CMS Manual System

Department of Health &

Human Services (DHHS)

Pub 100-04 Medicare Claims Processing

Centers for Medicare &
Medicaid Services (CMS)

Transmittal 1423

Date: February 1, 2008

Change Request 5895

SUBJECT: Summary of Policies in the 2008 Medicare Physician Fee Schedule and the Telehealth
Originating Site Facility Fee Payment Amount

I. SUMMARY OF CHANGES: This Change Request contains policies in the 2008 Medicare Physician
Fee Schedule and the Telehealth Originating Site Facility Fee.

NEW / REVISED MATERIAL

EFFECTIVE DATE: *January 1, 2008

IMPLEMENTATION DATE: January 7, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized
material. Any other material was previously published and remains unchanged. However, if this revision
contains a table of contents, you will receive the new/revised information only, and not the entire table of
contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Attachment – Recurring Update Notification

Pub. 100-04

Transmittal: 1423

Date: February 1, 2008

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SUBJECT: Summary of Policies in the 2008 Medicare Physician Fee Schedule and the Telehealth
Originating Site Facility Fee Payment Amount

EFFECTIVE DATE: January 1, 2008

IMPLEMENTATION DATE: January 7, 2008

I. GENERAL INFORMATION

(Note: This change request does not include any changes that would be affected by recent legislation (i.e., 0.5
percent update to the conversion factor, changes to the geographic practice cost indices floor, etc. Information
regarding these changes can be found in Change Request 5944, Legislative Change Affecting the 2008
Medicare Physician Fee Schedule (MPFS) and Extension of the 2008 Participation Open Enrollment Period)

A. Background: The purpose of this change request is to provide a summary of the policies in the 2008
MPFS and the telehealth originating site facility fee payment amount. Section 1848(b)(1) of the Social Security
Act (the Act) requires the Secretary to establish by regulation before November 1 of each year, fee schedules
that establish payment amounts for physicians' services for subsequent year. We published a document that
would affect payments to physicians effective January 1, 2008.

Section 1834(m) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001 through December 21, 2002 at $20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased as of the first day of the year by the percentage increase in the Medicare Economic Index (MEI) as defined in §1842(i)(3) of the Act. The MEI increase for 2008 is 1.8 percent.

B. Policy: For calendar year 2008, the payment amount for HCPCS code "Q3014, Telehealth originating site facility fee" is 80 percent of the lesser of the actual charge or $23.35. The beneficiary is responsible for any unmet deductible amount or coinsurance

For CY 2008, the CPT Editorial Panel has created two new Category I CPT codes for reporting alcohol and/or substance abuse screening. They are CPT code 99408 (Alcohol and/or substance (other than tobacco) abuse structured screening (e.g., AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes) and CPT code 99409 (Alcohol and/or substance (other than tobacco) abuse structured screening (e.g., AUDIT, DAST), and brief intervention (SBI) services; greater than 30 minutes).

The code descriptions for these CPT codes suggest that these CPT codes may describe services that include screening services. In general, screening services under Medicare are considered to be those services provided to beneficiaries in the absence of signs or symptoms of illness or injury; therefore, to the extent that the services described by these two CPT codes have a screening element, the screening component would not meet the statutory requirements for coverage under §1862(a)(1)(A) of the Act. Screening services are not covered by Medicare without specific statutory authority, such as has been provided for mammography, diabetes, and colorectal cancer screening. Accordingly, we will not recognize these CPT codes that incorporate screening for payment under the PFS.

Instead, we have created two parallel G-codes to allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services,

but that are performed in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS
code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST)
and brief intervention, 15 to 30 minutes) and HCPCS code G0397 (Alcohol and/or substance (other than
tobacco) abuse structured assessment (e.g., AUDIT, DAST) and intervention greater than 30 minutes).
Contractors shall consider payment for HCPCS codes G0396 and G0397 only when appropriate, reasonable and
necessary (i.e., when the service is provided to evaluate patients with signs/symptoms of illness or injury) as per
section 1862(a)(1)(A) of the Act.

See the attachment for a summary of issues discussed in CMS-1325-FC, 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.

