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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

**42 CFR Parts 405, 410, et al.
Medicare Program; Revisions to Payment
Policies, etc.; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, and 424

[CMS–1321–FC and CMS–1317–F]

RINs 0938–AO24 and 0938–AO11

Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007

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 Deficit Reduction Act of 2005, as well as making other changes to Medicare Part B payment policy. These changes are intended 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 geographic practice cost indices (GPCI) changes; requests for additions to the list of telehealth services; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; policies related to private contracts and opt-out; policies related to bone mass measurement (BMM) services, independent diagnostic testing facilities (IDTFs), the physician self-referral prohibition; laboratory billing for the technical component (TC) of physician pathology services; the clinical laboratory fee schedule; certification of advanced practice nurses; health information technology, the health care information transparency initiative; updates the list of certain services subject to the physician self-referral prohibitions, finalizes ASP reporting requirements, and codifies Medicare's longstanding policy that payment of bad debts associated with services paid under a fee schedule/charge-based system are not allowable.

We are also finalizing the calendar year (CY) 2006 interim RVUs and are issuing interim RVUs for new and revised procedure codes for CY 2007.

In addition, this rule includes revisions to payment policies under the

fee schedule for ambulance services and the ambulance inflation factor update for CY 2007.

As required by the statute, we are announcing that the physician fee schedule update for CY 2007 is –5.0 percent, the initial estimate for the sustainable growth rate for CY 2007 is 2.0 percent and the CF for CY 2007 is \$35.9848.

DATES: *Effective Date:* These regulations are effective on January 1, 2007.

Comment Date: Comments will be considered if we receive them at one of the addresses provided below, no later than 5 p.m. on January 2, 2007.

ADDRESSES: In commenting, please refer to file code CMS–1321–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–1321–FC, P.O. Box 8014, Baltimore, MD 21244–8014.

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–1321–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 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).

Stephanie Monroe, (410) 786–6864 (for issues related to the geographic practice cost index).

Craig Dobycki, (410) 786–4584 (for issues related to list of telehealth services).

Roberta Epps, (410) 786–4503 (for issues related to diagnostic imaging services).

Bill Larson, (410) 786–4639 (for issues related to coverage of bone mass measurement and addition of ultrasound screening for abdominal aortic aneurysm to the “Welcome to Medicare” benefit).

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

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

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

Fred Grabau, (410) 786–0206 (for issues related to private contracts and opt-out provision).

David Walczak, (410) 786–4475 (for issues related to reassignment provisions).

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

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

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

Anne Tayloe, (410) 786–4546; or

Glenn McGuirk, (410) 786-5723 (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 procedure codes identified in Addendum C and the physician self-referral designated health services (DHS) listed in Tables 18 and 19. You can assist us by referencing the file code CMS-1321-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*

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- 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
- AAD American Academy of Dermatology
- AAFP American Academy of Family Physicians
- AANS American Association of Neurological Surgeons
- AAO American Academy of Ophthalmology
- AAOS American Academy of Orthopaedic Surgeons
- AATS American Association for Thoracic Surgery
- ACC American College of Cardiology
- ACG American College of Gastroenterology
- ACHPN Advanced Certified Hospice and Palliative Nurse
- ACOG American College of Obstetrics and Gynecology
- ACR American College of Radiology
- ACS American College of Surgeons
- ADA American Dietetic Association
- AFROC Association of Freestanding Radiation Oncology Centers
- AGA American Gastroenterological Association
- AMA American Medical Association
- AMP Average manufacturer price
- APC Ambulatory payment classification
- ASA American Society of Anesthesiologists
- ASC Ambulatory surgical center
- ASCRS American Society of Colon and Rectal Surgeons
- ASGE American Society of Gastrointestinal Endoscopy
- ASP Average sales price
- ASSH American Society for Surgery of the Hand
- ASTRO American Society for Therapeutic Radiology and Oncology
- AUA American Urological Association
- 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

BMM Bone mass measurement

BN Budget neutrality

BNF Budget neutrality factor

BP Best price

CAD Computer-aided detection

CAH Critical access hospital

CAP Competitive acquisition program

CBSA Core-Based Statistical Area

CCI Correct Coding Initiative

CEO Chief executive officer

CF Conversion factor

CFO Chief financial officer

CFR Code of Federal Regulations

CMP Competitive medical plan

CMS Centers for Medicare & Medicaid Services

CNS Clinical nurse specialist

CPI Consumer Price Index

CPT (Physicians') Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)

