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Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Final 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, and 485

[CMS–1385–FC]

RIN 0938–AO65

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

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period addresses certain provisions of the Tax Relief and Health Care Act of 2006, as well as making other proposed changes to Medicare Part B payment policy. We are making these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This final rule with comment period 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; conforming and clarifying changes for comprehensive outpatient rehabilitation facilities (CORFs); a process for updating the drug compendia; 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; standards and requirements related to therapy services under Medicare Parts A and B; revisions to the ambulance fee schedule; the ambulance inflation factor for CY 2008; and amending the e-prescribing exemption for computer-generated facsimile transmissions. We are also finalizing the calendar year (CY) 2007 interim RVUs and are issuing interim RVUs for new and revised procedure codes for CY 2008.

As required by the statute, we are announcing that the physician fee schedule update for CY 2008 is −10.1 percent, the initial estimate for the sustainable growth rate for CY 2008 is −0.1 percent, and the conversion factor (CF) for CY 2008 is $34.0682.

DATES: *Effective Date:* The provisions of this final rule with comment period are effective January 1, 2008, except for the amendments to § 409.17 and § 409.23 which are effective July 1, 2008, and the amendments to § 423.160 which is effective January 1, 2009.

Comment Date: Comments will be considered if we receive them at one of the addresses provided below, no later than 5 p.m. e.s.t. on December 31, 2007.

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

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/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 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–FC, P.O. Box 8020, Baltimore, MD 21244–8020.

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–FC, 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) 786–7197 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey (HHH) 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 comprehensive outpatient rehabilitation facilities.

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.

Kate Tillman (410) 786–9252 or Brijit Burton (410) 786–7364 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 or Joanne Sinsheimer (410) 786–4620 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 physician quality reporting system for CY 2008.

Maria 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 caps.

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 the following issues: Interim Relative Value Units (RVUs) for selected codes identified in Addendum C and the physician self-referral designated health services (DHS) procedures listed in Addendum I. You can assist us by referencing the file code [CMS–1385–FC] 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.

This **Federal Register** document is also available from the **Federal Register** online database through Government Printing Office Access a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

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

1. Go to the following Web site: *http://www.cms.hhs.gov/PhysicianFeeSched/.*

2. Select ''PFS Federal Regulation Notices.''

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.

Table of Contents

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 Erythopoeitin
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
SLPs Speech—language pathologists
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

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 formula used to calculate payment 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).

counties within the Rest of California locality, and the methodologies we presented in each of the options would result in Santa Cruz County being removed from the Rest of California payment locality.

Comment: Many commenters were concerned about the description of the methodology used for Options 1 and 2. Specifically, these comments directed us to adopt a methodology suggested by the California Medical Association. The methodology compares the highest GAF county to the weighted average (GAF) of the remaining counties of the locality.

Response: To clarify, the methodology we used identified counties where the county GAF was at least 5 percent higher than the GAF of the locality and then we either left that county as a payment locality itself or joined it with other counties into a payment locality. In Option 1, each of these counties became a separate locality; in Option 2, we combined several of these counties into a single payment locality. This approach is not the ''iterative methodology'' that some commenters suggested we should follow. We recognize that there are alternative methodologies that can be used to consider reconfigurations to locality structures. We will consider the suggestions of the commenters in the future.

Comment: There were concerns that combining several counties into a single payment locality in Option 2 was arbitrary and led to lower payments for these counties.

Response: As we stated in the proposed rule, there are trade-offs involved in making any changes to localities, and we recognize the importance of trying to achieve a reasonable balance among competing priorities. One of our goals was to keep the number of payment localities manageable. Although we recognize that there are effects on each of the individual counties, combining counties with very similar costs was a reasonable way to meet this goal.

Comment: Numerous commenters from California recommended that we implement Option 3 but suggested that we erred in describing the methodology used in the development of Table 9 of the proposed rule and recommended that if we implement it, we should use their suggested methodology. Commenters suggested that we really meant to insert a hierarchical approach and discussed how these are both acceptable ways to accomplish the restructuring of the counties. Other State societies expressed interest in this option as long as we use the alternative methodology suggested by the California commenters.

Response: In Option 3 in the proposed rule, we ranked the counties by GAF from highest to lowest. We then combined into a new payment locality the county with the highest GAF and the other counties that have a GAF within 5 percent of the highest GAF county. Then, we found the county with the highest GAF among the remaining counties. We combined that county and all the counties that have a GAF within 5 percent of the new highest GAF county into a payment locality. We continued this method until all counties were included in a locality. As previously mentioned, there are multiple approaches to reconfiguring the localities that result in similar outcomes. We will further study the suggestions provided by the commenters.

Comment: We received a number of comments requesting that we provide a wide variety of data, at the county level, from numerous sources covering the years 1999 through 2006.

Response: We believe we provided commenters sufficient information to fairly evaluate our proposals. We note that many of these requests involved county level data. There is very little county level data available nationwide. Most of our data sources are collected at the MSA or Consolidated MSA, or Non-Metropolitan Area level, and our methodology was designed to be used to develop GPCIs within a payment locality analysis, not a county level analysis. We do our best to provide requestors with sources for publicly available data and to provide any other data that is requested of CMS. However, we often simply do not have data available at other than the locality level.

Comment: Several commenters are concerned that the data used to develop the latest GPCI update are out of date or inaccurate.