II. BUSINESS REQUIREMENTS TABLE

Use“Shall" to denote a mandatory requirement

Number

Requirement

Responsibility (place an “X” in each
applicable column)

A/
B

MAC

DME

MAC

FI

CARRIER

RHHI

Shared-
System
Maintainers

OTHER

FISS

MCS

VMS

CWF

5895.1

Medicare contractors shall pay for the Medicare telehealth originating site facility fee as described by HCPCS code Q3014 at 80 percent of the lesser of the actual charge or $23.35

X

X

X

5895.2

Medicare contractors shall consider payment for

HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (eg, AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397 (Alcohol and/or substance(other than tobacco) abuse structured assessment (eg, AUDIT, DAST) and intervention greater than 30 minutes), only when appropriate, reasonable and necessary (i.e., when the service is provided to evaluate patients with signs/symptoms of illness or injury) as per section 1862(a)(1)(A) of the Act.

X

X

X

III. PROVIDER EDUCATION TABLE

Number

Requirement

Responsibility (place an “X” in each applicable column)

A/
B

MAC

DME

MAC

FI

CARRIER

RHHI

Shared-
System
Maintainers

OTHER

FISS

MCS

VMS

CWF

5895.3

A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.

Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized

information that would benefit their provider community in billing and administering the Medicare program correctly.

X

X

X

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref

Requirement

Number

Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Gaysha Brooks, Gaysha.Brooks@cms.hhs.gov, (410) 786-9649

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

A. For Fiscal Intermediaries and Carriers, use the following statement:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. For Medicare Administrative Contractors (MAC), use the following statement:

The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachment

Attachment (Informational Only)

Summary of Significant Issues Discussed in CMS-1325-FC, 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

Physician Fee Schedule (PFS) Related Issues

Changes Related to Practice Expense (PE) RVUs

Practice expenses are the resources used in furnishing a service (such as office rent, wages of personnel, equipment and supplies).

In setting the PE RVUs in the PFS, we must take into consideration the cost of the equipment being used in a particular procedure or service and how often that equipment is being used. Currently, the PE methodology assumes a 50 percent utilization rate. In this final rule with comment period, we include a discussion of this issue indicating any proposal on equipment usage rates would be addressed in future rulemaking.

We also discuss the American Medical Association (AMA) - Practice Expense Review Committee (PERC) recommendations on PE inputs, refinements to PE inputs based on comments and additional data received from specialty societies, and a change to the PE per hour for radiology based upon additional information from the specialty society and discussions with our contractor.

Geographic Practice Cost Indices (GPCIs)

Section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure

resource cost differences among localities compared to the national average for each of the three fee schedule components.

• GPCI Update

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, to adjust the GPCIs at least every 3 years. This section of the Act also requires us to phase-in the adjustment over 2 years and to implement only one-half of any adjustment if more than 1 year has elapsed since the last GPCI revision. This final rule makes public the new budget neutralized GPCIs.

• California Payment localities

Medicare is required to develop geographic indexes to adjust payments to physicians to reflect variations in costs by geographic areas. There are currently 89 different localities across which the indexes apply and the fees are adjusted. HHS has the authority to change the structure of these payment localities in any single state or across all states but it must be done in a budget neutral manner which can lead to significant redistributions in payments. The locality structure has not changed since 1997. In response to concerns we

have been hearing about the status of the localities in California, in the proposed rule we solicited comments on three possible locality reconfigurations.

After evaluating the comments, we decided not to finalize any of the proposals. We intend to conduct a thorough analysis of approaches to reconfiguring localities and address this issue again in future rulemaking.

Coding Issues

Five Year Review of Work RVUs and Other Coding Issues

In this rule, we are finalizing the proposed RVUs for all the remaining 5 year review codes including increasing anesthesia work by 32 percent and are accepting the results of the refinement panel for 14 home and domiciliary codes. We decided not to proceed with our proposal to bundle the echocardiography code.

Reduction in the technical component (TC) for Imaging Services Under the PFS to outpatient prospective payment system (OPPS) Payment Amount

Effective January 1, 2007, the Deficit Reduction Act of 2005 provided for capping the payment for the technical component (TC) of certain diagnostic imaging procedures based on the on the Outpatient Prospective Payment System (OPPS) payment. Based on the statutory definition of imaging services under the DRA, we have determined that the following additional procedures are subject to the cap, effective January 1, 2008:

92135- Scanning computerized ophthalmic diagnostic imaging (e.g., scanning laser) with interpretation and report.

92235- Fluorscein angiography (includes multiframe imaging) with interpretation and report.

92240- Indocyanine-green angiography (includes multiframe imaging) with interpretation
and report.