CT Computed tomography

CTA Computed tomographic angiography

CY Calendar year

DHS Designated health services

DME Durable medical equipment

DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies

DRA Deficit Reduction Act

DSMT Diabetes outpatient self-management training services

DXA Dual energy x-ray absorptiometry

E/M Evaluation and management

EPO Erythropoietin

ESRD End stage renal disease

FAX Facsimile

FDA Food and Drug Administration (HHS)

FQHC Federally qualified health center

FR **Federal Register**

GAF Geographic adjustment factor

GAO Government Accountability Office

GDP Gross domestic product

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

HSA Health Savings Account

HHA Home health agency

HHS [Department of] Health and Human Services

HIT Health information technology

HMO Health maintenance organization

HOCM High osmolar contrast media

HPSA Health Professional Shortage Area

HRSA Health Resources Services Administration (HHS)

HUD [Department of] Housing and Urban Development

ICF Intermediate care facilities

IDTF Independent diagnostic testing facility

IFC Interim final rule with comment period

IPPE Initial preventive physical examination

IPPS Inpatient prospective payment system

IVIG Intravenous immune globulin

IWPUT Intra-service work per unit of time

JCAAI Joint Council of Allergy, Asthma, and Immunology

LCD Local coverage determination

LOCM Low osmolar contrast media

LOINC Logical Observation Identifiers Names and Codes

MA Medicare Advantage

MCP Monthly capitation payment

MedPAC Medicare Payment Advisory Commission

MEI Medicare Economic Index

MLN Medicare Learning Network

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

MNT Medical nutrition therapy

MRA Magnetic resonance angiography

MRI Magnetic resonance imaging

MSA Metropolitan statistical area

MSVP Multi-specialty visit package

NCD National coverage determination

NCQDIS National Coalition of Quality Diagnostic Imaging Services

NDC National drug code

NEMA National Electrical Manufacturers Association

NHE National health expenditures

NOP National Osteoporosis Foundation

NP Nurse practitioner

NPP Nonphysician practitioners

NPWP Nonphysician Work Pool

NSQIP National Surgical Quality Improvement Program

OBRA Omnibus Budget Reconciliation Act

OIG Office of Inspector General

OMB Office of Management and Budget

OPD Outpatient Department

OPPS Outpatient prospective payment system

OSCAR Online Survey and Certification and Reporting

PA Physician assistant

PBM Pharmacy benefit managers

PC Professional component

PE Practice Expense

PE/HR Practice expense per hour

PEAC Practice Expense Advisory Committee

PERC Practice Expense Review Committee

PET Positron emission tomography

PFS Physician Fee Schedule

PLI Professional liability insurance

PPI Producer price index

PPO Preferred provider organization

PPS Prospective payment system

PRA Paperwork Reduction Act

PRM Provider Reimbursement Manual

PT Physical therapy

QCT Quantitative computerized tomography

RFA Regulatory Flexibility Act

RHC Rural health clinic

RIA Regulatory impact analysis

RN Registered nurse

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

RVU Relative value unit

SGR Sustainable growth rate

SMS [AMA's] Socioeconomic Monitoring System

SNF Skilled nursing facility

SNM Society for Nuclear Medicine

SPA Single photon absorptiometry

STS Society of Thoracic Surgeons

SVS Society for Vascular Surgery

SXA Single energy x-ray absorptiometry

TA Technology Assessment

TC Technical Component

UAF Update adjustment factor

UPIN Unique Physician Identification Number

USPSTF United States Preventive Services Task Force

VA [Department of] Veteran Affairs

WAC Wholesale acquisition cost

WAMP Widely available market price

WHO World Health Organization

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)(A) of the Act specifies that the RVUs for radiology services are based on relative value scale we adopted under section

coverage of an ultrasound screening for abdominal aortic aneurysms).

Comment: Commenters were in agreement with the proposed payment amount for this service.

Response: We will adopt the proposed values for this new HCPCS code (that is, make it equivalent to CPT code 76775). This service will be identified by the following code number and descriptor G0389, *Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening.*

We will also finalize the proposed revisions to § 410.160 to include an exception from the Medicare Part B deductible for the ultrasound screening for AAA as described in § 410.19.

