

MEDICARE A Bulletin

A NEWSLETTER FOR FLORIDA MEDICARE PART A PROVIDERS

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The *Medicare A Bulletin* should be shared with all health care practitioners and managerial members of the provider/supplier staff.

Publications issued after October 1, 1997, are available at no-cost from our provider Web site at www.fcso.com.

Routing Suggestions :

- ☐ Medicare Manager
- ☐ Reimbursement Director
- ☐ Chief Financial Officer
- ☐ Compliance Officer
- ☐ DRG Coordinator
- ☐ _____
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Questions concerning this publication or its contents may be faxed to:

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A MESSAGE TO PROVIDERS

CMS HONORS FCSO's WEB TEAM WITH NATIONAL AWARD FOR OUTSTANDING CUSTOMER SERVICE

The Centers for Medicare & Medicaid Services (CMS) recently honored First Coast Service Options Inc.'s (FCSO) Web site team as "ROCSTARS" for its outstanding contribution to the redesigned Florida and Connecticut Web sites.

ROCSTARS is CMS' newest employee recognition program and stands for Recognizing Outstanding Customer Service that Achieves Results. The goal is to recognize individuals or teams that embody CMS' Provider Customer Service Program of continuously improving Medicare customer satisfaction through the timely delivery of accurate, accessible, and consistent information to providers.

Last year, FCSO unveiled its redesigned Medicare Web sites. Thanks to the hard work of Web site team members Kathryn Hammond, John Santangelo, and Bill Angel, the Web sites are more user friendly, with stronger navigation tools and an improved look and feel. The team also launched cutting-edge self-service tools to deliver information in creative ways, such as: interactive fee schedules, a hover tool that instantly defines acronyms on the Web site, a more powerful search engine, and an interactive voice response (IVR) converter tool that converts text into numbers and symbols for entry into the IVR.

FCSO's Web team was one of two national groups honored with this prestigious award.

The recipe for its success was equal parts experience, dedication, and creativity; but the essential ingredient that contributed to the team's success was the combination of Medicare knowledge and technical abilities. And results of online surveys that measure the overall performance of contractors' Web sites underscore their achievement: Since the redesign, FCSO's customer satisfaction scores have continued to increase. And according to the most recent results from the survey organization ForeSee Results, FCSO's Web site is among the top 10 contractors in the country in terms of customer satisfaction.

CMS offers the ROCSTARS program three times per year, with a different area of the contractor's Provider Customer Service Program recognized each time – provider telephone inquiries, provider written inquiries, and provider outreach & education. CMS announced the winners during its national conference call with all Medicare contractors and awarded them with a plaque. CMS also recognized the work of three other FCSO nominees: Donna Pisani and Andrea Freibauer for their excellent outreach efforts in the Connecticut provider community, and manager Shari Bailey for her work with data analysis to drive educational initiatives.

FCSO congratulates all of its shining ROCSTARS. ❖

ABOUT THE *MEDICARE A BULLETIN*

The *Medicare A Bulletin* is a comprehensive publication developed by First Coast Service Options, Inc. (FCSO) for Medicare Part A providers in Florida in accordance with the Centers for Medicare & Medicaid Services (CMS) notification parameters.

The Medicare Provider Outreach and Education Publication team distributes the *Medicare A Bulletin* on a monthly basis. Important notifications requiring communication in between publications will be posted to the FCSO Medicare provider education Web site <http://www.floridamedicare.com>.

WHO RECEIVES THE *BULLETIN*?

Anyone may view, print or download the *Bulletin* from our provider education Web site. Providers who cannot obtain the *Bulletin* from the Internet (because of a technical barrier) are required to register with us to receive a complimentary hardcopy (please see the hardcopy registration form published in the June 2007 *Medicare A Bulletin*, page 4). Registration forms must be submitted annually or when the provider's business practices have experienced a change in circumstances that impact electronic access.

Distribution of the *Medicare Part A Bulletin* in hardcopy format is limited to one copy per medical facility that has billed at least one Part A claim to the fiscal intermediary in Florida during the twelve months prior to the release of each issue. Providers meeting these criteria are eligible to receive a complimentary copy of that issue, *if a technical barrier exists that prevents them from obtaining it from the Internet and they have returned a completed hardcopy registration form to us.*

For additional copies, providers may purchase a separate annual subscription. A subscription order form may be found at the end of the *Educational Resources* section in each issue. Issues published since January 1997 may be downloaded from the Internet free of charge.

We use the same mailing address for *all* correspondence, and we cannot designate that the *Bulletin* be sent to a specific person/department within a medical facility. To ensure continued receipt of all Medicare correspondence, providers must keep their addresses current with the Medicare Provider Enrollment department. Please remember that address changes must be done using CMS-855A.

WHAT IS IN THE *BULLETIN*?

The *Bulletin* is divided into sections addressing general and coverage guidelines, and facility-specific information:

- Some issues of the publication may start with an important message from our contractor medical director.
- Following are sections comprise of administrative and general information, processing guidelines, billing issues, and Medicare coverage guidelines applicable to all Medicare Part A providers and facilities.
- Coverage guidelines and billing issues targeting specific facilities or Part A providers are usually included in individual sections named under the applicable facility type. These facility-specific sections are in the *Bulletin* only when an article in that category is published (for example, if no CORF/ORF information is in the issue, that section is omitted.)
- As needed, the *Bulletin* contains *Electronic Data Interchange* and *Fraud and Abuse* sections.
- The *Local Coverage Determination* (LCD) section contains notification of new finalized medical LCDs and additions, revisions, and corrections to previously published LCDs. In addition, this section may contain information on widespread probe reviews conducted by the fiscal intermediary.
- The *Educational Resources* section includes educational events and materials, such as seminar schedules, Medicare provider education Web site information, and reproducible forms.
- Important addresses and phone numbers are in the back of every issue.

THE *MEDICARE A BULLETIN* REPRESENTS FORMAL NOTICE OF COVERAGE POLICIES

Articles included in each *Medicare A Bulletin* represent formal notice that specific coverage policies have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined in this document to ensure compliance with Medicare coverage and payment guidelines.

Do You Have Comments?

The publications staff welcomes your comments and feedback on the *Bulletin* and appreciates your continued support. Please fax comments to:

Medicare Publications
1-904-361-0723

QUARTERLY PROVIDER UPDATE

The Centers for Medicare & Medicaid Services (CMS) publishes the Quarterly Provider Update (QPU) at the beginning of each quarter to inform the public about:

- Regulations and major policies currently under development during this quarter.
- Regulations and major policies completed or canceled.
- New/revised manual instructions.

CMS regulations establish or modify the way CMS administers the Medicare program. These regulations impact providers and suppliers providing services to Medicare beneficiaries.

Providers may access the Quarterly Provider Update by going to the CMS Web site at <http://www.cms.hhs.gov/QuarterlyProviderUpdates/>.

Providers may join the CMS-QPU listserv to ensure timely notification of all additions to the QPU. ❖

GENERAL INFORMATION

DATE OF SERVICE FOR CLINICAL LABORATORY AND PATHOLOGY SPECIMENS

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Providers who submit claims to Medicare administrative contractors (A/B MACs), fiscal intermediaries (FIs) or carriers, for laboratory tests, or the technical component of physician pathology services, provided to Medicare beneficiaries.

IMPACT ON PROVIDERS

This article is based on change request (CR) 6018 alerting providers that the Centers for Medicare & Medicaid Services (CMS) revised the date of service (DOS) policy for clinical laboratory tests and added the technical component of physician pathology service effective January 1, 2009. These changes were announced in the final Medicare physician fee schedule rule published in the *Federal Register* on November 27, 2007 (42 CFR section 414.510).

KEY POINTS OF CHANGE REQUEST 6018

The DOS policy as specified in 42 CFR section 414.510 for either a clinical laboratory test or the technical component of physician pathology service is as follows:

- **General Rule:** The DOS of the test/service must be the date the specimen was collected.
- **Variation:** If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

The following two exceptions apply to this DOS policy for either a clinical laboratory test or the technical component of physician pathology service:

1. DOS for Tests/Services Performed on Stored Specimens:

In the case of a test/service performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

- The patient's physician orders the test/service at least 14 days following the date of the patient's discharge from the hospital.
- The specimen was collected while the patient was undergoing a hospital surgical procedure.
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted.
- The results of the test/service do not guide treatment provided during the hospital stay.

- The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

1. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge.
- The specimen was collected while the patient was undergoing a hospital surgical procedure.
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted.
- The results of the test/service do not guide treatment provided during the hospital stay.
- The test/service was reasonable and medically necessary for treatment of an illness.

For purposes of applying the above exception, a "chemotherapy sensitivity test" is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies such tests through program instructions issued to the Medicare contractors.

ADDITIONAL INFORMATION

For complete details regarding this CR please see the official instruction (CR 6018) issued to your Medicare FI, A/B MAC, or carrier. That instruction may be viewed by going to the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1515CP.pdf>.

If you have questions, please contact your Medicare FI, A/B MAC, or carrier at their toll-free number which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

Source: CMS Pub. 100-04, Transmittal 1515, CR 6018

Disclaimer – This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

MEDICARE TRAVEL ALLOWANCE FEES FOR COLLECTION OF SPECIMENS

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Clinical laboratories submitting claims to Medicare contractors (carriers, fiscal intermediaries [FIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for clinical laboratory services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

STOP – IMPACT TO YOU

This article is based on change request (CR) 5996, which clarifies payment of travel allowances, either on a per mileage basis (HCPCS code P9603) or on a flat rate basis (HCPCS code P9604) for calendar year (CY) 2008.

CAUTION – WHAT YOU NEED TO KNOW

Note that Medicare contractors will not re-process claims that were processed before the new rates were implemented unless you bring such claims to their attention.

GO – WHAT YOU NEED TO DO

See the *Background* and *Additional Information* sections of this article for further details regarding these changes.

BACKGROUND

Part B of Medicare covers 1) a specimen collection fee and 2) a travel allowance for a laboratory technician to draw the specimen from either a nursing home patient or homebound patient, and payment is made based on the clinical laboratory fee schedule. (See section 1833(h)(3) of the Social Security Act on the Internet at http://www.ssa.gov/OP_Home/ssact/title18/1833.htm.)

Furthermore, the travel codes allow for payment of the travel allowance either on a per mileage basis (P9603) or on a flat rate per trip basis (P9604), and payment of the travel allowance is made only if a specimen collection fee is also payable.

The travel allowance is intended to cover estimated travel costs of collecting the specimen (including the laboratory technician's salary and travel expenses), and Medicare contractors have the discretion to choose:

- Either a flat rate or a mileage basis, and
- How to set each type of allowance.

The per flat rate trip basis travel allowance (P9604) is \$9.55, and the per mile travel allowance (P9603) is \$0.955 cents per mile and is used in situations where the average trip to the patients' homes is:

- Longer than 20 miles round trip, and
- To be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip.

The per mile allowance rate of \$0.955 cents per mile was computed using the federal mileage rate of \$0.505 cents per mile for automobile expenses plus an additional \$0.45 cents per mile to cover the technician's time and travel costs. Medicare contractors have the option of establishing a higher per mile rate in excess of the minimum of \$0.955 cents per mile if local conditions warrant it.

The standard mileage rate for business is based on a study of the fixed and variable costs of operating an automobile, and the study is conducted on an annual basis for the Internal Revenue Service (IRS). CMS reviews the minimum mileage rate and updates it in conjunction with the clinical laboratory fee schedule as needed.

Under either method (i.e., flat rate allowance or per mile travel allowance), when one trip is made for multiple specimen collections (e.g., at a nursing home), the travel payment component is prorated based on the number of specimens collected on that trip (for both Medicare and non-Medicare patients) either at the time the claim is submitted by the laboratory or when the flat rate is set by the Medicare contractor.

Note: Because of confusion that some laboratories have had regarding the per mile fee basis and the need to claim the minimum distance necessary for a laboratory technician to travel for specimen collection, some Medicare contractors have established local policy to pay based on a flat rate basis only.

At no time will a laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

ADDITIONAL INFORMATION

The official instruction, CR 5996, issued to your carrier, FI, and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1524CP.pdf>.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options, Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM5996

Related Change Request (CR) Number: 5996

Related CR Release Date: May 30, 2008

Related CR Transmittal Number: R1524CP

Effective Date: January 1, 2008

Implementation Date: June 30, 2008

Source: CMS Pub. 100-04, Transmittal 1524, CR 5996

JULY 2008 QUARTERLY AVERAGE SALES PRICE MEDICARE PART B DRUG PRICING FILES AND REVISIONS TO PRIOR QUARTERLY PRICING FILES

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

All physicians, providers and suppliers who submit claims to Medicare contractors (Medicare administrative contractors (A/B MACs), fiscal intermediaries [FIs], carriers, durable medical equipment Medicare administrative contractors [DME MACs] or regional home health intermediaries [RHHIs]) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change request (CR) 6049, from which this article is taken, instructs Medicare contractors to download and implement the July 2008 average sales price (ASP) drug pricing file for Medicare Part B drugs; and if released by CMS, also the revised April 2008, January 2008, January 2007, April 2007, July 2007, and October 2007 files.

BACKGROUND

Section 303(c) of the Medicare Modernization Act of 2003 revised the payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. Beginning January 1, 2005, the vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology, and pricing for compounded drugs has been performed by the local contractor.

Additionally, beginning in 2006, all end-stage renal disease (ESRD) drugs (that both independent and hospital-based ESRD facilities furnish), as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the outpatient prospective payment system (OPPS), are paid based on the ASP methodology.

The ASP methodology is based on quarterly data that drug manufacturers submit to the Centers for Medicare & Medicaid Services (CMS), which CMS then provides (quarterly) to Medicare contractors (carriers, DME MACs, FIs, A/B MACs, and/or RHHIs) through the ASP drug pricing files for Medicare Part B drugs.

As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of the effort to ensure compliance with this requirement, CMS has also reviewed how the terms "single source drug," "multiple source drug," and "biological product" have been operationalized in the context of payment under section 1847A.

For the purpose of identifying "single source drugs" and "biological products" subject to payment under section 1847A, CMS (and its contractors) will generally utilize a multi-step process that will consider:

- The Food and Drug Administration (FDA) approval
- Therapeutic equivalents as determined by the FDA
- The date of first sale in the United States.

The payment limit for the following will be based on the pricing information for products marketed or sold under the applicable FDA approval:

- A biological product (as evidenced by a new FDA biologic license application or other relevant FDA approval), first sold in the United States after October 1, 2003; or
- A single source drug (a drug for which there are not two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book), first sold in the United States after October 1, 2003.

As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of "not otherwise classified, (NOC)" HCPCS codes.

ASP Methodology

Beginning January 1, 2005, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Further, beginning January 1, 2006, payment allowance limits are paid based on 106 percent of the ASP for the following:

- ESRD drugs (when separately billed by freestanding and hospital-based ESRD facilities).
- Specified covered outpatient drugs and drugs and biologicals with pass-through status under the OPPS.

Beginning January 1, 2008, under the OPPS, payment allowance limits for specified covered outpatient drugs are paid based on 105 percent of the ASP. Drugs and biologicals with pass-through status under the OPPS continue to have a payment allowance limit of 106 percent of the ASP. CMS will update the payment allowance limits quarterly.

Exceptions are summarized as follows:

- The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a prospective payment basis are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits are updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPPS at the amount specified for the ambulatory payment classification (APC) to which the product is assigned.
- Payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2005, will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. **The payment allowance limits are not being updated in 2008.** The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service.

July 2008 Quarterly ASP Medicare Part B Drug Pricing Files and Revisions to prior Quarterly Pricing Files (continued)

- The payment allowance limits for influenza, pneumococcal and hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost.
- The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B drug pricing file or NOC pricing file, other than new drugs and biologicals that are produced or distributed under a new drug application (or other application) approved by the FDA, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in the Medicare Claims Processing Manual, Chapter 17, Drugs and Biologicals, for calculating the AWP but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC. For 2006, the blood clotting furnishing factor of \$0.146 per I.U. is added to the payment amount for the blood-clotting factor when the blood-clotting factor is not included on the ASP file. For 2007, the blood clotting furnishing factor of \$0.152 per I.U. is added to the payment amount for the blood-clotting factor when the blood-clotting factor is not included on the ASP file. **For 2008, the blood clotting furnishing factor of \$0.158 per I.U. is added to the payment amount for the blood-clotting factor when the blood-clotting factor is not included on the ASP file.**
- The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the FDA and that are not included in the ASP Medicare Part B drug pricing file or NOC pricing file are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs and biologicals that were first sold on or after January 1, 2005.
- The payment allowance limits for radiopharmaceuticals are not subject to the ASP payment methodology. Medicare contractors determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Radiopharmaceuticals furnished in the hospital outpatient department are paid charges reduced to cost by the hospital's overall cost to charge ratio.

On or after June 16, 2008, the July 2008 ASP file will be available for download along with revisions to prior ASP payment files, if CMS determines that revisions to these prior files are necessary. On or after June 16, 2008, the July 2008 ASP NOC files will be available for retrieval from the CMS ASP Webpage along with revisions to prior ASP NOC files, if CMS determines that revisions to these prior files are necessary. The payment limits included in revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document.

The payment files will be applied to claims processed or reprocessed on or after the implementation date of CR 6049 for the dates of service noted in the following table:

Payment Allowance Limit Revision Date	Applicable Dates of Service
July 2008 ASP and ASP NOC files	July 1, 2008, through September 30, 2008
April 2008 ASP and ASP NOC files	April 1, 2008, through June 30, 2008
January 2008 ASP and ASP NOC files	January 1, 2008, through March 31, 2008
October 2007 ASP and ASP NOC files	October 1, 2007, through December 31, 2007
July 2007 ASP and ASP NOC files	July 1, 2007, through September 30, 2007
April 2007 ASP and ASP NOC files	April 1, 2007, through June 30, 2007
January 2007 ASP and ASP NOC files	January 1, 2007, through March 31, 2007

Note: The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The local Medicare contractor processing the claim makes these determinations.

Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

Physicians may be paid for filling or refilling an implantable pump or reservoir when it is medically necessary for the physician (or other practitioner) to perform the service. Medicare contractors must find the use of the implantable pump or reservoir medically reasonable and

necessary in order to allow payment for the professional service to fill or refill the implantable pump or reservoir and to allow payment for drugs furnished incident to the professional service.

If a physician (or other practitioner) is prescribing medication for a patient with an implantable pump, a nurse may refill the pump if the medication administered is accepted as a safe and effective treatment of the patient's illness or injury; there is a medical reason that the medication cannot be taken orally; and the skills of the nurse are needed to infuse the medication safely and effectively. Payment for drugs furnished incident to the filling or refilling of an implantable pump or reservoir is determined under the ASP methodology as described above. Note that your local Medicare contractor does pricing for compounded drugs.

July 2008 Quarterly ASP Medicare Part B Drug Pricing Files and Revisions to prior Quarterly Pricing Files (continued)**ADDITIONAL INFORMATION**

To see the official instruction (CR 6049) issued to your Medicare contractor visit the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1529CP.pdf>.

If you have questions, please contact your Medicare contractor at their toll-free number which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6049

Related Change Request (CR) Number: 6049

Related CR Release Date: June 6, 2008

Related CR Transmittal #: R1529CP

Effective Date: July 1, 2008

Implementation Date: July 7, 2008

Source: CMS Pub. 100-04, Transmittal 1529, CR 6049

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AVERAGE SALES PRICE UPDATES

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Physicians, providers, and suppliers who submit claims to Medicare contractors (carriers, fiscal intermediaries [FIs], Part A/B Medicare administrative contractors [A/B MACs], and durable medical equipment Medicare administrative contractors [DME MACs]) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article is based on change request (CR) 5798 and provides you with updates and additions to language in the *Medicare Claims Processing Manual* relating to the average sale price (ASP) drug pricing and payment methodology. This article is informational to advise providers that the information is now in the Medicare manual and this information has been supplied in prior *MLN Matters* articles.

KEY POINTS

The Centers for Medicare & Medicaid Services (CMS) provides an ASP file to each FI, carrier, DME MAC, and A/B MAC for pricing drugs. Each FI, carrier, DME MAC, and A/B MAC must accept the ASP files made available by CMS for pricing bills/claims for any drug identified on the price files as **these files are the single national payment limit** established by CMS.

- The payment limits included in the revised ASP and not otherwise classified (NOC) payment files supersede the payment limits for these codes in any earlier publication.

Average Sale Price Payment Methodology

- The ASP methodology is based on quarterly data submitted to CMS by manufacturers and the updated and new guidelines established that relate to ASP pricing, payment methodology, and exceptions, are stated in chapter 17, section 20 of the *Medicare Claims Processing Manual* on the CMS Web site at <http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf>.
- The absence or presence of a Healthcare Common Procedure Coding System (HCPCS) code and its

associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. Your local Medicare contractor processing the claim will make these determinations.

- The vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the ASP methodology.
- Your local contractor does pricing for compounded drugs.
- End-stage renal disease (ESRD) drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the outpatient prospective payment system (OPPS), will be priced based on the ASP methodology.
- The payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP.
- The payment allowance limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP.
- For the purposes of identifying “single source drugs” and “biological products” subject to payment under section 1847A, generally CMS (and its contractors) will utilize a multi-step process, in which CMS considers:
 1. The Food and Drug Administration (FDA)-approval
 2. Therapeutic equivalents as determined by the FDA
 3. The date of first sale in the United States.

Average Sales Price Updates (continued)

- For a biological product (as evidenced by a new FDA biologic license application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA-approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment, which may be made operational through use of "not otherwise classified" HCPCS codes.

Exceptions to the ASP Payment Methodology

- The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or prospective payment basis, are determined in the same manner the payment allowance limits were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia.
- The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2005, will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service.
- The payment allowance limits for influenza, pneumococcal and hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department.

Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost.

- The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B drug pricing file or NOC pricing file, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the FDA, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC,

the contractors follow the methodology specified in the *Medicare Claims Processing Manual*, chapter 17, Drugs and Biologicals, <http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf> on the CMS Web site, for calculating the AWP, but substitutes WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC.

- Carriers, DME MACs, and A/B MACs will develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug-pricing file.
- The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the FDA, and that are not included in the ASP Medicare Part B drug pricing file or NOC pricing file, are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP.
- The payment allowance limits for radiopharmaceuticals are not subject to ASP. Carriers will determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Please refer to chapter 17, section 90.2 of the *Medicare Claims Processing Manual* regarding radiopharmaceuticals furnished in the hospital outpatient department.

ADDITIONAL INFORMATION

You may see the official instruction (CR 5798) issued to your Medicare contractor by visiting the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1513CP.pdf>.