92250- Fundus photography with interpretation and report.

92285- External ocular photography with interpretation and report for documentation of
medical progress (e.g., close-up Photography, slit lamp photography, goniophotography,
stereo-photography).

92286- Special anterior segment photography with interpretation and report; with specular endothelial microscopy and cell count.

Non-Face-to Face Physician and Qualified Healthcare Professional Services

For CY 2008, the CPT Editorial Panel has created eight new Category I CPT codes for
reporting non-face-to-face physician and qualified healthcare professional services. The
codes and their descriptors are reflected in the table below:

CPT Code	Descriptor
98966	Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous seven days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
98967	Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous seven days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion
98968	Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous seven days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion
98969	Online evaluation and management service provided by a qualified non-physician health care professional to an established patient, guardian or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network (Do not report 98969 when using 99339-99340, 99374-99380 for the same communication(s)) (Do not report 98969 for anticoagulation management when reporting 99363 to 99364)

99441

Telephone evaluation and management service provided by a physician to an established patient, parent, or guardian not originating from a related E/M service
provided within the previous seven days nor leading to an E/M service or procedure
within the next 24 hours or soonest available appointment; 5-10 minutes of medical
discussion

99442

Telephone evaluation and management service provided by a physician to an established patient, parent, or guardian not originating from a related E/M service
provided within the previous seven days nor leading to an E/M service or procedure
within the next 24 hours or soonest available appointment; 11-20 minutes of medical
discussion

99443

Telephone evaluation and management service provided by a physician to an established patient, parent, or guardian not originating from a related E/M service
provided within the previous seven days nor leading to an E/M service or procedure
within the next 24 hours or soonest available appointment; 21-30 minutes of medical
discussion

(Do not report 99441-99443 when using 99339-99340, 99374-99380 for the same call(s))

(Do not report 99441-99443 for anticoagulation management when reporting 99363-99364)

99444

Online evaluation and management service provided by a physician to an established
patient, guardian or health care provider not originating from a related E/M service
provided within the previous 7 days, using the Internet or similar electronic communications network

(Do not report 99444 when using 99339-99340, 99374-99380 for the same communication(s))

(Do not report 99444 for anticoagulation management when reporting 99363 to 99364)

Medicare does not pay separately for physician or nonphysician telephone conversations with patients (or their families), but that these conversations may be taken into account when the physician is determining which level of evaluation and management (E/M) code to assign on the next claim for a face-to-face E/M visit. Codes meeting this criteria are bundled under the Medicare physician fee schedule. However, because the code descriptors for CPT codes 98966 through 98969 and 99441 through 99444 state “not originating from a related E/M service nor leading to an E/M service” we assigned a status indicator of “N” (Non-covered service) to these services. Because these are noncovered services under the Medicare physician fee schedule, the physician or nonphysician practitioner may bill the beneficiary directly for these services as defined in the CPT, at his/her established rate. Although an ABN is not required, we would strongly encourage providers to issue the voluntary “Notice of Exclusion from Medicare Benefits (NEMB” so patients can make informed decisions in these situations. Information about these notices can be found at: http://www.cms.hhs.gov/BNI/11_FFSNEMBGeneral.asp#TopOfPage. We would like to remind providers that to be billable to the beneficiary the service must not be related to an E/M visit and must meet every part of the CPT definition and must be documented in the patient’s record. (Note: Contractor discretion should be used to determine if service is related to an E/M visit.)

Payment for Preadmission-related services for intravenous infusion of immunoglobulin (IVIG)

In this rule, we finalize our proposal to continue payment for G0332 in 2008 and assign the same level of PE RVUs as last year.

Application of Multiple Procedure Payment Reduction for Mohs Micrographic Surgery (CPT codes 17311 and 17313)

Under the multiple procedure payment reduction policy, reimbursement for subsequent procedures performed during the same operative session by the same physician is reduced by 50 percent. The Mohs surgery codes have been exempt from the multiple procedure reduction rules since the inception of the PFS [56 FR, November 25, 1991. In this rule, we finalize our proposal to apply the multiple procedure payment reduction rules to these codes. (Note: CPT codes 17312, 17314, and 17315 are not subject to the multiple surgery payment reduction because they are add-on codes.)

