.100 is amended by—

A. Revising the introductory text and paragraphs (a), (e), and (h).

- B. Removing paragraphs (i) and (k).
- C. Redesignating paragraphs (j), (l), and (m) to (i), (j), and (k), respectively.
- D. Revising new paragraphs (i), (j), and (k).

The revisions read as follows:

§ 410.100 Included services.

Subject to the conditions and limitations set forth in § 410.102 and § 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter. Payment for CORF services are made in accordance with § 414.1101 of this chapter.

(a) *Physician's services.* CORF facility physician services are administrative in nature and include consultation with and medical supervision of nonphysician staff, participate in plan of treatment reviews and patient care review conferences, and other medical and facility administration activities. Diagnostic and therapeutic services furnished to an individual CORF patient by a physician in a CORF facility are not CORF physician services. These services, if covered, are physician services under § 410.20 with payment for these services made to the physician in accordance with part 414 subpart B of this chapter.

* * * * *

(e) *Respiratory therapy services.* (1) Respiratory therapy services are for the treatment, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) Respiratory therapy services include the following:

- (i) Application of techniques for support of oxygenation and ventilation of the patient.
- (ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment.
- (iii) Bronchial hygiene therapy.
- (iv) Pulmonary rehabilitation techniques to develop strength and endurance of respiratory muscles and other techniques to increase respiratory function, such as graded activity services; these services include physiologic monitoring and patient education.

* * * * *

(h) *Social and psychological services.* Social and psychological services include the assessment and treatment of an individual's mental and emotional functioning and the response to and rate of progress as it relates to the individual's rehabilitation plan of treatment, including physical therapy services, occupational therapy services, speech-language pathology services and respiratory therapy services.

(i) *Nursing care services.* Nursing care services include nursing services provided by a registered nurse that are prescribed by a physician and are specified in or directly related to the rehabilitation treatment plan and necessary for the attainment of the rehabilitation goals of the physical therapy, occupational therapy, speech-language pathology, or respiratory therapy plan of treatment.

(j) *Supplies and durable medical equipment.* Supplies and durable medical equipment include the following:

- (1) Disposable supplies.
- (2) Durable medical equipment of the type specified in § 410.38 (except for renal dialysis systems) for a patient's use outside the CORF, whether purchased or rented.

(k) *Home environment evaluation.* A home environment evaluation—

- (1) Is a single home visit to evaluate the potential impact of the home situation on the patient's rehabilitation goals.
- (2) Requires the presence of the patient and the physical therapist, occupational therapist, or speech-language pathologist, as appropriate.

13. Section 410.105 is amended by revising paragraphs (b)(3)(i) and (ii), (c)(1) introductory text, and (c)(1)(ii) to read as follows:

§ 410.105 Requirements for coverage of CORF services.

* * * * *

- (b) * * *
- (3) * * *

(i) Physical therapy, occupational therapy, and speech-language pathology services may be furnished away from the premises of the CORF including the individual's home when payment is not otherwise made under Title XVIII of the Act.

(ii) The single home environment evaluation visit specified in § 410.100(m) is also covered.

(c) * * *

(1) The service must be furnished under a written rehabilitation plan of treatment that—

- (i) * * *
- (ii) Indicates the diagnosis and rehabilitation goals, and prescribes the type, amount, frequency, and duration of the services to be furnished that relate directly to such rehabilitation goals.

* * * * *

Subpart G—Medical Nutrition Therapy

14. Section 410.132 is amended by revising paragraph (a) to read as follows:

§ 410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT

services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Except as provided at § 410.78, services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally-accepted dietary or nutritional protocols.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

15. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

Subpart A—General Exclusions and Exclusion of Particular Services

- 16. Section 411.15 is amended by—
 - A. Revising paragraph (a)(1).
 - B. Adding paragraphs (k)(13) and (k)(14).

The revision and additions read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(a) * * *

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, initial preventive physical exams, ultrasound screening for abdominal aortic aneurysms (AAA), cardiovascular disease screening tests, or diabetes screening tests that meet the criteria specified in paragraphs (k)(6) through (k)(14) of this section.

* * * * *

(k) * * *

(13) In the case of cardiovascular disease screening tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease, subject to the conditions specified in § 410.17 of this chapter.

(14) In the case of diabetes screening tests furnished to an individual at risk for diabetes for the purpose of the early detection of that disease, subject to the conditions specified in § 410.18 of this chapter.

* * * * *

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

17. Section 411.351 is amended by revising the definition of “entity” to read as follows:

§ 411.351 Definitions.

* * * * *

Entity means—

(1) A physician’s sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed the DHS, or

(ii) Presented a claim or caused a claim to be presented for Medicare benefits for the DHS.

(2) For purposes of this subpart, “entity” includes a health plan, managed care organization (MCO), provider sponsored organization (PSO), or independent practice association (IPA) that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to § 424.80 of this chapter, with respect to any designated health services provided by that supplier; “entity” does not include a health care delivery system that is a health plan (as defined in § 1001.952(l) of this title), or any MCO, PSO or IPA with which a health plan contracts for services provided to plan enrollees.