Response: We used the most up-to-date data available for the GPCIs used in the calculation of the proposed options. Descriptions of the data sources we use can be found in previous regulations (69 FR 66261) but we will reiterate them here. For the physician work GPCI, we use data files from the latest decennial census (currently 2000) supplied to CMS by the Census Bureau. These data are available to any individual or group interested in obtaining them from the Census Bureau. Data for the rental portion of the PE GPCI update come from HUD rental files, and these data are available online to anyone wishing to obtain them. Wage data for the PE GPCI come from the 2000 Census files which are available from the Census Bureau. Data for the malpractice GPCI come from premium data that are filed by companies writing Professional Liability Insurance in each state. These filings are provided, upon request by our contractor, to CMS by each State Department of Insurance. Our latest update covers premium data for 2004, 2005 and 2006.

Comment: We received comments from certain physicians in Ohio requesting that we examine Ohio for a possible change in the current Statewide payment locality.

Response: We are currently examining alternatives to the current locality structure. As a part of our study we will revisit Statewide localities to determine if revisions are appropriate.

Comment: We received a number of comments from ambulance suppliers throughout the mid-West requesting that we make no changes that would have a negative impact on the GPCIs in rural areas. Other commenters expressed similar concerns about the impact of locality changes on rural physicians and beneficiaries.

Response: The vulnerability of rural areas to decreases in relative payments as a result of locality revisions is an issue that is of considerable concern to us and something we take very seriously. However, as previously noted we must find an acceptable balance between the multiple competing concerns when making changes in localities in order to best meet the needs of the entire program and this generally cannot be done without having any impact on rural areas.

Comment: MedPAC provided comments outlining two possible mechanisms for developing changes in the payment localities of the States. These methods are similar but differ in that one method begins at the locality level and the other starts with MSA level data. MedPAC also suggests that we determine whether those States that are currently single payment localities wish to remain single payment localities.

Response: As always, we value the input of MedPAC and we intend to analyze their suggested methods carefully as we discuss possible national policy changes.

Comment: Comments regarding changes in the payment localities in California were universally accompanied with a belief that we should implement these changes, without decreasing payments to any counties.

Response: We understand the desire to avoid the negative impact implementing any of these options might have on certain areas. However,

are dedicated to improving the quality of imaging services.

Response: The comment is outside the scope of the proposed rule. Moreover, currently we do not have the statutory authority to restrict payment for these procedures to physicians who possess the training and accreditation recommended by the commenter.

Comment: One commenter urged us to enforce the anti-markup requirements on purchased diagnostic tests by auditing pathology practices and laboratories. The commenter contended that there is widespread ordering of unnecessary tests by pathologists with no regulatory oversight by CMS. The commenter suggested that effective enforcement and application of current anti-markup rules to the pathology community would obviate the need to add new regulations that would limit physician practices from providing quality pathology services to their Medicare patients. The commenter also suggested that we adopt reasonable protocols and standards for the review of Pap smears, among other tests, which, according to the commenter, would significantly reduce unnecessary testing by pathologists and result in tremendous cost savings to the Medicare program.

Response: Our contractors perform pre-pay and post-pay reviews of services, including reviews to determine if the services were reasonable and necessary. However, the extremely large number of claims that contractors must handle each year, as well as the difficulty in sometimes knowing whether services were reasonable and necessary, underscores the need to adopt rules to address the potential for overutilization in other ways, rather than relying solely on reviews for medical necessity. The proposed anti-markup provisions would apply equally to all physicians, including pathologists. However, section 1842(n)(1) of the Act does not authorize the anti-markup on diagnostic tests to apply to clinical laboratory tests, and we did not propose to extend the anti-markup provisions to such tests. We are concerned with preventing the billing supplier from ordering unnecessary tests for profit. Laboratories typically do not order tests, and therefore, there has not been a concern about abuse by laboratories in purchasing diagnostic tests. The comment that we should adopt protocols or standards for the review of Pap smears and other tests is outside the scope of the proposed rule.

Comment: One commenter urged us to prohibit any markup of the TC of surgical pathology specimens and let each physician decide where the TC is performed in addition to where the PC is performed.

Response: Section 414.50 and section 30.2.9 of Pub. 100–04, Chapter 1, CMS Internet-Only Manual, currently prohibit markups of the TC of a diagnostic test if the TC is performed by an outside supplier. As finalized, our revisions to § 414.50 will prohibit the markup of a TC if the TC is ordered by the billing supplier and is either purchased or performed somewhere other than the office of the billing supplier. Physicians are permitted to determine where the TC and PC are performed, provided that the arrangement is in compliance with the purchased test rules and physician self-referral rules.

Comment: One commenter stated that the proposed anti-markup provisions are unfair and would interfere with existing business relationships. The commenter asserted that medical practices should have the freedom to hire in-house professionals or contract with other practices to perform services without fear of financial penalty.

Response: We are not persuaded that our anti-markup proposals, as finalized in this final rule with comment, are unfair. The proposals as finalized are designed to reduce overutilization of diagnostic tests, so that tests are ordered because they are medically necessary and are not ordered because a profit can be made on each test. Practices can maintain relationships with other professionals on a part-time or contractual basis. If the services are furnished in the office of the billing supplier, the anti-markup rules will not apply, unless the services of an independent contractor are billed as a purchased test.

N. Beneficiary Signature for Ambulance Transport Services

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. However, ambulance suppliers and providers have stated that, in emergency situations, it is often 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; (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 is unwilling 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.