Medicare Telehealth Services

We received a request to add the following services to the list of Medicare telehealth services: (1) subsequent hospital care; (2) neurobehavioral status exam; and (3) neuropsychological testing. In this rule, we finalize our proposal to add neurobehavioral status exam to the list of telehealth services and requested comments as to how we could determine when subsequent hospital care is actually a follow-up inpatient consultation and specific information on neuropsychological testing.

Conforming/clarifying changes for Comprehensive Outpatient Rehabilitation Facilities (CORFs)

The 1997 BBA required that all CORF services specified at section 1861(cc) of the Act be paid under existing fee schedule(s) rather than a “reasonable cost” basis that had been in place since 1982. The PFS is currently used to pay for rehabilitation therapy services and other CORF clinical services permitted through the benefit, such as social and psychological services. Because the CORF regulations were never entirely updated to reflect the change to the PFS payment methodology, we proposed a number of changes to the CORF regulations at 42 CFR Part 410 to ensure the regulations reflect the statutory requirements. In this rule, we adopt these changes, with a few modifications, as proposed.

Therapy Services

In this rule, we finalize our proposals concerning the timing of recertification of plans of care, the application of consistent standards across all settings, and updating the personnel qualifications for therapists. We also expand the grandfather clause to include those practicing in all settings. We will delay implementation of the consistent standards for six months and the personnel qualifications for two years to allow individuals and facilities time to come into compliance.

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

Section 101(b) of the MIEA-TRHCA--Quality Reporting System for Physician Payment for CY 2008

Section 101(b) of the MIEA-TRHCA authorizes the establishment of a physician quality reporting system by CMS. We have titled the statutory program the Physician Quality Reporting Initiative (PQRI). We have finalized for 2008 a total of 119 quality measures

selected from the 148 we proposed across the following 7 broad categories. Measures are included in the final set for 2008 provided that, in the case of each measure, it is either National Quality Forum (NQF) endorsed or Ambulatory Quality Alliance (AQA) adopted by October 31, 2007, with exception of 2007 PQRI Measures. Because all of the 2007 PQRI measures have been considered by NQF, we will retain from this category only those measures that achieved NQF endorsement.

MEIA-TRHCA Section 101 also requires that we address in 2008 a registry-based mechanism for data submission. We state in the final rule that we plan to test two options for how the registry-based submission mechanism might work, and describe the specific options we plan to test. Although not specifically required by MEIA-TRHCA, we also address in the final rule our plan to test a mechanism for submitting clinical quality data extracted from electronic health records and uploaded directly to a clinical data warehouse.

We identify the minimum characteristics that a registry or EHR vendor and/or EHR product will need to possess in order to be able to participate in the testing. We also

provide the address to which interested registries and vendors may submit letters of self-nomination, and establish that self-nomination letters must be received at that address by January 4, 2008.

Section 110 of the MIEA-TRHCA--Reporting of Anemia Quality Indicators for Medicare Part B Cancer Anti-Anemia Drugs

Section 110(b) of TRCHA 2006 requires CMS to add a requirement for reporting of hemoglobin or hematocrit data on claims for drugs used to treat anemia secondary to anticancer treatment. The reporting requirement is effective January 1, 2008. In this rule, we finalize this requirement for all claims for ESAs and for some claims of other drugs.

Other Issues

Average Sales Price (ASP) issues

In January 2007, MedPAC recommended that we clarify our policy on the treatment of bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. In recent rulemaking, Medicaid provided guidance on bundled sales in the context of Average Manufacturer Price (AMP). In the CY 2008 PFS Proposed Rule, we proposed that all manufacturers would be required to allocate bundled price concessions proportionately to the dollar value of units of each drug sold under the bundled arrangement. We received many comments on our proposal. Based on comments recommending a delay and to better understand the concerns stated by the commenters, we did not finalize the proposed regulatory changes in the CY 2008 PFS Final Rule.

Although we did not establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of calculating ASP at this time, we

restated existing guidance in the preamble section of the final rule that, in the absence of specific guidance, manufacturers may make reasonable assumptions in their calculation of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and their customary business practices. Further, we clarified that, in making reasonable assumptions, we believe that one method manufacturers could use is to reallocate price concessions that are conditioned upon other purchases or a performance requirement so that the total value of all price concessions are allocated proportionately according to the dollar value of the units of each drug sold. Manufacturers are to submit their reasonable assumptions along with their ASP data.

