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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 409, et al.

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 409, 410, 411, 413, 414, 415, 423, 424, 485, 486, and 489

[CMS–1403–FC] [CMS–1270–F2]

RINs 0938–AP18, 0938–AN14

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period implements changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also finalizes the calendar year (CY) 2008 interim relative value units (RVUs) and issues interim RVUs for new and revised codes for CY 2009. In addition, as required by the statute, it announces that the physician fee schedule update is 1.1 percent for CY 2009, the preliminary estimate for the sustainable growth rate for CY 2009 is 7.4 percent, and the conversion factor (CF) for CY 2009 is $36.0666. This final rule with comment period also implements or discusses certain provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). (See the Table of Contents for a listing of the specific issues addressed in this rule.)

DATES: *Effective Date:* This final rule with comment period is effective on January 1, 2009 except for amendments to § 410.62 and § 411.351 which are effective July 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 29, 2008.

ADDRESSES: In commenting, please refer to file code CMS–1403–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1403–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1403–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 either of the following addresses:

7500 Security Boulevard, Baltimore, MD 21244–1850; or

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(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.

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

Stephanie Monroe, (410) 786–6864, for issues related to malpractice RVUs.

Esther Markowitz, (410) 786–4595, for issues related to telehealth services.

Craig Dobyski, (410) 786–4584, for issues related to geographic practice cost indices.

Ken Marsalek, (410) 786–4502, for issues related to the multiple procedure payment reduction for diagnostic imaging.

Catherine Jansto, (410) 786–7762, or Cheryl Gilbreath, (410) 786–5919, for issues related to payment for covered outpatient drugs and biologicals.

Edmund Kasaitis, (410) 786–0477, or Bonny Dahm, (410) 786–4006, for issues related to the Competitive Acquisition Program (CAP) for Part B drugs.

Corinne Axelrod, (410) 786–5620, for issues related to Health Professional Shortage Area Bonus Payments.

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

Lisa Grabert, (410) 786–6827, for issues related to hospital-acquired conditions and the Physician Resource Use Feedback Program.

August Nemec, (410) 786–0612, for issues related to independent diagnostic testing facilities; enrollment issues; and the revision to the ''Appeals of CMS or CMS contractor Determinations When a Provider or Supplier Fails To Meet the Requirements for Medicare Billing Privileges'' final rule.

Lisa Ohrin, (410) 786–4565, Kristin Bohl, (410) 786–8680, or Don Romano, (410) 786–1401, for issues related to anti-markup provisions and physician self-referral (incentive payment and shared savings programs).

Diane Stern, (410) 786–1133, for issues related to the quality reporting system for physician payment for CY 2009.

Andrew Morgan, (410) 786–2543, for issues related to the e-prescribing exemption for computer-generated fax transmissions.

Terri Harris, (410) 786–6830, for issues related to payment for comprehensive outpatient rehabilitation facilities (CORFs).

Lauren Oviatt, (410) 786–4683, for issues related to CORF conditions of coverage.

Trisha Brooks, (410) 786–4561, for issues related to personnel standards for portable x-ray suppliers.

David Walczak, (410) 786–4475, for issues related to beneficiary signature for nonemergency ambulance transport services.

Jean Stiller, (410) 786–0708, for issues related to the prohibition concerning providers of sleep tests

Mark Horney, (410) 786–4554, for issues related to the solicitation for comments and data pertaining to physician organ retrieval services.

Regina Walker-Wren, (410) 786–9160, for information concerning educational

requirements for nurse practitioners and clinical nurse specialists.

Randy Throndset, (410) 786–0131, for information concerning physician certification and recertification for Medicare home health services.

William Larson, (410) 786–4639, for coverage issues related to the initial preventive physical examination.

Cathleen Scally, (410) 786–5714, for payment issues related to the initial preventive physical examination.

Dorothy Shannon, (410) 786–3396, for issues related to speech language pathology.

Kendra Hedgebeth, (410) 786–4644, or Gina Longus, (410) 786–1287, for issues related to low vision aids.