4. Section 5113—Non-Application of the Part B Deductible for Colorectal Cancer Screening Tests

Current Medicare policy requires that, with limited exceptions, incurred expenses for covered part B services are subject to, and count toward meeting the Part B annual deductible. Section 5113 of the DRA amended section 1833(b) of the Act to provide for an exception to the application of the Part B deductible for colorectal cancer screening tests. Beginning January 1, 2007, colorectal cancer screening services, as described in section 1861(pp)(1) of the Act, are no longer subject to the Part B deductible. The conditions for and limitations on coverage for colorectal cancer screening tests under Medicare Part B are described in § 410.37.

To conform our regulations to this statutory change, we proposed to revise § 410.160 to include an exception from the Part B annual deductible for the colorectal cancer screening services described in § 410.37.

Comment: Commenters were supportive of this conforming change. However, it was pointed out that we had failed to address the situation where a colorectal cancer screening service actually results in a beneficiary having a biopsy or a growth removed, requiring the service to be coded as a diagnostic procedure. Clarification was requested as to whether in such situations, the deductible would still be waived.

Response: Section 1834(d)(3)(D) of the Act states “if during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.” Based on this statutory language, in such

instances the test or procedure is no longer classified as a “screening test.” Thus, the deductible would not be waived in such situations.

After reviewing the public comments, we are finalizing § 410.160 as proposed.

5. Section 5114—Addition of Diabetes Outpatient Self-Management Training Services (DSMT) and Medical Nutrition Therapy (MNT) for the FQHC Program

Section 5114 of the DRA amended section 1861(aa)(3) the Act to add DSMT and MNT services to the list of Medicare covered and reimbursed services under the Medicare FQHC benefit, effective for services provided on or after January 1, 2006. Although this statutory change has already been implemented in administrative instructions, we proposed to conform the regulations to the new statutory requirement.

FQHCs certified as DSMT and MNT providers have been allowed to bundle the cost of those services into their FQHC payment rates. But before the enactment of the DRA, the provision of these services would not generate a separate FQHC visit payment. Effective for services furnished on or after January 1, 2006, FQHCs that are certified providers of DSMT and MNT services can receive per visit payments for covered services furnished by registered dietitians or nutrition professionals. That is, if all relevant program requirements are met, these services are included under the Medicare FQHC benefit as billable visits.

In public response to the proposed rule, we received a small number of comments expressing support for our proposal. Therefore, we will finalize the changes as proposed.

To conform the regulations, we are amending § 405.2446(b) to expand the scope of FQHC services to include certified providers of DSMT and MNT services by adding a new paragraph (b)(10). We are also revising § 405.2463 by—

- Revising paragraph (a) to expand the definition of an FQHC visit to include certified providers of DSMT and MNT services under new paragraph (a)(1)(ii)(B). We are also revising the definition of a rural health clinic (RHC) visit in new paragraph (a)(1)(i) to include a face-to-face encounter between a patient and a clinical psychologist or clinical social worker to conform to statutory language at section 1861(aa)(1)(B) of the Act. We also proposed to redesignate and revise paragraphs (b) and (c) as new paragraphs (a)(2) and (a)(3), respectively.

- We are incorporating paragraph (a)(2) into (a)(1), and redesignating and revising current paragraph (a)(3) as new paragraph (b). We also clarify that it is generally permissible for both FQHCs and RHCs to furnish, when necessary, most types of medical and other health visits on the same day to the same patient. We also amend this paragraph to permit a separate additional FQHC visit for DSMT and MNT services (which may occur on the same date of service when the beneficiary receives care from their FQHC physician or NPP) when reasonable and necessary, consistent with the Congressional mandate under section 5114 of the DRA to provide coverage and adequate access to these services in the FQHC setting.

- Finally, we are redesignating and revising current paragraph (a)(4) as new paragraph (c).

F. Payment for Covered Outpatient Drugs and Biologicals (ASP Issues)

Medicare Part B covers a limited number of prescription drugs and biologicals. For the purposes of this final rule with comment period, the term “drugs” will hereinafter refer to both drugs and biologicals. Medicare Part B covered drugs not paid on a cost or prospective payment basis generally fall into the following three categories:

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

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

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

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

B. Geographic Practice Cost Indices (GPCI)—Payment Localities

As discussed in section II.B. of the preamble to this final rule with comment period, we proposed new GPCIs for 2007. In the CY 2005 PFS final rule with comment period, we published 2005 and 2006 GPCI and GAF values reflecting the 2-year phase-in of updated GPCI data. In 2007, the proposed GPCI and GAF values will reflect the removal of the 1,000 MMA floor from the physician work GPCI. The negative impact of these changes on a number of payment localities is shown in section II.B. in Table 7.

C. Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

As discussed in section II.D.1. of this final rule with comment period, we are revising the global period for these services. We do not anticipate this change will have a significant impact on Medicare expenditures. Current brachytherapy coding allows for billing only one time for the entire physician services provided during a 90-day period. Any expected increase in the billing of brachytherapy physician services is offset by the reduction in the work RVUs.

D. DRA 5112: Addition of the Ultrasound Screening for Abdominal Aortic Aneurysm to "Welcome to Medicare" Benefit

As discussed in section II.E.3. of this final rule with comment period, section 5112 of the DRA authorizes coverage of an ultrasound screening for abdominal aortic aneurysms effective January 1, 2007, subject to certain eligibility and other limitations. We estimate that this new benefit would result in an increase in Medicare expenditures to physicians and other practitioners and suppliers of ultrasound services and related follow-up tests and treatment that may be required as a result of the coverage of these screening examinations. However, this is not expected to have a significant

cost impact on the Medicare program because of the limited scope of the benefit.

E. DRA 5113: Colorectal Screening Exemption From Part B Deductible

As discussed in section II.E.4. of this final rule with comment period, beginning January 1, 2007, colorectal cancer screening services as described in section 1861(pp)(1) of the Act are no longer subject to the Part B deductible. While waiver of this deductible will be beneficial to Medicare beneficiaries, we do not anticipate that this change will have a significant cost impact on the Medicare program.

F. Section 5114: Addition of Diabetes Outpatient Self-Management Training Services (DSMT) and Medical Nutrition Therapy (MNT) for the FQHC Program

As discussed in section II.E.5. of this final rule with comment period, section 5114 of the DRA amended section 1861(aa)(3) the Act to add DSMT and MNT to the list of Medicare covered and reimbursed services under the Medicare FQHC benefit, effective for services provided on or after January 1, 2006. Although this statutory change has already been implemented in administrative instructions, we proposed to conform the regulations to meet the new statutory requirement. FQHCs certified as DSMT and MNT providers have been allowed to bundle the cost of those services into their FQHC payment rates. But before the enactment of the DRA, the provision of these services would not generate a separate FQHC visit payment. Effective for services furnished on or after January 1, 2006, FQHCs that are certified providers of DSMT and MNT services can receive per visit payments for covered services furnished by registered dietitians or nutrition professionals. Because there are a limited number of qualified centers for DSMT and MNT services, the increase in Medicare expenditures should be negligible.

G. Payment for Covered Outpatient Drugs and Biologicals (ASP Issues)

While it is difficult to quantify the impact of clarifications in ASP reporting guidelines on Medicare expenditures, we expect that the changes discussed in section II.F. of this final rule with comment period, for payment for covered outpatient drugs and biologicals, will have a minimal impact on Medicare expenditures.

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

In section II.G. of this final rule with comment period, we discuss the ESRD-related provisions. To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments under the current year (2006 payments) to estimated payments under the revisions to the composite rate payment system as discussed in II.G. of this final rule with comment period (2007 payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and projected payments contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both current 2006 payments and 2007 payments.

ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). We also used the June 2006 update of CY 2005 National Claims History file as a basis for Medicare dialysis treatments and separately billable drugs and biologicals. Due to data limitations, we are unable to estimate current and proposed payments for 130 of the 4,669 ESRD facilities that bill for ESRD dialysis treatments.

TABLE 37.—IMPACT OF CY 2007 CHANGES IN PAYMENTS TO HOSPITAL BASED AND INDEPENDENT ESRD FACILITIES
[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 wage index ¹	Overall effect ²
All Providers	4,539	34.4	0.0	0.5
Independent	3,958	30.7	-0.1	0.5
Hospital Based	581	3.7	0.4	1.0
By Facility Size:				
Less than 5000 treatments	1,628	4.6	-0.3	0.2
5000 to 9999 treatments	1,756	12.9	0.0	0.5
Greater than 9999 treatments	1,155	16.9	0.1	0.6

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).

To illustrate this point, as shown in Table 36, the 2006 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new), is \$97.02 which means that currently a beneficiary is responsible for 20 percent of this amount, or \$19.40. Based on this final rule with comment

period, the 2007 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 36, is \$87.44 which means that, in 2007, the beneficiary coinsurance for this service would be \$17.49.