As stated in the CY 2008 PFS proposed rule (72 FR 38187), we are sympathetic to the concerns of ambulance providers and suppliers insofar as emergency transport services are involved. Therefore, we proposed to revise § 424.36 to provide 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 (b)(5) [2] was available or willing to sign a claim on behalf of the beneficiary, the ambulance provider or supplier could submit the claim without a beneficiary signature. Under our proposal, 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 (b)(4) 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 (b)(4) 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

[2] We are making a technical change in the final rule. The references in the proposed rule to § 424.36(b)(5) were in error, as individuals are specified only in § 424.36(b)(1) through (b)(4).

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 (b)(4)) prior to submitting claims to Medicare.

We received comments from two national associations that represent providers and suppliers of ambulance services and hospitals. The remainder of the comments came from ambulance owners and employees. The commenters generally agreed that we should eliminate the beneficiary signature requirement entirely when a beneficiary is mentally or physically incapable of signing a claim and no other person authorized to sign a claim on behalf of the beneficiary is available or willing to sign at the time of transport. In addition, the commenters argued that the proposed documentation requirements would be costly and burdensome to ambulance providers and suppliers.

We are adopting our proposal, with modification. Specifically, we are allowing a secondary form of verification to be used in lieu of the proposed signed contemporaneous statement from a representative of the facility that received the beneficiary (which remains an alternative). We are also amending § 424.32(a) to clarify that the beneficiary signature requirement is satisfied if one of the exceptions in § 424.36 is satisfied. Finally, we are making a technical change to our proposal. In the proposed rule, we stated that ambulance providers and suppliers could utilize proposed § 424.36(b)(6) if none of the individuals listed in § 424.36(b)(1) through (b)(5) were available or willing to sign the claim on behalf of the beneficiary at the time the service was provided. The references to § 424.36(b)(5) were in error, as individuals are specified only in § 424.36(b)(1) through (b)(4).

Comment: The majority of the commenters opposed our proposed changes to the beneficiary signature requirements in § 424.36. The commenters stated that the proposed changes would have the unintended effect of increasing the administrative and compliance burden on providers and suppliers of ambulance services and on the hospitals.

Response: The proposal would not have imposed any additional burdens on providers and suppliers of ambulance services. Rather, the proposal, which we are adopting with some modification, set forth an alternate method of satisfying the beneficiary signature requirement for claims submitted for emergency ambulance services. Those ambulance providers and suppliers that believe that it is burdensome to comply with new § 424.36(b)(6), may avail themselves of the other means specified in § 424.36 for satisfying the beneficiary signature requirement.

Comment: Commenters asserted that when a beneficiary is physically or mentally incapable of signing a claim, the ambulance industry has already been signing claims on behalf of such beneficiaries in accordance with the requirements listed in the CMS Internet-Only Manual (IOM), Pub. 100–02, Medicare Benefit Policy Manual, Chapter 10, Section 20.1.2 and IOM, Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 50.1.6(A)(3)(c), without any objections from CMS contractors. The commenters stated that the ambulance industry has also been relying on § 424.36(b)(5) as further authority to sign claims on behalf of beneficiaries when beneficiaries are incapable of signing and the requirements of § 424.36(b)(1) through (b)(4) have not been met.

Response: Section 424.36(b)(5) applies only if the beneficiary is physically or mentally incapable of signing the claim and none of the persons listed in § 424.36(b)(1) through (b)(4) is available to sign the claim. Note that we interpret § 424.36(b), including § 424.36(b)(5), as meaning that neither the beneficiary nor any of the persons listed in § 424.36(b)(1) through (b)(4) is available at all, not just that none of them is available at the time the service is performed. Thus, even assuming that § 424.36(b)(5) applies to ambulance providers (and we believe that this subparagraph was intended to apply only to institutional providers such as a hospital), an ambulance provider would not be allowed to rely on § 424.36(b)(5) to sign a claim for ambulance services simply because the beneficiary was incapable of signing the claim at the time of delivery to the hospital or ESRD facility and none of the persons listed in § 424.36(b)(1) through (b)(4) was available and willing to sign the claim for ambulance services at the time of delivery. Instead, the provider would be required, in advance of submitting the claim, to make reasonable efforts to locate and obtain a signature from the beneficiary or, if the beneficiary is not capable of signing, one of the alternative individuals specified in § 424.36(b)(1) through (b)(4). It would make little sense to specify different categories of individuals in § 424.36(b)(1) through (b)(4) who could sign a claim on behalf of a beneficiary who is unable to sign, if a provider was allowed to file a claim without making an effort to obtain a signature from one of the other authorized individuals. To the extent that ambulance *suppliers* have been relying on § 424.36(b)(5) under any circumstances, such suppliers have been failing to follow the regulations, as this subparagraph does not pertain to suppliers. We are clarifying § 424.36(b)(5) to provide that, before a provider may avail itself of the exception in § 424.36(b)(5), it must make reasonable efforts (including over a reasonable period of time) to have either the beneficiary or one of the individuals specified in § 424.36(b)(1) through (b)(4) to sign the claim. Similarly, the sections of the CMS IOM cited by the commenters, Pub. 100–02, Chapter 10, section 20.1.2 and Pub. 100–04, Chapter 1, section 50.1.6(A)(3)(c) imply that reasonable efforts must be made to locate other individuals prior to submitting the claim. We plan to issue clarifying instructions in the near future, to ensure that our regulations and manual instructions on the beneficiary signature requirement are fully consistent with each other.

In contrast, the proposal, as adopted with modification, allows ambulance providers and suppliers, in the case of emergency transport, to sign the claim, if certain documentation requirements are met, where the beneficiary is not capable of signing the claim *at the time of transport*.