(3) For purposes of this subpart, “entity” does not include a physician’s practice when it bills Medicare for a diagnostic testing accordance with § 414.50 of this chapter (Physician billing for purchased diagnostic tests) and section 30.2.9 of the Internet-Only Manual, Pub.100–04, Chapter 1, General Billing Requirements.

* * * * *

18. Section 411.353 is amended by adding paragraph (g) to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) *Denial of payment for services furnished under a prohibited referral.* When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed, the burden is on the entity submitting the claim for payment

to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral).

19. Section 411.354 is amended by revising paragraphs (b)(3)(i) and (d)(1) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(b) * * *

(3) * * *

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician or immediate family member through the physician’s or immediate family member’s employment with that entity;

* * * * *

(d) * * *

(1) Compensation will be considered “set in advance” if the aggregate compensation, a time-based or per unit of service based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician. Percentage-based compensation, other than compensation based on revenues directly resulting from personally performed physician services (as defined in § 410.20(a)), is not considered set in advance.

* * * * *

20. Section 411.357 is amended by revising paragraphs (a)(5) and (b)(4) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(a) * * *

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(b) * * *

(4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Per unit-of-service rental charges are not allowed to the extent that such payments reflect services provided to patients referred by the lessor to the lessee.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

21. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–133 (113 Stat. 1501A–332).

Subpart A—Introduction and General Rules

§ 413.1 [Amended]

22. Section 413.1 is amended by—

A. Removing paragraphs (a)(2)(iv) and (vi).

B. Redesignating paragraphs (a)(2)(v) and (vii) as paragraphs (a)(2)(iv) and (v), respectively.

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

23. Section 413.184 is amended by revising the section heading as set forth below:

§ 413.184 Payment exception: Pediatric patient mix.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

24. The authority citation for part 414 is revised to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

Subpart B—Physicians and Other Practitioners

25. Section 414.50 is revised to read as follows:

§ 414.50 Physician billing for purchased diagnostic tests.

(a) *General rule.* (1) For services covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act), if a physician or medical group bills for the technical or professional component of a diagnostic test that was performed by an outside supplier, the payment to the physician or the medical group (less the applicable deductibles and coinsurance) for the technical or professional component of the test may not exceed the lowest of the following amounts:

- (i) The supplier's net charge to the physician or medical group.
- (ii) The physician's or medical group's actual charge.
- (iii) The fee schedule amount for the test that would be allowed if the supplier billed directly.

(2) This provision applies regardless of whether the test or its interpretation was purchased by the physician or medical group billing for the test or the interpretation, or whether the right to bill for the test or its interpretation was reassigned to the physician or medical group billing for the test or the interpretation.

(3) For purposes of paragraph (a) of this section—

(i) The physician's or other supplier's net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the outside supplier by or through the billing physician or medical group.

(ii) An outside supplier is someone other than a full-time employee of the billing physician or medical group.

(b) *Restriction on payment.* (1) The physician or medical group must identify the supplier and indicate the supplier's net charge for the test. If the physician or medical group fails to provide this information, CMS makes no payment to the physician or medical group and the physician or medical group may not bill the beneficiary.

(2) Physicians and medical groups that accept Medicare assignment may bill beneficiaries for only the applicable deductibles and co-insurance.

(3) Physicians and medical groups that do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

26. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, consultation, individual psychotherapy, psychiatric diagnostic interview examination, pharmacologic management, end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site), individual medical nutrition therapy, and neurobehavioral status exam furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

* * * * *

Subpart G—Payment for New Clinical Diagnostic Laboratory Tests

27. Section § 414.502 is amended by adding the definition, "New test" in alphabetical order to read as follows:

§ 414.502 Definitions.

* * * * *

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

* * * * *

28. Section 414.506 is amended by revising the introductory text to read as follows:

§ 414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new test, CMS determines the basis for and amount of payment after performance of the following:

* * * * *

29. Section 414.508 is amended by revising paragraph (b)(3) to read as follows:

§ 414.508 Payment for a new clinical diagnostic laboratory test.

* * * * *

(b) * * *

(3) For a new test for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the carrier-specific amounts will pay for the test appropriately. If CMS determines that the carrier-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

30. Section 414.509 is added to read as follows:

§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new test for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment.* (1) CMS will receive public comments in written format for 60 days after making a determination of the basis for payment under § 414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a commenter recommends that the basis for payment should be changed from gapfilling to crosswalking, the commenter may also recommend the code or codes to which to crosswalk the new test.

(2) At the meeting convened under § 414.506(c), those commenters who submitted comments within the 60-day comment period may present their comments.

(3) Considering comments received, CMS may reconsider its determination of the basis for payment. As the result of such a reconsideration, CMS may change the basis for payment from crosswalking to gapfilling or from gapfilling to crosswalking.

(4) If the basis for payment is revised as the result of a reconsideration, the new basis for payment is final and is not subject to further reconsideration.

(b) *Reconsideration of amount of payment—*(1) *Crosswalking.* (i) For 60 days after making a determination under § 414.506(d)(2) of the code or codes to which a new test will be crosswalked, CMS receives public comments in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii) At the meeting convened under § 414.506(c), those commenters who submitted comments within the 60-day comment period may present their comments.