The ASP methodology files are posted on the CMS Web site at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>.

If you have questions, please contact your Medicare contractor at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM5798
Related Change Request (CR) Number: 5798
Related CR Release Date: May 23, 2008
Related CR Transmittal Number: R1513CP
Effective Date: June 23, 2008
Implementation Date: June 23, 2008

Source: CMS Pub. 100-04, Transmittal 1513, CR 5798

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JULY UPDATE TO THE 2008 MEDICARE PHYSICIAN FEE SCHEDULE DATABASE

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Physicians and providers who submit claims to Medicare carriers and Part A/B Medicare administrative contractors (A/B MACs) for services rendered to Medicare beneficiaries that are paid based on the Medicare physician fee schedule database (MPFSDB).

PROVIDER ACTION NEEDED

STOP – IMPACT TO YOU

Payment files for the MPFS were issued based on the 2008 Medicare physician fee schedule final rule. Change request (CR) 6087 amends those files **and** includes new/revised codes for the Physician Quality Reporting Initiative (PQRI).

CAUTION – WHAT YOU NEED TO KNOW

Physicians and providers may want to pay particular attention to the issue that effective July 1, 2008, payments are calculated using the conversion factor of \$34.0682, update factor of 0.899 and without the work geographic adjustment, which is the previous payment methodology that was outlined in the 2008 MPFS final rule but was delayed as a result of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007.

GO – WHAT YOU NEED TO DO

Make certain that your billing staffs are aware of these changes.

BACKGROUND

Section 1848 (c)(4) of the Social Security Act provides for the establishment of the policies needed in order to implement relative values for physicians' services. CR 6087 is the official document that announces these changes in the Medicare schedule. Rather than duplicate all the additions, deletions and changes in this article, the Centers for Medicare & Medicaid Services (CMS) directs you to CR 6087, which contains lengthy lists of these items. CR 6087 is available on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1528CP.pdf>.

As mentioned above, the key portions of CR 6087 include the following information:

New G-codes for the Home Sleep Study Test Portable Monitor

New G-codes effective for services performed **on or after March 13, 2008**, are:

Code	Long Descriptor	Short Descriptor
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation	Home sleep test/type 2 Porta
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation	Home sleep test/type 3 Porta
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels	Home sleep test/type 4 Porta

New G-codes for the Physician Quality Reporting Initiative

Effective for dates of service **on or after July 1, 2008**, the following HCPCS codes will be added to the MPFSDB:

Code	Long Descriptor	Short Descriptor
G8485	Clinician intends to report the diabetes measure group	Report, Diabetes Measures
G8486	Clinician intends to report the preventive care measure group	Report, Prev Care Measures
G8487	Clinician intends to report the chronic kidney disease (CKD) measure group	Report CKD Measures
G8488	Clinician intends to report the end-stage renal disease (ESRD) measure group	Report ESRD Measures

New Category II Codes

Effective for dates of service on or after July 1, 2008, the following category II codes will be added to the MPFSDB. (These codes are not part of the PQRI for 2008.)

GENERAL INFORMATION

July Update to the 2008 Medicare Physician Fee Schedule Database (continued)

Code	Long Descriptor	Short Descriptor
3351F	Negative screen for depressive symptoms as categorized by using a standardized depression screening/assessment tool	Neg scrn dep symp by deptool
3352F	No significant depressive symptoms as categorized by using a standardized depression assessment tool	No sig dep symp by dep tool
3353F	Mild to moderate depressive symptoms as categorized by using a standardized depression screening/assessment tool	Mild-mod dep symp by deptool
3354F	Clinically significant depressive symptoms as categorized by using a standardized depression screening/assessment tool	Clin sig dep sym by dep tool

Please note that G-codes and CPT category II codes are used to report quality measures under the PQRI program or for measure testing. The G-codes and CPT category II codes applicable to the 2008 PQRI measure set are available in the "2008 PQRI Quality Measures Specification" document on the CMS Web site at http://www.cms.hhs.gov/PQRI/15_MeasuresCodes.asp#TopOfPage.

New Category III Codes

Effective for dates of service on or after July 1, 2008, the following category III codes (0188T through 0192T) will be added to the MPFSDB:

Code	Long Descriptor	Short Descriptor
0188T	Videoconferenced Critical Care First 30-74 Min	Videoconf crit care 74 min
0189T	Videoconferenced Critical Care Ea Addl 30min	Videoconf crit care addl 30
0190	Intraocular Radiation Src Applicator Placement	Place intraoc radiation src
0191T	Ant Segment Insertion Drainage W/O Reservoir Int	Insert ant segment drain int
0192T	Ant Segment Insertion Drainage W/O Reservoir Ext	Insert ant segment drain ext

Note that your carrier or MAC will not reprocess claims already paid prior to implementation of this update. However, if you bring such claims to your contractor's attention, they will adjust such claims.

ADDITIONAL INFORMATION

To see the official instruction (CR 6087) issued to your Medicare carrier or A/B MAC visit the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1528CP.pdf>.

If you have questions, please contact your Medicare Carrier or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6087

Related Change Request (CR) Number: 6087

Related CR Release Date: May 30, 2008

Related CR Transmittal Number: R1528CP

Effective Date: January 1, 2008, unless otherwise noted in CR6087

Implementation Date: July 7, 2008

Source: CMS Pub. 100-04, Transmittal 1528, CR 6087

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HHS TAKES ACTION TO HELP MEDICARE BENEFICIARIES AND PROVIDERS IN IOWA AND INDIANA

Health & Human Services (HHS) Secretary Mike Leavitt declared a public health emergency in the flood-stricken states of Iowa and Indiana. The action gives HHS' Centers for Medicare & Medicaid Services (CMS) Medicare beneficiaries and their health care providers greater flexibility in meeting emergency health needs. Secretary Leavitt acted under his authority in the Public Health Service Act.

Because of flood damage to local health care facilities, many beneficiaries have been evacuated to neighboring communities, where receiving hospitals and nursing homes may have no health care records, information on current health status or even verification of the person's status as a Medicare beneficiary. CMS is assuring those facilities that in this circumstance, the normal burden of documentation will be waived and that they can act under a presumption of eligibility.

In response to the emergencies resulting from the Midwest flooding, CMS is providing resources to ensure effective health care coverage and quality of care for beneficiaries. CMS extreme weather and emergencies relief activities resource link for Midwest Floods is located by clicking: http://www.cms.hhs.gov/emergency/20_midwestflooding.asp

Questions and Answers on Question and Answer on the Midwest Flooding page may be downloaded by clicking on https://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_pv=2.1019&p_prods=318%2C1019&prod_lv1=318&prod_lv2=1019 (click **New** – CMS Response to Midwest Floods Emergency – go under File Attachments).

To read the HHS Public Health Emergency News Release issued click here: <http://www.hhs.gov/news/press/2008pres/06/20080616a.html>. ❖

Source: CMS Provider Education Resource 200806-15

NEW “K” CODE FOR REPLACEMENT INTERFACE MATERIAL

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Providers who bill Medicare fiscal intermediaries and Medicare administrative contractors (A/B MAC) for providing lower extremity orthosis services to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change request (CR) 6075, from which this article is taken, announces that (effective April 1, 2008) a new temporary “K” code (K0672 – Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each) has been established for replacement interface material. Make sure that your billing staffs are aware of this new temporary K code.

ADDITIONAL INFORMATION

You may find more information in the official instruction (CR 6075) issued regarding the new “K” code for replacement interface material on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1534CP.pdf>.

If you have any questions, please contact your FI or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6075

Related Change Request (CR) Number: 6075

Related CR Release Date: June 13, 2008

Related CR Transmittal Number: R1534CP

Effective Date: April 1, 2008

Implementation Date: June 27, 2008

Source: CMS Pub. 100-04, Transmittal 1534, CR 6075

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THE FOOD AND DRUG ADMINISTRATION RECALLS HEPARIN

Please help the Food and Drug Administration (FDA) spread the word about recalls of injectable heparin products and heparin flush solutions that may be contaminated with oversulfated chondroitin sulfate (OSCS). Affected heparin products have been found in medical care facilities in one state since the recall announcement. Although product recall instructions were widely distributed, they may not have been fully acted upon at all sites where heparin is used. There have been many reports of deaths associated with allergic or hypotensive symptoms after heparin administration (see FDA link at http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm).

We ask that health professionals and facilities please review and examine all drug/device storage areas, including emergency kits, dialysis units and automated drug storage

cabinets to ensure that all of the recalled heparin products have been removed and are no longer available for patient use. In addition, FDA would like to inform health professionals about other types of medical devices that contain, or are coated with, heparin. To read this update, and to learn how to report these problems to FDA, please go to: <http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html>.

Please report to FDA adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions. If you have questions or would like more information about this request, contact the Division of Drug Information at 1-301-796-3400. ❖

Source: CMS Provider Education Resource 200806-06

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INDEPENDENT DIAGNOSTIC TESTING FACILITIES—NEW PROCESSING CHAPTER

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Independent diagnostic testing facilities (IDTFs) submitting claims to Medicare administrative contractors (A/B MACs), fiscal intermediaries (FIs), or carriers for services provided to Medicare beneficiaries.

IMPACT ON PROVIDERS

Change request (CR) 5815 alerts providers to the fact that information from the Medicare Program Integrity Manual, Chapter 10, **regarding claims processing instructions for IDTF's is being excerpted and added to Medicare Claims Processing Manual via Chapter 35**—a new chapter in the *Medicare Claims Processing Manual*. Currently, the *Medicare Claims Processing Manual* does not have claims processing instructions for IDTFs and this CR notifies providers of the availability of this information in that manual. No changes in policy are conveyed in CR 5815.

KEY POINTS OF CHANGE REQUEST 5815

Providers note that information regarding IDTF claims processing has been excerpted from the Medicare Program Integrity Manual, chapter 10, and **moved to the Medicare Claims Processing Manual, chapter 35**, which is a new chapter. The new chapter 35 is available as an attachment to the official instruction of CR 5815. The new chapter contains information on the following:

- General coverage and payment policies applicable to IDTFs
- Medicare's definition of an IDTF
- Claims processing instructions with emphasis on:
 - Billing issues
 - Transtelephonic and electronic monitoring services
 - Slide preparation facilities and radiation therapy centers

- Ordering of tests
- Purchased diagnostic tests
- Interpretations of tests performed off the premises of the IDTF
- Restrictions that do not allow billing for strictly therapeutic procedures.

IDTFs are reminded that the national provider identifier (NPI) of the ordering physician must be supplied in box 17B of the CMS-1500 form and in the appropriate loop of the ANSI X12 837P electronic claim format, effective for services on or after May 23, 2008.

ADDITIONAL INFORMATION

To see the official instruction (CR 5815) issued to your Medicare carrier, FI, or A/B MAC refer to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1504CP.pdf>.

As already mentioned, the new chapter 35 of the *Medicare Claims Processing Manual* is attached to CR 5815.

If you have questions, please contact your Medicare FI, A/B MAC, or carrier at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM5815
Related Change Request (CR) Number: 5815
Related CR Release Date: May 16, 2008
Related CR Transmittal Number: R1504CP
Effective Date: June 16, 2008
Implementation Date: June 16, 2008

Source: CMS Pub. 100-04, Transmittal 1504, CR 5815

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JULY QUARTERLY UPDATE FOR 2008 DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES FEE SCHEDULE

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Providers and suppliers submitting claims to Medicare contractors (carriers, DME Medicare administrative contractors [DME MACs], fiscal intermediaries [FIs], Part A/B Medicare administrative contractors [A/B MACs], and/or regional home health intermediaries [RHHIs]) for DMEPOS provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article is based on change request (CR) 6022, which provides the quarterly update to the July 2008 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedules in order to implement fee schedule amounts for new codes and to revise any fee schedule amounts for existing codes that were calculated in error. Be sure your billing staffs are aware of these changes.

BACKGROUND

This recurring update notification, CR 6022, provides specific instructions regarding the July quarterly update for 2008 for the DMEPOS fee schedule. Payment on a fee schedule basis is required for durable medical equipment (DME), prosthetic devices, orthotics, prosthetics, and surgical dressings by section 1834(a), (h), and (i) of the Social Security Act. Payment on a fee schedule basis is required for parenteral and enteral nutrition (PEN) by regulations contained at 42 CFR 414.102.

The update process for the DMEPOS fee schedule is located in the *Medicare Claims Processing Manual*, chapter 23, section 60, which is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/manuals/downloads/clm104c23.pdf>.

Other information on the fee schedule, including access to the DMEPOS fee schedules is on the CMS Web site at http://www.cms.hhs.gov/DMEPOSFeeSched/01_overview.asp.

KEY POINTS

- The following Healthcare Common Procedure Coding System (HCPCS) codes were added to the HCPCS file effective January 1, 2008, and the fee schedule amounts for these HCPCS codes may be established as part of this update and are effective for claims with dates of service on or after January 1, 2008.

Code Description

A5083	Continent device, stoma absorptive cover for continent stoma
E0856	Cervical traction device, cervical collar with inflatable air bladder
E2227	Manual wheelchair accessory, gear reduction drive wheel, each
E2228	Manual wheelchair accessory, wheel braking system and lock, complete, each
E2397	Power wheelchair accessory, lithium-based battery, each

L3927	Finger orthosis, proximal interphalangeal (pip)/distal interphalangeal (dip), without joint/spring, extension/flexion (e.g. static or ring type), may include soft interface material, prefabricated, includes fitting and adjustment
L7611	Terminal device, hook, mechanical, voluntary opening, any material, any size, lined or unlined, pediatric
L7612	Terminal device, hook, mechanical, voluntary closing, any material, any size, lined or unlined, pediatric
L7613	Terminal device, hand, mechanical, voluntary opening, any material, any size, pediatric
L7614	Terminal device, hand, mechanical, voluntary closing, any material, any size, pediatric
L7621	Terminal device, hook or hand, heavy duty, mechanical, voluntary opening, any material, any size, lined or unlined
L7622	Terminal device, hook or hand, heavy duty, mechanical, voluntary closing, any material, any size, lined or unlined

- The above codes were paid on a local fee schedule basis prior to implementation of the fee schedule amounts established in accordance with this update. Claims for these codes with dates of service on or after January 1, 2008, that have already been processed will not be adjusted to reflect the newly established fees if they are resubmitted for adjustment.
- The fee schedule amounts for the following codes are being revised as part of this quarterly update to correct fee schedule calculation errors and the revised fee schedule amounts will be added to the fee schedule file as part of this update.

Code Description

L3905	Wrist hand orthosis, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3806	Wrist hand finger orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material straps, custom fabricated, includes fitting and adjustment

- Your Medicare contractor will adjust previously processed claims for codes L3905, L3806 and L3808 with dates of service on or after January 1, 2008, if they are resubmitted for adjustments.
- HCPCS code K0672 (Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each) was added to the HCPCS file effective April 1, 2008.

July Quarterly Update for 2008 DMEPOS Fee Schedule (continued)

- The fee schedule amounts for HCPCS code E0461 (Volume control ventilator, without pressure support mode, may include pressure control mode, used with non-invasive interface (e.g. mask)) were inadvertently dropped from the January 2008 DMEPOS fee schedule file and the file was subsequently revised to add the fee schedule amounts for code E0461.

ADDITIONAL INFORMATION

For complete details regarding this CR please see the official instruction (CR 6022) issued to your Medicare contractor. That instruction may be viewed by going to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1516CP.pdf>.

If you have questions, please contact your Medicare contractor at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6022

Related Change Request (CR) Number: 6022

Related CR Release Date: May 23, 2008

Related CR Transmittal Number: R1516CP

Effective Date: January 1, 2008

Implementation Date: July 7, 2008

Source: CMS Pub. 100-04, Transmittal 1516, CR 6022

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DMEPOS COMPETITIVE BIDDING PROGRAM

PHASE 1 OF MANUAL REVISIONS FOR THE DMEPOS COMPETITIVE BIDDING PROGRAM

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

This phase includes important information about the processes that suppliers should follow when making their grandfathering decisions prior to July 1, 2008.

PROVIDER TYPES AFFECTED

Medicare DMEPOS suppliers that bill durable medical equipment Medicare administrative contractors (DME MACs) as well as providers that bill Medicare carriers, fiscal intermediaries (FIs), regional home health intermediaries (RHHIs), or Part A/B Medicare administrative contractors (A/B MACs) that refer or order durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) for Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change request (CR) 5978, from which this article is developed, adds chapter 36 (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program) to the *Medicare Claims Processing Manual*.

This chapter manualizes policies and instructions for Medicare contractors on the DMEPOS Competitive Bidding program. This first installment provides a general overview and guidance for Medicare contractors and suppliers on this program.

Subsequent installments will provide additional instructions and guidelines.

This article complements *MLN Matters* special edition articles SE0805, SE0806, and SE0807, which already cover many of the sections of chapter 36 being added to the *Medicare Claims Processing Manual*.

BACKGROUND

Medicare payment for most DMEPOS is currently based on fee schedules. However, section 1847 of the Social Security Act (the Act), as amended by section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates a competitive bidding program to replace the current DMEPOS methodology for determining payment rates for certain DMEPOS items that are subject to competitive bidding under this statute.

The Centers for Medicare & Medicaid Services (CMS) issued the regulation for the Medicare DMEPOS Competitive Bidding program (published on April 10, 2007 (72 *Federal Register* 68 (10 April 2007) pp. 17991-18090)). This regulation is available on the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>.

CMS encourages readers of this article to also review *MLN Matters* article MM6119, which describes additional sections of chapter 36 of the *Medicare Claims Processing Manual*. (The article is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6119.pdf>.)

The new sections added via CR 6119 all apply to the competitive bidding program. The topics added include the following:

Phase 1 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

- Payment for rental of inexpensive or routinely purchased DME
- Payment for oxygen and oxygen equipment and changing suppliers for oxygen and oxygen equipment
- Payment for capped rental DME items and changing suppliers for capped rental DME items
- Payment for purchased equipment and for repair and replacement of beneficiary-owned equipment
- Payment for enteral nutrition equipment and maintenance and servicing of that equipment
- Traveling beneficiaries and transfer of title of oxygen equipment or capped rental items for traveling beneficiaries
- Advance beneficiary notice (ABN) information pertaining to upgrades under the competitive bidding program
- Billing procedures related to downcoding under the competitive bidding program.

KEY INFORMATION IN CHANGE REQUEST 5978**Contract Supplier Requirements**

Chapter 36 documents contract supplier requirements. For example:

- A contract supplier is required to furnish items under its contract to any Medicare beneficiaries who maintain a permanent residence in or visit the competitive bidding area (CBA).
- A contract supplier must provide competitively bid items unless an exception applies.
- Contract suppliers will be paid for DMEPOS competitively bid items based on bids submitted by qualified DMEPOS suppliers. These payments will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services from qualified suppliers.
- To be considered for participation as a contract supplier in the Medicare DMEPOS Competitive Bidding program, suppliers must submit a bid for each product category in each CBA that they want to furnish to Medicare beneficiaries. DMEPOS suppliers must submit a bid amount for every item within a product category.

Contract supplier requirements and responsibilities are specified in chapter 36 and include topics such as: who is eligible to submit bids; small supplier contract suppliers and networks; prescriptions for particular brand, item or mode of delivery; reports; change of ownership; billing privileges, and accreditation. This article will provide detail on some of these provisions, but impacted providers and suppliers should review the official manual revisions contained in CR 5978, as well as in the recently released CR 6119.

Noncontract Suppliers That Elect To Become “Grandfathered” Suppliers – Notice to Beneficiaries

A “Grandfathered” supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA to whom the supplier had furnished the items prior to implementation of the competitive bidding program.

A noncontract supplier that elects to become a grandfathered supplier is responsible for **notifying all its Medicare customers** residing in CBAs to whom it supplies items identified in section 20.6.1 of the new manual chapter 36. This chapter is available on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf>.

Note: As discussed in the expanded section 20.6.1

attached to CR 6119, this notification should only be sent to beneficiaries who the supplier is currently serving and who maintain a permanent residence in a CBA. The list of ZIP codes for each CBA, the list of the HCPCS for competitively bid items, and the single payment amounts for these items are located in public use files on the CBIC Web site on the Internet at <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home> or on the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

The beneficiary notification should include the following:

- It should state that the supplier is offering to continue to furnish rental DME, oxygen and oxygen equipment and/or related accessories and supplies that it is currently furnishing to the beneficiary (i.e., before the start of the competitive bidding program) and to provide these items to the beneficiary for the remainder of the rental period.
- It should state that the supplier is offering to continue to furnish rental DME and/or oxygen and oxygen equipment that it had been furnishing to the beneficiary before the start of the competitive bidding program and to provide these items for the remainder of the rental period.
- It should state that the beneficiary has the choice to continue to receive a grandfathered item from the grandfathered supplier or to elect to begin receiving the item from a contract supplier after the competitive bidding program begins.
- It should provide the supplier’s telephone number so the beneficiary or caregiver may call and notify the supplier of his/her election.
- The supplier should provide the written notification to the beneficiary at least 30 days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding program.
- The supplier should receive an election from a beneficiary and maintain a record as to whether the beneficiary chose to continue to receive the item from a grandfathered supplier, chose to go to a contract supplier to receive the item or did not respond.
- The supplier should inform the beneficiary of the end date of service and that arrangements will be made to pick-up the item within 10 days of picking up the item.

Sample election/notification letters are available on the Internet at <http://www.dmecompetitivebid.com>.

Noncontract Suppliers That Do Not Elect To Become “Grandfathered” Suppliers: Notice to Beneficiaries

A noncontract supplier that elects not to become a grandfathered supplier as defined above should provide

Phase 1 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

notification to the beneficiary stating the supplier will not continue to furnish, after the start of the Medicare DMEPOS Competitive Bidding program, the competitively bid item(s) that the beneficiary has been receiving from the supplier.

Note: As mentioned in the updated section 20.6.1 attached to CR 6119, this notification should only be sent to beneficiaries who the supplier is currently serving and who maintain a permanent residence in a CBA. The list of ZIP codes for each CBA, the list of the HCPCS for competitively bid items, and the single payment amounts for these items are located in public use files on the CBIC Web site at <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home> or on the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

The notification should include the following:

- It should state that the supplier will not continue to furnish rental DME and/or oxygen and oxygen equipment that it had been furnishing to the beneficiary **after** the start of the competitive bidding program and that the beneficiary will need to select a contract supplier to continue to receive these items.
- It should inform the beneficiary of the start of the competitive bidding program and the date the supplier plans to pick up the item.
- It should inform the beneficiary that he/she may obtain further information on the program by calling 1-800-Medicare or accessing on the Internet <http://www.medicare.gov>.
- The supplier should provide this written notification to the beneficiary 30 days before the start date for the Medicare DMEPOS Competitive Bidding program.
- The supplier should inform the beneficiary of the end date of service and that arrangements will be made to pick-up the item within 10 days of picking up the item.