Comment: Most of the commenters agreed that some of our proposed documentation requirements are already being followed by ambulance providers and suppliers. However, they strongly objected to proposed § 424.36(b)(6)(ii)(C), which would have required a signed contemporaneous statement from a representative of the facility that received the beneficiary, documenting the name of the beneficiary, and the date and time the beneficiary was received by that facility. The commenters asserted that it is not practical or feasible to obtain a signed contemporaneous statement from a representative of the receiving facility documenting the name of the beneficiary and the date and time the beneficiary was received by that facility. The commenters stated that hospital personnel in emergency departments often are either too busy or refuse to sign any forms when receiving a patient. In addition, the commenters contended that attempting to obtain a signature from a representative of the hospital would decrease the amount of time available for ambulances to serve their respective communities. Therefore, the commenters recommended that CMS modify the proposed beneficiary

signature requirements for ambulance services in § 424.36(b)(6) to include only proposed subsection § 424.36(b)(6)(i). One commenter stated that a signature from hospital staff does not add any more credibility to the ambulance provider or supplier's claim that the patient was unable to sign the claim than what is already present from the EMT's attestation that the patient was unable to sign.

Response: We are not persuaded to modify the proposed alternative to the beneficiary signature requirement in § 424.36(b)(6) to include only § 424.36(b)(6)(i). The purpose of the proposed requirement to secure a signed contemporaneous statement from a representative of the facility that received the beneficiary, as a means of satisfying the alternative, was to ensure that someone other than an ambulance employee verifies the transport and receipt of the beneficiary; the purpose was not to obtain verification that the beneficiary was unable to sign the claim. We continue to believe that in many, if not most, cases the ambulance transport personnel will have no difficulty in securing a signature from personnel at the hospital or other facility that acknowledges receipt of the patient. Indeed, it is our understanding that, as protection from liability or for other purposes, some ambulance providers and suppliers routinely secure a signature from the receiving facility in order to document that the patient was transported. We note that our proposal would not have required the hospital or other receiving facility to do anything more than acknowledge receipt through a signature. That is, the ambulance provider or supplier could add a signature block and an attestation clause, acknowledging receipt, to its trip ticket or other form that would already contain the necessary patient information (that is, the beneficiary's name and the date and time of delivery). However, after further consideration, we are revising § 424.36(b)(6)(ii)(C) to provide an alternative to the requirement under § 424.36(b)(6) that ambulance providers or suppliers must obtain 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. The final rule allows the ambulance provider or supplier to meet the condition specified in § 424.36(b)(6) by obtaining a secondary form of verification, prior to submitting the claim for payment. Secondary methods of verification may include the patient care or trip report, the patient medical record, the hospital registration/admissions sheet, the hospital log, or other internal hospital or facility records. Regardless of its specific form, the documentation must be from the receiving facility must indicate that the beneficiary in question was transported to the facility by the ambulance provider or supplier that is submitting the claim, and must be signed by a representative of the facility.

Comment: One commenter stated that the proposal was fair and correct, would not create a heavy burden on the service provider and can be accomplished in a timely manner. A signed contemporaneous statement used on a limited basis and tightly controlled so that it will not become a routine event should help compliance in this area. A clear and standardized format for the contemporaneous statement should be issued to allow for proper compliance with the new rule.

Response: We understand the commenter as supporting our proposal and as saying that ambulance providers and suppliers should not be entitled to routinely rely on proposed § 424.36(b)(6), but rather should be able to rely on this exception only when the beneficiary is, in fact, unable to sign the claim, and only when the proposed documentation requirements have been satisfied. We agree that in most cases an ambulance provider or supplier should not have difficulty in obtaining a signature from the hospital or other facility that acknowledges receipt of the beneficiary; however, we are modifying the proposal to provide for an alternate method of documenting that the beneficiary was transported to the facility. We do not believe that it is necessary to prescribe a specific form for ambulance providers and suppliers to use as a contemporaneous statement to document the transport of the beneficiary, but instead are allowing ambulance providers and suppliers to use existing forms of their own, or, where necessary, to modify their forms to comply with the requirements of the new § 424.36(b)(6)(ii). We again emphasize that ambulance providers and suppliers that do not wish to take advantage of the new exception in § 424.36(b)(6) to the beneficiary signature requirement, may instead obtain the beneficiary's signature prior to submitting the claim, satisfy one of the exceptions in § 424.36(b)(1) through (b)(5), or, where appropriate, bill the beneficiary.

Comment: Several commenters recommended that we eliminate the beneficiary signature requirement entirely. They believe that the requirement is not necessary because, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report that described the condition of the beneficiary, treatment, origin/destination, etc. Also, the origin and destination facilities complete their own records, which document that the beneficiary was sent or received. Commenters stated that if it becomes necessary to audit claims, CMS can obtain information from the transporting and receiving facilities in order to establish that the beneficiary was, in fact, transported as claimed by the ambulance provider or supplier.

Response: We proposed an alternative, optional method of fulfilling the beneficiary signature requirement for claims for emergency transport services. We did not propose to eliminate the signature requirement and are not prepared to do so at this time. The beneficiary signature requirements help ensure that services were in fact rendered and were rendered as billed. Although we agree that documentation obtained from the transporting and (particularly) from the receiving facility may help to alleviate any concern whether services were furnished or were furnished as claimed, we do not believe that it is our responsibility to attempt to locate such documentation should claims be called into question (and it is also uncertain whether we would have the right to compel the transporting or receiving facility to provide us with such documentation). Therefore, to the extent that an ambulance provider or supplier wishes to use third-party documentation to demonstrate that a beneficiary was transported as claimed, instead of having the beneficiary sign the claim or meeting one of the exceptions in § 424.36(b)(1) through (b)(4), it must follow the procedures in new § 424.36(b)(6).