Policies discussed above in this section that do affect overall spending, such as DRA 5102 imaging provisions, would similarly impact beneficiaries' coinsurance.

S. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 40, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule with comment period. This table provides our best estimate of the decrease in Medicare payments under the physician fee schedule as a result of the provisions presented in this final rule with comment period for CY 2007. All expenditures are classified as transfers.

www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table 40, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule with comment period. This table provides our best estimate of the decrease in Medicare payments under the physician fee schedule as a result of the provisions presented in this final rule with comment period for CY 2007. All expenditures are classified as transfers.

TABLE 40.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED CY 2007 EXPENDITURES ASSOCIATED WITH CY 2007 FINAL RULE PROVISIONS

Category	Transfers
Annualized Monetized Transfers	Estimated decrease in expenditures of \$3.7 billion.
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, and Medicare suppliers billing for Part B drugs.

In accordance with the provisions of Executive Order 12866, this final rule 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 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 424

Emergency medical services, Health facilities, Health professions, 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 follows:

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 D—Private Contracts

■ 2. Section 405.400 is amended by revising the definition of “Practitioner” to read as follows:

§ 405.400 Definitions.

* * * * *

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in which he or

she furnishes services to patients or clients.

* * * * *

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services Payment for Rural Health Clinic and Federally Qualified Health Center Services

■ 3. Section 405.2446 is amended by adding paragraph (b)(10) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(10) Medical nutrition therapy services as specified in part 410, subpart G of this chapter, and diabetes outpatient self-management training services as specified in part 410, subpart H of this chapter.

* * * * *

■ 4. Section 405.2463 is revised to read as follows:

§ 405.2463 What constitutes a visit.

(a) *Visit*—(1) *General.* (i) For rural health clinics, a visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse midwife, visiting nurse, clinical psychologist, or clinical social worker.

(ii) For FQHCs, a visit is—

(A) A face-to-face encounter, as described in paragraph (a)(1)(i) of this section; or

(B) A face-to-face encounter between a patient and a qualified provider of medical nutrition therapy services as

defined in part 410, subpart G of this chapter; or a qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H of this chapter.

(2) *Medical visit.* A medical visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse midwife, or a visiting nurse; and for FQHCs only, a medical visit also includes a separately billable medical nutrition therapy visit or a diabetes outpatient self-management training visit.

(3) *Other health visit.* An other health visit is a face-to-face encounter between a clinic or center patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

(b) *Encounters.* Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(1) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(2) The patient has a medical visit and other health visit(s), as defined in paragraph (a) of this section.

(c) *Payment.* Medicare pays for more than one visit per day when the conditions in paragraph (b) of this section are met or a separate visit under paragraph (a)(1)(ii)(B) of this section is made.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

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

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

Subpart B—Medical and Other Health Services

■ 6. In § 410.16 paragraph (a) is amended by revising paragraph (7) of the definition of “initial preventive physical examination” to read as follows:

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

(a) * * *

Initial preventive physical examination * * *

(7) Education, counseling, and referral, including a written plan such

as a checklist provided to the beneficiary for obtaining the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in section 1861(s)(10), section 1861(jj), section 1861(nn), section 1861(oo), section 1861(pp), section 1861(qq)(1), section 1861(rr), section 1861(uu), section 1861(vv), section 1861(xx)(1), section 1861(yy), and section 1861(bbb) of the Act.

* * * * *

■ 7. A new § 410.19 is added to read as follows:

§ 410.19 Ultrasound screening for abdominal aortic aneurysms: Condition for and limitation on coverage.

(a) *Definitions:* As used in this section, the following definitions apply:

Eligible beneficiary means an individual who—

(1) Has received a referral for an ultrasound screening for an abdominal aortic aneurysm as a result of an initial preventive physical examination (as defined in section 1861(wv)(1) of the Act);

(2) Has not been previously furnished an ultrasound screening for an abdominal aortic aneurysm under Medicare program; and

(3) Is included in at least one of the following risk categories:

(i) Has a family history of an abdominal aortic aneurysm.

(ii) Is a man age 65 to 75 who has smoked at least 100 cigarettes in his lifetime.

(iii) Is an individual who manifests other risk factors in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms, as specified by the Secretary through a national coverage determination process.