Sample election/notification letters are available on the Internet at <http://www.dmecompetitivebid.com>.

Picking-up Equipment

Under no circumstances may the supplier discontinue services by picking up a medically necessary item(s) prior to the end of a month for which the supplier is eligible to receive a rental payment, even if the last day ends after the start date of the Medicare DMEPOS Competitive Bidding program. A noncontract supplier may only pick up medically necessary oxygen equipment or capped rental DME prior to the start of the competitive bidding program or prior to the end of the month for which the supplier is eligible to receive payment if the beneficiary relocates his/her permanent residence outside the CBA and outside the normal service area of the supplier.

The pick-up by the noncontract supplier and the delivery by the contract supplier of the equipment should occur on the same day and month as the item rental anniversary date. The anniversary date is the day of the month on which the item was first delivered to the beneficiary.

In all cases, CMS expects the contract supplier to consult with the noncontract supplier to obtain the

anniversary date. The noncontract supplier should work with the contract supplier so that there is no break in service or furnishing of medically necessary items. CMS expects the contract supplier and the current supplier will work together to make arrangements suitable to the beneficiary's needs.

- Examples: Using July 1 as the beginning date of the Medicare DMEPOS Competitive Bidding program:
 - A. If a beneficiary's last anniversary date before the beginning of the competitive bidding program is **June 29**, the noncontract supplier must submit a claim for the rental month beginning June 29 and ending July 28. The noncontract supplier must not pick up the equipment prior to July 29. In this case, the current supplier would pick up its equipment, on July 29, and the contract supplier would deliver its equipment on July 29.
 - B. If a beneficiary's anniversary date is **July 1**, the beginning date for the competitive bidding program, the noncontract supplier must not pick up the equipment before July 1 and must not submit a claim for the July rental period. The contract supplier should deliver the equipment to the beneficiary on July 1 and must submit a claim for this month.

For capped rental DME or oxygen and oxygen equipment, the noncontract supplier is responsible for submitting a claim for any rental period that begins prior to the start of the competitive bidding program.

Exceptions

Medicare DME MACS will continue to apply all existing instructions for DMEPOS unless otherwise noted in CR 5978. In general, noncontract suppliers will not be paid for furnishing DMEPOS competitively bid items to beneficiaries in a CBA.

Only a contract supplier is eligible for Medicare payment for competitively bid items furnished to a Medicare beneficiary within a CBA, unless an exception applies. For example:

1. A noncontract supplier that has a valid national supplier clearinghouse (NSC) number may receive a Medicare secondary payment for a competitively bid item furnished to a beneficiary residing in a CBA if the beneficiary is required to use that supplier under his/her primary insurance policy.
2. A grandfathered supplier may continue to furnish a grandfathered item to a beneficiary residing in a CBA. Grandfathered items are limited to inexpensive or routinely purchased items furnished on a rental basis; items requiring frequent and substantial servicing; oxygen and oxygen equipment; and capped rental items furnished on a rental basis.
3. A physician, treating practitioner, physical therapist in private practice or occupational therapist in private practice may furnish certain competitively bid items in a CBA if certain requirements are met.

Phase 1 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)**Important Note Regarding Rented Enteral Nutrition Infusion Pumps**

The grandfathering option does **NOT** apply to enteral nutrition equipment. In accordance with current instructions in section 30.7.1 of chapter 20 of the *Medicare Claims Processing Manual*, payment for rental of enteral infusion pumps is limited to a total of 15 months during a period of medical need. The supplier that collects the last month of rental (i.e., the 15th month) is responsible for ensuring that the beneficiary has a pump for the duration of medical necessity and for maintenance and servicing of the pump during the duration of therapy. Therefore, if a supplier is currently furnishing an enteral nutrition infusion pump to a Medicare beneficiary in a CBA on a rental basis and has not been awarded a contract to furnish enteral nutrients, supplies, and equipment, the supplier must either:

1. Inform the beneficiary if they are in rental months 1 thru 14 that they will need to contact a contract supplier for this product category to arrange for continuation of all of their enteral nutrition services; or
2. Inform the beneficiary if they are beyond rental month 15 that they will continue to furnish and maintain the pump for the duration of medical necessity, but that the beneficiary will need to contact a contract supplier to arrange for continuation of the services of furnishing the enteral nutrients and supplies.

With regard to scenario number 1 above, under no circumstances may the supplier discontinue services by picking up a medically necessary item(s) prior to the end of a month for which the supplier is eligible to receive a rental payment, even if the last day ends after the start date of the Medicare DMEPOS Competitive Bidding Program. The pick up by the noncontract supplier and the delivery by the contract supplier of the equipment should occur on the same day and month as the item rental anniversary date. The anniversary date is the day of the month on which the item was first delivered to the beneficiary. In all cases, CMS expects the contract supplier to consult with the noncontract supplier to obtain the anniversary date.

With regard to both scenarios above, the noncontract supplier should work with the contract supplier so that there is no break in service or furnishing of medically necessary nutrients, supplies, and equipment. CMS expects the contract supplier and the current supplier will work together to make arrangements suitable to the beneficiary's needs.

Payment

- The Medicare payment amount for competitively bid items is based on the CBA in which the beneficiary maintains a permanent residence.
- Medicare will make payment for competitively bid items on an assignment-related basis equal to 80 percent of the applicable single payment amount.

Prescription for Particular Brand, Item, or Mode of Delivery

As discussed in section 30.4 on the manual section added in CR 6119, contract suppliers are not required to furnish a specific brand name item or mode of delivery to a beneficiary unless prescribed by a physician or treating

practitioner to avoid an adverse medical outcome. A physician or treating practitioner (that is a physician assistant, clinical nurse specialist, or nurse practitioner) may prescribe, in writing, a particular brand of a competitively bid item or mode of delivery for an item if he or she determines that the particular brand or mode of delivery is necessary to avoid an adverse medical outcome for the beneficiary. The physician or treating practitioner must document in the beneficiary's medical record the reason why the specific brand or mode of delivery is necessary to avoid an adverse medical outcome.

This documentation should include the following:

- The product's brand name or mode of delivery
- The features that this product or mode of delivery has versus other brand name products or modes of delivery.
- An explanation of how these features are necessary to avoid an adverse medical outcome.

If a physician or treating practitioner prescribes a particular brand or mode of delivery to avoid an adverse medical outcome, the contract supplier must either:

1. Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner.
2. Consult with the physician or treating practitioner to find another appropriate brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or
3. Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

Any change in the prescription requires a revised written prescription for Medicare payment. A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner.

Other Provisions Already Covered in MLN Matters Special Edition Articles SE0805, SE0806, SE0807 and MM6119

- Medicare will pay mail order contract suppliers the single payment amount for furnishing competitively bid mail order diabetic testing supplies to Medicare beneficiaries residing in the CBAs for which they have contracts. All mail order diabetic supplies suppliers must use the HCPCS modifier **KL** on each claim to indicate that the competitively bid item was furnished on a mail order basis. The modifier must be used for both competitive bidding and non-competitive bidding mail order diabetic supplies claims. Suppliers that furnish mail order diabetic supplies that fail to use the HCPCS modifier **KL** on the claim may be subject to penalties under the False Claims Act.
- Medicare will pay the fee schedule amount for non-mail order diabetic testing supplies to Medicare enrolled suppliers for the state where the beneficiary maintains a permanent residence.

Phase 1 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

- Medicare allows for the repair and replacement of parts for beneficiary-owned items by any Medicare enrolled supplier. **Note:** *Labor to repair equipment is not subject to competitive bidding and will be paid according to Medicare's general payment rules.*
- Competitive bidding applies to skilled nursing facilities (SNFs) and nursing facilities (NFs) to the extent that their residents receive competitively bid items under Medicare Part B. SNFs and NFs have the option to bid for, and be awarded contracts to be "specialty suppliers" that only furnish competitively bid items to their own residents or become a regular contract supplier that furnishes competitively bid items to beneficiaries throughout a CBA. If a SNF or NF is not a contract supplier (either a specialty contract supplier or a regular contract supplier), it must use a contract supplier for its CBA to furnish competitively bid items to its residents.
- Except where an exception applies, a beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA, unless the beneficiary has signed an advance beneficiary notice (ABN). ABN forms are available on the CMS Web site at http://www.cms.hhs.gov/BNI/02_ABNGABNL.asp.
- As related in CR 6119, home health agencies must submit a bid and be awarded a contract for the DMEPOS Competitive Bidding program in order to furnish competitively bid items directly to Medicare beneficiaries who maintain a permanent residence in a CBA. If a home health agency is not awarded a contract to furnish competitively bid items, then they must use a contract supplier for these items.

Important Previously Issued Capped Rental Instructions

All suppliers should pay attention to the new chapter 36, sections 20.6.4 (Transfer of Title for Oxygen Equipment and Capped Rental DME) and 20.6.5 (Capped Rental DME Furnished Prior to January 1, 2006). Previously, CR 5010 detailed the changes in the payment for oxygen equipment and capped rental equipment as a result of the Deficit Reduction Act (DRA) of 2005. The MLN Matters article on that issue, MM5010, is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5010.pdf>.

CR 5461 covered changes in maintaining and servicing capped rental DME and oxygen equipment as a result of the DRA, especially requirements for maintenance of **capped**

rental DME furnished PRIOR TO January 1, 2006. These items are subject to the capped rental payment rules in effect prior to the changes made by the DRA. For such items, the supplier that provides the item in the 15th month of the rental period is responsible for supplying the equipment and its maintenance and servicing after the 15—month period. This requirement is not eliminated by the competitive bidding program and applies to contract and noncontract suppliers whether or not the noncontract supplier is a grandfathered supplier. The MLN Matters article related to CR 5461 is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5461.pdf>.

ADDITIONAL INFORMATION

You may find more information about the payment changes for DMEPOS items as a result of the DMEPOS competitive bidding program and the Deficit Reduction Act of 2005 by going to CR 5978, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf>.

You will find the updated *Medicare Claims Processing Manual* Chapter 36 (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program) as an attachment to that CR. CR6119 is also available on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.

Additional information regarding this program, including tip sheets for specific Medicare provider audiences, may be found on the CMS dedicated Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

Click on the "Provider Educational Products and Resources" tab and scroll down to the "Downloads" section.

If you have any questions, please contact your carrier, FI, RHHI, A/B MAC, or DME MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

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PHASE 2 OF MANUAL REVISIONS FOR THE DMEPOS COMPETITIVE BIDDING PROGRAM

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

Note: The Centers for Medicare & Medicaid Services (CMS) issued MLN Matters article MM6112 announcing the availability of important information regarding the ordering of certain power mobility devices during the transition period just prior to implementation of the DMEPOS competitive bidding program. This information is available in MLN Matters article, MM6112, on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6112.pdf>.

PROVIDER TYPES AFFECTED

All Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers who bill DME Medicare administrative contractors (MACs) as well as any providers who refer or order DMEPOS for Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change request (CR) 6119, from which this article is developed, is the second installment of, and adds information to, chapter 36 DMEPOS Competitive Bidding program in the *Medicare Claims Processing Manual*. CR 5978 provided the first installment of chapter 36 and details the initial requirements of this program. The companion MLN Matters article to CR 5978 is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5978.pdf>.

Chapter 36 manualizes policies and instructions for Medicare contractors on the DMEPOS Competitive Bidding program. Subsequent installments may follow providing additional sections to the chapter.

This article complements MLN Matters articles MM5978, SE0805, SE0806, and SE0807, which already cover many of the sections of the new chapter being added to the *Medicare Claims Processing Manual*. These articles in combination with this one cover the key sections of chapter 36.

BACKGROUND

The Medicare payment for most DMEPOS is currently based on fee schedules. However, in amending section 1847 of the Social Security Act (the Act), section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates a competitive bidding program to replace the current DMEPOS methodology for determining payment rates for certain DMEPOS items that are subject to competitive bidding under this statute.

In compliance with the statute mandate that this competitive bidding program be phased-in beginning in 2007, CMS issued the regulation for the competitive bidding program (published on April 10, 2007 (72 *Federal Register* 68 (10 April 2007) pp. 17991-18090)). This regulation is available on the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>.

CHANGE REQUEST 6119 KEY POINTS

Key points of CR 6119 that address a number of areas detailed in chapter 36 of the *Medicare Claims Processing Manual* are as follows:

Home Health Agencies

Home health agencies must submit a bid and be awarded a contract for the DMEPOS Competitive Bidding program in order to furnish competitively bid items directly to Medicare beneficiaries who maintain a permanent residence

in a competitive bidding area (CBA). If a home health agency is not awarded a contract to furnish competitively bid items, then they must use a contract supplier for these items.

Prescription for Particular Brand, Item, or Mode of Delivery

Contract suppliers are required to furnish a specific brand name item or mode of delivery to a beneficiary if prescribed by a physician or treating practitioner (that is a physician assistant, clinical nurse specialist, or nurse practitioner) to avoid an adverse medical outcome for the beneficiary. The physician or treating practitioner must document in the beneficiary's medical record the reason why the specific brand or mode of delivery is necessary to avoid an adverse medical outcome. This documentation should include the following:

- The product brand name or mode of delivery
- The features that this product or mode of delivery has versus other brand name products or modes of delivery.
- An explanation of how these features are necessary to avoid an adverse medical outcome.

If a physician or treating practitioner prescribes a particular brand or mode of delivery to avoid an adverse medical outcome, the contract supplier must either:

- Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;
- Consult with the physician or treating practitioner to find another appropriate brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or
- Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

Any change in the prescription requires a revised written prescription for Medicare payment. A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner.

Payment for Rental of Inexpensive or Routinely Purchased DME

The monthly rental payment amounts for inexpensive or routinely purchased DME (identified using Healthcare Common Procedure Coding System (HCPCS) modifier RR) are equal to 10 percent of the single payment amount established for purchase of the item.

Payment for Oxygen and Oxygen Equipment

The monthly payment amounts for oxygen and oxygen equipment are equal to the single payment amounts established for the following classes of items:

Phase 2 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

- Stationary oxygen equipment (including stationary oxygen concentrators) and oxygen contents (stationary and portable)
- Portable equipment only (gaseous or liquid tanks)
- Oxygen generating portable equipment (OGPE) only (used in lieu of traditional portable oxygen equipment/tanks)
- Stationary oxygen contents (for beneficiary-owned stationary liquid or gaseous equipment)
- Portable oxygen contents (for beneficiary-owned portable liquid or gaseous equipment).

In cases where a supplier is furnishing both stationary oxygen contents and portable oxygen contents, the supplier is paid both the single payment amount for stationary oxygen contents and the single payment amount for portable oxygen contents. The payment amounts for purchase of supplies and accessories used with beneficiary-owned oxygen equipment are equal to the single payment amounts established for the supply or accessory.

Change in Suppliers for Oxygen and Oxygen Equipment

The following rules apply when the beneficiary switches from one supplier of oxygen and oxygen equipment to another supplier after the beginning of each round of competitive bidding:

Noncontract supplier to contract supplier

In general, monthly payment amounts may not exceed a period of continuous use of longer than 36 months. However, if the beneficiary switches from a noncontract supplier to a contract supplier before the end of the 36-month period, at least 10 monthly payment amounts would be made to a contract supplier that begins furnishing oxygen and oxygen equipment in these situations provided that medical necessity for oxygen continues.

For example, if a contract supplier begins furnishing oxygen equipment to a beneficiary in months two through 26, payment would be made for the remaining number of months in the 36-month period, because the number of payments to the contract supplier would be at least 10 payments. To provide a more specific example, a contract supplier that begins furnishing oxygen equipment beginning with the 20th month of continuous use would receive 17 payments (17 for the remaining number of months in the 36-month period). However, if a contract supplier begins furnishing oxygen equipment to a beneficiary in month 27 or later, no more than 10 monthly payments would be made assuming the oxygen equipment remains medically necessary.

Contract supplier to another contract supplier

This rule does not apply when a beneficiary switches from a contract supplier to another contract supplier to receive his/her oxygen and oxygen equipment. In this scenario, the new contract supplier is paid based on the single payment amount for the remaining number of months in the 36-month period assuming the oxygen equipment remains medically necessary.

Payment for Capped Rental DME Items

The monthly rental payment amounts for capped rental DME (identified using HCPCS modifier RR) are equal to 10

percent of the single payment amount established for purchase of the item for each of the first 3 months and 7.5 percent of the single payment amount established for purchase of the item for months 4 through 13.

Change in Suppliers for Capped Rental DME Items

The following rules apply when the beneficiary switches from one supplier of capped rental DME to another supplier after the beginning of each round of competitive bidding:

Noncontract supplier to contract supplier

In general, rental payments may not exceed a period of continuous use of longer than 13 months. However, if the beneficiary switches from a noncontract supplier to a contract supplier before the end of the 13-month rental period, a new 13-month period begins and payment is made on the basis of the single payment amounts described above under "Payment for Capped Rental DME Items." The contract supplier that the beneficiary switches to is responsible for furnishing the item until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier. On the first day following the end of the new 13-month rental period, the contract supplier is required to transfer title of the capped rental item to the beneficiary. Once the beneficiary switches from a noncontract supplier to a contract supplier, he/she may not switch back to a noncontract supplier if he/she continues to maintain a permanent residence in a CBA. If, however, the beneficiary relocates out of the CBA to a non-CBA, then he/she may switch to a noncontract supplier and a new 13-month rental period does not begin.

Contract supplier to another contract supplier

If the beneficiary switches from one contract supplier to another contract supplier before the end of the 13-month rental period, a new 13-month period does not begin. This rule applies in situations where the beneficiary changes suppliers within a CBA and in situations where the beneficiary relocates and switches from a contract supplier in one CBA to a contract supplier in another CBA. The contract supplier that the beneficiary switches to is responsible for furnishing the item until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier. On the first day following the end of the 13-month rental period, the contract supplier is required to transfer title of the capped rental item to the beneficiary.

Payment for Purchased Equipment

Payment for purchase of new equipment (identified using HCPCS modifier NU), including inexpensive or routinely purchased DME, power wheelchairs, and enteral nutrition equipment, is equal to 100 percent of the single payment amounts established for these items. Payment for purchase of used equipment (identified using HCPCS modifier UE), including inexpensive or routinely purchased DME, power wheelchairs, and enteral nutrition equipment, is equal to 75 percent of the single payment amounts established for new purchase equipment items.

Phase 2 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

Payment for Repair and Replacement of Beneficiary-Owned Equipment

Beneficiaries who maintain a permanent residence in a CBA may go to any Medicare-enrolled supplier (contract or noncontract supplier) for the maintenance or repair of beneficiary-owned equipment, including parts that need to be replaced in order to make the equipment serviceable. Labor to repair equipment is not subject to competitive bidding and, therefore, will be paid in accordance with Medicare's general payment rules. Payment for replacement parts that are part of the competitive bidding program for the CBA in which the beneficiary resides is based on the single payment amount in that CBA for that replacement part. Payment is not made for parts and labor covered under a manufacturer's or supplier's warranty.

Beneficiaries must obtain replacements of all items that are part of the competitive bidding program for the areas in which the beneficiary resides from a contract supplier unless the item is a replacement part or accessory that is replaced as part of the service of repairing beneficiary-owned base equipment (e.g. wheelchair, walker, hospital bed, continuous positive pressure airway device, oxygen concentrator, etc.). All base equipment that is replaced in its entirety because of a change in the beneficiary's medical condition or because the base equipment the beneficiary was using was either lost, stolen, irreparably damaged, or used beyond the equipment's reasonable useful lifetime (see section 110.2.C of chapter 15 of the *Medicare Benefit Policy Manual* on the CMS Web site at <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>) must be obtained from a contract supplier in order for Medicare to pay for the replacement. Payment for replacement of items that are part of the competitive bidding program for the CBA in which the beneficiary resides is based on the single payment amount for that item. The contract supplier is not required to replace an entire competitively bid item with the same make and model as the previous item unless a physician or treating practitioner prescribes that make and model.

If beneficiary-owned oxygen equipment or capped rental DME that is a competitively bid item for the CBA in which the beneficiary maintains a permanent residence has to be replaced prior to the end of its reasonable useful lifetime, then the replacement item must be furnished by the supplier (contract or noncontract supplier) that transferred ownership of the item to the beneficiary.

Payment for Enteral Nutrition Equipment

The monthly rental payment amounts for enteral nutrition equipment (identified using HCPCS modifier RR) are equal to 10 percent of the single payment amount established for purchase of the item for each of the first three months and 7.5 percent of the single payment amount established for purchase of the item for months four through 15.

Maintenance and Servicing of Enteral Nutrition Equipment

The contract supplier that furnishes the equipment to the beneficiary in the 15th month of the rental period must continue to furnish, maintain, and service the equipment after the 15 month rental period is completed until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary. The payment for maintenance and servicing enteral nutrition equipment is five percent of the single payment amount established for purchase of the item.

Traveling Beneficiaries

Beneficiaries, who travel outside their CBA, for example, to visit family members or reside in a state with warmer climates during winter months, need to consider the following three factors when traveling:

- Where to go to obtain a DMEPOS item.
- Identify whether the item is a competitively bid item or not.
- Determine the Medicare payment amount for that item.

Depending on where the beneficiary travels (whether to a CBA or a non-CBA), the beneficiary may need to obtain DMEPOS from a contract supplier in order for Medicare to cover the item. For example, a beneficiary who travels to a non-CBA may obtain DMEPOS, if medically necessary, from any Medicare-enrolled supplier. On the other hand, a beneficiary who travels to a CBA should obtain competitively bid items in that CBA from a contract supplier in that CBA in order for Medicare to cover the item. The chart below shows whether a beneficiary should go to a contract supplier or any Medicare-enrolled supplier when the beneficiary travels.

Beneficiary Permanently Resides in	Travels to	Type of Supplier
a CBA	a CBA	The beneficiary should obtain competitively bid items in that CBA from a contract supplier located in that CBA if the beneficiary wants Medicare to cover the item.
	a non-CBA	Medicare will cover DMEPOS, if medically necessary, from any Medicare-enrolled DMEPOS supplier.
a non-CBA	a CBA	The beneficiary should obtain the competitively bid item from a contract supplier in the CBA if the beneficiary wants Medicare to cover the item.
	a non-CBA	Medicare-enrolled DMEPOS supplier.

Suppliers that furnish DMEPOS items to Medicare beneficiaries who maintain a permanent residence in a CBA and who travel to a non-CBA need to be aware of the public use files on the competitive bidding implementation contractor (CBIC) Web site at <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home>.