Comment: Most of the commenters questioned the need for the beneficiary signature, because they asserted that the beneficiary signature is no longer necessary given that it is not required for the assignment of benefits or the authorization of records release to CMS or its contractors. In addition, the commenters stated that almost every covered ambulance transport is to or from a facility (that is, a hospital or skilled nursing facility) where a valid signature is already on file. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services, or any related services. The commenters believe that ambulance transport to a facility, for purposes of receiving treatment at that facility, constitutes a

''related service,'' because the ambulance transports the patient to or from that facility for treatment or admission. Commenters also noted that, with respect to beneficiaries who are eligible both for Medicare and Medicaid, a signature is already on file with the State Medicaid office. Therefore, they argued that duplicating the requirement for a signature is costly and burdensome on ambulance service providers.

Response: The purpose of the assignment of benefits signature is different than the purpose of the beneficiary signature to file a claim. As stated above, the purpose of the beneficiary signature to file a claim is to ensure that services were furnished and were furnished as billed. Although the assignment of benefits signature is not required for services billed on mandatory assignment, the beneficiary signature is still required for submitting a claim to Medicare.

A beneficiary's signature on file at a hospital or a skilled nursing facility does not indicate that an ambulance provider or supplier was authorized to submit a claim for transport services on behalf of the beneficiary or that transport services in fact were furnished. Rather, the signature on file at a facility is used for claims filed by that facility for treatment the facility furnished to the beneficiary. Similarly, the fact that a beneficiary's signature may be on file with a State Medicaid office (or elsewhere) does not in any way speak to the issue of whether the ambulance provider or supplier was authorized to submit a claim for transport services on behalf of the beneficiary or that transport services in fact were furnished.

Comment: A commenter stated that when submitting claims electronically, a provider or supplier must answer ''Y'' or ''N'' for the question of whether the provider or supplier has obtained a beneficiary signature. The commenter suggested that we should add language to the regulations to indicate that the beneficiary signature requirement will be met if one of the exceptions to the requirement is met.

Response: We agree that it is proper and accurate to answer ''Y'' (for yes) to the question in the case where the beneficiary has not signed the claim but one of the alternatives in § 424.36(b) through § 424.36(e) has been satisfied. We are clarifying § 424.32(a)(3) (basic requirements of all claims) accordingly.

Comment: Many commenters stated that the proposal would encourage ambulance providers and suppliers to seek signatures from patients who are in need of medical care and under mental duress. They stated that beneficiaries under duress should not be required to sign anything.

Response: We agree that beneficiaries under duress should not be required to sign claims; in fact, we consider a beneficiary signature obtained under duress to be invalid. We do not agree, however, that our proposal encouraged ambulance providers and suppliers to obtain beneficiary signatures under duress. As stated above, the proposal was intended to provide ambulance providers and suppliers with another alternative to obtaining the beneficiary's signature. It was not, and the final rule is not, a narrowing of the available alternatives to ambulance providers and suppliers. Moreover, the commenters appear to assume that if ambulance providers and suppliers are to obtain a beneficiary's signature, they must do so at the time of transport. However, ambulance providers and suppliers have always been able to obtain the beneficiary's signature (or the signature of one of the persons specified in § 424.36(b)(1) through (b)(4)) at any time prior to submitting the claim. In fact, as noted above, before providers may avail themselves of the exception in § 424.36(b)(5), they are required to make reasonable efforts to have the beneficiary or one of the persons specified in § 424.36(b)(1) through (b)(4) sign the claim. With this final rule, ambulance providers and suppliers, in the case of emergency transport services, may submit the claim without making such reasonable efforts if they satisfy the documentation requirements of new § 424.36(b)(6).

O. Update to Fee Schedules for Class III Durable Medical Equipment (DME) for CYs 2007 and 2008

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. See the CY 2008 PFS proposed rule (72 FR 38188) for a specific explanation of the three regulatory classifications of devices.

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 et seq.) cannot be included in the competitive acquisition programs. As part of the transition to competitive acquisition, the Congress mandated in sections 1834(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)).[3] Specifically, for 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

[3] Section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act has been codified as 21 U.S.C. 360c(a)(1)(C). Accordingly, we believe that the references to 21 U.S.C. 360(c)(1)(C) in sections 1834(a)(14)(G)(i), (H)(i), and (I)(i) of the Act are scrivener's errors.

reflect the variation in practice costs from area to area.

III. Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; Ambulatory Inflation Factor Update for CY 2007

As discussed in the CY 2008 PFS proposed rule (72 FR 38207), 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).
- Advanced Life Support, Level 2 (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. In the CY 2008 PFS proposed rule, we stated the AIF for CY 2008 would be announced as part of this final rule with comment period. For CY 2008, the percentage is 2.7 percent. In addition, as set forth in Section III.D., we also proposed to announce the AIF for CY 2009 and subsequent years via CMS instruction and on the CMS Web site.

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

Currently, § 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. As explained in the CY 2008 PFS proposed rule, 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.

As discussed in the proposed rule, 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, § 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 to implement the proper payment for Medicare ambulance claims by January 1 of the coming year. 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 systems 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 proposed 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**.