(iii) Considering comments received, CMS may reconsider its determination of the amount of payment. As the result of such a reconsideration, CMS may change the code or codes to which the new test is crosswalked.

(iv) If CMS changes the basis for payment from gapfilling to crosswalking as a result of a reconsideration, the crosswalked amount of payment is not subject to reconsideration.

(2) *Gapfilling.* (i) By April 30 of the year after CMS makes a determination under § 414.506(d)(2) or § 414.509(a)(3) that the basis for payment for a new test will be gapfilling, CMS posts interim

carrier-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim carrier-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding whether CMS should reconsider the interim payment amounts and the appropriate national limitation amount for the new test.

(iii) Considering comments received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the national limitation amount for the new test.

(3) For both gapfilled and crosswalked new tests, if CMS revises the amount of payment as the result of a reconsideration, the new amount of payment is final and is not subject to further reconsideration.

(c) *Effective date.* If CMS changes a determination as the result of a reconsideration, the new determination regarding the basis for or amount of payment is effective January 1 of the year following reconsideration. Claims for services with dates of service prior to the effective date will not be reopened or otherwise reprocessed.

(d) *Jurisdiction for Reconsideration Decisions.* Jurisdiction for reconsidering a determination rests exclusively with the Secretary. A decision whether to reconsider a determination is committed to the discretion of the Secretary. A decision not to reconsider an initial determination is not subject to administrative or judicial review.

31. Section 414.510 is amended by—

A. Revising the section heading to read as set forth below.

B. Revising the introductory text.

The revisions read as follows:

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

* * * * *

Subpart H—Fee Schedule for Ambulance Services

§ 414.620 [Amended]

32. In § 414.620, the phrase “notice in the Federal Register without opportunity for prior comment” is removed and the phrase “CMS by instruction and on the CMS Web site” is added in its place.

Subpart I—Payment for Drugs and Biologicals

33. Section 414.707 is amended by adding paragraph (c) to read as follows:

§ 414.707 Basis of payment.

* * * * *

(c) *Mandatory reporting of anemia quality indicators for Medicare part B cancer anti-anemia drugs.* Effective January 1, 2008, each request for payment for anti-anemia drugs furnished to treat anemia resulting from the treatment of cancer must report the beneficiary’s most recent hemoglobin or hematocrit level in a manner specified by the Secretary.

Subpart J—Submission of Manufacturer’s Average Sales Price Data

34. Section 414.802 is amended by adding the definition of “bundled arrangement” in alphabetical order to read as follows:

§ 414.802 Definitions.

* * * * *

Bundled arrangement means 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 bundled drugs or biologicals been purchased separately or outside of the bundled arrangement.

* * * * *

35. Section 414.804 is amended by adding paragraph (a)(2)(iii) to read as follows:

§ 414.804 Basis of payment.

(a) * * *

(2) * * *

(iii) For the purposes of paragraph (a)(2)(i) of this section, the total value of all price concessions on all drugs sold under a bundled arrangement must be allocated proportionately according to the dollar value of the units of each drug sold under the bundled arrangement.

* * * * *

Subpart K—Payment for Drugs and Biologicals Under Part B

36. Section 414.904 is amended by revising paragraph (d)(3) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2008, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

* * * * *

37. Section 414.908 is amended by—

A. Revising paragraph (a)(2)(iv).

B. Revising paragraph (a)(3)(xi).

C. Removing paragraph (a)(5).

The revision reads as follows:

§ 414.908 Competitive acquisition program.

(a) * * *

(2) * * *

(iv) For other exigent circumstances defined by CMS, including—

(A) If the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(h) have been met, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor.

(B) If, during the first 30 days of participation in the CAP, the participating physician can document significant burden to the practice and the physician has attempted resolution through the vendor’s grievance process, the CAP dispute resolution process, and the request has been approved by CMS.

(3) * * *

(xi) Agrees to submit documentation such as medical records or certification, as necessary, to support payment for a CAP drug;

* * * * *

38. Section 414.914 is amended by—

A. Redesignating paragraph (h) as (i)

B. Adding new paragraph (h).

C. Revising new paragraphs (i)(1) and (2).

The addition and revision reads as follows:

§ 414.914 Terms of contract.

* * * * *

(h) The approved CAP vendor must verify drug administration prior to collection of any applicable cost sharing amount.

(1) The approved CAP vendor is expected to document, in writing, the following information necessary to verify drug administration:

(i) Beneficiary's name.
 (ii) Medicare health insurance number (HIC).

(iii) Expected date of service.

(iv) Actual date of service.

(v) Name of the CAP physician.

(vi) CAP prescription order number.

(2) If the information is obtained verbally, the approved CAP vendor must also maintain the following information:

(i) The identities of individuals who exchanged the information.

(ii) The date and time that the information was obtained.

(3) The approved CAP vendor must provide this information to CMS or the beneficiary upon request.

(j) * * *

(1) Subsequent to receipt of 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.

(2) An approved CAP vendor that has received payment for the CAP-designated carrier for CAP drugs that have not been administered must promptly refund payment for such drugs to the CAP-designated carrier and must refund any coinsurance and deductible collected from the beneficiary and his or her supplemental insurer.