These files contain the ZIP codes for the CBAs, the HCPCS codes for competitively bid items, and related single payment amounts for competitively bid items. The Medicare payment amount is always based on the location in which the beneficiary maintains a permanent residence. For example:

Phase 2 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

1. If a beneficiary maintains a permanent residence in a CBA and travels outside of the CBA, payment for a competitively bid item for the CBA in which the beneficiary maintains a permanent residence is the single payment amount for that item in the beneficiary's CBA.
2. When a beneficiary maintains a permanent residence in an area that is not in a CBA and travels to CBA or non-CBA, the supplier that furnishes the item will be paid the fee schedule amount for the area where the beneficiary maintains a permanent residence.

Traveling Beneficiaries and Transfer of Title of Oxygen Equipment or Capped Rental Items

If a beneficiary who has two residences in different areas and uses a local supplier in each area or if a beneficiary changes suppliers during or after the rental period, this does not result in a new rental episode. The supplier that provides the item in the 36th month of rental for oxygen equipment or the 13th month of rental for capped rental DME is responsible for transferring title to the equipment to the beneficiary. This applies to "snow bird" or extended travel patients and coordinated services for patients who travel after they have purchased the item.

Advance Beneficiary Notice Billing Procedures Related to Advance Beneficiary Notice Upgrades Under the Competitive Bidding Program

In general, a contract supplier must furnish an item included in a competitive bidding program for Medicare to make payment. This requirement applies to situations where the item is furnished directly or indirectly as an upgrade. An upgrade is an item with features that go beyond what is medically necessary. An upgrade may include an excess component. An excess component may be an item feature or service, which is in addition to, or is more extensive than, the item that is reasonable and necessary under Medicare coverage requirements. An item is indirectly furnished if Medicare makes payment for it because it is medically necessary and is furnished as part of an upgraded item. The billing instructions for upgraded equipment found in section 120 of chapter 20 of the Medicare Claims Processing Manual (available on the CMS Web site at <http://www.cms.hhs.gov/manuals/Downloads/clm104c20.pdf>) continue to apply under the DMEPOS Competitive Bidding program. Consider the following:

1. **Where a beneficiary, residing in a competitive bidding area, elects to upgrade to an item with features or upgrades that are not medically necessary:**
 - **Upgrades from a bid item to a non-bid item**
In this situation, Medicare payment will only be made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the single payment amount for the medically necessary bid item.
 - **Upgrades from a non-bid item to a bid item**
When upgrading from a non-bid to a bid item, Medicare payment is made to a contract supplier on either an assigned or unassigned basis. Medicare

payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.

- **Upgrades from a bid item in one product category (category "S") to a bid item in another product category (category "U")**

In this case, Medicare payment is only made to a contract supplier for the product category "U" on an assignment-related basis. Medicare payment would be equal to 80 percent of the single payment amount for the medically necessary bid item in product category "S."

1. **Where a beneficiary, who does not reside in a competitive bidding area, but travels to a competitive bidding area, elects to upgrade to an item with features that are not medically necessary:**

- **Upgrades from a bid item to a non-bid item**
In this situation, Medicare payment is only made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary bid item.
- **Upgrades from a non-bid item to a bid item**
When upgrading from a non-bid to a bid item, Medicare payment is made to a contract supplier on either an assigned or unassigned basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.
- **Upgrades from a bid item in one product category (category "S") to a bid item in another product category (category "U")**
In this case, Medicare payment is only made to a contract supplier for the product category "U" on an assignment-related basis. Medicare payment would be equal to 80 percent of lower of the actual charge or the fee schedule amount for the medically necessary bid item in product category "S."

Note: In the *Medicare Claims Processing Manual* chapter 36 section 40.11 attached to CR 6119 on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>, a detailed chart describe situations where a beneficiary, residing in a CBA, elects to upgrade to an item with features or upgrades that are not medically necessary.

Beneficiary Liability

Under the competitive bidding program, a beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a competitive bidding area, unless the beneficiary has signed an advance beneficiary notice (ABN). Similarly, beneficiaries who receive an upgraded item from a noncontract supplier in a competitive bidding area are not financially liable for the item unless the supplier has obtained a signed ABN from the beneficiary.

In the case of upgrades, for a beneficiary to be liable for the extra cost of an item that exceeds their medical needs, the beneficiary must sign the appropriate ABN. See chapter 20, section 120 of the *Medicare Claims Processing Manual*

Phase 2 of Manual Revisions for the DMEPOS Competitive Bidding Program (continued)

on the CMS Web site at <http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf> or additional information on ABN upgrades.

Billing Procedures Related to Downcoding under the Competitive Bidding Program

The following downcoding guidelines describe situations where Medicare reduces the level of payment for the prescribed item based on a medical necessity partial denial of coverage for the additional, not medically necessary, expenses associated with the prescribed item.

1. For beneficiaries who reside in a CBA and for whom Medicare determines that the prescribed item should be downcoded to an item that is reasonable and necessary under Medicare coverage requirements.

- **Downcodes from a non-bid item to a bid item**
In this situation, Medicare payment will be made to any Medicare enrolled supplier on an assigned or unassigned basis. Medicare payment will be equal to 80 percent of the single payment amount for the medically necessary bid item.
- **Downcodes from a bid item to a non-bid item**
Medicare payment in this downcoding scenario will be made to a contract supplier on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.
- **Downcodes from a bid item in one product category (category "U") to a bid item in another product category (category "S")**
In this case, Medicare payment will be made to a contract supplier for the product category "U" on an assignment-related basis. Medicare payment would be equal to 80 percent of the single payment amount for the medically necessary bid item in product category "S."

2. For a beneficiary who does not reside in a CBA, but travels to a CBA and for whom Medicare determines that the prescribed item is downcoded to an item that is reasonable and necessary under Medicare's coverage requirements.

- **Downcodes from a non-bid item to a bid item**
In this situation, Medicare payment will be made to any Medicare enrolled supplier on an assigned or unassigned basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary bid item.
- **Downcodes from a bid item to a non-bid item**
Medicare payment in this downcoding scenario will only be made to a contract supplier on an

assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary non-bid item.

- Downcodes from a bid item in one product category (category "U") to a bid item in another product category (category "S")
In this case, Medicare payment will only be made to a contract supplier for the product category "U" on an assignment-related basis. Medicare payment will be equal to 80 percent of the lower of the actual charge or the fee schedule amount for the medically necessary bid item in product category "S."

A detailed chart of downcoding scenarios is in the new chapter 36, section 40.12 (attached to CR 6119) for beneficiaries who reside in a CBA and for whom Medicare determines that the prescribed item should be downcoded to an item that is reasonable and necessary under Medicare's coverage requirements.

ADDITIONAL INFORMATION

You may find more information about the payment changes for DMEPOS items as a result of the DMEPOS competitive bidding program and the Deficit Reduction Act of 2005 by going to CR 6119, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.

You will find the updated *Medicare Claims Processing Manual*, chapter 36 (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program) as an attachment to that CR.

Additional information regarding this program, including tip sheets for specific Medicare provider audiences, may be found on the CMS dedicated Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

Click on the "Provider Educational Products and Resources" tab and scroll down to the "Downloads" section.

If you have any questions, please contact your carrier, FI, RHII, A/B MAC, or DME MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

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MARKETING RULES REMINDERS FOR DME SUPPLIERS UNDER THE DMEPOS COMPETITIVE BIDDING PROGRAM

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Medicare durable medical equipment suppliers

OVERVIEW

- All of the existing rules and regulations marketing durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to beneficiaries under the fee-for-service program also apply to DMEPOS suppliers under competitive bidding.
- There is no difference for contract versus non-contract suppliers when it comes to these marketing rules.
- The Medicare program does not have specific rules or guidelines that provide guidance as to what a provider is allowed to do in marketing its items and services to the public.
- The Medicare program does not try to interfere with the internal administration or processes that a DMEPOS supplier will use to run its business. However, there are a few certain prohibitions that do apply to the DMEPOS suppliers.

MARKETING PROHIBITIONS

When enrolling in the Medicare program, DMEPOS suppliers agree to abide by the 21 DMEPOS standards that are noted in our regulations at 42 C.F.R. section 424.57. The area of marketing prohibition is addressed as one of the standards that must be met. Failure to comply with this standard may also result in the supplier's Medicare number being revoked.

Use of HHS or CMS Logos

All of the existing rules and regulations regarding supplier marketing to beneficiaries under the Medicare fee-for-service program apply under the Medicare DMEPOS competitive bidding program. For example, suppliers are prohibited from misusing symbols, emblems or names in reference to Centers for Medicare & Medicaid Services (CMS) or Medicare. (See section 1140(a) of the Social Security Act at the Internet http://www.socialsecurity.gov/OP_Home/ssact/title11/1140.htm.)

The use of such logos, names or words in its advertisements which may convey to the public (or may be reasonably interpreted by a consumer) the false impression that its items or services are approved, endorsed or authorized by the agency are prohibited. However, in limited situations, a DMEPOS supplier may be authorized to promote these prohibited logos, names or endorsements only if they have obtained a specific and written authorization from the agency. Such permission is only granted by CMS' Public Affairs Office. If a DMEPOS supplier is found to misrepresent and produce such logos, names or words in its advertisements through various means (newspapers, magazines, television, mailings, Internet Web sites etc.) and has not been authorized to use such logos or a manner that misrepresents, the supplier may be subject to sanctions imposed by the Office of Inspector General. (The sanction is a civil monetary penalty [depending on the type of

conveyance, such penalty may not exceed \$5,000 to \$25,000] for each and every violation identified.)

Unsolicited Telephone Contacts to Medicare Beneficiaries

Under section 1834(a)(17) of the Social Security Act, DMEPOS suppliers are prohibited from making unsolicited telephone contacts, sometimes referred to as "cold calling" to Medicare beneficiaries. (See the section of the Act on the Internet at http://www.socialsecurity.gov/OP_Home/ssact/title18/1834.htm.)

There are however, three exceptions where a supplier may contact our beneficiaries by telephone. These exceptions are:

1. The beneficiary has given written permission to the supplier to contact them by telephone about furnishing a DMEPOS item.
2. The supplier has furnished a covered DMEPOS item and the supplier is contacting the beneficiary only regarding the furnishing of the item; or
3. If the supplier has furnished a covered item to the beneficiary during the past 15 months of the telephone contact, the supplier may contact the beneficiary about other items that they are able to provide to the beneficiary if needed.

If a supplier unsolicited contact does not fall into one of these exceptions, neither CMS nor the beneficiary is obligated to pay the supplier for items. Furthermore, if the supplier knowingly contacts beneficiaries in violation of Medicare rules on unsolicited contacts to Medicare beneficiaries, and to the extent such behavior establishes a pattern of conduct, CMS may consider excluding the supplier from the program.

CMS MONITORING OF DMEPOS MARKETING UNDER THE COMPETITIVE BIDDING PROGRAM

CMS will be actively encouraging the monitoring of non-compliance with the marketing prohibitions noted above. CMS will promote the awareness of these prohibitions through calls with the DMEPOS supplier communities, through the beneficiary and supplier outreach activities of our competitive bid implementation contractor (CBIC) Ombudsman and various other activities being coordinated from the CMS regional offices. CMS will suggest the public report potential violations to their respective CBIC Ombudsman, to 1-800-MEDICARE, or to the OIG hotline. If reported to the CBIC Ombudsman, the Ombudsman will be directed to forward the potential violation to the CMS program Integrity contact. If reported to 1-800-MEDICARE, they will forward the information to the DME MAC or DME Program safeguard contractor (PSC), who in turn will forward the information to the program integrity contact. Furthermore, CMS regional offices (ROs) will proactively do environmental scanning of the marketed materials. Where RO staff identifies potential marketing violations as described above, they will forward the information to the CMS program integrity contact.

Marketing Rules Reminders for DME Suppliers under the DMEPOS Competitive Bidding Program (continued)

Once referred to the CMS program integrity contact, the information will be reviewed and where appropriate, will be further developed for possible sanctions either by CMS or the OIG.

If anyone has knowledge of a potential marketing violation by a DMEPOS supplier, they may call and report the violation at 1-800-Medicare or 1-800-HHS-TIPS. Additionally, persons receiving any written materials, which are in violation of marketing rules should be prepared to make the material available to CMS.

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DMEPOS COMPETITIVE BIDDING PROGRAM—NEW EDUCATIONAL PRODUCTS

TIP SHEET FOR PHYSICIANS AND OTHER TREATING PRACTITIONERS WHO ARE ENROLLED MEDICARE DMEPOS SUPPLIERS

CMS has posted a new tip sheet for physicians and other treating practitioners who are enrolled Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers that describes how the new DMEPOS Competitive Bidding program that begins July 1, 2008, affects this particular group of providers. The tip sheet outlines an exception under the program, where physicians and other treating practitioners who are enrolled as Medicare DMEPOS suppliers, can provide certain types of competitively bid items in a CBA to their own patients without being selected as a contract supplier. The tip sheet may be found on the CMS dedicated Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>. Just click on the Provider Educational Products and Resources tab and scroll down to the “Downloads” section.

NEW MLN MATTERS ARTICLE ON CMS MEDICARE MANUAL SECTION COVERING THE DMEPOS COMPETITIVE BIDDING PROGRAM

On May 9, CMS issued change request (CR) 5978 “Phase 1 of Manual Revisions to Reflect Payment Changes for DMEPOS Items as a Result of the DMEPOS Competitive Bidding Program and the Deficit Reduction Act (DRA) of 2005”. The companion *MLN Matters* article MM5978 is now available.

CR 5978 is the first of several installments in adding a new chapter (chapter 36) to the existing *Medicare Claims*

Processing Manual in an effort to manualize policies and instructions for Medicare contractors on the DMEPOS Competitive Bidding program. *MLN Matters* article MM5978 is designed to help Medicare providers gain a broad understanding of all aspects of the new program, including when non-contract suppliers should obtain a signed advance beneficiary notice (ABN), which indicates that the beneficiary was informed in writing prior to receiving the item that there would be no Medicare coverage due to the supplier's contract status, and that the beneficiary understands that he/she will be liable for all costs that the non-contract supplier may charge the beneficiary for the item. This manual section, in conjunction with the provider tip sheets upcoming and already released, can help providers gain a quick and thorough understanding of the program.

MM5978 may be found at, <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5978.pdf>.

It will also be available on the CMS dedicated Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>.

Just click on the Provider Educational Products and Resources tab and scroll down to the “Downloads” section. All 2008 *MLN Matters* on the DME Competitive Bidding program are maintained here. ❖

Source: CMS Provider Education Resource Message 200806-01

TIP SHEET FOR GRANDFATHERED SUPPLIERS UNDER DMEPOS

COMPETITIVE BIDDING

Non-contract suppliers in the 10 competitive bidding areas (CBAs) can now access a tip sheet that describes the actions durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers need to take to become a grandfathered supplier.

This tip sheet includes a link to a sample beneficiary notice form that may be used to meet the recommended 30-day advance notification to beneficiaries regarding a supplier's decision to become (or not become) a grandfathered supplier. Supplier notice to Medicare beneficiaries should occur by June 1, 2008, to give adequate time should the beneficiary elect or need to transition to a contract supplier.

The tip sheet may be found on the Centers for Medicare & Medicaid Services dedicated Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>. Just click on the Provider Educational Products and Resources tab and scroll down to the "Downloads" section. ❖

Source: CMS Provider Education Resource Message 200805-24

TIP SHEET FOR REFERRAL AGENTS UNDER THE DMEPOS COMPETITIVE BIDDING PROGRAM

Medicare providers in the 10 competitive bidding areas (CBAs) who order or refer Medicare beneficiaries for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) can now access a tip sheet that describes the DMEPOS Competitive Bidding program and outlines the important role you will play as someone who may assist beneficiaries residing in or traveling to competitive bidding areas (CBAs) take the proper actions before July 1, 2008. Many beneficiaries will be required to transition to a contract supplier. For some items, however, Medicare beneficiaries may choose to continue their relationship with current suppliers.

EXAMPLES

1. Medicare patients in the 10 CBAs who use oxygen will need to take action to either transition to a new contract supplier, or, in the case where their current oxygen supplier elects to become a grandfathered supplier, continue services with their current non-contract supplier.
2. Medicare patients in the 10 CBAs who use enteral nutrients, supplies, and equipment must transition to a contract supplier as of July 1, 2008. If they reside in a skilled nursing facility (SNF) or nursing facility (NF) that is not a contract supplier, the SNF/NF will have to make new arrangements with a contract supplier to furnish items to their residents. If they live at home, the beneficiary must make new arrangements with a contract supplier.

The "Referral Agent" tip sheet may be found on the CMS dedicated Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>. Just click on the Provider Educational Products and Resources tab and scroll down to the "Downloads" section. ❖

Source: CMS Provider Education Resource Message 200805-24

DMEPOS COMPETITIVE BIDDING NEW TIP SHEET AND TRANSCRIPT

This notification contains news on the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding program, and new tip sheet and transcript from May 13, 2008, national provider call.

NEW TIP SHEET FOR MAIL ORDER CONTRACT DIABETIC SUPPLIERS

Under the DMEPOS Competitive Bidding program, which is effective July 1, 2008, beneficiaries who permanently reside in, or travel to, the 10 designated competitive bidding areas (CBA) are required to obtain competitively bid items from a contract supplier, unless an exception applies. This program may affect mail order suppliers that provide diabetic testing supplies to a Medicare beneficiary.

A new tip sheet is now available that further explains how this part of the program works.

This new resource may be found on the CMS dedicated Web site at, <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>.

Just click on the "Provider Educational Products and Resources" tab and scroll down to the "Downloads" section.

TRANSCRIPT FROM MAY 13, 2008, NATIONAL PROVIDER CALL NOW AVAILABLE

The Centers for Medicare & Medicaid Services (CMS) held a national provider audio call for providers, suppliers, referral agents, and others interested in the DMEPOS Competitive Bidding program on May 13, 2008. In addition to an overview of the program, questions and answers from participants were answered.

To access the written transcript from this call, visit the CMS dedicated Web site at, <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>.

Just click on the "Announcements and Communications" tab and scroll down to the "Downloads" section. ❖

Source: CMS Provider Education Resource 200806-08

OVERVIEW OF NEW MEDICARE COMPETITIVE BIDDING PROGRAM FOR DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES

The first in a series of articles on the implementation of this program.

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

Note: CMS has revised this *MLN Matters* special edition article on June 11, 2008, to add the Web address for viewing *MLN Matters* articles related to the new chapter 36 of the *Medicare Claims Processing Manual*. CMS has also added a reference point in this article to the appropriate section in the new manual chapter. That chapter contains the official manual instructions for the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Bidding program. All other information remains the same. The *MLN Matters* article SE0805 was published in the May 2008 *Medicare A Bulletin* (pages 15-17).

PROVIDER TYPES AFFECTED

Any Medicare fee-for-service (FFS) provider that may be in a position of ordering, referring, or supplying DMEPOS to a Medicare beneficiary may be affected by this program. This includes DMEPOS suppliers, physicians (including podiatric physicians), other treating practitioners (nurse practitioners, physician assistants, and clinical nurse specialists), physical and occupational therapists, and institutional providers (especially skilled nursing facilities and their social workers or care coordinators, hospitals and their discharge planners, home health agencies and pharmacists).

Note that those who refer or order DMEPOS for Medicare beneficiaries are being described as "referral agents" throughout this series.

PROVIDER ACTION NEEDED

STOP – IMPACT TO YOU

Effective July 1, 2008, Medicare will begin implementation of a new program for purchasing DMEPOS for Medicare patients. For Medicare beneficiaries whose permanent residence is in one of the 10 metropolitan statistical areas (MSAs) affected by the first phase of this program, only contract suppliers, in most instances, will be eligible to provide competitive bid items and receive payment from Medicare. While new payment rules may not impact referral agents directly, they may impact your patients. Therefore, the Centers for Medicare & Medicaid Services (CMS) is providing this information to make you aware of the program so you can discuss it with your patients when necessary.

CAUTION – WHAT YOU NEED TO KNOW

This program, initially, will affect patients obtaining DMEPOS in 10 competitive bidding areas (CBAs) that align with the 10 MSAs affected by the first phase of this program and will include 10 product categories of DMEPOS. These areas and product categories will be identified later in this article. In general, if your patients reside in one of the CBAs, they must use a Medicare contract supplier for competitive bid items, unless they are willing to be responsible for full payment of these items. This means that some of your patients may have to change from a noncontract supplier to a contract supplier. Also, certain suppliers that rent DMEPOS that were not awarded contracts may be "grandfathered" under this program and may be able to continue to supply certain DMEPOS items/services should the beneficiary choose to continue to receive these items from a grandfathered supplier.

GO – WHAT YOU NEED TO DO

It is important that all affected providers know this information. This program determines how much Medicare

will pay for competitive bidding items and which suppliers are eligible to receive Medicare payments for these items. Be aware that the new program impacts payment amounts for certain DMEPOS items received by beneficiaries residing in one of the CBAs no matter where in the country they obtain their DMEPOS.

Be prepared for this program if you treat Medicare patients in one of the 10 areas affected by the first phase of this program, which are listed later in this article. Note that the program will expand to 70 additional MSAs in 2009.

BACKGROUND

Currently, Medicare payment for most DMEPOS is based on fee schedules. Recent amendments to the Social Security Act (the Act), however, will alter the process for determining payment amounts for certain DMEPOS items. Specifically, section 1847 of the Act mandates that competitive bidding payment amounts replace the current DMEPOS fee schedule payment amounts for selected items in selected areas. The intent is to improve the effectiveness of the Medicare methodology for setting DMEPOS payment amounts, which will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality items and services. The new method brings the payment amount for these items in line with that of a competitive market and reduces your patients' out-of-pocket expenses. The program also ensures the availability of a sufficient number of accredited suppliers for access to quality items and services. For more information on accreditation of DME suppliers, visit the CMS Web site at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/06_Quality_Standards_and_Accreditation.asp#TopOfPage.

The law also provides for phasing in competitive bidding beginning in 10 of the largest MSAs. The program will be expanded into 70 additional MSAs in 2009 and the program will be expanded into additional areas after 2009. Areas that may be exempt from competitive acquisition of DMEPOS include rural areas and areas with low population density that are not competitive, unless there is a significant national market through mail order for a particular item or service. An area is chosen for the competitive bidding program based on several variables, including the size of its Medicare population and the amount of money spent on medical equipment and supplies in those areas.