Comment: Comments received regarding the issue of announcing the AIF via CMS instruction and on the CMS Web site were very supportive of this proposal.

Response: As we proposed, we are revising § 414.620 to state that CMS 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. Refinement of RVUs for CY 2008 and Response to Public Comments on Interim RVUs for 2007

[If you choose to comment on issues in this section, please include the caption ''Interim Relative Value Units'' at the beginning of your comments.]

A. Summary of Issues Discussed Related to the Adjustment of Relative Value Units

Section IV.B. and IV.C. of this final rule with comment describes the methodology used to review the comments received on the RVUs for physician work, including the additional codes from the 5-Year Review of work RVUs, and the process used to establish RVUs for new and revised CPT codes. Changes to the RVUs and billing status codes reflected in Addendum B are effective for services furnished beginning January 1, 2008.

B. Process for Establishing Work Relative Value Units for the Physician Fee Schedule

The CY 2007 PFS final rule with comment period (71 FR 69624) contained the work RVUs for Medicare payment for existing procedure codes under the PFS and interim RVUs for new and revised codes beginning January 1, 2007. We considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. In the CY 2008 PFS proposed rule we also proposed work RVUs for additional codes from the 5-Year Review of work RVUs. In this section, we address comments and summarize the refinements to the additional codes from the 5-Year Review of work RVUs, the interim work RVUs published in the CY 2007 PFS final rule with comment period, and our establishment of the work RVUs for new and revised codes for the CY 2008 PFS.

C. 5-Year Review of Work RVUS

1. Additional Codes From the 5-Year Review of Work RVUs

The CY 2008 PFS proposed rule (72 FR 38146) discussed the RUC recommendations on work RVUs for a number of codes from the 5-Year Review that were deferred from the CY 2007 PFS rulemaking and listed the specific codes in Table 10. We proposed to accept all of the RUC recommendations, with the exception of CPT code 93325, *Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography),* which we proposed to bundle. We also noted that CPT codes 92557, 92567, 92568, 92569, 92579, 92601, 92602, 92603 and 92604 previously had no work RVUs assigned to them.

Many commenters expressed support for our proposed valuations of many of the services. However, other commenters expressed specific concern or disagreement with the proposed valuation of approximately 17 codes.

To evaluate these comments, we used a process similar to the process used since 1997. (See the CY 1998 PFS final rule published in the October 31, 1997 **Federal Register** (62 FR 59084) for the discussion of refinement of CPT codes with interim work RVUs.) We convened a multi specialty panel of physicians to assist us in the review of the comments. The comments that we did not submit to panel review are discussed at the end of this section, as well as those that were reviewed by the panel, which are contained in Table 14: Work RVU Revisions for Additional 5-Year Review Codes. We invited representatives from the organizations from which we received substantive comments to attend a panel for discussion of the code on which they had commented. The panel was moderated by our medical staff, and consisted of the following voting members:

- Clinicians representing the commenting specialty(ies), based on our determination of those specialties which are most identified with the services in question. Although commenting specialties were welcomed to observe the entire refinement process, they were only involved in the discussion of those services for which they were invited to participate.
- Primary care clinicians nominated by the AAFP and the American College of Physicians.
- Carrier Medical Directors.
- Clinicians who practice in related specialties and have knowledge of the services under review.

The panel discussed the work involved in the procedure under review in comparison to the work associated with other services under the PFS. We assembled a set of reference services and asked the panel members to compare the clinical aspects of the work for the service a commenter believed was incorrectly valued to one or more of the reference services. In compiling the reference set, we attempted to include: (1) Services that are commonly furnished for which work RVUs are not controversial; (2) services that span the entire spectrum of work intensity from the easiest to the most difficult; and (3) at least three services furnished by each of the major specialties so that each specialty would be represented. The intent of the panel process was to capture each participant's independent judgment based on the discussion and his or her clinical experience. Following the discussion for each service, each participant rated the work for that procedure. Ratings were individual and confidential; there was no attempt to achieve consensus among the panel members.

We then analyzed the ratings based on a presumption that the interim RVUs were correct. To overcome that presumption, the inaccuracy of the interim RVUs had to be apparent to the broad range of physicians participating in each panel.

Ratings of work were analyzed for consistency among the groups represented on each panel. In general terms, we used statistical tests to determine whether there was enough agreement among the groups on the panel and, if so, whether the agreed-upon work RVUs were significantly different from the proposed work RVUs

TABLE 36.—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD

Facility fee	MEI increase (percent)	Period
$20.00	N/A	10/01/2001–12/31/2002
$20.60	3.0	01/01/2003–12/31/2003
$21.20	2.9	01/01/2004–12/31/2004
$21.86	3.1	01/01/2005–12/31/2005
$22.47	2.8	01/01/2006–12/31/2006
$22.94	2.1	01/01/2007–12/31/2007
$23.35	1.8	01/01/2008–12/31/2008

X. Provisions of the Final Rule

The provisions of this final rule with comment restate the provisions of the CY 2008 PFS proposed rule, except as noted elsewhere in the preamble.

XI. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national drug coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services and procedures.

The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for CMS to provide prior notice and solicit comment on these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. We also assign interim RVUs to any new codes based on a review of the RUC recommendations for valuing these services. By reviewing these RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with providing the services. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each carrier establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes.