* * * * *

39. Section 414.917 is amended by—

A. Revising the section heading.

B. Adding paragraph (d).

The revision and addition reads as follows:

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract and termination of physician participation under exigent circumstances.

* * * * *

(d) *CAP participating physicians' exigent circumstances provision.* The following process must be completed for CAP participating physicians' requesting to terminate their participation in the program under exigent circumstances provisions described in § 414.908(a)(2)(iv):

(1) The designated carrier must—

(i) Determine whether a request to terminate CAP participation was related to approved CAP vendor service and whether to forward the issue to the approved CAP vendor's grievance process within 1 business day of the receipt of the request; or,

(ii) Continue to investigate and within 2 business days of receipt, and may do any of the following:

(A) Request a single, 2-business day extension.

(B) Recommend to CMS that the requesting physician be permitted to

terminate his or her participation in the CAP.

(C) Recommend to CMS that the physician not be permitted to terminate his or her participation in the CAP and refer to the CAP designated carrier's dispute resolution process.

(2) As a result of the findings as specified in paragraph (d)(1) of the section, CMS will—:

(i) Consider the designated carrier's recommendation and approve or deny the request to terminate participation in the CAP within 2 business days of receipt of the recommendation. A denial of the participating CAP physician's request to terminate participation in the CAP and will include notification of the right to request reconsideration under this section.

(ii) Communicate the decision to the appropriate Medicare contractors and the participating CAP physician.

(3) Upon termination of participation in the CAP a physician must agree to the following:

(i) Continue to submit claims for drugs supplied and administered under the CAP prior to the effective date of the physician's termination consistent with § 414.908(a) until all such claims are timely submitted.

(ii) Return any unused CAP drugs that had not been administered to the beneficiary prior to the effective date of the physician's termination from the CAP to the approved CAP vendor consistent with applicable law and regulation and any agreement with the approved CAP vendor.

(iii) Cooperate in any post-payment review activities on claims submitted under the CAP, as required under section 1847B(a)(3) of the Act.

(4) An approved CAP vendor that has billed and been paid for CAP drugs that have not been administered must refund any payments made by CMS or the beneficiary and his or her supplemental insurer in accordance with § 414.914(h)(3)(i)(2).

40. Section 414.930 is added to subpart K to read as follows:

§ 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

(a) *Definition.* For purposes of this section, *compendium* means a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment. A compendium includes a summary of the pharmacologic characteristics of each drug or biological and may include

information on dosage, as well as recommended or endorsed uses in specific diseases. A compendium is indexed by drug or biological.

(b) Process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment. (1) The process states that CMS—

(i) Solicits requests annually for changes to the list of compendia. This solicitation specifies a 30-day time period within which CMS receives requests, to begin no earlier than 45 days after publication of the solicitation.

(ii) Publishes a listing of the timely complete requests received and solicit public comment on the requests for 30 days. The listing identifies the requestor and the requested action.

(iii) Considers a compendium's attainment of the MedCAC (Medicare Evidence Development and Coverage Advisory Committee, previously known as the MCAC-Medicare Coverage Advisory Committee) recommended desirable characteristics of compendia in reviewing requests. CMS may consider additional reasonable factors.

(iv) Considers a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

(v) Publishes its decision no later than 120 days after the close of the public comment period.

(2) *Exception.* In addition to the annual process outlined in paragraph (b)(1) of this section, CMS may generate a request for changes to the list of compendia at any time.

(c) *Written request for review.* (1) CMS will review a complete, written request that is submitted in writing, electronically or via hard copy (no duplicate submissions) and includes the following:

(i) The full name and contact information of the requestor.

(ii) The full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

(iii) A complete written copy of the compendium that is the subject of the request.

(iv) The specific action that is requested of CMS.

(v) Materials that the requestor must submit for CMS review in support of the requested action.

(vi) A single compendium as its subject.

(2) CMS may at its discretion combine and consider multiple requests that refer to the same compendium.

(d) *Other provisions.* (1) For each compendium that is determined by CMS to be included on the list, the publisher or its designee must notify CMS, within 45 days of any update or revision that a new edition or version is available. Failure to meet this requirement may result in removal of the compendium from the list.

(2) For the purposes of this section, publication by CMS may be accomplished by posting on the CMS Web site.

41. Subpart M is added to read as follows:

Subpart M—Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 414.1100 Basis and Scope.

This subpart implements sections 1834(k)(1) and (k)(3) of the Act by specifying the payment methodology for comprehensive outpatient rehabilitation facility services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act.

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services.

(a) *Payment under the physician fee schedule.* Except as otherwise specified under paragraphs (b), (c), and (d) of this section payment for CORF services, as defined under § 410.100 of this chapter, is paid the lesser of 80 percent of the following:

(1) The actual charge for the item or service; or

(2) The nonfacility amount determined under the physician fee schedule established under section 1848(b) of the Act for the item or service.

(b) *Payment for physician services.* No separate payment for physician services that are CORF services under § 410.100(a) of this chapter will be made.