In the final rule, we also stated that we will continue to monitor this issue, consider the comments on this issue, and may provide more specific guidance in the future through rulemaking or through program instruction or other guidance (consistent with our authority under section 1847A(c)(5)(C) of the Act) if we determine it is warranted. As we continue to review these issues, we want to be sure we are aware of concerns from all stakeholders, and encourage the public to provide additional information or concerns to us on this issue as they may arise.

Competitive Acquisition Program (CAP) Issues

• Provisions for Collection of Beneficiary Coinsurance

Section 108 of the MIEA-TRHCA requires that payment for drugs and biologicals supplied under the CAP be made upon receipt of an approved CAP vendor's claim. However, applicable beneficiary cost sharing amounts may still only be collected after the administration of the drug has been verified. Current CAP claims processing and payment procedures do not provide a way for CMS to immediately verify that a drug was administered on behalf of the vendor. Therefore, this rule describes steps that an approved CAP vendor may take in order to verify that a drug was administered, and finalizes specific information that must be collected by the approved CAP vendor before collecting cost sharing amounts from a beneficiary. We are also finalizing a minor change to regulation text at 414.914(i) in order to clarify that the approved CAP vendor may bill the supplemental insurer immediately after the designated carrier makes the initial payment on a CAP drug claim. Under our current regulations, the approved CAP vendor may also bill the beneficiary if drug administration is verified by the participating CAP physician. This provision remains unchanged.

• Approved CAP Vendor Appeals for Denied Drug Claims

Currently, an approved CAP vendor has appeal rights as a party to the redetermination of a physician's drug administration claim. In addition, the approved CAP vendor is considered a party to an initial determination on the claim for payment for the drug product the approved CAP vendor filed with the designated carrier. Currently, the local carrier conducts appeals and the process requires a participating CAP physician's cooperation because the vendor's appeal rights are generally dependent upon the physician's drug administration claim.

Under the MIEA-TRHCA, an approved CAP vendor is paid upon receipt of the vendor's drug claim. The change in timing of the initial payment to the vendor creates direct appeals rights for the approved CAP vendor.

We are finalizing our clarification that, for pre-payment denials, the approved CAP

vendor, as a supplier, has a direct right to appeal the initial determination made by the designated carrier on its drug product claim. Furthermore, because the local carrier is expected to have the most familiarity with applicable policies, the local carrier will conduct the prepayment appeals.

We are also finalizing our proposal that the appeal of post payment denials be considered a reopening of an initial determination; that the designated carrier would conduct this appeal and issue a revised determination if a claim cannot be verified or is found to be medically unnecessary. The designated carrier would then seek to recover overpayment. An approved CAP vendor would have the right to appeal a post payment denial to the designated carrier by requesting a redetermination of the revised coverage determination and the overpayment assessment.

• Definition of Exigent Circumstance/ Description of Process for Requesting Removal
from the CAP
Originally we interpreted the CAP statute to require that physicians must stay in the
program and remain with their original vendor for a year with only a few exceptions,
such as exigent circumstances as defined by CMS.

Since then, we have had several cases of physicians requesting to opt out of the CAP for
reasons that we believe are justified. We are recognizing the burden to a physician's
practice as an "exigent circumstance", especially when such difficulties become apparent
during the first 60 days of CAP participation. In addition, we are also specifying that,
beginning after 60 days from the effective date of the physician's CAP election
agreement, the physician may request to leave the program due to a change in
circumstances of which the physician was previously unaware that would create a burden
for the physician if he or she continued in the CAP.

• Other CAP Topics

We also responded to comments on potential alternatives to the CAP prescription order
number, whether to allow for pre-filled syringes under limited circumstances in the CAP,
and potential contractual changes to encourage compliance with CAP requirements. No
changes are being implemented at this time.

We also finalized regulations and addressed remaining comments from the July 6, 2005
CAP interim final rule with comment period. These topics included the use of electronic
prescriptions in the CAP, CAP physician administrative and financial burden, the impact
of CAP participation on clinical trials research, licensure requirements for CAP
distributors and pharmacies, community mental health centers and CAP participation,
updating CAP prices and data reporting, the application of Comprehensive Error Rate
Testing (CERT) to CAP claims, and the 14-day participating CAP physician billing
requirement.