For the reasons outlined above in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

In addition, we ordinarily publish a notice of proposed rulemaking in the **Federal Register** and provide a period for public comment before we make final the provisions of the notice. We can waive this procedure, however, if we find good cause that notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and we incorporate a statement of finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in this instance for the ambulance inflation factor because the law specifies the method of computation of annual updates, and we have no discretion in this matter. Further, we are merely applying the update method specified in statute and regulation. Therefore, under 5 U.S.C. 553(b)(B), for good cause, we waive notice and comment procedures for this ambulance inflation factor update.

XII. 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. In order 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.

This final rule with comment period does not contain any new information collection requirements. However, we are republishing the discussion of the information collection requirements as it appeared in the CY 2008 PFS

proposed rule (72 FR 38122). We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Independent Diagnostic Testing Facility (§ 410.33)

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, changes of location, changes in 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 they must have a comprehensive insurance policy to 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 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) and is not subject to the PRA.

Basis of Payment (§ 414.707)

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.

Term of Contract (§ 414.914)

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) states 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)(1–2) 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.

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

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 provide an annual opportunity to request changes to the list of compendia. As stated in § 414.930(c)(1), CMS 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.

The burden associated with the requirements contained in § 414.930(b) through (c) is the time and effort required to draft and submit to CMS a complete written request for changes to the list of compendia. 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 only 6 compendia that could reasonably be expected to be the subject of a request, so 6 requests is a likely maximum.

Signature Requirements (§ 424.36)

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 parties 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 parties 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 9,000 ambulance providers or suppliers will comply with these requirements. We estimate that it will take no more than five 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 five 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 of 2007, and thus does not include the number of emergency ambulance transport services billed to fiscal intermediaries by ambulance providers (which 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 final rule with comment period imposes collection of information requirements as outlined in the regulation text and specified above. However, this final rule with comment period 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 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.d 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.f of the preamble discusses details of the competitive acquisition program. 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.g. 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 60 days of his or her participation if he or she can show that CAP participation imposes a burden on the practice, or later if he or she can show that a change in circumstances that was not known to the practice previously results in a burden to the practice. 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 cases basis.

If the designated carrier receives an exigent circumstance removal request related to the approved CAP vendor's service, it is required to refer the physician to his or her approved CAP vendor within 1 business day of its receipt of the request. As part of the grievance process, the CAP vendor will try to work with the physician to address their concerns with respect to participation in the program. The designated carrier can alternatively continue to investigate, and within 2

TABLE 41.—IMPACT OF CY 2008 CHANGES IN PAYMENTS TO HOSPITAL BASED AND INDEPENDENT ESRD FACILITIES—Continued

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

	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]
5000 to 9999 treatments	1,800	13.0	0.0	0.0	0.5
Greater than 9999 treatments	1,210	17.7	0.0	0.1	0.6
Type of Ownership					
Profit	3,745	28.9	0.0	−0.1	0.4
Nonprofit	915	6.5	0.0	0.3	0.9
By Geographic Location					
Rural	1,261	7.3	−0.4	−0.6	0.0
Urban	3,399	28.1	0.1	0.1	0.7
By Region					
New England	141	1.1	0.1	1.4	2.0
Middle Atlantic	553	4.5	0.1	0.5	1.0
East North Central	727	5.7	0.1	−0.6	−0.1
West North Central	358	1.9	0.1	−0.3	0.3
South Atlantic	1,063	8.1	0.0	0.0	0.6
East South Central	365	2.6	−0.5	−1.4	−0.8
West South Central	646	5.0	−0.1	−0.7	−0.2
Mountain	254	1.6	0.1	0.3	0.8
Pacific	523	4.4	0.1	1.4	2.0
Puerto Rico	30	0.4	−2.1	−3.0	−2.5

[1] This column shows the effect of the wage index floor changes on ESRD providers. 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.

[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% drug add-on times treatments The CY 2007 payments to ESRD facilities includes the CY 2007 wage adjusted composite rate and the 14.9% drug add-on times treatments.

G. IDTF Changes

We believe that our provisions regarding IDTFs as discussed in section II.I. of this final rule with comment period 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 IDTF provisions contained in this final 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 changes related to the compendia discussed in section II.L. of this final rule with comment period will have a negligible cost to the Medicare program. The 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 provisions in section II.M. of this final rule with comment period for the reassignment and anti-markup provisions, and the physician self-referral provisions will 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 provision in section II.N. of this final rule with comment period 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 final rule with comment period, we discuss the 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 establishment of an update for 2007 of zero percent for class III devices, rather than 4.3 percent based on the CPI–U, this results 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.R.2., we are changing the certification requirement for 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. As we stated in the proposed rule, analysis of Medicare claims data shows negative or no impact for this change and this was also supported by commenters. 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.

We will 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 section II.S.1. of this rule, the final 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, measures that the Secretary proposes as appropriate for eligible professionals to use to submit data to the Secretary in 2008. We also expect to address registry- and EHR-based data submission on a test basis in 2008, as discussed in section II.T.1. of this rule. Although there may be some cost incurred for maintaining the measures and their associated code sets, and for enhancing an existing clinical data warehouse to accommodate the registry- and EHR-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.S.5. of this final rule with comment period, 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 physicians' services furnished during 2008. As discussed in section II.S.5. of this final rule with comment period, we will scale aggregate payments to physicians in a manner such that Medicare would pay $1.35 billion during CY 2009 for measures reported for services furnished during CY 2008. We are unable to provide an exact percentage for the bonus payment, but 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 would exceed 2 percent). We also note that the Transitional Medical Assistance, Abstinence Education, and Qualifying Individual Programs Extension Act of 2007 (Pub. L. 110–90) provided an additional $325 million to be used as a part of the PAQI Fund for payment with regard to services furnished in 2009 and $60,000,000 for payment with respect to physicians' services furnished on or after January 1, 2013.