(c) *Payment for supplies and durable medical equipment, and prosthetic and orthotic devices.* Supplies and durable medical equipment that are CORF services under § 410.100(l) of this chapter, prosthetic device services that are CORF services under § 410.100(f) and orthotic devices that are CORF services under § 410.100(g) of this chapter are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraph (a) of this section; or

(2) The amount determined under the DMEPOS fee schedule established under part 414 Subparts D and F for the item, provided that payment for such item is not included in the payment amount for other CORF services paid under paragraph (a) of this section.

(d) *Payment for CORF services when no fee schedule amount for the service.* If there is no fee schedule amount established for a CORF service, payment for the item or service will be the lesser of 80 percent of:

(i) The actual charge for the service provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a) or (c) of this section.

(ii) The amount determined under the fee schedule established for a comparable service as specified by the Secretary provided that payment for such item or service is not included in the payment amount for other CORF services paid under paragraphs (a) or (c) of this section.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

42. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers

43. Section 415.130 is amended by revising paragraph (d) to read as follows:

§ 415.130 Conditions for payment: Physician pathology services.

* * * * *

(d) *Physician pathology services furnished by an independent laboratory.* The technical component of physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient on or before December 31, 2007, may be paid to the laboratory by the carrier under the physician fee schedule if the Medicare beneficiary is a patient of a covered hospital as defined in paragraph (a)(1) of this section. For services furnished after December 31, 2007, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient. For services furnished on or after January 1, 2008, the date of service policy in

§ 414.510 of this chapter applies for the technical component of specimens for physician pathology services.

PART 418—HOSPICE CARE

44. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart E—Condition of Participation: Other Services

45. Section 418.92 is amended by revising paragraph (a) to read as follows:

§ 418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.

(a) Physical therapy, occupational therapy, and speech-language pathology services must be—

(1) Available, and when provided, offered in a manner consistent with accepted standards of practice; and

(2) Furnished by personnel who meet the qualifications specified in § 484.4 of this chapter.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

46. The authority citation for part 423 continues to read as follows:

Authority: Secs 1102, 1860D'1 through 1860D'42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w'101 through 1395w'152, and 1395hh).

Subpart D—Cost Control and Quality Improvement Requirements

§ 423.160 [Amended]

47. Section 423.160 is amended by—

A. Removing paragraph (a)(3)(i).
B. Redesignating paragraphs (a)(3)(ii) and (iii) to (a)(3)(i) and (ii), respectively.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

48. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Certification and Plan of Treatment Requirements

49. Section 424.24 is amended by revising paragraphs (c)(2) and (c)(4) to read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(c) * * *

(2) *Timing*. The certification must be obtained at the time the plan of treatment is established or as soon thereafter as possible.

(4) *Recertification*—(i) *Timing*.

Recertification is required at least every 90 days.

(ii) *Content*. When it is recertified, the plan or other documentation in the patient's record must indicate the continuing need for physical therapy, occupational therapy or speech-language pathology services.

(iii) *Signature*. The physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment must recertify the plan by signing the medical record.

* * * * *

Subpart C—Claims for Payment

50. Section 424.36 is amended by adding paragraph (b)(6) to read as follows:

§ 424.36 Signature requirements.

* * * * *

(b) * * *

(6) An ambulance provider or supplier with respect to emergency ambulance transport services, if the following conditions and documentation requirements are met.

(i) None of the individuals listed in paragraphs (b)(1) through (b)(5) of this section was available or willing to sign the claim on behalf of the beneficiary at the time the service was provided;

(ii) The ambulance provider or supplier maintains in its files the following information and documentation for a period of at least 4 years from the date of service:

(A) A contemporaneous statement, signed by an ambulance employee present during the trip to the receiving facility, that at the time the service was provided the beneficiary was physically or mentally incapable of signing the claim and that none of the individuals listed in paragraphs (b)(1) through (5) of this section were available or willing to sign the claim on behalf of the beneficiary.

(B) Documentation with the date and time the beneficiary was transported, and the name and location of the facility that received the beneficiary.

(C) A signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility.

* * * * *

§ 424.37 [Amended]

51. Section 424.37(a) is amended by removing the reference to “§ 424.36(b)”

and adding in its place the reference “§ 424.36(b)(1) through (5).”

Subpart F—Limitations on Assignment and Reassignment of Claims

52. Section 424.80 is amended by adding paragraph (d)(3) to read as follows:

§ 424.80 Prohibition of reassignment of claims by suppliers.

* * * * *

(d) * * *

(3) *Reassignment of the technical or professional component of diagnostic test services*. If a physician or medical group bills for the technical or professional component of a diagnostic test covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act), following a reassignment from a physician or other supplier who performed the technical or professional component and who was not a full-time employee of the billing physician or medical group at the time the service was performed, each of the following conditions must be met:

(i) The payment to the billing physician, or medical group, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts:

(A) The physician's or other supplier's net charge to the billing physician or medical group. The physician's or other supplier's net charge must be determined without regard to any charge that is intended to cover or address the cost of equipment or space leased to the physician or the other supplier by or through the billing physician or medical group.

(B) The billing physician's or medical group's actual charge.

(C) The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

(ii) The physician or medical group billing for the test must identify the physician or other supplier that performed the test and indicate the supplier's net charge for the test. If the physician or medical group billing for the test fails to provide this information, CMS will not make any payment to the physician or medical group billing for the test and the billing physician or medical group can not bill the beneficiary.