Christopher Molling, (410) 786–6399, or Anita Greenberg, (410) 786–4601, for issues related to the repeal to transfer of title for oxygen equipment.

Karen Jacobs, (410) 786–2173, or Hafsa Bora, (410) 786–7899, for issues related to the therapeutic shoes 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:

- The Exception for Incentive Payment and Shared Savings Programs (§ 411.357(x)) in section II.N.1. of this final rule with comment period;
- Sections 131(c), 144(b), and 149 of the MIPPA as described in sections III.C., III.J., and III.M. of this final rule with comment period.
- Interim Relative Value Units (RVUs) for selected codes identified in Addendum C;
- Information on pricing for items in Tables 2 through 5;
- Issues related to the Physician Resource Use Feedback Program described in section II.S.6. of this final rule with comment period; and
- The physician self-referral designated health services (DHS) codes listed in Tables 29, 30, and 31. You can assist us by referencing the file code [CMS–1403–FC] and the section heading 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.regulations.gov.* Follow the search instructions 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.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a 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* (CFR). Information on the regulation's impact appears throughout the preamble, and therefore, is not exclusively in section XVI. of this final rule with comment period.

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:

ACC American College of Cardiology
ACR American College of Radiology
AFROC Association of Freestanding Radiation Oncology Centers
AHA American Heart Association
AHRQ [HHS] Agency for Healthcare Research and Quality
AIDS Acquired immune deficiency syndrome
AMA American Medical Association
AMP Average manufacturer price
AOA American Osteopathic Association
ASC Ambulatory surgical center
ASP Average sales price
ASRT American Society of Radiologic Technologists
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 (Pub. L. 106–554)
BLS Bureau of Labor Statistics
BN Budget neutrality
CABG Coronary artery bypass graft
CAD Coronary artery disease
CAH Critical access hospital
CAHEA Committee on Allied Health Education and Accreditation
CAP Competitive acquisition program
CBSA Core-Based Statistical Area
CCHIT Certification Commission for Healthcare Information Technology
CEAMA Council on Education of the American Medical Association
CF Conversion factor
CfC Conditions for Coverage
CFR Code of Federal Regulations
CKD Chronic kidney disease
CLFS Clinical laboratory fee schedule
CMA California Medical Association
CMHC Community mental health center
CMP Civil money penalty
CMS Centers for Medicare & Medicaid Services
CNS Clinical nurse specialist
CoP Condition of participation
CORF Comprehensive Outpatient Rehabilitation Facility
CPAP Continuous positive air pressure
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 Certified respiratory therapist
CSW Clinical social worker
CY Calendar year
DHS Designated health services
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DNP Doctor of Nursing Practice
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DSMT Diabetes self-management training
E/M Evaluation and management
EDI Electronic data interchange
EEG Electroencephalogram
EHR Electronic health record
EKG Electrocardiogram
EMG Electromyogram
EMTALA Emergency Medical Treatment and Active Labor Act
EOG Electro-oculogram
EPO Erythopoeitin
ESRD End-stage renal disease
FAX Facsimile
FDA Food and Drug Administration (HHS)
FFS Fee-for-service
FMS [Department of the Treasury's] Financial Management Service
FPLP Federal Payment Levy Program
FR **Federal Register**
GAF Geographic adjustment factor
GAO General Accounting Office
GPO Group purchasing organization
GPCI Geographic practice cost index
HAC Hospital-acquired conditions
HCPAC Health Care Professional Advisory Committee
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System

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 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

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 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 485

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

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 489

Health facilities, 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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart H—Appeals Under the Medicare Part B Program

■ 2. Section 405.874 as is amended by revising paragraph (b)(2) to read as follows:

§ 405.874 Appeals of CMS or a CMS contractor.

* * * * *

(b) * * *

(2) *Effective date of revocation.* The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

* * * * *

PART 409—HOSPITAL INSURANCE BENEFITS

■ 3. 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

■ 4. Section 409.17 is amended by revising paragraph (a)(1) to read as follows:

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

(a) * * *

(1) Except as specified in this section, physical therapy, occupational therapy, or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, or speech-language pathologists who meet the requirements specified in part 484 of this chapter.

