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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.

Rochel 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.

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- Acronyms**
- In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:
- AAA Abdominal aortic aneurysm
 AAP Average acquisition price
 ACOTE Accreditation Council for Occupational Therapy Education
 ACR American College of Radiology
 AFROC Association of Freestanding Radiation Oncology Centers
 AHFS—DI American Hospital Formulary Service—Drug Information
 AHRQ Agency for Healthcare Research and Quality (HHS)
- AIF Ambulance inflation factor**
- AMA American Medical Association
 AMA—DE American Medical Association Drug Evaluations
 AMP Average manufacturer price
 AOTA American Occupational Therapy Association
 APC Ambulatory payment classification
 APTA American Physical Therapy Association
 ASA American Society of Anesthesiologists
 ASC Ambulatory surgical center
 ASP Average sales price
 ASTRO American Society for Therapeutic Radiology and Oncology
 ATA American Telemedicine Association
 AWP Average wholesale price
 BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
 BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
 BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000
 BLS Bureau of Labor Statistics
 BMD Bone mineral density
 BMI Body mass index
 BMM Bone mass measurement
 BN Budget neutrality
 BSA Body surface area
 CAD Computer aided detection
 CAH Critical access hospital
 CAP Competitive acquisition program
 CBSA Core-Based Statistical Area
 CEM Cardiac event monitoring
 CF Conversion factor
 CFR Code of Federal Regulations
 CMA California Medical Association
 CMS Centers for Medicare & Medicaid Services
 CNS Clinical nurse specialist
 CORF Comprehensive Outpatient Rehabilitation Facility
 COTA Certified Occupational Therapy Assistant
 CPEP Clinical Practice Expert Panel
 CPI Consumer Price Index
 CPI—U Consumer price index for urban customers
 CPT (Physicians') Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)
 CRT—D Cardiac resynchronization therapy defibrillator
 CT Computed tomography
 CTA Computed tomographic angiography
 CY Calendar year
 DEXA Dual energy x-ray absorptiometry
 DHS Designated health services
 DME Durable medical equipment
 DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
 DO Doctor of Osteopathy
 DRA Deficit Reduction Act of 2005 (Pub. L. 109–432)
 E/M Evaluation and management
 ECI Employment cost index
 EHR Electronic health record
 EPC [Duke] Evidence-based Practice Centers
 EPO Erythropoietin
 ESRD End stage renal disease
 F&C Facts and Comparisons
 FAW Furnish as written

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

(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