P. TRHCA 110 Reporting of Anemia Quality Indicators

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

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

The amendment of the exemption for computer-generated fax transactions under Medicare Part D is discussed in section II.R.3. of this rule. E-prescribing is voluntary for providers and pharmacies. This amendment only affects 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 amendment 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. We also will continue to allow computer-generated faxes as a fallback in cases of temporary/transient transmission failures and communications problems.

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.

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

For the purposes of the RFA, ambulance providers and suppliers are considered to be small entities. Removing the requirement that the AIF be published annually via **Federal Register** notice 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.

We estimate that the total program expenditure for CY 2007 for ambulance services covered by the Medicare program is approximately $5.2 billion. Application of an AIF of 2.7 percent will result in an additional total program expenditure for CY 2008 of approximately $140 million over CY 2007 expenditures.

S. Alternatives Considered

This final rule with comment period 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 final rule with comment period 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 furnished to Medicare beneficiaries.

We do not believe that beneficiaries will experience drug access issues as a result of the 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 40, 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 final rule with comment period, the 2008 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 40, is $81.42 which means that, in 2008, the beneficiary coinsurance for this service would be $16.28.

Policies discussed in this rule that do affect overall spending, such as the 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 42, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule with comment period. This estimate includes the incurred benefit impact associated with the estimated CY 2008 PFS update, shown in this final rule with comment period, based on the 2007 Trustees Report baseline. All estimated impacts are classified as transfers.

TABLE 42.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR CY 2008

[In billions]

Category	Transfers
Annualized Monetized Transfers.	−$6.0.
From Whom To Whom?	Federal Government to 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.

In accordance with the provisions of Executive Order 12866, this final rule with comment period 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.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 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. Section 409.17 is added to read as follows:

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

(a) *General rules.* (1) Except as specified in paragraph (a)(1)(ii) of this section, physical therapy, occupational

(3) Considering reconsideration requests and other 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 reconsideration requests in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii)(A) A requestor that submitted a request under paragraph (b)(1)(i) of this section may also present its reconsideration request at the public meeting convened under § 414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (b)(1)(i) of this section.

(B) If a requestor presents its reconsideration request at the public meeting convened under § 414.506(c), members of public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(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 the interim carrier-specific amounts.

(iii) After considering the public comments, CMS will post final carrier-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final carrier-specific amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final payment amounts and the appropriate national limitation amount for the new test.

(v) Considering reconsideration requests 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.

■ 28. 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]

■ 29. 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

■ 30. 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.* The following provisions are effective January 1, 2008:

(1) 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;

(2) Each request for payment for use of erythropoiesis stimulating agents must report the beneficiary's most recent hemoglobin or hematocrit level.

Subpart K—Payment for Drugs and Biologicals Under Part B

■ 31. 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 CY 2005, 2006, 2007 or 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.

* * * * *

■ 32. Section 414.908 is amended by—

■ A. Revising paragraphs (a)(2)(iv), (a)(3)(x), and (a)(3)(xi).

■ B. Adding paragraph (a)(2)(v).

■ C. Removing paragraph (a)(5).

The revisions and addition read as follows:

§ 414.908 Competitive acquisition program.

(a) * * *

(2) * * *

(iv) The approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(i) have been met (if this subparagraph (a)(2)(iv) applies, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor); or

(v) Other exigent circumstances defined by CMS are present, including—

(A) If, up to and including 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement

§ 424.32 Basic requirements for all claims.

(a) * * *

(3) A claim must be signed by the beneficiary or on behalf of the beneficiary (in accordance with § 424.36).

* * * * * *

Subpart C—Claims for Payment

■ 49. Section 424.36 is amended by—

■ A. Revising paragraph (b)(5).

■ B. Adding paragraph (b)(6).

The revision and addition read as follows:

§ 424.36 Signature requirements.

* * * * * *

(b) * * *

(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b)(1), (2), (3), or (4) of this section after making reasonable efforts to locate and obtain the signature of one of the individuals specified in paragraph (b)(1), (2), (3), or (4) of this section.

(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 paragraph (b)(1), (2), (3), or (4) 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 four 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 paragraph (b)(1), (2), (3), or (4) of this section were available or willing to sign the claim on behalf of the beneficiary, and

(B) Documentation with the date and time the beneficiary was transported, and the name and location of the facility that received the beneficiary, and

(C) Either of the following:

(*1*) 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; or

(*2*) The requested information from a representative of the facility using a secondary form of verification obtained at a later date, but prior to submitting the claim to Medicare for payment. Secondary forms of verification include a copy of any of the following—

(*i*) The signed patient care/trip report;

(*ii*) The hospital registration/admissions sheet;

(*iii*) The patient medical record;

(*iv*) The hospital log; or

(*v*) Other internal hospital records.

* * * * * *

Subpart F—Limitations on Assignment and Reassignment of Claims

■ 50. 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 a diagnostic test.* If a physician or other supplier 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, the amount payable to the billing physician or other supplier may be subject to the limits specified in § 414.50 of this chapter.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 51. 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).

■ 52. 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) Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of this chapter.

(b) *Standard: Delivery of services.* 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. The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of § 409.17

PART 484—HOME HEALTH SERVICES

■ 53. 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

■ 54. 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—

(a)(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(2) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(3) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(2) When licensure or other regulation does not apply—

(i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and