Definitions

The following definitions are provided to explain several terms and their usage in this series of articles:

- **Contract Supplier** – An entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

Overview of New Medicare Competitive Bidding Program for DMEPO and Supplies (continued)

- **Noncontract Supplier** – A supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.
- **Referral Agents** – This term applies to the range of physicians, practitioners or providers who prescribe DMEPOS (in essence, “order” or “refer”) for their patients.
- **Grandfathered Supplier** – A noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.
- **Grandfathered Item** – Any one of the items (as described in CFR section 414.220, 222, 226, and 229) for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish the items in accordance with section 414.408(j).
- **Single payment amount** – It means the allowed payment for an item furnished under a competitive bidding program.

For more information on single payment amounts, visit on the Internet <http://www.dmecompetitivebid.com/>.

Initial Competitive Bidding Areas

Effective July 1, 2008, the competitive bidding program will be implemented in the following CBAs within these 10 MSAs:

- Charlotte-Gastonia-Concord, North Carolina and South Carolina
- Cincinnati-Middletown, Ohio, Kentucky, and Indiana
- Cleveland-Elyria-Mentor, Ohio
- Dallas-Fort Worth-Arlington, Texas
- Kansas City, Missouri and Kansas
- Miami-Fort Lauderdale-Miami Beach, Florida
- Orlando-Kissimmee, Florida
- Pittsburgh, Pennsylvania
- Riverside-San Bernardino-Ontario, California
- San Juan-Caguas-Guaynabo, Puerto Rico.

Product Categories

Effective July 1, 2008, the competitive bidding program will be implemented for the following product categories:

- Oxygen supplies and equipment
- Standard power wheelchairs, scooters, and related accessories
- Complex rehabilitative power wheelchairs and related accessories
- Mail-order diabetic supplies
- Enteral nutrients, equipment, and supplies
- Continuous positive airway pressure (CPAP), respiratory assist devices (RADs), and related supplies and accessories
- Hospital beds and related accessories
- Negative pressure wound therapy (NPWT) pumps and related supplies and accessories
- Walkers and related accessories
- Support surfaces (group 2 mattresses and overlays [Miami MSAs only]).

Traveling Beneficiaries

As previously mentioned, any beneficiary obtaining competitive bidding items in one of the CBAs is affected by the rules of the Medicare DMEPOS competitive bidding program. Beneficiaries who reside in a CBA and travels outside their CBAs may obtain competitive bid items and the supplier will be paid the single payment amount under the program. (The official CMS instructions regarding traveling beneficiaries are in Section 40.10 of the new chapter 36 of the *Medicare Claims Processing Manual*. That section is attached to CR 6119 on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.)

In addition, beneficiaries who do not reside in CBAs and who travel to CBAs are also affected. If they require competitive bid items, they must obtain competitive bid items from a contract supplier for that CBA. In such instances, Medicare will pay that contract supplier the DMEPOS fee schedule amount.

The following table details how DMEPOS supplies may be acquired, given different scenarios:

If a beneficiary permanently lives in...	And travels to...	Type of supplier a beneficiary may go to...
A competitive bidding area	A competitive bidding area	A beneficiary must get competitively bid items from a contract supplier located in the competitive bidding area to which he/she traveled.
A competitive bidding area	An area not covered by the competitive bidding program	A beneficiary may get items from any Medicare-enrolled DME supplier, and Medicare will pay the supplier as if it were in the beneficiary's competitive bidding area.
An area not covered by the competitive bidding program	A competitive bidding area	A beneficiary must get the competitively bid item from a contract supplier in the competitive bidding area. If the beneficiary does not use a contract supplier, the noncontract supplier must ask him/her to sign an advance beneficiary notice. Medicare will not pay for competitively bid items furnished by noncontract suppliers.
An area not covered by the competitive bidding program	An area not covered by the competitive bidding program	A beneficiary may get items from any Medicare-enrolled DMEPOS supplier.

Overview of New Medicare Competitive Bidding Program for DMEPO and Supplies (continued)

CMS is conducting extensive outreach to Medicare beneficiaries who reside in the CBAs and will be offering to help them identify contract suppliers.

If DMEPOS suppliers or referral agents are unsure whether a beneficiary resides in a CBA and is affected by this program effective July 1, they can make that determination by comparing the ZIP code of the patient's residence to the list of ZIP codes for the CBAs, which is available on the Internet at <http://dmecompetitivebid.com/Palmetto/Cbic.nsf/docsCat/DMEPOS%20Competitive%20Bidding%20Areas%20Zip%20Codes?opendocument>.

Payment

Payment for contract DMEPOS items will be the single payment amounts that were announced by CMS on March 20, 2008 (versus the current fee schedule determination of payment) for:

- Contract Suppliers
- Noncontract Suppliers that provide item to traveling beneficiaries.

ADDITIONAL INFORMATION

DMEPOS suppliers should note that previous articles have explained the program in more detail as it relates to DMEPOS suppliers. *MLN Matters* article SE0714, "Pre-Bidding Activities for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program," is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0714.pdf>.

Also, *MLN Matters* article MM5574, "Program Instructions Designating the Competitive Bidding Areas and Product Categories Included in the CY 2007 DMEPOS Competitive Bid Program," is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5574.pdf>.

CMS has released a new chapter 36 of the *Medicare Claims Processing Manual* in CR 5978 and CR 6119. The *MLN Matters* articles related to these CRs are available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5978.pdf> and <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6119.pdf>.

In addition, all providers may find more detailed information on the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

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Source: CMS Special Edition *MLN Matters* Article SE0805

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NEW DMEPOS COMPETITIVE BIDDING MLN MATTERS ARTICLE NOW AVAILABLE

The Centers for Medicare & Medicaid Services (CMS) has issued a *MLN Matters* special edition article SE0820 entitled "Marketing Rules Reminders for DME Suppliers Including Contract Suppliers under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program." This article is now posted on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0820.pdf> and may also be found on the DMEPOS Competitive Bidding Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>.

Click on the "Provider Educational Products and Resources" tab and scroll down to the "Downloads" section.

This article describes the existing marketing rules and prohibitions that apply to all Medicare enrolled DMEPOS suppliers.

For more information about DMEPOS competitive bidding, please visit the dedicated Web page on the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid>. ❖

Source: CMS Provider Education Resource Message 200806-04

GRANDFATHERING, REPAIR AND REPLACEMENT, MAIL ORDER DIABETIC SUPPLIES AND ADVANCED BENEFICIARY NOTICES

The second in a series of articles on the new DMEPOS competitive bidding program.

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

Note: CMS has revised this *MLN Matters* special edition article on June 11, 2008, to add the Web address for viewing *MLN Matters* articles related to the new chapter 36 of the *Medicare Claims Processing Manual*. CMS has also added a reference point in this article to the appropriate section in the new manual chapter. That chapter contains the official manual instructions for the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Bidding program. All other information remains the same. The *MLN Matters* article SE0806 was published in the May 2008 *Medicare A Bulletin* (pages 18-19).

PROVIDER TYPES AFFECTED

Any Medicare fee-for-service (FFS) provider supplying DMEPOS to a Medicare beneficiary. This article also contains information of interest to those who order DMEPOS and to referral agents as defined in *MLN Matters* article SE0805.

PROVIDER ACTION NEEDED

The first article (SE0805) in this series on the DMEPOS competitive bidding program being instituted by the Centers for Medicare & Medicaid Services (CMS) presented an overview of how the program may affect your patients. There are also some key provisions of the program about which your patients may raise questions. While the competitive bidding program only affects ten areas of the country as of July 1, 2008, it will expand to 70 additional geographic areas in 2009. Thus, it is important for you to be familiar with this program.

BACKGROUND

MLN Matters article SE0805, entitled "Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)," which is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0805.pdf>, summarizes information on competitive bidding that may impact your patients. Article SE0805 contains the list of competitive bidding areas for the first phase of competitive bidding as well as a list of the DMEPOS product categories that are included in the initial implementation of the program.

In using this series of DMEPOS articles, it is important to remember that in most instances, beneficiaries maintaining a permanent residence in one of the competitive bidding areas (CBAs) must obtain competitive bidding items from a contract supplier. There are also program requirements that apply to beneficiaries who reside in CBAs but travel outside of those CBAs and to beneficiaries who do not live in CBAs but travel to them.

Grandfathered Suppliers

Note: See section 20.6.1.1 of the new chapter 36 of the *Medicare Claims Processing Manual* for official CMS instructions regarding grandfathered suppliers. That section is attached on the CMS Web site to change request (CR) 5978 at <http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf> and is amended by CR 6119 at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.

The Medicare DMEPOS competitive bidding program requires Medicare beneficiaries to obtain competitive bidding items from a contract supplier, unless an exception applies. Therefore, in some instances, your patient may be required to change from a noncontract supplier to a contract supplier. However, the program does allow for certain suppliers to be "grandfathered." Grandfathered suppliers are allowed to continue to provide certain rented DME items and services even though they are not contract suppliers.

Grandfathering only applies when the patient is renting DME or oxygen equipment at the time the competitive bidding program becomes effective and the rental period for the item began before the start of the competitive bidding program.

Beneficiaries who are receiving oxygen, oxygen equipment or rented DME at the time the competitive bidding program becomes effective may elect to continue to receive these items from a noncontract supplier, if the supplier is willing to continue furnishing these items. If a noncontract supplier chooses not to be "grandfathered" or if a beneficiary wants to change to a contract supplier, the noncontract supplier must pick up the rental equipment and oxygen equipment. Unless a beneficiary relocates outside of the CBA and the supplier service area, the supplier cannot discontinue services by picking up a medically necessary item prior to the end of a rental month for which the supplier was eligible to receive a rental payment, even if the last day of a rental month is after the start date of the program. If the date of the beginning of a monthly rental period is prior to the start of the competitive bidding program, the supplier must submit a claim for that month. Note that the grandfathering provision also applies to Medicare beneficiaries who transition from a Medicare Advantage plan to the fee-for-service program.

If the beneficiary stays with a "grandfathered" supplier, he or she may elect to change to a contract supplier at any time, and the contract supplier would be required to accept the beneficiary as a customer. For more details on the grandfathering provision, visit the CMS Web site <http://www.dmecompetitivebid.com>.

Repair and Replacement of Beneficiary-Owned Items

Note: See section 40.8 of the new chapter 36 regarding repair and replacement of beneficiary-owned equipment. That section is attached to CR 6119 on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.

Grandfathering, Repair and Replacement, Mail Order Diabetic Supplies and Advanced Beneficiary Notices (continued)**Repair ONLY**

A beneficiary who owns a competitively bid item that needs to be repaired may have the repairs performed by either a contract supplier or by a noncontract supplier. In these cases, Medicare pays for reasonable and necessary labor not otherwise covered under a manufacturer's or supplier's warranty.

Repair and Replacement

If a part needs to be replaced in order to make the beneficiary-owned equipment serviceable, and the replacement part is also a competitively bid item for the CBA in which the beneficiary maintains a permanent residence, the part may be obtained from either a contract supplier or a noncontract supplier. In either case, Medicare pays the single payment amount provided under the competitive bidding program for the replacement part.

Replacement ONLY

Beneficiaries maintaining permanent residences in a CBA are required to obtain replacement of all items subject to competitive bidding from a contract supplier. This includes replacement of base equipment and replacement of parts or accessories for base equipment that are being replaced for reasons other than servicing of the base equipment.

Beneficiaries who are not permanent residents of a CBA but require a replacement of a competitively bid item while visiting a CBA, must obtain the replacement item from a contract supplier. The supplier will be paid the fee schedule amount for the state where the beneficiary is a permanent resident.

Mail Order Diabetic Supplies under the Program

Note: See section 20.5.4.1 of the new chapter 36 for the official CMS instructions regarding mail order diabetic supplies. That section is attached to CR 6119 on the CMS site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.

Medicare beneficiaries who permanently reside in a CBA may purchase their diabetic testing supplies from:

- A mail order contract supplier for the area in which the beneficiary maintains a permanent residence; or
- A noncontract supplier in cases where the supplies are not furnished on a mail order basis.

The mail order contract period covers diabetic testing supplies furnished from **July 1, 2008, through March 31, 2010**.

The term "mail order" refers to items ordered remotely (i.e., by phone, e-mail, Internet, or mail) and delivered to the beneficiary's residence by common carriers (e.g., U.S. Postal Service, Federal Express, United Parcel Service) and does not include items obtained by beneficiaries from local supplier storefronts.

Mail order contract suppliers will be reimbursed at the single payment amount for the CBA where the beneficiary maintains a permanent residence.

For diabetic supplies that are not furnished through mail order, suppliers will be paid the fee schedule amount.

Medicare payment will not be made to noncontract suppliers that furnish mail order diabetic testing supplies to Medicare beneficiaries residing in a CBA. A special modifier, **KL**, will be used on each claim to indicate that the item was furnished on a mail order basis.

Note: Suppliers that furnish diabetic testing supplies on a mail order basis and do not attach the mail order modifier could be subject to significant penalties under the False Claims Act.

Both the Medicare program and beneficiaries will save money each time a mail order contract supplier is used; **however, it is solely up to the beneficiaries to decide whether or not they wish to obtain their diabetic testing supplies on a mail order basis.**

All mail order contract suppliers are required to report the manufacturer or make and model number of products they furnish and must update this list on a quarterly basis. This information will be made available to the public once the contract suppliers have been announced and will be updated on a routine basis. Contract suppliers will be required to make available the same range of products to Medicare beneficiaries that they make available to non-Medicare customers.

Advance Beneficiary Notice Information

Note: See section 20.7 of the new chapter 36 for the official instructions related to the use of an advance beneficiary notice (ABN) under the competitive bidding program. That section is attached to CR 5978 on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf>.

In general, if a noncontract supplier in a CBA furnishes a competitively bid item to any Medicare beneficiary regardless of whether that beneficiary maintains a permanent residence in the CBA or another area, and no applicable exceptions apply, Medicare will not make payment. In addition, the beneficiary is not liable for payment unless the noncontract supplier in a CBA obtains an ABN signed by the beneficiary.

A signed ABN indicates that the beneficiary was informed in writing prior to receiving the item that there would be no Medicare coverage due to the supplier's contract status, and that the beneficiary understands that he/she will be liable for all costs that the noncontract supplier may charge the beneficiary for the item.

If a noncontract supplier furnishes a competitively bid item to a beneficiary and the beneficiary signs an ABN, the supplier must use modifier **GA** on their claim. If modifier the **GA** is not present on the claim, the supplier may not hold the beneficiary liable for the cost of the item.

Grandfathering, Repair and Replacement, Mail Order Diabetic Supplies and Advanced Beneficiary Notices (continued)

ADDITIONAL INFORMATION

CMS contracted with the competitive bidding implementation contractor (CBIC) to administer the DMEPOS competitive bidding program. Downloadable **Patient Education Fact Sheets** may be found at

<http://www.dmecompetitivebid.com/palmetto/CBIC.nsf/docsCat/>

[CBIC-Referral%20Providers-Patient%20Education%20Fact%20Sheets?open&cat=CBIC-Referral%20Providers-Patient%20Education%20Fact%20Sheets](http://www.dmecompetitivebid.com/palmetto/CBIC.nsf/docsCat/CBIC-Referral%20Providers-Patient%20Education%20Fact%20Sheets?open&cat=CBIC-Referral%20Providers-Patient%20Education%20Fact%20Sheets)

If you have concerns, questions, or complaints about the quality of an item or the service that a patient received from a contract supplier, please call the competitive bidding program helpline at 1-877-577-5331.

CMS has released a new chapter 36 of the *Medicare Claims Processing Manual*. This chapter was initially issued with CR 5978 was amended by CR 6119. The MLN Matters articles related to CR 5978 and CR 6119 are available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5978.pdf> and <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6119.pdf>.

For more information about the Competitive Bidding program, call 1-877-577-5331. TTY users call 1-877-486-2048. Stay tuned for additional articles in this series. You may also visit the CMS Web site at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

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IMPORTANT EXCEPTIONS AND SPECIAL CIRCUMSTANCES UNDER THE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES COMPETITIVE BIDDING PROGRAM

The third in a series of articles on the new DMEPOS competitive bidding program.

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

Note: CMS has revised this *MLN Matters* special edition article on June 11, 2008, to add the Web address for viewing MLN Matters articles related to the new chapter 36 of the *Medicare Claims Processing Manual*. CMS has also added a reference point in this article to the appropriate section in the new manual chapter. That chapter contains the official manual instructions for the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Bidding program. All other information remains the same. The *MLN Matters* article SE0807 was published in the May 2008 *Medicare A Bulletin* (pages 20-21).

PROVIDER TYPES AFFECTED

The following providers may be affected by this program:

- Physicians and other treating practitioners who are Medicare enrolled DMEPOS suppliers.
- Physicians and others who order or refer DMEPOS items or services for their patients.
- Skilled nursing facilities (SNFs) and nursing facilities (NFs).
- Physical therapists and occupational therapists in private practice who are Medicare enrolled DMEPOS suppliers.

Many Medicare fee-for-service (FFS) providers may be in a position of ordering, referring, or supplying DMEPOS to a Medicare beneficiary. This includes physicians (including podiatric physicians), other treating practitioners (nurse

practitioners, physician assistants, and clinical nurse specialists), physical and occupational therapists, and institutional providers (especially skilled nursing facilities and their social workers or care coordinators, hospitals and their discharge planners, home health agencies and pharmacists).

PROVIDER ACTION NEEDED

Understand these special program rules that may affect you. This article is especially important if you are a Medicare enrolled DMEPOS supplier of items governed by the new program, even if you are not located in a competitive bidding area (CBA). It is important to understand that the program affects any beneficiaries who permanently reside in or travel to CBAs. Some program requirements apply to beneficiaries who reside in CBAs even if these beneficiaries travel outside their CBAs. Thus, it is important for you to be familiar with this program.

Important Exceptions and Special Circumstances under the DMEPOS Competitive Bidding Program (continued)

While the first phase of the competitive bidding program only affects ten CBAs in the country as of July 1, 2008, the second phase will expand to 70 additional geographic areas in 2009. See *MLN Matters* article SE0805 for information about CBAs and items governed by this new program and for information about how the program applies to traveling beneficiaries.

BACKGROUND

MLN Matters article SE0805 that is entitled, "Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)," which is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0805.pdf>, summarizes information on competitive bidding that may impact your patients. *MLN Matters* article SE0805 contains the list of competitive bidding areas for the first phase of competitive bidding as well as a list of the DMEPOS product categories that are included in the program's initial implementation.

MLN Matters article SE0806 that is entitled, "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Grandfathering, Repair and Replacement, Mail Order Diabetic Supplies and Advanced Beneficiary Notices (ABNs)," which is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0806.pdf>, provides an overview of the rules regarding grandfathered suppliers, repair and replacement of beneficiary-owned equipment, mail order diabetic supplies under the program, and ABNs.

In this, the third in a series of articles on the new DMEPOS competitive bidding program, we provide information on some special circumstances and exceptions of particular interest to physicians and other treating practitioners, SNFs and NFs, and physical and occupational therapists in independent practice.

Note: It is important to note that the Competitive Bidding program does not affect your patients' choice of physician or treating practitioner.

In using this series of DMEPOS articles, remember that in most instances, beneficiaries maintaining a permanent residence in one of the competitive bidding areas (CBAs) must obtain competitive bidding items from a contract supplier. There are also program requirements that apply to beneficiaries who reside in CBAs but travel outside of those CBAs and to beneficiaries who do not live in CBAs but travel to them.

Physicians and Other Treating Practitioners Who Are Enrolled Medicare DMEPOS Suppliers

Medicare physicians and treating practitioners who have also enrolled as Medicare DMEPOS suppliers via the 855S enrollment form have the option to furnish certain types of competitively bid items to their own patients without submitting a bid or being awarded a competitive bid contract, provided the following requirements are met:

- For the first phase of the program being implemented July 1 2008, the item furnished must be a walker. In the future, the items will be limited to crutches, canes,

walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME.

- The physician or treating practitioner DMEPOS supplier must furnish the items **to his or her own patients as part of his or her professional service.**
- The items must be billed to a DME MAC using the DMEPOS billing number that is assigned to the physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

Where the furnished item is a bid item and the beneficiary resides in a CBA, the physician or treating practitioner will be paid the single payment amount established by this program for the item. This exception does not affect the applicability of the physician self-referral (Stark law) provisions in section 1877 of the Act. All provisions of the physician self-referral law remain fully in effect.

Physicians and Other Treating Practitioners Who Prescribe Specific Brand or Mode of Delivery to Avoid an Adverse Medical Outcome

Note: Section 30.4 of chapter 36 of the *Medicare Claims Processing Manual* contains the official instructions related to this provision. Of particular note are the documentation requirements of that section. The section is attached to CR 6119, which is available on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1532CP.pdf>.

A physician (including a podiatric physician) or treating practitioner may prescribe, in writing, a particular brand of DMEPOS bid item or mode of delivery for an item if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary. The physician or treating practitioner must document in the beneficiary's medical record the reason why the specific brand or mode of delivery is necessary to avoid an adverse medical outcome.

In these cases, the contract supplier under the competitive bidding program must:

- Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;
- Consult with the physician or treating practitioner to find another appropriate brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or
- Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

Any change in the prescription requires a revised written prescription. A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner.

Important Exceptions and Special Circumstances under the DMEPOS Competitive Bidding Program (continued)

Skilled Nursing Facilities and Nursing Facilities Specialty Suppliers

Note: Section 20.5.2 of chapter 36 of the *Medicare Claims Processing Manual* contains the official competitive bidding program instructions related to SNFs and NFs. That section is attached to CR 5978, which is available on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1502CP.pdf>.

The DMEPOS competitive bidding program applies to skilled nursing facilities (SNFs) and nursing facilities (NFs) to the extent that their residents receive competitively bid items under Medicare Part B. Unlike most suppliers, SNFs and NFs have the option to bid for, and be awarded, contracts to be “specialty suppliers” that **only furnish competitively bid items to their own residents**. SNFs and NFs that become specialty suppliers may not furnish competitively bid items and services to Medicare beneficiaries outside their facilities for purposes of Medicare payment. SNFs and NFs can also become regular contract suppliers that furnish competitively bid items to beneficiaries throughout a CBA.

If a SNF or NF is not a contract supplier (either a specialty contract supplier or a regular contract supplier), it must use a contract supplier for its CBA to furnish competitively bid items to its residents.

Physical Therapists and Occupational Therapists in Private Practice Who are Enrolled Medicare DMEPOS Suppliers

Physical therapists and occupational therapists in private practice who are enrolled DMEPOS suppliers may eventually have the option to furnish certain types of competitively bid items to their own patients and be paid the single payment amount for such items without being contract suppliers, provided the following requirements are met:

- The items are limited to off-the-shelf (OTS) orthotics; and
- The items must be furnished only to their own patients as part of the physical or occupational therapy service.