(iii) To bill for the technical component of the service, the physician or medical group must directly perform

the professional component of the service.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

53. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart D—Optional Hospital Services

54. Section 482.56 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 482.56 Condition of participation: Rehabilitation services.

(a) * * *

(2) Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

(b) *Standard: Delivery of services*. (1) Except as specified in paragraph (c)(1)(ii) of this section, physical therapy, occupational therapy, or speech-language pathology services must be furnished—

(i) By qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists as defined in § 484.4 of this chapter; or

(ii) By qualified physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered, or otherwise recognized by the State in which practicing before January 1, 2008 and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

(2) The physical therapy, occupational therapy, or speech-language pathology must be in accordance with a written plan of treatment that meets the requirements of paragraphs (b)(3)(i) through (b)(3)(iv) of this section.

(3) *Plan of treatment requirements*—(i) *Establishment of the plan*. The plan must be established by one of the following before treatment begins:

(A) A physician.

(B) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(C) The physical therapist furnishing the physical therapy services.

(D) The speech-language pathologist furnishing the speech-language pathology services.

(E) The occupational therapist furnishing the occupational therapy services.

(ii) *Content of the plan.* The plan must—

(A) Prescribe the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and

(B) Indicate the diagnosis and anticipated goals.

(iii) *Changes in the plan.* Any changes in the plan must be made in writing, incorporated immediately, and signed by one of the following:

(A) A physician.

(B) A nurse practitioner, clinical nurse specialist, or a physician assistant.

(C) The physical therapist furnishing the physical therapy services.

(D) The speech-language pathologist furnishing the speech-language pathology services.

(E) The occupational therapist furnishing the occupational therapy services.

(F) A registered professional nurse or a staff physician, in accordance with verbal orders from one the practitioners listed in paragraphs (b)(3)(iii)(A) through (iii)(E) of this section.

(iv) *Review of the plan.* The physician, nurse practitioner, clinical nurse specialist, or physician assistant reviews the plan as often as the individual's condition requires, but at least at the time of certification and at recertification, if applicable.

PART 484—HOME HEALTH SERVICES

55. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

Subpart A—General Provisions

56. Section 484.4 is amended by revising the definitions of “Occupational therapist,” “Occupational therapy assistant,” “Physical therapist,” “Physical therapist assistant” and “Speech-language pathologist” to read as follows:

§ 484.4 Personnel Qualifications.

* * * * *

Occupational therapist. A person who meets one of the one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Meets all practice requirements set forth by the State in which occupational therapy services are furnished and meets one of the

following educational/training requirements on or after January 1, 2008:

(i)(A) Graduated after successful completion of an occupational therapist curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and

(B) Successfully completed the National Registration Examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) If educated outside the United States, or trained by the United States military—

(A) Graduated after successful completion of an occupational therapist curriculum accredited by the World Federation of Occupational Therapists, (WFOT);

(B) Is deemed eligible to test as a result of completing the NBCOT International Occupational Therapy Eligibility Determination (IOTED) review; and

(C) Successfully completed the National Registration Examination developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT)).

(2) *Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008.* Meets the one following requirements after December 31, 1977 and before January 1, 2008:

(i) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association.

(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association.

(3) *Requirements for individuals beginning their practice on or before December 31, 1977.* (i) Has 2 years of appropriate experience as an occupational therapist; and

(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.

Occupational therapy assistant. A person who meets one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Provides certain occupational therapy services under the supervision of a qualified occupational

therapist, continues to meet all practice requirements set forth by the State in which occupational therapy services are furnished, and meets one of the educational/training requirements if his or her professional practice begins on or after January 1, 2008:

(i)(A) Graduated after successful completion of coursework and clinical field work from an occupational therapy assistant curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and

(B) Successfully completed the certification examination for Certified Occupational Therapy Assistant developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) If educated outside the United States or trained in the United States military, graduated after successful completion of an occupational therapy assistant curriculum that by credentials evaluation conducted or approved by the American Occupational Therapy Association is determined to be comparable, with respect to occupational therapy assistant entry level education in the United States.

(2) *Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008.* Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association after December 31, 1977 and before January 1, 2008.

(3) *Requirements for individuals beginning their practice on or before December 31, 1977.* Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.

Physical therapist. A person who is licensed by the State in which practicing and meets one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Meets all practice requirements set forth by the State in which the physical therapy services are furnished and meets one of the following educational/training requirements on or after January 1, 2008:

(i)(A) Graduated after successful completion of a college or university physical therapy curriculum approved by the Commission on Accreditation in

Physical Therapy Education (CAPTE); and

(B) Passed the National Examination approved by the American Physical Therapy Association.

(ii) If educated outside the United States or trained by the United States military—

(A) Graduated after successful completion of an education program that, by a credentials evaluation process approved by the American Physical Therapy Association, is determined to be comparable with respect to physical therapist entry level education in the United States; and

(B) Passed the National Examination approved by the American Physical Therapy Association.

(2) *Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008.* Has graduated from a physical therapy curriculum approved by one of the following after December 31, 1977 and before January 1, 2008:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(3) *Requirements for individuals beginning their practice on or after January 1, 1966 and on or before December 31, 1977.* Had 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.