* * * * *

Subpart C—Posthospital SNF Care

■ 5. Section 409.23 is amended by revising the section heading to read as follows:

§ 409.23 Physical therapy, occupational therapy and speech-language pathology.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

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

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

Subpart B—Medical and Other Health Services

■ 7. Section 410.16 is amended in paragraph (a) by—

■ A. Revising the definition of ''Eligible beneficiary''.

■ B. Adding the definition of ''End-of-life planning'' in alphabetical order.

■ C. Revising paragraphs (4), (5), and (7) of the definition ''Initial preventive physical examination.''

§ 410.16 Initial preventive physical exam: Conditions for and limitations on coverage.

(a) * * *

Eligible beneficiary means, for the purposes of this section, an individual who receives his or her initial preventive examination not more than 1 year after the effective date of his or her first Medicare Part B coverage period.

End-of-life planning means, for purposes of this section, verbal or written information regarding the following areas:

(1) An individual's ability to prepare an advance directive in the case where

§ 414.226 Oxygen and oxygen equipment.

* * * * *

(d) * * *

(3) The fee schedule amount for items described in paragraph (c)(1)(iv) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (c)(1)(v) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in (c)(1)(ii) of this section;

(ii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

* * * * *

(f) *Furnishing oxygen and oxygen equipment after the 36-month rental cap.* (1) The supplier that furnishes oxygen equipment for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen equipment with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(2) The supplier that furnishes liquid or gaseous oxygen equipment (stationary or portable) for the 36th continuous month during which payment is made under this section must—

(i) Continue to furnish the oxygen contents necessary for the effective use of the liquid or gaseous equipment during any period of medical need for the remainder of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1); or

(ii) Arrange for furnishing the oxygen contents with another supplier if the beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment.

(g) * * *

(1) The supplier that furnishes oxygen equipment for the first month during which payment is made under this section must continue to furnish the equipment for the entire 36-month period of continuous use, unless medical necessity ends or—

* * * * *

(2) Oxygen equipment furnished under this section may not be replaced by the supplier prior to the expiration of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1) unless:

* * * * *

(3) Before furnishing oxygen equipment, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

■ 28. Section 414.228 is amended by adding paragraph (c) to read as follows:

§ 414.228 Prosthetic and orthotic devices.

* * * * *

(c) *Payment for therapeutic shoes.* The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

■ 29. Section 414.230 is amended by adding paragraph (h) to read as follows:

§ 414.230 Determining a period of continuous use.

* * * * *

(h) Oxygen equipment furnished after the 36-month rental period. A new period of continuous use does not begin under any circumstance in the case of oxygen equipment furnished after the 36-month rental period in accordance with § 414.226(f) until the end of the reasonable useful lifetime established for such equipment in accordance with § 414.210(f).

Subpart H—Fee Schedule for Ambulance Services

■ 30. Section 414.610 is amended by—

■ A. Revising paragraph (c)(1) introductory text.

■ B. Adding new paragraph (h).

The revision and addition read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) *Ground ambulance service levels.* (i) The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate. For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in urban areas (both base rate and mileage) are paid based on a rate that is one percent higher than otherwise is applicable under this section, and ambulance services originating in rural areas (both base rate and mileage) are paid based on a rate that is two percent higher than otherwise is applicable under this section. For services furnished during the period July 1, 2008 through December 31, 2009, ambulance services originating in urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section, and ambulance services originating in rural areas (both base rate and mileage) are paid based on a rate that is three percent higher than otherwise is applicable under this section.

(ii) The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the actual charge or the GAF adjusted base rate amount is added to the lesser of the actual mileage charges or the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Subpart K—Payment for Drugs and Biologicals Under Part B

■ 31. Section 414.904 is amended by revising paragraphs (b)(2), (c)(2), (d)(3), and (e)(1)(i) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(b) * * *

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—