Note: OTS orthotics are not included in the first phase of competitive bidding, this exception is not relevant in the first phase of the DMEPOS competitive bidding program beginning July 1, 2008.

ADDITIONAL INFORMATION

CMS has released a new chapter 36 of the *Medicare Claims Processing Manual*. This chapter is contained in CR 5978 and is amended by CR 6119 and contains the initial, official manual instructions for this program. The *MLN Matters* articles related to CR 5978 and CR 6119 are available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5978.pdf> and <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6119.pdf>.

If you have concerns, questions, or complaints about the quality of an item or the service that a patient received from a contract supplier please call the competitive bidding program helpline at 1-877-577-5331.

For more information about the competitive bidding program, call 1-877-577-5331. TTY users call 1-877-486-2048. Stay tuned for additional articles in this series.

You can also visit the CMS website for more details at <http://www.cms.hhs.gov/DMEPOSCompetitiveBid/>.

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AMBULANCE SERVICES

NOTIFICATION OF NEW QUARTERLY UPDATES TO THE AMBULANCE FEE SCHEDULE PUBLIC USE FILE

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Ambulance providers and suppliers submitting claims to Medicare contractors (carriers, fiscal intermediaries [FIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for ambulance services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

This article is based on change request (CR) 6091, which informs Medicare providers that the Centers for Medicare & Medicaid Services (CMS) wants providers to know that since **Medicare Claims Processing Contracting reform is on-going, some of the contractor/carrier numbers included in the 2008 annual ambulance fee schedule public use file (PUF) posted to the CMS Web site may be outdated.** To ensure that the contractor/carrier numbers contained in the file are as accurate as possible, a quarterly update to the PUF file, containing new contractor/carrier numbers, will be **posted to the CMS Web site until all contracting reform is completed.** The updated information will be highlighted with italicized red text and may be reviewed on the CMS Web site at http://www.cms.hhs.gov/AmbulanceFeeSchedule/02_afspuf.asp#TopOfPage.

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ADDITIONAL INFORMATION

You may see the official instruction (CR 6091) issued to your Medicare contractor on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R352OTN.pdf>.

If you have questions, please contact your Medicare contractor at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6091
Related Change Request (CR) Number: 6091
Related CR Release Date: June 13, 2008
Related CR Transmittal Number: R532OTN
Effective Date: July 28, 2008
Implementation Date: July 28, 2008

Source: CMS Pub. 100-20, Transmittal 352, CR 6091

NATIONAL PROVIDER IDENTIFIER

NPI NEWS UPDATE FOR MEDICARE FEE-FOR-SERVICE PROVIDERS

NPI IS HERE. NPI IS NOW. ARE YOU USING IT?

Medicare fee-for-service (FFS) has made excellent progress over the past week, since fully implementing the national provider identifier (NPI). In fact, the favorable trend in NPI compliance is better than the Centers for Medicare & Medicaid Services (CMS) expected with most of the Medicare contractors reporting that over 90 percent of claims are NPI-compliant, with some reporting 100 percent compliance. Furthermore, CMS has experienced relatively few problems to date and CMS is working daily with Medicare contractors to help resolve those issues that exist.

CMS would like to point out that, on May 23, there were a number of rejections for claims with legacy numbers in the SECONDARY provider identifier field. As indicated, we are seeing this particular issue rapidly improve as more and more providers realize the need for NPI-only in secondary identifier fields and the relative ease in which they can appropriately complete these fields.

In the way of background, Medicare allowed legacy-only numbers in the secondary fields up until May 23. To assist those billing providers that, after reasonable effort, are still unable to obtain NPIs for secondary providers, Medicare has instituted a temporary measure that allows billing providers to use their own NPI in secondary identifier fields. Thus, providers are not unduly burdened to ensure secondary identifier fields have an NPI.

NPI News Update for Medicare Fee-for-Service Providers (continued)

While CMS is seeing some issues in some areas of the country, CMS is continuing to monitor and assist providers in becoming fully NPI-compliant. Progress has been substantial in recent days and weeks and this favorable trend is expected to continue. CMS would also like to mention that they are monitoring Medicare Part C (Medicare Advantage) and Part D (Prescription Drug Program) and CMS has received no reports of NPI problems.

MEDICARE REMINDER – ACCELERATED/ADVANCE PAYMENTS MAY BE AVAILABLE FOR FINANCIAL HARDSHIPS ASSOCIATED WITH NPI IMPLEMENTATION

Some Medicare providers, physicians, other practitioners, and suppliers might experience cash flow issues during their efforts to implement the NPI. The Medicare contractors and CMS will consider, in limited circumstances, the availability of advance or accelerated payments where facts and circumstances fall within the scope of the CMS regulations and/or manual requirements for such payments.

In general, entities who bill without an NPI do not warrant consideration for an advance or accelerated payment since Medicare providers have been given ample time to secure an NPI.

Medicare providers who may be experiencing cash flow problems related to NPI claims processing issues should contact their Medicare contractor to determine if they are eligible for an advance or accelerated payment. The Medicare contractor will review the request and provide a decision.

NEED MORE INFORMATION?

Still not sure what an NPI is and how you can get it, share it and use it? As always, more information and education on the NPI may be found at the CMS NPI Web page <http://www.cms.hhs.gov/NationalProvIdentStand>.

Providers can apply for an NPI online at <https://nppes.cms.hhs.gov> or can call the NPI enumerator to request a paper application at 1-800-465-3203.

Having trouble viewing any of the URLs in this message? If so, try to cut and paste any URL in this message into your Web browser to view the intended information.

Note: All current and past CMS NPI communications are available by clicking “CMS Communications” in the left column of the CMS Web page <http://www.cms.hhs.gov/NationalProvIdentStand>. ❖

Source: CMS Provider Education Resource 200806-03

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NPI AND INTERNAL REVENUE SERVICE DATA MATCH

NPI IS HERE. NPI IS NOW. ARE YOU USING IT?

In an effort to ensure that the data submitted to the National Plan and Provider Enumeration System (NPPES) for organization health care providers is accurate, CMS initiated an NPPES – Internal Revenue Service (IRS) data match to ensure that the legal business name (LBN) and employer identification number (EIN) in NPPES are consistent with IRS data.

This week, CMS will mail out letters to organization health care providers that have an EIN/LBN combination in NPPES that are different from the information maintained by the IRS. These letters request that the health care providers review and update their LBN and/or EIN in NPPES. If health care providers cannot furnish data that are consistent with the IRS, CMS will deactivate the national provider identifier in NPPES. CMS will continue to match these health care provider data in NPPES against IRS data to ensure the accuracy of NPPES data.

NEED MORE INFORMATION?

Still not sure what an NPI is and how you can get it, share it and use it? As always, more information and education on the NPI may be found at the CMS NPI Web page <http://www.cms.hhs.gov/NationalProvIdentStand>.

Providers can apply for an NPI online at <https://nppes.cms.hhs.gov> or can call the NPI enumerator to request a paper application at 1-800-465-3203.

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Note: All current and past CMS NPI communications are available by clicking “CMS Communications” in the left column of the CMS Web page <http://www.cms.hhs.gov/NationalProvIdentStand>. ❖

Source: CMS Provider Education Resource 200806-10

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INSTITUTIONAL PROVIDERS AND SUPPLIERS BILLING SELF-REFERRED MAMMOGRAPHY CLAIMS

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Institutional providers and suppliers submitting claims to Medicare contractors (carriers, fiscal intermediaries [FIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for self-referred mammography services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

STOP – IMPACT TO YOU

This article is based on change request (CR) 6023 which provides national provider identifier (NPI) instructions for institutional providers and suppliers billing for self-referred mammography services. Do not use the surrogate unique physician identification number (UPIN) of “SLF000” on claims **effective May 23, 2008**.

CAUTION – WHAT YOU NEED TO KNOW

Providers of mammography services are instructed to report their own facility NPI in the attending physician NPI field in cases where the service is self-referred by the patient (beneficiary) and no attending/referring physician NPI is available.

GO – WHAT YOU NEED TO DO

See the *Background* and *Additional Information* sections of this article for further details regarding these changes.

BACKGROUND

Effective May 23, 2008, covered health care providers, suppliers and health plans (other than small plans) are required to use NPIs. In reviewing the Medicare program's business needs in preparation for the implementation of the NPI, the Centers for Medicare & Medicaid Services (CMS) identified that clarifying instructions are needed for institutional and supplier billing of self-referred mammography services.

The Medicare Claims Processing Manual (Pub. 100-04, Chapter 18 (Preventive and Screening Services), Section 20 (Mammography Services) indicates that a doctor's prescription or referral is not necessary for screening mammography services to be covered. In self-referral cases, an NPI for an attending/referring physician is not

available to the institution or supplier providing the mammography service. CR 6023 modifies that instruction to alleviate this in self-referral cases.

In the past, Medicare FIs instructed providers to use the surrogate UPIN of “SLF000” in the Attending Physician UPIN field on the institutional claim form. Since UPINs will no longer be accepted on Medicare claims after May 23, 2008, an alternate means of identifying self-referral is needed.

Therefore, CR 6023 clarifies how providers and suppliers will reflect this situation on Medicare claims submitted **on or after May 23, 2008**, as follows:

- Institutional providers submitting claims for self-referred mammography services will duplicate the institution's own NPI in the attending physician NPI field on their claims.
- Suppliers submitting claims for self-referred mammography services will duplicate the supplier's own NPI in the attending/referring physician NPI field on their claims.

ADDITIONAL INFORMATION

The official instruction, CR 6023, issued to your carrier, FI, and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1519CP.pdf>.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6023

Related Change Request (CR) Number: 6023

Related CR Release Date: May 30, 2008

Related CR Transmittal Number: R1519CP

Effective Date: May 23, 2008

Implementation Date: June 30, 2008

Source: CMS Pub. 100-04, Transmittal 1519, CR 6023

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Join our *eNews* mailing list and receive urgent and other critical information issued by First Coast Service Options, Inc. (FCSO), your Florida Medicare intermediary. By signing up, you will receive automatic e-mail notification when new or updated information is posted to the provider education Web site. It's very easy to do. Simply go to our Web site <http://www.fcso.com>, select Medicare Providers Florida Part A or B, click on the “*eNews*” link located on the upper-right-hand corner of the page and follow the prompts.

GENERAL COVERAGE

SCREENING PELVIC EXAMINATION

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Physicians and other providers who bill Medicare contractors (carriers, fiscal intermediaries [FI], and Medicare administrative contractors [A/B MAC]) for providing screening pelvic examinations for Medicare beneficiaries.

WHAT YOU NEED TO KNOW

The Centers for Medicare & Medicaid Services (CMS) has become aware that the *Medicare Claims Processing Manual*, chapter 18 (Preventive and Screening Services), section 40 (Screening Pelvic Examinations) is not clear on what elements are needed during a screening pelvic examination. Change request (CR) 6085, from which this article is taken, clarifies this unclear information, specifically adding the following language (displayed below in bolded and italics):

- Section 4102 of the Balanced Budget Act of 1997 (P.L. 105-33) amended section 1861(nn) of the Act (42 USC 1395X(nn)) to include Medicare Part B coverage of screening pelvic examinations ***(including a clinical breast examination)*** for all female beneficiaries for services provided January 1, 1998 and later; and
- A screening pelvic examination ***with or without specimen collection for smears and cultures***, should include at least ***seven*** of the following ***eleven*** elements:
 - ♦ Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge
 - ♦ Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses
 - ♦ External genitalia (for example, general appearance, hair distribution, or lesions)
 - ♦ Urethral meatus (for example, size, location, lesions, or prolapse)
 - ♦ Urethra (for example, masses, tenderness, or scarring)
 - ♦ Bladder (for example, fullness, masses, or tenderness)

- ♦ Vagina (for example, general appearance, estrogen effect, discharge, lesions, pelvic support, cystocele, or rectocele)
- ♦ Cervix (for example, general appearance, lesions or discharge)
- ♦ Uterus (for example, size, contour, position, mobility, tenderness, consistency, descent, or support)
- ♦ Adnexa/parametria (for example, masses, tenderness, organomegaly, or nodularity)
- ♦ Anus and perineum.

Please note that CR 6085 does not provide any change in policy. It simply clarifies unclear information in the manual as stated above.

ADDITIONAL INFORMATION

You can find more information about screening pelvic examinations by going to CR 6085, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1541CP.pdf>.

You will find the updated *Medicare Claims Processing Manual*, chapter 18 (Preventive and Screening Services), section 40 (Screening Pelvic Examinations) as an attachment to CR 6085.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6085
Related Change Request (CR) Number: 6085
Related CR Release Date: June 20, 2008
Effective Date: September 23, 2008
Related CR Transmittal Number: R1541CP
Implementation Date: September 23, 2008

Source: CMS Pub. 100-04, Transmittal 1541, CR 6085

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LABORATORY NATIONAL COVERAGE DETERMINATION EDIT SOFTWARE—JULY 2008 CHANGES

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Clinical diagnostic laboratories billing Medicare contractors (carriers, fiscal intermediaries [FIs] and/or Part A/ B Medicare administrative contractors [AB MACs]).

PROVIDER ACTION NEEDED

This article is based on change request (CR) 6084, which announces the changes that will be included in the July 2008 quarterly release of the edit module for clinical diagnostic laboratory services. The last quarterly release of the edit module was issued in April 2007. CR 6084 incorporates all changes from April 2007 to the present and has no other changes.

BACKGROUND

The national coverage determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and published in a final rule on November 23, 2001. Nationally uniform software was developed and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs were processed uniformly throughout the nation effective January 1, 2003.

In accordance with the Medicare Claims Processing Manual, chapter 16, section 120.2; (see <http://www.cms.hhs.gov/manuals/downloads/clm104c16.pdf> on the Centers for Medicare & Medicaid Services [CMS] Web site) the laboratory edit module is updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. These changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the ICD-9-CM codes.

CR 6084 announces changes to the laboratory edit module for changes in laboratory NCD code lists for July 2008 as described below. These changes become effective for services furnished on or after July 1, 2008.

Note: Medicare contractors use the appropriate effective dates for the ICD-9-CM and CPT codes, which are October 1, 2007 for the ICD-9-CM codes and January 1, 2008, for the CPT codes.

Contractors are not required to search their files to adjust affected claims between the July 1, 2007, and the July 1, 2008, quarterly clinical lab edit module updates.

CR 6084 reports the following changes effective July 1, 2008:

For HIV Testing:

- Add ICD-9-CM codes 079.83 and 288.66 to the list of ICD-9-CM codes covered by Medicare for the HIV testing (190.14) NCD.
- Modify the descriptor for *Current Procedural Terminology* (CPT) code 86701 in the HIV testing (190.14) NCD to read “antibody; HIV-1.”
- Modify the descriptor for CPT code 86702 in the HIV testing (190.14) NCD to read “Antibody; HIV-2.”
- Modify the descriptor for CPT code 86703 in the HIV testing (190.14) NCD to read “Antibody; HIV-1 and HIV-2, single assay.”

For Blood Counts:

- Add ICD-9-CM codes 388.45, 389.05, 389.06, 389.13, 389.17, 389.20, 389.21, 389.22, V25.04, V26.41, V26.49, V26.81, V26.89, V49.85 and V72.12 to the list of ICD-9-CM codes that do not support medical necessity for the blood counts (190.15) NCD.
- Delete ICD-9-CM codes 389.2, V26.4 and V26.8 from the list of ICD-9-CM codes that do not support medical necessity for the blood counts (190.15) NCD.
- Modify the descriptor for ICD-9-CM code 389.14 to read “Central hearing loss” in the list of ICD-9-CM codes that do not support medical necessity for the blood counts (190.15) NCD.
- Modify the descriptor for ICD-9-CM code 389.18 to read “Sensorineural hearing loss, bilateral” in the list of ICD-9-CM codes that do not support medical necessity for the blood counts (190.15) NCD.
- Modify the descriptor for ICD-9-CM code 389.7 to read “Deaf, non-speaking, not elsewhere classifiable” from the list of ICD-9-CM codes that do not support medical necessity for the blood counts (190.15) NCD.

For Prothrombin Time:

- Add ICD-9-CM codes 415.12, 789.51, 789.59, V12.53, and V12.54 to the list of ICD-9-CM codes covered by Medicare for the prothrombin time (190.17) NCD.
- Delete ICD-9-CM code 789.5 from the list of ICD-9-CM codes covered by Medicare for the prothrombin time (190.17) NCD.

For Serum Iron Studies:

- Add ICD-9-CM codes 233.30, 233.31, 233.32, and 233.39 to the list of ICD-9-CM codes covered by Medicare for the serum iron studies (190.18) NCD.
- Delete ICD-9-CM code 233.3 from the list of ICD-9-CM codes covered by Medicare for the serum iron studies (190.18) NCD.

For Glycated Hemoglobin/Glycated Protein:

- Add ICD-9-CM codes 258.01, 258.02 and 258.03 to the list of ICD-9-CM codes covered by Medicare for the glycated hemoglobin/glycated protein (190.21) NCD.
- Delete ICD-9-CM code 258.0 from the list of ICD-9-CM codes covered by Medicare for glycated hemoglobin/glycated protein (190.21) NCD.

For Thyroid Testing:

- Add ICD-9-CM codes 255.41, 255.42, 258.01, 258.02, 258.03, 787.20, 787.21, 787.22, 787.23, 787.24, 787.29, 789.51 and 789.59 to the list of ICD-9-CM codes covered by Medicare for the thyroid testing (190.22) NCD.
- Delete ICD-9-CM codes 255.4, 258.0, 787.2 and 789.5 from the list of ICD-9-CM codes covered by Medicare for the thyroid testing (190.22) NCD.

Laboratory National Coverage Determination Edit Software—July 2008 Changes (continued)

For Gamma Glutamyl Transferase:

- Add ICD-9-CM codes 359.21, 359.22, 359.23, 359.24 and 359.29 to the list of ICD-9-CM codes covered by Medicare for the gamma glutamyl transferase (190.32) NCD.
- Delete ICD-9-CM code 359.2 from the list of ICD-9-CM codes covered by Medicare for the gamma glutamyl transferase (190.32) NCD.

For Hepatitis Panel/Acute Hepatitis Panel:

- Delete ICD-9-CM code 999.3 from the list of ICD-9-CM codes covered by Medicare for the hepatitis panel/acute hepatitis panel (190.33) NCD.

For Fecal Occult Blood Test:

- Add ICD-9-CM codes 569.43, 787.20, 787.21, 787.22, 787.23, 787.24, 787.29, 789.51 and 789.59 to the list of ICD-9-CM codes covered by Medicare for the fecal occult blood test (190.34) NCD.
- Delete ICD-9-CM codes 787.2 and 789.5 from the list of ICD-9-CM codes covered by Medicare for the fecal occult blood test (190.34) NCD.
- Modify the descriptor for ICD-9-CM code 005.1 in the Fecal Occult Blood Test (190.34) NCD to read "Botulism food poisoning."

- Modify the descriptor for CPT code 82272 in the fecal occult blood test (190.34) NCD to read "Blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening."

ADDITIONAL INFORMATION

The official instruction, CR 6084, issued to your carrier, FI, and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1531CP.pdf>.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6084
Related Change Request (CR) Number: 6084
Related CR Release Date: June 6, 2008
Related CR Transmittal Number: R1531CP
Effective Date: July 1, 2008
Implementation Date: July 7, 2008

Source: CMS Pub. 100-04, Transmittal 1531, CR 6084

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INAPPROPRIATE DENIALS OF CLAIMS FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Physicians and hospitals who submit claims to Medicare carriers, fiscal intermediaries (FIs) and Part A/B Medicare administrative contractors (A/B MACs) for percutaneous transluminal angioplasty (PTA) services provided to Medicare beneficiaries.

WHAT PROVIDERS NEED TO KNOW

Be aware that the Centers for Medicare & Medicaid Services (CMS) using change request (CR) 6046 reminds providers and Medicare contractors that **certifying and recertifying facilities for Medicare payment is solely under the Center for Medicare & Medicaid Services (CMS) jurisdiction**. When CMS certifies a facility, the facility name and effective date appear on a list of approved facilities located on the CMS Web site at <http://www.cms.hhs.gov/MedicareApprovedFacilities/CASF/list.asp>. If CMS disapproves a facility at any time, that facility is placed on a separate list of formerly approved facilities indicating the time period during which the facility was certified (also accessible on the above-noted Web site). Therefore, **as long as a facility appears on the approved list, it is considered certified by CMS whether or not**

recertification is in pending status. Your Medicare contractors are expected to consult the two facility lists in determining certification status and they **should not deny claims based on any other certification factors such as erroneously applied expiration date edits**.

All requirements contained in CR 3811 and CR 5660 remain in effect. You may review related *MLN Matters* articles MM5660, which clarifies the national coverage determination (NCD) policy for PTA on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5660.pdf>, and MM3811, which outlines the initial NCD policy for PTA at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.pdf>.

BACKGROUND

This article is based on CR 6046 and in this article CMS states that it has come to their attention that some contractors are misapplying the initial certification and recertification requirements contained in CR 3811 and CR 5660, respectively, thereby inappropriately denying claims when a facility is not immediately recertified at the end of a two-year period.

Inappropriate Denials of Claims for Percutaneous Transluminal Angioplasty (continued)

Effective March 17, 2005, CMS revised the NCD for PTA of the carotid artery concurrent with placement of a Food Drug Administration (FDA)-approved carotid stent for certain beneficiaries at high risk for carotid endarterectomy. On April 22, 2005, CMS issued CR 3811 to implement NCD 20.7, which included detailed steps facilities must follow to become certified by CMS to perform this procedure.

On April 30, 2007, as a result of a request for reconsideration of NCD 20.7, CMS posted a final decision that the current coverage policy would remain unchanged. CR 5660 was subsequently released on September 12, 2007, reiterating its decision. CR 5660 also made clarifying revisions to NCD 20.7, which included additional, detailed recertification steps a facility must follow every two years in order to maintain Medicare coverage of carotid artery stenting (CAS) procedures.

ADDITIONAL INFORMATION

You may see the official instruction (CR 6046) issued to your Medicare carrier, FI, or A/B MAC, by going to the CMS

Web site <http://www.cms.hhs.gov/Transmittals/downloads/R3490TN.pdf>.