(4) *Requirements for individuals beginning their practice before January 1, 1966.* Meets one of the following requirements before January 1, 1966:

(i) Was admitted to membership by the American Physical Therapy Association.

(ii) Was admitted to registration by the American Registry of Physical Therapists.

(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(iv) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(5) *Requirements for individuals trained outside of the United States before January 1, 2008.* If trained outside the United States before January 1, 2008 meets the following requirements:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Physical therapist assistant. A person who meets one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* A person who provides certain physical therapy services under the supervision of a qualified physical therapist and is licensed, registered, certified or otherwise recognized as a physical therapist assistant, if applicable, by the State in which practicing, continues to meet all practice requirements set forth by the State in which physical therapy services are furnished, and meets one of the following educational/training requirements:

(i) Graduated after successful completion of a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association.

(ii) If educated outside the United States or trained in the United States military, graduated after successful completion of an education program that by a credentials evaluation process approved by the American Physical Therapy Association, is determined to be comparable with respect to physical therapist assistant entry level education in the United States.

(2) *Requirements for individuals beginning their practice before January 1, 2008.* Is licensed as a physical therapist assistant, if applicable, by the State in which practicing, meets either of the following requirements:

(i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association.

(ii) Has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not

apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977.

* * * * *

Speech-language pathologist. A person who meets either of the following requirements:

(1) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language Hearing Association.

(2) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

57. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

58. Section 485.51 is amended by—

A. Revising paragraph (a).

B. Adding paragraph (c).

The revision and addition read as follows:

§ 485.51 Definition.

* * * * *

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician except as provided in paragraph (c) of this section;

* * * * *

(c) *Exception.* May provide influenza, pneumococcal and Hepatitis B vaccines provided the applicable conditions of coverage under § 410.58 and § 410.63 of this chapter are met.

59. Section 485.70 is amended by revising paragraphs (c), (e), and (m) to read as follows:

§ 485.70 Personnel qualifications.

* * * * *

(c) An occupational therapist and an occupational therapy assistant must meet one of the following qualifications:

(1) As set forth in § 484.4 of this chapter.

(2) Occupational therapists or occupational therapy assistants must have been licensed, certified, registered, or otherwise recognized as occupational

therapists or occupational therapy assistants by the State in which practicing before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

* * * * *

(e) A physical therapist and a physical therapist assistant must meet one of the following qualifications:

(1) As set forth in § 484.4 of this chapter.

(2) Qualified physical therapists or physical therapist assistants must have been licensed, certified, registered, or otherwise recognized as physical therapists or physical therapist assistants by the State in which practicing before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

* * * * *

(m) A speech-language pathologist must meet the qualifications set forth in § 484.4 of this chapter.

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

60. Section 485.705 is amended by revising paragraph (a) to read as follows:

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy and speech-language pathology services directly by or under arrangements with an organization must—

(1) Be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions.

(2) Act only within the scope of their State license or State certification or registration.

(3) Meet one of the following requirements:

(i) Meet the qualifications specified in § 484.4 of this chapter.

(ii) Physical therapy, occupational therapy or speech-language pathology services may be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered or otherwise recognized as physical therapists, physical therapist assistants,

occupational therapists, or occupational therapy assistants by the State in which practicing before January 1, 2008 and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

* * * * *

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

61. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

62. Section 491.9 is amended by adding paragraph (c)(4) to read as follows:

§ 491.9 Provision of services.

* * * * *

(c) * * *

(4) Physical therapy, occupational therapy or speech-language pathology services, if provided, must be furnished—

(i) By clinicians who meet either of the following qualifications:

(A) The qualifications specified in § 484.4 of this subchapter.

(B) Physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered or otherwise recognized as physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants by the State in which practicing before January 1, 2008 and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.

(ii) In accordance with a written plan of treatment as described in § 410.61 of this chapter.

* * * * *

Authority

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 24, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 28, 2007.

Michael O. Leavitt,

Secretary.

Note: These addenda will not appear in the Code of Federal Regulations.

The addenda on the following pages provide various data pertaining to the Medicare fee schedule for physicians' services furnished in 2008.

Addendum A: Explanation and Use of Addendum B

Addendum B contains the RVUs for work, non-facility PE, facility PE, and malpractice expense, and other information for all services included in the PFS.

In previous years, we have listed many services in Addendum B that are not paid under the PFS. To avoid publishing as many pages of codes for these services, we are not including clinical laboratory codes or the alphanumeric codes (Healthcare Common Procedure Coding System (HCPCS) codes not included in CPT) not paid under the PFS in Addendum B.

Addendum B contains the following information for each CPT code and alphanumeric HCPCS code, except for: alphanumeric codes beginning with B (enteral and parenteral therapy), E (durable medical equipment), K (temporary codes for nonphysicians' services or items), or L (orthotics); and codes for anesthesiology. Please also note the following:

- An "NA" in the "Non-facility PE RVUs" column of Addendum B means that CMS has not developed a PE RVU in the nonfacility setting for the service because it is typically performed in the hospital (for example, an open heart surgery is generally performed in the hospital setting and not a physician's office). If there is an "NA" in the nonfacility PE RVU column, and the contractor determines that this service can be performed in the nonfacility setting, the service will be paid at the facility PE RVU rate.