Issues Related to the Clinical Laboratory Fee Schedule

• Date of Service Clarification for Technical Component of Pathology Specimens

In this rule, we are finalizing our proposal to amend the title and introductory sentence for §414.510, laboratory date of service for specimens, to specify that the regulation applies to both clinical laboratory services and the technical component for physician pathology services to promote consistency between testing based on the comments that we received. This amendment concerning the date of service for laboratory specimens will assist in improving claims processing efficiency, adjudication, and detection of duplicate services. This will also clearly state what services are bundled into the hospital payment and what services are payable under the PFS.

• Reconsideration Process

In the final rule, we are implementing the following process which will be effective on January 1, 2008:

-The public will have 60 days from the date the new clinical laboratory fee schedule amounts were published to request a reconsideration.

- The public can comment on the decision to cross walk or gap fill a specific code, a CMS crosswalk determination, or the CMS calculation of the National Limitation Amount for new codes gap filled in the previous year.

- Commenters will be invited to present their comments at the Laboratory Public Meeting on Payment for New Clinical Laboratory Tests.

In addition, for payments for new tests established through gapfilling by the contractors:

- We will post the contractor's payment amounts for new codes each spring.

- The public will have 30 days from the date the contractor's final payment amounts are posted to request a reconsideration.

- We will consider requests for reconsideration when we decide whether to reconsider carrier-specific final payment amounts and the National Limitation Amount (NLA).

- Consistent with current regulations, we could decide after the first year of gapfilling that the carrier-specific gapfilled amount would not pay for the test appropriately, and could crosswalk the test instead.

ESRD facility related issues

For calendar year 2008, we did not propose any significant changes to the composite rate payment methodology. In the 2008 final rule, we have two updates--1) wage index and transition; and, 2) drug add-on adjustment. The following discussion summarizes the changes affecting the composite rate payments.

• Wage Index Update

For 2008, we are updating the wage data and implementing the third year of the transition using a 25/75 blend of the old MSA-based wage index and the new CBSA-based wage index. In addition, we are reducing the wage index floor from 0.8 to 0.75 for 2008.

• Update to the Drug Add-on Adjustment to the Composite Payment Rate

Section 623 of MMA established the drug add-on adjustment to the composite payment rate to account for the difference between payment amounts for separately billable drugs under pre-MMA payments and the new payment methodology established under that section of the statute. In addition, beginning in 2006, the MMA requires that we annually update the drug add-on adjustment to reflect the estimated growth in ESRD drug expenditures from the previous year. The current add-on adjustment is 14.9 percent and includes a 0.5 percent update for 2007. The 14.9 percent adjustment reflects an average per treatment adjustment of $19.64. For 2008, based on the update methodology established in the CY 2007 PFS final rule, CMS used ESRD drug expenditure data from 2005 and 2006 to project utilization growth. Since hospital-based facilities are reimbursed on a cost basis, CMS is unable to isolate the per unit payment differential for

hospital-based facility drug expenditures between 2005 and 2006 for purposes of estimating the residual utilization change between years. To deal with this data issue,
CMS estimated utilization changes in ESRD drugs between 2005 and 2006 using only data from freestanding facilities. The result is no utilization growth estimated for 2008.

The final update to the drug add-on adjustment to the composite rate is 0.5 percent for a
total drug add-on adjustment for 2008 of 15.5 percent (1.005 x 1.149). The 15.5 percent
adjustment reflects an average per treatment adjustment of $20.33 for 2008. This represents an additional $0.69 over the amount for 2007.

Independent Diagnostic Testing Facility (IDTF)

• Background

During the course of a national review in 2003-2004, the Office of Inspector General
(OIG) found an error rate of 68 percent for Independent Diagnostic Testing Facility
(IDTF). The OIG found that payment errors were the result of poor or missing documentation and the lack of medical necessity. Moreover, in recent years, CMS and its
contractors have determined that a number of IDTFs in California and other states are
perpetuating schemes to defraud the Medicare program.

In last year’s physician fee schedule, CMS adopted 14 IDTF performance standards and
established several other provisions to improve quality and reduce improper payments.

• Provisions of the Final Rule

Building on the IDTF supplier standards established in last year’s physician fee schedule

final rule, we are adopting several new provisions that impact IDTFs and revise several

existing IDTF performance standards. These include:

o Limiting IDTF billing so that it begins upon the later of (1) the time of filing of
the enrollment application, or (2) the date the new practice location is open.

o Prohibiting an IDTF from sharing a practice location with another Medicare enrolled individual organization or sharing equipment used in taking the initial diagnostic test or allowing an IDTF to lease or sublease its operations to another
individual or organization.