Ultrasound screening for abdominal aortic aneurysms means the following services furnished to an asymptomatic individual for the early detection of an abdominal aortic aneurysm:

(1) A procedure using soundwaves (or other procedures using alternative technologies of commensurate accuracy and cost, as specified by the Secretary through a national coverage determination process) provided for the early detection of abdominal aortic aneurysms.

(2) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage of an ultrasound screening for abdominal aortic aneurysms.* Medicare Part B pays for one ultrasound screening for an abdominal aortic aneurysm provided to

eligible beneficiaries, as described in this section, after a referral from a physician or a qualified nonphysician practitioner as defined in § 410.16(a), when the test is performed by a provider or supplier that is authorized to provide covered ultrasound diagnostic services.

(c) *Limitation on coverage of ultrasound screening for abdominal aortic aneurysms.* Payment may not be made for an ultrasound screening for an abdominal aortic aneurysm that is performed for an individual that does not meet the definition of “eligible beneficiary” specified in this section.

■ 8. Section 410.31 is revised to read as follows:

§ 410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) *Definition.* As used in this section unless specified otherwise, the following definition applies:

Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing for this use by the FDA under 21 CFR part 807, or approved for marketing by the FDA for this use under 21 CFR part 814.

(3) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage.* (1) Medicare covers a medically necessary bone mass measurement if the following conditions are met:

(i) Following an evaluation of the beneficiary's need for the measurement, including a determination as to the medically appropriate procedure to be used for the beneficiary, it is ordered by the physician or a qualified nonphysician practitioner (as these terms are defined in § 410.32(a)) treating the beneficiary.

(ii) It is performed under the appropriate level of supervision of a physician (as set forth in § 410.32(b)).

(iii) It is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(2) Medicare covers a medically necessary bone mass measurement for an individual defined under paragraph (d)(5) of this section if the conditions under paragraph (b)(1) of this section are met and the monitoring is performed

by the use of a dual energy x-ray absorptiometry system (axial skeleton).

(3) Medicare covers a medically necessary confirmatory baseline bone mass measurement for an individual defined under paragraph (d) of this section, if the conditions under paragraph (b)(1) of this section are met and the confirmatory baseline bone mass measurement is performed by a dual energy x-ray absorptiometry system (axial skeleton) and the initial measurement was not performed by a dual energy x-ray absorptiometry system (axial skeleton).

(c) *Standards on frequency of coverage*—(1) *General rule.* Except as allowed under paragraph (c)(2) of this section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.

(2) *Exception.* If medically necessary, Medicare may cover a bone mass measurement for a beneficiary more frequently than allowed under paragraph (c)(1) of this section. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to the following medical circumstances:

(i) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

(ii) Allowing for a confirmatory baseline measurement to permit monitoring of beneficiaries in the future if the requirements of paragraph (b)(3) of this section are met.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary.* If CMS determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not “reasonable” and “necessary” under section 1862(a)(1)(A) of the Act and § 411.15(k) of this chapter.

(f) *Use of the National Coverage Determination Process.* For the purposes of paragraphs (b)(2) and (b)(3) of this section, CMS may determine through the National Coverage Determination process that additional bone mass measurement systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline bone mass measurements.

* * * * *

■ 9. Section 410.33 is amended by—

■ A. Revising paragraph (b)(1).

■ B. Revising paragraph (e).

■ C. Adding paragraphs (g) and (h).

The revision and additions read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(b) *Supervising physician.* (1) Each supervising physician must be limited to providing supervision to no more than three IDTF sites. The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

* * * * *

(e) *Multi-State entities.* (1) An IDTF that operates across State boundaries must—

(i) Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and

(ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

(2) The point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary’s location, the beneficiary’s location is the place of service. When one or more aspects of the diagnostic testing are

performed at the IDTF, the IDTF is the place of service.

* * * * *

(g) *Application certification standards.* The IDTF must certify in its enrollment application that it meets the following standards and related requirements:

(1) Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

(2) Provides complete and accurate information on its enrollment application. Any change in enrollment information must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change.

(3) Maintains a physical facility on an appropriate site. For the purposes of this standard, a post office box or commercial mail box is not considered a physical facility. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

(4) Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request.

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

(5) Maintain a primary business phone under the name of the designated business. The IDTF must have its—

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance.

(6) Have a comprehensive liability insurance policy of at least \$300,000 per