If you have questions, please contact your Medicare Carrier, FI, or A/B MAC, at their toll-free number which may be found on the CMS Web site at: <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6046

Related Change Request (CR) Number: 6046

Related CR Release Date: June 6, 2008

Related CR Transmittal Number: R3490TN

Effective Date: March 17, 2005

Implementation Date: July 7, 2008

Source: CMS Pub. 100-20, Transmittal 349, CR 6046

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MEDICARE PROVIDES COVERAGE OF DIABETES SCREENING TESTS—REMINDER

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

All Medicare fee-for-service (FFS) physicians, qualified nonphysician practitioners (physician assistants, nurse practitioners, and clinical nurses), providers, suppliers, and other health care professionals who furnish or provide referrals for and/or file claims for Medicare-covered diabetes screening tests.

PROVIDER ACTION NEEDED

This article conveys no new policy information. This article serves as a reminder to health care professionals and their staff that Medicare pays for diabetes screening tests. To ensure proper reimbursement for these screening tests the correct procedure and diagnosis codes and modifier (when appropriate) must be used when filing claims.

IMPORTANT CLAIM FILING INFORMATION

When filing claims for diabetes screening tests the following Healthcare Common Procedure Coding System (HCPCS) codes/Current Procedural Terminology (CPT) codes, and diagnosis codes must be used to ensure proper reimbursement:

CPT Codes Code Descriptors

82947 Glucose; quantitative, blood (except reagent strip)

82950 Glucose; post glucose dose (includes glucose)

82951 Glucose; Tolerance Test (GTT), three specimens (includes glucose)

Diagnosis Code and Descriptor

Diagnosis Code	Code Descriptor	Modifier	Criteria
V77.1	To indicate that the purpose of the test(s) is for diabetes screening for a beneficiary who does not meet the *definition of pre-diabetes, screening diagnosis code V77.1 is required in the header diagnosis section of the claim.	None	It does not meet criterion
V77.1	To indicate that the purpose of the test(s) is for diabetes screening for a beneficiary who meets the *definition of pre-diabetes, screening diagnosis code V77.1 is required in the header diagnosis section of the claim <i>and</i> modifier "TS" (follow-up service) is to be reported on the line item.	TS	It meets criterion

Note: The Centers for Medicare & Medicaid Services (CMS) monitors the use of its preventive and screening benefits. By correctly coding for diabetes screening and other benefits, providers can help CMS to more accurately track the use of these important services and identify opportunities for improvement. *When submitting a claim for a diabetes screening test it is important to use diagnosis code V77.1 and the "TS" modifier on the claim as indicated above along with the correct CPT code so that the provider/supplier can be reimbursed correctly for a screening service and not for another type of diabetes testing service.*

Medicare Provides Coverage of Diabetes Screening Tests—Reminder (continued)

*Definitions

Diabetes: Diabetes mellitus, is defined as a condition of abnormal glucose metabolism diagnosed using the following criteria:

- a fasting blood glucose greater than or equal to 126 mg/dL on two different occasions;
- a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or
- a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Pre-diabetes: A condition of abnormal glucose metabolism diagnosed using the following criteria:

- a fasting glucose level of 100 to 125 mg/dL, or
- a two-hour post-glucose challenge of 140 to 199 mg/dL.

The term “pre-diabetes” includes:

- impaired fasting glucose; and
- impaired glucose tolerance.

COVERED TESTS

Medicare will pay for the following diabetes screening tests:

- a fasting blood glucose test, and
- a post-glucose challenge test; not limited to
 - an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults), **OR**
- a two-hour post-glucose challenge test alone.

Note: Other diabetes screening tests for which the CMS has not specifically indicated national coverage continue to be noncovered.

ELIGIBILITY

Medicare beneficiaries who have any of the following risk factors for diabetes are eligible for this screening benefit:

- Hypertension
- Dyslipidemia
- Obesity (a body mass index equal to or greater than 30 kg/m²); or
- Previous identification of elevated impaired fasting glucose or glucose tolerance, **OR**

Medicare beneficiaries who have a risk factor consisting of *at least two* of the following characteristics are eligible for this screening benefit:

- Overweight (a body mass index greater than 25, but less than 30 kg/m²)
- A family history of diabetes

- Age 65 years or older
- A history of gestational diabetes mellitus, or of delivering a baby weighing greater than nine pounds.

Note: No coverage is permitted under the screening benefit for beneficiaries previously diagnosed with diabetes since these individuals do not require screening.

FREQUENCY

Medicare provides coverage for diabetes screening tests with the following frequency:

Beneficiaries diagnosed with pre-diabetes:

Medicare provides coverage for a maximum of two diabetes-screening tests per calendar year (but not less than six months apart) for beneficiaries diagnosed with pre-diabetes.

Beneficiaries previously tested but not diagnosed with pre-diabetes or who have never been tested:

Medicare provides coverage for one diabetes-screening test per year (i.e., at least 11 months have passed following the month in which the last Medicare-covered diabetes screening test was performed) for beneficiaries who were previously tested and who were not diagnosed with pre-diabetes, or who have never been tested.

Note: A physician or qualified nonphysician practitioner must provide the Medicare beneficiary with a referral for the diabetes screening test(s). The diabetes screening service covered by Medicare is a stand alone billable service separate from the initial preventive physical examination (also referred to as the Welcome to Medicare Physical Examination) and does not have to be obtained within the first six months of a beneficiary's Medicare Part B coverage.

ADDITIONAL INFORMATION

If you have any questions, please contact your Medicare carrier or your Medicare administrative contractor at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: SE0821
Related Change Request (CR) Number: N/A
Related CR Release Date: N/A
Related CR Transmittal Number: N/A
Effective Date: N/A
Implementation Date: N/A

Source: CMS Special Edition *MLN Matters* Article SE0821

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REPORTING OF HEMATOCRIT OR HEMOGLOBIN LEVELS FOR THE ADMINISTRATION OF ERYTHROPOIESIS STIMULATING AGENTS

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

Note: CMS has revised this *MLN Matters* article on May 16, 2008, to delete the words “decimal implied” from the bulleted paragraph addressing billing instructions for professional electronic claims (837P) billed to carriers, under the “What You Need To Know” section. All other information remains the same. The previously revised *MLN Matters* article MM5699 was published in the March 2008 *Medicare A Bulletin* (pages 20-21).

PROVIDER TYPES AFFECTED

Physicians, providers, and suppliers who bill Medicare contractors (carriers, including durable medical equipment Medicare administrative contractors [DME MACs], fiscal intermediaries [FIs], competitive acquisition plan [CAP] designated carriers, and A/B Medicare administrative contractors [A/B MACs]) for providing erythropoiesis stimulating agents (ESAs) and related anti-anemia administration services to Medicare beneficiaries.

IMPACT ON PROVIDERS

Effective for services on or after January 1, 2008, you must report the most recent hemoglobin or hematocrit levels on any claim for a Medicare patient receiving: (1) ESA administrations, or (2) Part B anti-anemia drugs other than ESAs used in the treatment of cancer that are not self-administered. In addition, non-end-stage renal disease (ESRD) claims for the administration of ESAs must also contain one of three new Healthcare Common Procedure Coding System (HCPCS) modifiers effective January 1, 2008.

Failure to report this information will result in your claim being returned as unprocessed. **(Note that renal dialysis facilities are already reporting this information on claim types 72x, so change request (CR) 5699 applies to providers billing with other types of bills.)** See the rest of this article for reporting details.

BACKGROUND

Medicare Part B provides payment for certain drugs used to treat anemia caused by the cancer itself or by various anti-cancer treatments, including chemotherapy, radiation, and surgical therapy. The treatment of anemia in cancer patients commonly includes the use of drugs, specifically ESAs such as recombinant erythropoietin and darbepoetin. Emerging data and recent research has raised the possibility that ESAs administered for a number of clinical indications may be associated with significant adverse effects, including a higher risk of mortality in some populations.

Most recently, section 110 of Division B of the Tax Relief and Health Care Act (TRHCA) of 2006 directs the Secretary to amend Section 1842 of the Social Security Act by adding at the end the following new subsection: “*Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.*”

In light of the health and safety factors and the TRHCA legislation, effective January 1, 2008, the Centers for Medicare & Medicaid Services (CMS) is implementing an expanded reporting requirement for all claims billing for

administrations of an ESA. Hematocrit and /or hemoglobin readings are already required for ESRD claims for administrations of an ESA. Effective with the implementation of CR 5699, all other claims for ESA administrations will also require the reporting of the most recent hematocrit or hemoglobin reading, along with one of three new HCPCS modifiers effective January 1, 2008.

In addition, CR 5699 requires the reporting of the most recent hematocrit or hemoglobin readings on all claims for the administration of Part B anti-anemia drugs **other than** ESAs used in the treatment of cancer that are not self-administered.

WHAT YOU NEED TO KNOW

CR 5699, from which this article is taken, instructs all providers and suppliers that:

1. Effective January 1, 2008, all claims billing for the administration of an ESA with HCPCS codes J0881, J0882, J0885, J0886 and Q4081 must report the most recent hematocrit or hemoglobin reading available when the billed ESA dose was administered. Facilities should bill at a frequency that allows for the reporting of the most recent hematocrit or hemoglobin reading prior to the start of the billing period that is applicable to the administrations billed on the claim. For new patients this would be the most recent reading prior to the onset of treatment. Note that a provider may have to submit more than one claim for the month if there were multiple readings that were applicable to the administrations given during the month. Claims submitted prior to the publication of CR 5699 that were not completed per the instructions in CR 5699 should be re-submitted.
 - For institutional claims, the hemoglobin reading is reported with a value code 48 and a hematocrit reading is reported with the value code 49. Such claims for ESAs not reporting a value code 48 or 49 will be returned to the provider.
 - Effective for services on or after January 1, 2008, for professional paper claims, test results are reported in item 19 of the CMS-1500 claim form. For professional electronic claims (837P) billed to carriers or A/B MACs, providers report the hemoglobin or hematocrit readings in loop 2400 MEA segment. The specifics are MEA01=TR (for test results), MEA02=R1 (for hemoglobin) or R2 (for hematocrit), and MEA03=the test results. The test results should be entered as follows: TR= test results, R1=hemoglobin or R2=hematocrit (a 2-byte alpha-numeric element), and the most recent numeric test result (a 3-byte numeric element [xx.x]). Results exceeding 3-byte position numeric elements (10.50) are reported as 10.5.

Reporting of Hematocrit or Hemoglobin Levels for the Administration of ESA (continued)

Examples: If the most recent hemoglobin test results are 10.50, providers should enter: TR/R1/10.5, or, if the most recent hematocrit results are 32.3, providers would enter: TR/R2/32.3.

- Effective for dates of service on and after January 1, 2008, contractors will return to provider paper and electronic professional claims, or return as unprocessable paper and electronic institutional claims for ESAs when the most recent hemoglobin or hematocrit test results are not reported.
 - When Medicare returns a claim as unprocessable for ESAs with HCPCS codes J0881, J0882, J0885, J0886, or Q4081 for failure to report the most recent hemoglobin or hematocrit test results, it will include claim adjustment reason code 16 (Claim/service lacks information which is needed for adjudication) and remittance advice code MA130 (Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with complete/correct information.)
2. Effective January 1, 2008, all non-ESRD ESA claims billing HCPCS J0881 and J0885 must begin reporting one (**and only one**) of the following three modifiers on the same line as the ESA HCPCS:
- ♦ EA: ESA, anemia, chemo-induced
 - ♦ EB: ESA, anemia, radio-induced; or
 - ♦ EC: ESA, anemia, non-chemo/radio
- Non-ESRD ESA institutional claims that do not report one of the above three modifiers along with HCPCS J0881 or J0885 will be returned to the provider.
 - Non-ESRD ESA professional claims that are billed without one of the three required modifiers as line items along with HCPCS J0881 or J0885 will be returned as unprocessable with reason code 4 and remark code MA130. If more than one modifier is reported, the claim will be returned with reason code 125 and remark code N63.
3. Effective January 1, 2008, all non-ESRD, non-ESA claims billing for the administration of Part B anti-anemia drugs used in the treatment of cancer that are not self-administered must report the most recent hematocrit or hemoglobin reading. Facilities should bill at a frequency

that allows for the reporting of the most recent hematocrit or hemoglobin reading prior to the start of the billing period that is applicable to the administrations billed on the claim. For new patients this would be the most recent reading prior to the onset of treatment. Note that a provider may have to submit more than one claim for the month if there were multiple readings that were applicable to the administrations given during the month.

- Institutional claims that do not report the most recent hematocrit or hemoglobin reading will be returned to the provider.
- Professional claims that do not report the most recent hematocrit or hemoglobin reading will be returned as unprocessable using reason code 16, and remarks codes MA130 and N395
- Your Medicare contractor will not search for claims with dates of service on or after January 1, 2008, processed prior to implementation of this CR, but will adjust such claims when you bring them to the attention of your contractor.

ADDITIONAL INFORMATION

For complete details regarding this CR please see the official instruction (CR 5699) issued to your Medicare carrier, FI, DME MAC, CAP designated carrier, and A/B MAC. That instruction may be viewed by going to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1412CP.pdf>.

If you have questions, please contact your Medicare carrier, FI, DME MAC, CAP designated carrier, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM5699 – Revised
Related Change Request (CR) Number: 5699
Related CR Release Date: January 11, 2008
Related CR Transmittal Number: R1412CP
Effective Date: January 1, 2008
Implementation Date: April 7, 2008

Source: CMS Pub. 100-04, Transmittal 1412, CR 5699

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LOCAL COVERAGE DETERMINATIONS

In accordance with publications specified by CMS, Medicare contractors no longer distribute full-text local coverage determinations (LCDs) to providers in hardcopy format. Providers may obtain full-text LCDs from our provider education Web site <http://www.fcso.com>.

Final LCDs, draft LCDs available for comment, LCD statuses, and LCD comment/response summaries may be printed from the Part A section under the Part A Medical Coverage section.

This section of the *Medicare A Bulletin* features summaries of new and revised LCDs developed as a result of either local medical review or comprehensive data analysis initiatives. These initiatives are designed to ensure the appropriateness of medical care and to make sure that the fiscal intermediary's LCDs and review guidelines are consistent with accepted standards of medical practice.

EFFECTIVE AND NOTICE DATES

Effective dates are provided in each LCD, and are based on the date services are furnished unless otherwise noted in the LCD. Medicare contractors are required to offer a 45-day notice period for LCDs; the date the LCD is posted to the provider education Web site is considered the notice date.

ELECTRONIC NOTIFICATION

To receive quick, automatic notification when new and revised LCDs are posted to the Web site, subscribe to the FCSO *eNews* mailing list. It is very easy to do. Simply go to our Web site <http://www.fcso.com>, Medicare Providers Florida Part A or B, click on the "eNews" link located on the upper-right-hand corner of the page and follow the prompts.

MORE INFORMATION

If you do not have Internet access, contact the Medical Policy and Procedures department at:

Medical Policy and Procedures – 19T
First Coast Service Options, Inc.
P.O. Box 2078
Jacksonville, FL 32231-0048

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ADVANCE BENEFICIARY NOTICE

- **Modifier GZ** must be used when providers, physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they **have not had** an advance beneficiary notification (ABN) signed by the beneficiary.
- **Modifier GA** must be used when providers, physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they **do have** on file an ABN signed by the beneficiary.
- All claims not meeting medical necessity of a local coverage determination (LCD) must append the billed service with **modifier GA or GZ**.

This Bulletin Should Be Shared with All Health Care Practitioners and Managerial Members of the Provider Staff. Bulletins Are Available at no Cost from Our Provider Education Web site at <http://www.fcso.com>.

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ADDITIONS/REVISIONS TO EXISTING LCDs

AJ7187 HEMOPHILIA CLOTTING FACTORS—CODING GUIDELINES RETIRED

LCD ID NUMBER: L1323

The coding guidelines attachment of the hemophilia clotting factors local coverage determination (LCD) was last revised January 1, 2007. Since that time, it has been determined that the coding guidelines are not applicable to claims submitted by Part A providers. Therefore, the coding guidelines have been retired.

EFFECTIVE DATE

This retirement of the coding guidelines is effective for services provided **on or after June 12, 2008**.

The full text of this LCD (L1323) is available through the CMS Medicare Coverage Database ([List of LCDs for FCSO Inc. \(00090, Intermediary\)](#)) on or after this effective date. ❖

ATHERSERVCS: THERAPY AND REHABILITATION SERVICES—REVISION TO THE LCD

LCD ID NUMBER: L1125

The local coverage determination (LCD) for therapy and rehabilitation services was last revised on January 1, 2008. Since that time, language has been added based on change request 5921, transmittal 88, dated May 7, 2008. This change request outlines updated therapy personnel qualifications and revised recertification requirements. The "Indications and Limitations of Coverage and/or Medical Necessity" and "Documentation Requirements" sections of the LCD have been revised to incorporate the new language. A complete discussion of the updated policies may be found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 220-230.

EFFECTIVE DATE

This LCD revision is effective for claims processed **on or after June 9, 2008**, for services provided **on or after April 1, 2008**.

The full text of this LCD (L1125) is available through the CMS Medicare Coverage Database ([List of LCDs for FCSO Inc. \(00090, Intermediary\)](#)) on or after this effective date. ❖

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ADDITIONAL MEDICAL INFORMATION

AJ0881: ERYTHROPOIESIS STIMULATING AGENTS—CLARIFICATION ON CORRECT CODING OF ESAs

LCD ID NUMBER: L895

Providers are required to bill a dual diagnosis and the notes located at the end of each list of medically necessary ICD-9-CM diagnosis codes are meant to identify the dual diagnosis requirements for each HCPCS code in the local coverage determination (LCD). To further assist providers in understanding the dual diagnosis requirements, these notes will be revised in the LCD for erythropoiesis stimulating agents as follows:

HCPCS Code J0881

ICD-9-CM diagnosis code **285.21** must be billed with **one** of the following diagnosis codes:

403.01	403.11	403.91	404.02	404.03	404.12	404.13	404.92
404.93	585.1	585.2	585.3	585.4	585.5	585.9.	

ICD-9-CM diagnosis code **285.29 or 285.9** must be billed with one of the following diagnosis codes:

238.71	238.72	238.73	238.74	238.75	238.76	273.3
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or **one** of the malignancy codes listed in the [LCD](#).

HCPCS Code J0885

ICD-9-CM diagnosis code **285.21** must be billed with **one** of the following diagnosis codes:

403.01	403.11	403.91	404.02	404.03	404.12	404.13	404.92
404.93	585.1	585.2	585.3	585.4	585.5	585.9	

ICD-9-CM diagnosis code **285.29 or 285.9** must be billed with **one** of the following diagnosis codes:

042	070.54	070.70	238.71	238.72	238.73	238.74	238.75
238.76	273.3	V07.8	714.0				

or **one** of the malignancy codes listed in the [LCD](#).

HCPCS Code J0882

ICD-9-CM diagnosis code **285.21 and 585.6** must be billed together.

The full text of this LCD (L895) is available through the CMS Medicare Coverage Database ([List of LCDs for FCSO Inc. \(00090, Intermediary\)](#)). ❖

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HOSPITAL SERVICES

HOSPITALS EXEMPT FROM PRESENT ON ADMISSION REPORTING AND GROUPER INTERFACE

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Inpatient prospective payment system (IPPS) exempt hospitals submitting claims to Medicare contractors (fiscal intermediaries [FIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

STOP – IMPACT TO YOU

This article is based on change request (CR) 6086, which provides updated information to hospitals that are exempt from present on admission (POA) reporting, but still report the POA.

CAUTION – WHAT YOU NEED TO KNOW

Although POA reporting is not required for IPPS exempt hospitals, their claims still process through the GROUPER software. Some exempt hospitals report the POA, however, due to other payer requirements or business needs. When exempt hospitals report the POA, they must include an 'X' to indicate the end of POA reporting in the K3 segment of the claim. The 'X' indicator will prevent the GROUPER from applying hospital acquired condition (HAC) logic to the claim.

GO – WHAT YOU NEED TO DO

See the *Background* and *Additional Information* sections of this article for further details regarding these changes.

BACKGROUND

The Deficit Reduction Act (DRA) of 2005 (section 5001(c); see CMS Web site <http://www.cms.hhs.gov/LegislativeUpdate/downloads/DRA0307.pdf>) requires the Centers for Medicare & Medicaid Services (CMS) to identify (by October 1, 2007) at least two conditions that:

- Are high cost or high volume or both
- Result in the assignment of a case to a diagnosis related group (DRG) that has a higher payment when present as a secondary diagnosis
- Could reasonably have been prevented through the application of evidence-based guidelines.

For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case would be paid as though the secondary diagnosis were not present.

The DRA (Section 5001(c)):

- Provides that CMS can revise the list of conditions from time to time, as long as it contains at least two conditions; and
- Requires hospitals to report POA information for both primary and secondary diagnoses when submitting claims for discharges on or after October 1, 2007.

CR 5679 (transmittal R2890TN, dated July 20, 2007) provided information on the requirements for completing a POA indicator for every diagnosis on an inpatient acute care hospital claim beginning with discharges on or after October 1, 2007, and provides your Medicare contractor with the coding and editing requirements, and software modifications needed to successfully implement this indicator. You may review CR 5679 on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R2890TN.pdf>.

Exempt providers that report POA information (due to other payer requirements or any other business need) must include an 'X' to indicate the end of POA reporting in the K3 segment. The 'X' is necessary so that IPPS GROUPER software will not apply hospital-acquired condition (HAC) DRG logic to these claims.

Note: Effective October 1, 2008, FISS will automatically replace any reported 'Z' indicator with an 'X' for providers exempt from reporting POA. **However, exempt providers should begin to report an 'X' to indicate the end of POA reporting as soon as possible.**

ADDITIONAL INFORMATION

The official instruction, CR 6086, issued to your FI and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R3540TN.pdf>.

If you have any questions, please contact your FI or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6086
Related Change Request (CR) #: 6086
Related CR Release Date: June 13, 2008
Related CR Transmittal #: R3540TN
Effective Date: October 1, 2008
Implementation Date: October 6, 2008

Source: CMS Pub. 100-20, Transmittal 354, CR 6086

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DELAY IN IMPLEMENTATION OF NEW HEMOPHILIA CLOTTING FACTOR—HCPCS CODE Q4096

The Center for Medicare & Medicaid Services (CMS) has extended the implementation of the new Healthcare Procedure Code System (HCPCS) Level II code Q4096 from October 2008 to January 2009. The following billing and processing instructions published in the May 2008 *Medicare A Bulletin* (page 43) remain in effect.

Effective for claims with dates of service on or after April 1, 2008, the following new HCPCS code will be payable for Medicare.