In addition to the two new provisions discussed above, we are adopting revisions to
several existing performance standards:

o Revising existing performance standard 6 to allow us to verify comprehensive liability insurance with an insurance agent and/or underwriter.

o Revising existing performance standard 2 which requires the reporting of all changes within 30 days to requiring an IDTF to report:

.. Certain reportable changes, including a change in ownership, a change of practice location, a change in supervising physician, or an adverse legal action, within 30 days, and
.. Reporting all other reportable changes within 90 days.

o Revising performance standard 8 to require documentation of written clinical complaints.

Finally, we have removed the expanded definition of the role of a supervising

physician published in last year's physician fee schedule rule.

Ambulance-related provisions

Section 1834 (l) (3) (B) of the Act provides the basis for updating the payment amount 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. For CY 2008, the AIF will be 2.7 percent. In addition, as discussed in the final rule, we will announce the AIF for CY 2009 and subsequent years via CMS instruction and on the CMS Web site.

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

The statute, as amended by section 302(c)(1) of the MMA, mandates a zero percent DME fee schedule update from CYs 2004 through 2008 for all DME other than class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)(C)). The class III update factors for these years (other than 2007) are equal to the annual percentage change in the consumer price index

for urban consumers (CPI-U). The statute mandates that the Secretary determine the appropriate class III update percentage for 2007, taking into account recommendations contained in a report from the GAO regarding the appropriate update percentage for these devices. The GAO report, published March 1, 2006, recommends that the Secretary establish a uniform payment update to the DME fee schedule for 2007 for class II and

class III devices, that is, zero percent. In this final rule with comment period, we announce a zero percent update for CY 2007 for class III devices and an update equal to the CPI-U for CY 2008.

Compendia for the Determination of Medically Accepted Uses of Drugs and Biologicals in Anticancer Treatment under Section 1861(t)(2)(B)

The Social Security Act Section 1861(t)(2)(B)(ii)(I) recognizes certain compendia for use in the determination of a “medically-accepted indication” of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen. Only one named source is currently in publication. In the Act, the Secretary is given the authority to “revise the list of compendia…as appropriate”. However, there has not been an established process to revise the list. The Medicare Evidence Development and Coverage Advisory Committee (MedCAC) considered the issue in a 2006 public meeting and identified desirable characteristics for compendia used for this purpose. We proposed an annual process in which CMS would review requests for revisions to the list based largely on the MedCAC-identified desirable characteristics. In this final rule, we are reducing the entire

compendia review process to 180 days as opposed to 225 days. Requests for actions regarding any individual compendium will be considered in the annual public process rather than in the final rule.

E--prescribing – Amendment to the Exemption for Computer-Generated Faxes

The MMA e-prescribing final rule on foundation standards contained an exemption for entities that transmit and receive prescriptions via computer-generated faxes from the requirement to use the adopted NCPDP SCRIPT standard (a standard for transmitting prescription and prescription-related information between prescribers and dispensers). Since computer-generated faxing retains some of the disadvantages of paper prescribing (e.g., potential for transcription errors when keying the prescription into the pharmacy system), we believe it is now appropriate to take the next step toward e-prescribing using electronic data interchange. Thus, we are amending the exemption to allow electronic transmission by means of computer-generated fax only in instances of temporary/transient transmission failure or communication problems that would preclude the use of the adopted NCPDP SCRIPT standard. In other words, we are eliminating the computer-generated fax exemption except for in the limited circumstances described above. This amendment will take effect on January 1, 2009.

Beneficiary signatures for emergency ambulance claims

A beneficiary’s signature must appear on all claims submitted for Medicare services, unless the beneficiary has died, or another exception applies. However, ambulance suppliers and providers have stated that, in emergency situations, it is impossible or impractical to do this. In the NPRM, we proposed that, where the ambulance provider or supplier documents that the beneficiary was physically or mentally incapable of signing a claim for emergency ambulance transport service at the time the service was provided and that none of the individuals listed in the regulations was available or willing to sign a claim on behalf of the beneficiary, the ambulance provider or supplier may submit the

claim without a beneficiary signature if the ambulance provider or supplier maintains in its files for a period of at least 4 years from the date of service certain documentation.

In the final rule, we have modified our proposal to allow the ambulance provider or supplier to obtain a secondary form of verification, prior to submitting the claim to Medicare for payment.