- Services that have an "NA" in the "Facility PE RVUs" column of Addendum B are typically not paid using the PFS when provided in a facility setting. These services (which include "incident to" services and the technical portion of diagnostic tests) are generally paid under either the outpatient hospital prospective payment system or bundled into the hospital inpatient prospective payment system payment.

1. *CPT/HCPCS code.* This is the CPT or alphanumeric HCPCS number for the service. Alphanumeric HCPCS codes are included at the end of this addendum.

2. *Modifier.* A modifier is shown if there is a technical component (modifier TC) and a professional component (PC) (modifier – 26) for the service. If there is a PC and a TC for the service, Addendum B contains three entries for the code. A code for: the global values

(both professional and technical); modifier –26 (PC); and, modifier TC. The global service is not designated by a modifier, and physicians must bill using the code without a modifier if the physician furnishes both the PC and the TC of the service.

Modifier-53 is shown for a discontinued procedure, for example, a colonoscopy that is not completed. There will be RVUs for a code with this modifier.

3. *Status indicator.* This indicator shows whether the CPT/HCPCS code is in the PFS and whether it is separately payable if the service is covered.

A = Active code. These codes are separately payable under the PFS if covered. There will be RVUs for codes with this status. The presence of an “A” indicator does not mean that Medicare has made a national coverage determination regarding the service. Carriers remain responsible for coverage decisions in the absence of a national Medicare policy.

B = Bundled code. Payments for covered services are always bundled into payment for other services not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are incident (an example is a telephone call from a hospital nurse regarding care of a patient).

C = Carriers price the code. Carriers will establish RVUs and payment amounts for these services, generally on an individual case basis following review of documentation, such as an operative report.

D* = Deleted/discontinued code.

E = Excluded from the PFS by regulation. These codes are for items and services that CMS chose to exclude from the fee schedule payment by regulation. No RVUs are shown, and no payment may be made under the PFS for these codes. Payment for them, when covered, continues under reasonable charge procedures.

F = Deleted/discontinued codes. (Code not subject to a 90-day grace period.) These codes are deleted effective with the beginning of the year and are never subject to a grace period.

This indicator is no longer effective beginning with the CY 2005 PFS as of January 1, 2005.

G = Code not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services. (Codes subject to a 90-day grace period.) This indicator is no longer effective with the 2005 PFS as of January 1, 2005.

H* = Deleted modifier. For 2000 and later years, either the TC or PC component shown for the code has been deleted and the deleted component is shown in the database with the H status indicator.

I = Not valid for Medicare purposes. Medicare uses another code for the reporting of, and the payment for these services. (Codes not subject to a 90-day grace period.)

L = Local codes. Carriers will apply this status to all local codes in effect on January 1, 1998 or subsequently approved by central office for use. Carriers will complete the RVUs and payment amounts for these codes.

M = Measurement codes, used for reporting purposes only. There are no RVUs and no payment amounts for these codes. Medicare uses them to aid with performance measurement.

N = Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment.

R = Restricted coverage. Special coverage instructions apply. If the service is covered and no RVUs are shown, it is carrier-priced.

T = There are RVUs for these services, but they are only paid if there are no other services payable under the PFS billed on the same date by the same provider. If any other services payable under the PFS are billed on the same date by the same provider, these services are bundled into the service(s) for which payment is made.

X = Statutory exclusion. These codes represent an item or service that is not within the statutory definition of “physicians’ services” for PFS payment purposes. No RVUs are shown for these codes, and no payment may be made under the PFS. (Examples are

ambulance services and clinical diagnostic laboratory services.)

4. *Description of code.* This is an abbreviated version of the narrative description of the code.

5. *Physician work RVUs.* These are the RVUs for the physician work for this service in 2008.

Note: The separate BN adjuster is not reflected in these physician work RVUs.

6. *Fully implemented nonfacility practice expense RVUs.* These are the fully implemented resource-based PE RVUs for nonfacility settings.

7. *Year 2008 Transitional Nonfacility practice expense RVUs.* These are the 2008 resource-based PE RVUs for nonfacility settings.

8. *Fully implemented facility practice expense RVUs.* These are the fully implemented resource-based PE RVUs for facility settings.

9. *Year 2008 Transitional facility practice expense RVUs.* These are the 2008 resource-based PE RVUs for facility settings.

10. *Malpractice expense RVUs.* These are the RVUs for the malpractice expense for the service for 2006.

11. *Global period.* This indicator shows the number of days in the global period for the code (0, 10, or 90 days).

An explanation of the alpha codes follows:

MMM = Code describes a service furnished in uncomplicated maternity cases including antepartum care, delivery, and postpartum care. The usual global surgical concept does not apply. See the 1999 Physicians’ Current Procedural Terminology for specific definitions.

XXX = The global concept does not apply.

YYY = The global period is to be set by the carrier (for example, unlisted surgery codes).

ZZZ = Code related to another service that is always included in the global period of the other service. (Note: Physician work and PE are associated with intra-service time and in some instances in the post-service time.)

*Codes with these indicators had a 90-day grace period before January 1, 2005.