HCPCS Description

Q4096 Injection, von Willebrand factor complex, human, ristocetin cofactor (not otherwise specified), per I.U. vWF:RCO
Short Descriptor: VWF complex, not Humate-P

Payment for HCPCS code Q4096 requires fiscal intermediary shared system (FISS) modifications. Implementation of these modifications has been extended to the January 2009 quarterly release scheduled for January 6, 2009. Until then, CMS is asking providers to omit HCPCS code Q4096 from the inpatient hospital claims. Once the share system has been appropriately updated, providers can submit an adjustment request that includes HCPCS code Q4096. At that time, contractors will be able to process claims for this HCPCS code and make payment.

ACTION REQUIRED BY PROVIDERS

- Providers shall submit claims for hospital inpatient care omitting the line item(s) for HCPCS code Q4096 for dates of discharge on and after April 1, 2008 but prior to January 5, 2009.

For the purpose of these instructions, inpatient care includes hospitals paid under:

- the inpatient prospective payment system (IPPS)
- the long term care prospective payment system (LTCH PPS)
- the inpatient rehabilitation facility prospective payment system (IRF PPS)
- those paid on the basis of reasonable cost [TEFRA hospitals, critical access hospitals (CAHs), and Indian Health Service (IHS) hospital inpatient services (actually paid on a DRG basis)]

This does not apply to claims from inpatient psychiatric facilities (IPFs) paid under IPF PPS; IPFs receive a comorbidity adjustment under IPF PPS based on the presence of a hemophilia diagnosis on the claim.

- Once the system has been updated, the provider shall submit an adjustment request (TOB = 117) including HCPCS code Q4096.

Any inpatient claims (TOB 11x) containing HCPCS code Q4096 with discharge dates on and after April 1, 2008 but prior to January 5, 2009, will be returned to the provider (RTP). ❖

Source: CMS JSM 08357, June 20, 2008

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SKILLED NURSING FACILITY SERVICES

CHARGES TO HOLD A BED DURING SKILLED NURSING FACILITY ABSENCE

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Skilled nursing facilities (SNFs) submitting claims to Medicare contractors (fiscal intermediaries (FIs), and/or Part A/B Medicare administrative contractors (A/B MACs)) for SNF services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

This article is based on change request (CR) 6030 which describes the policies relating to bed-hold payments in an SNF by updating the *Medicare Claims Processing Manual* (chapter 1 (General Billing Requirements), section 30.1 (Charges to Hold a Bed during SNF Absence)).

BACKGROUND

Charges to a beneficiary for admission or readmission to an SNF are not allowable. However, when temporarily leaving an SNF, a resident can choose to make bed-hold payments to the SNF. Under the Social Security Act (Section 1819(c)(1)(B)(iii)); (see http://www.ssa.gov/OP_Home/ssact/title18/1819.htm on the Internet) and the *Code of Federal Regulations* (42 CFR section 483.10(b)(5)-(6)), a SNF must inform residents in advance of their option to make bed-hold payments, as well as the amount of the facility's charge.

Note: SNFs, but not hospitals, may bill the beneficiary for holding a bed during a leave of absence if Medicare requirements are met.

Bed-hold payments are readily distinguishable from payments made prior to initial admission, in that the absent individual has already been admitted to the facility and has established residence in a particular living space within it. Similarly, bed-hold payments are distinguishable from payments for readmission, in that the latter compensate the facility merely for agreeing in advance to allow a departing resident to reenter the facility upon return, while bed-hold payments represent remuneration for the privilege of actually maintaining the resident's personal effects in the particular living space that the resident has temporarily vacated.

One indicator that post-admission payments do, in fact, represent permissible bed-hold charges related to maintaining personal effects in a particular living space (rather than a prohibited charge for the act of readmission

itself) would be that the charges are calculated on the basis of a per diem bed-hold payment rate multiplied by however many days the resident is absent, as opposed to assessing the resident a fixed sum at the time of departure from the facility.

Under section 1819(c)(1)(B)(iii) of the Act and 42 CFR 483.10(b)(5)-(6), the facility must inform residents in advance of their option to make bed-hold payments, as well as the amount of the facility's charge. For these optional payments, the facility should make clear that the resident must affirmatively elect to make them prior to being billed. A facility cannot simply deem a resident to have opted to make such payments and then automatically bill for them upon the resident's departure from the facility."

See chapter 30 of the *Medicare Claims Processing Manual* for related notification requirements. That chapter is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf>.

ADDITIONAL INFORMATION

The official instruction, CR 6030, issued to your FI or A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1522CP.pdf>.

The revised section of the *Medicare Claims Processing Manual* is attached to CR 6030.

If you have any questions, please contact your FI or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6030
Related Change Request (CR) Number: 6030
Related CR Release Date: May 30, 2008
Related CR Transmittal Number: R1522CP
Effective Date: June 30, 2008
Implementation Date: June 30, 2008

Source: CMS Pub. 100-04, Transmittal 1522, CR 6030

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CORF SERVICES

REMINDER—EXCEPTIONS TO THERAPY CAPS ARE RESTRICTED AS OF JULY 1, 2008

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Therapists and other suppliers or providers, who bill Medicare contractors (carriers, fiscal intermediaries [FIs], or Medicare administrative contractors [A/B MAC]) for outpatient therapy services for Medicare beneficiaries.

PROVIDER ACTION NEEDED

As stated in *MLN Matters* article MM5871, exceptions to the \$1810 outpatient therapy caps were allowed from January 1, 2008, to June 30, 2008, for medically necessary services that were appropriately billed with modifier KX. **On or after July 1, 2008, the exceptions to therapy caps are restricted to those medically necessary services billed by the outpatient departments of hospitals. Use of the modifier KX will not be effective on or after July 1, 2008.**

If, on July 1, 2008, a cap has already been reached, a beneficiary who is not a resident in the Medicare certified part of a skilled nursing facility will be able to obtain medically necessary services that exceed the cap only when the services are billed by the outpatient department of a hospital. A beneficiary in the Medicare certified part of a skilled nursing facility is restricted by consolidated billing rules from coverage of services that are billed by a hospital.

You should make sure that your billing staff is aware that outpatient therapy caps apply to all services in calendar year 2008, with exceptions for medically necessary services in all settings on or prior to June 30, 2008 and with exceptions limited to the outpatient hospital setting after June 30, 2008. You might also want to refer to the updated *Medicare Claims Processing Manual*, Chapter 5 (Part B Outpatient Rehabilitation and CORF/OPT Services), section 10.2 (The Financial Limitation), for the complete documentation of the outpatient therapy services exceptions clarifications. That chapter is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/manuals/downloads/clm104c05.pdf>.

BACKGROUND

The Balanced Budget Act of 1997 enacted financial limitations on outpatient physical therapy, occupational therapy, and speech-language pathology services in all settings except outpatient hospital services. The 2006 Deficit Reduction Act enacted further exceptions to the limits, and the Medicare, Medicaid, and SCHIP Extension Act of 2007 extended the cap exceptions process through June 30, 2008.

Change request (CR) 5871 announced the dollar amount of outpatient therapy caps for 2008. Effective January 1, 2008, the financial limits on outpatient therapy services were \$1,810 for combined physical therapy and speech-language pathology services; and \$1,810 for occupational therapy services. Exceptions are allowed for medically necessary outpatient therapy services in all settings for services furnished on or before June 30, 2008. This article announces, and reminds providers, that exceptions are restricted for services furnished on or after July 1, 2008.

ADDITIONAL INFORMATION

Medlearn Matters article MM5871 is available on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5871.pdf>.

If you have questions, contact your carrier, FI, or MAC at their toll-free number, which is available on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: SE0815
Related Change Request (CR) Number: 5871
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal Number: N/A
Implementation Date: N/A

Source: CMS Special Edition *MLN Matters* Article SE0815

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HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

JULY 2008 INTEGRATED OUTPATIENT CODE EDITOR SPECIFICATIONS VERSION 9.2

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Providers submitting claims to Medicare contractors (fiscal intermediaries [FIs], regional home health intermediaries [RHHIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for outpatient services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article is based on change request (CR) 6080 which provides the integrated outpatient code editor (I/OCE) instructions and specifications for the July, 2008, I/OCE that will be used for processing outpatient prospective payment system (OPPS) and non-OPPS claims from hospital outpatient departments, community mental health centers (CMHCs), and for all non-OPPS providers, and for limited services when provided in a home health agency (HHA) not under the home health prospective payment system (HH PPS) or to a hospice patient for the treatment of a non-terminal illness.

BACKGROUND

CR 6080 informs providers, FIs and A/B MACs that the I/OCE is updated for July 1, 2008. The I/OCE routes all institutional outpatient claims (which includes non-OPPS through a single integrated OCE eliminating the need to update, install, and maintain two separate OCE software packages on a quarterly basis.

Claims with dates of service prior to July 1, 2007, are

routed through the non-integrated versions of the OCE software (OPPS and non-OPPS OCEs) that coincide with the versions in effect for the date of service on the claim.

CR 6080 provides the I/OCE instructions and specifications that will be utilized under the OPPS and non-OPPS for hospital outpatient departments, CMHCs, and for all non-OPPS providers, and for limited services when provided in an HHA not under the HH PPS or to a hospice patient for the treatment of a non-terminal illness. The I/OCE instructions are attached to CR 6080 and will also be posted on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/OutpatientCodeEdit/>.

CR 6080 also includes as an attachment with detailed lists of the ambulatory payment classifications (APC), Health Care Common Procedure Coding System (HCPCS), and *Current Procedural Terminology (CPT)* code changes, additions, and deletions. This article will not repeat all of those changes. However, the key modifications of the OCE for the July 2008 release (V9.2) are summarized in the table below.

In the table note that:

- Highlighted sections indicate change from the prior release of the software.
- Some I/OCE modifications in the release may also be retroactively added to prior releases. If so, the retroactive date will appear in the 'Effective Date' column.

Effective Date	Edit	Summary of Change
7/1/08	24	Modify the software to maintain/retain 28 prior quarters (seven years) of programs and codes in each release. Remove older versions with each release. (The earliest version date included in the July 2008 release will be 4/1/01).
7/1/08	50	Change disposition for edit 50 to RTP (Return to Provider). Note: The IOCE change to RTP this claim will no longer trigger an initial determination. The provider should bill statutorily excluded services as noncovered and affix liability with the GY modifier (beneficiary liable).
4/1/01		Exclude denied or rejected lines from PHP (partial hospitalization program) processing and from daily mental health assignment criteria.
		Make HCPCS/APC/SI changes as specified by CMS
	19, 20, 39, 40	Implement version 14.1 of the NCCI (National Correct Coding Initiative) file, removing all code pairs which include anesthesia (00100-01999), E&M (92002-92014, 99201-99499), or MH (90804-90911).
1/1/08	17	Remove codes 92621 and 92627 from the Inherently bilateral list – change bilateral indicator to '0'.
7/1/08	15	Change all max units to zero for all codes that currently have max unit values other than zero.
1/1/08	78	Update nuclear medicine/radiopharmaceutical edit requirements.
7/1/08	71/77	Update procedure/device edit requirements.

July 2008 Integrated Outpatient Code Editor Specifications Version 9.2 (continued)

Effective Date	Edit	Summary of Change
7/1/08	22	Add new modified CG (“Policy criteria applied”) to the valid modifier list.
		Documented some ‘general programming notes’ that were in effect but not previously documented.
		Documented the exclusion of denied or reject lines from composite criteria.
		Clarified the text in appendix D that includes some non-type T procedures in bilateral procedure discounting.
		Modify description for SI “H” – “Pass-through device categories.”
		Modify description for SI “K” – Non pass-through drugs and biologicals, therapeutic radiopharmaceutical, brachytherapy sources, blood and blood products.
		Create a 508 compliant version of the document (modify as necessary) – for publication on CMS Web site.

ADDITIONAL INFORMATION

The official instruction, CR 6080, issued to your FI, RHHI, and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1523CP.pdf>.

If you have any questions, please contact your FI, RHHI, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options, Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6080

Related Change Request (CR) Number: 6080

Related CR Release Date: May 30, 2008

Related CR Transmittal Number: R1523CP

Effective Date: July 1, 2008

Implementation Date: July 7, 2008

Source: CMS Pub. 100-04, Transmittal 1523, CR 6080

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JULY 2008 UPDATE TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals.

PROVIDER TYPES AFFECTED

Providers submitting claims to Medicare contractors (fiscal intermediaries [FIs], regional home health intermediaries [RHHIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for services provided to Medicare beneficiaries that are paid under the OPPS.

PROVIDER ACTION NEEDED

This article is based on change request (CR) 6094, which describes changes to, and billing instructions for various payment policies implemented in the July 2008 outpatient prospective payment (OPPS) update. The July 2008 integrated outpatient code editor (I/OCE) software and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), ambulatory payment classification (APC), HCPCS modifier, and revenue code additions, changes, and deletions identified in this notification.

The July 2008 revisions to the I/OCE data files, instructions, and specifications are discussed in *MLN Matters* article MM6080, which is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6080.pdf>.

Be sure your billing staff is aware of these changes.

BACKGROUND

Following are the key changes effective for July 1, 2008, update of the OPPS:

Applicability of OPPS to Specific HCPCS Codes

Current Procedural Terminology (CPT) codes generally are created to describe and report physician services, but are also used by other providers/suppliers to describe and report services that they provide. Therefore, the *CPT* code descriptors do not necessarily reflect the facility component of a service furnished by the hospital. Some *CPT* code descriptors include reference to a physician performing a service. For OPPS purposes, unless indicated otherwise, the usage of the term “physician” does not restrict the reporting of the code or application of related policies to physicians only but applies to all practitioners, hospitals, providers, or suppliers eligible to bill the relevant *CPT* codes pursuant to applicable portions of the Social Security Act (SSA) of 1965, the *Code of Federal Regulations (CFR)*, and Medicare rules. In cases where there are separate codes for the technical component, professional component, and/or complete procedure, hospitals should report the code that represents the technical component for their facility services. If there is no separate technical component code for the service, hospitals should report the code that represents the complete procedure.

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

July 2008 Update to the Hospital Outpatient Prospective Payment System (continued)

Changes to Procedure and Device Edits for July 2008

Procedure to device edits requires that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code. Failure to pass these edits will result in the claim being returned to the provider. Device to procedure edits require that a claim that contains one of a specified set of device codes be returned to the provider if it fails to contain an appropriate procedure code. The updated lists of both types of edits may be found under "2008 Device and Procedure Edits" on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

Payment for Brachytherapy Sources as of July 1, 2008

The Medicare, Medicaid, and SCHIP Extension Act of 2007 requires CMS to pay for brachytherapy sources for the period of January 1 through June 30, 2008, at hospitals' charges adjusted to the costs. Therefore, the CMS is paying for brachytherapy sources based on charges adjusted to cost through June 30, 2008, and CMS will pay at prospective rates as of July 1, 2008. The prospective payment rates for each source, which are listed in addendum B to the CY 2008 final rule dated November 27, 2007, will be used for payment from July 1 through December 31, 2008. (Addendum B is available on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>.)

The "H" payment status indicators of brachytherapy source HCPCS codes (except C2637), which were previously paid at charges adjusted to cost, will change to payment status indicator "K" effective July 1, 2008, through December 31, 2008.

In addition, because the sources will be paid based on prospective rates as of July 1, brachytherapy sources will be eligible for outlier payments and for the rural sole community hospital (SCH) adjustment as of July 1, 2008. The HCPCS codes for separately payable brachytherapy sources, long descriptors, status indicators, and APCs for calendar year (CY) 2008 are listed in table 1 below, a comprehensive list of payable brachytherapy sources.

Note: When billing for stranded sources, providers should bill the number of units of the appropriate source HCPCS C-code according to the number of brachytherapy sources in the strand, and should not bill as one unit per strand. See *MLN Matters* article MM5623 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5623.pdf> for further information on billing for brachytherapy sources and the OPPS coding changes made for brachytherapy sources effective July 1, 2007.

Table 1 – Comprehensive List of Brachytherapy Sources Payable as of July 1, 2008

CPT/HCPCS	Long Descriptor	**SI	APC
A9527	Iodine I-125, sodium iodide solution, therapeutic, per millicurie	K	2632
C1716	Brachytherapy source, nonstranded, gold-198, per source	K	1716
C1717	Brachytherapy source, nonstranded, high dose rate iridium-192, per source	K	1717
C1719	Brachytherapy source, nonstranded, nonhigh dose rate iridium-192, per source	K	1719
C2616	Brachytherapy source, nonstranded, yttrium-90, per source	K	2616
C2634	Brachytherapy source, nonstranded, high activity, iodine-125, greater than 1.01 mCi (NIST), per source	K	2634
C2635	Brachytherapy source, nonstranded, high activity, palladium-103, greater than 2.2 mCi (NIST), per source	K	2635
C2636	Brachytherapy linear source, nonstranded, palladium-103, per 1 mm	K	2636
C2638	Brachytherapy source, stranded, iodine-125, per source	K	2638
C2639	Brachytherapy source, nonstranded, iodine-125, per source	K	2639
C2640	Brachytherapy source, stranded, palladium-103, per source	K	2640
C2641	Brachytherapy source, nonstranded, palladium-103, per source	K	2641
C2642	Brachytherapy source, stranded, cesium-131, per source	K	2642
C2643	Brachytherapy source, non-stranded, cesium-131, per source	K	2643
C2698	Brachytherapy source, stranded, not otherwise specified, per source	K	2698
C2699	Brachytherapy source, nonstranded, not otherwise specified, per source	K	2699

**SI = (status indicator)

Continuous Positive Airway Pressure (CPAP) Therapy

CMS revised its national coverage determination (NCD) for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA). CMS now allows coverage of CPAP when used in adult patients may be found in section 240.4 of the NCD Manual, available on the CMS Web site at <http://www.cms.hhs.gov/manuals/IOM/list.asp>.

To adequately report the home sleep study test for CPAP therapy, CMS has created the following three G-codes. Under OPPS, the G-codes have been assigned to APC 0213 (Level I extended EEG and sleep studies). Payment rates for these services may be found in addendum B of the July 2008 OPPS update that is posted on the CMS Web site.

HCPCS	Long Descriptor	APC	SI
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation	0213	S
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation	0213	S
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels	0213	S

July 2008 Update to the Hospital Outpatient Prospective Payment System (continued)

Category III CPT Codes

The American Medical Association (AMA) releases Category III CPT codes in January, for implementation beginning the following July, and in July, for implementation beginning the following January. Prior to CY 2006, CMS implemented new Category III CPT codes once a year in January of the following year. As discussed in the CY 2006 OPPTS final rule with comment period (70 FR 68567), CMS modified the process for implementing the Category III codes that the AMA releases each January for implementation in July to ensure timely collection of data pertinent to the services described by the codes; to ensure patient access to the services the codes describe; and to eliminate potential redundancy between Category III CPT codes and some of the C-codes that are payable under the OPPTS and were created by CMS in response to applications for new technology services. Therefore, on July 1, 2008, CMS implemented in the OPPTS five Category III CPT codes that the AMA released in January 2008 for implementation in July 2008. The codes, along with their status indicators and APCs, are shown in table 3 below. Payment rates for these services may be found in addendum B of the July 2008 OPPTS update that is posted on the CMS Web site.

Table 3 – Category III CPT Codes Implemented as of July 1, 2008

HCPSCS	Long Descriptor	APC	SI
0188T	Remote real-time interactive videoconferenced critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes	N/A	M
0189T	Remote real-time interactive videoconferenced critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes	N/A	M
0190T	Placement of intraocular radiation source applicator	0237	T
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach	0234	T
0192T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach	0234	T

Cardiac Echocardiography with Contrast (C8921-C8928)

In the April 2008 update to the OPPTS, CMS listed the revised short and long descriptors for the eight new C-codes for cardiac echocardiography with contrast services that were effective January 1, 2008. The codes, along with the revised short and long descriptors, were listed in table 3. Unfortunately, the long descriptors for C8922 and C8924 were incorrect in table 3. The correct short and long descriptors for the eight C-codes for cardiac echocardiography with contrast services were posted on the CMS HCPCS Web site, specifically on the CMS Web site at http://www.cms.hhs.gov/HCPCSReleaseCodeSets/02_HCPCS_Quarterly_Update.asp#TopOfPage.

Refer to the April 2008 HCPCS C-codes list dated March 25, 2008. **Hospitals are advised to download this file to view the correct long descriptors for C8922 and C8924.**

Billing for Drugs, Biologicals, and Radiopharmaceuticals

Hospitals are strongly encouraged to report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

CMS reminds hospitals that under the OPPTS, if two or more drugs or biologicals are mixed together to facilitate administration, the correct HCPCS codes should be reported separately for each product used in the care of the patient. The mixing together of two or more products does not constitute a “new” drug as regulated by the Food and Drug Administration (FDA) under the new drug application (NDA) process. In these situations, hospitals are reminded that it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, unclassified drug or biological, is for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.

Unless otherwise specified in the long description, HCPCS descriptions refer to the non-compounded, FDA-approved final product. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the hospital should report an appropriate unlisted code such as J9999 or J3490.

a. Drugs and Biologicals with Payments Based on Average Sales Price Effective July 1, 2008

In the CY 2008 OPPTS final rule, it was stated that payments for separately payable drugs and biologicals based on average sale prices (ASPs) will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary based on the most recent ASP submissions, CMS will incorporate changes to the payment rates in the July 2008 release of the OPPTS PRICER. The updated payment rates effective July 1, 2008, will be included in the July 2008 update of the OPPTS addendum A and addendum B, which will be posted on the CMS Web site shortly at <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>.

b. Drugs and Biologicals with OPPTS Pass-Through Status Effective July 1, 2008

Six drugs have been granted OPPTS pass-through status effective July 1, 2008. These drugs, their descriptors, and APC assignments are identified in table 4 below.

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

July 2008 Update to the Hospital Outpatient Prospective Payment System (continued)

Table 4 – Drugs Granted Pass-Through Status Effective July 1, 2008

HCPCS	Long Descriptor	SI	APC
C9242*	Injection, fosaprepitant, 1 mg	G	9242
C9356*	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter	G	9356
C9357*	Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc	G	9357
C9358*	Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters	G	9358
J1571	Injection, hepatitis B immune globulin (Hepagam B), intramuscular, 0.5 ml	G	0946
J1573	Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5 ml	G	1138

Note: Those HCPCS codes identified with a "*" indicate that they are new codes effective July 1, 2008.

c. Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2007 through December 31, 2007

The payment rates for several HCPCS codes were incorrect in the October 2007 OPPS PRICER. The corrected payment rates are listed below and have been installed in the July 2008 OPPS PRICER, effective for services furnished on October 1, 2007, through implementation of the January 2008 update. Your Medicare contractor will adjust any claims that you bring to their attention that were not processed correctly due to the incorrect rates in the October 2007 OPPS PRICER.

Table 5 – Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2007 through December 31, 2007

HCPCS	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
90675	9139	Rabies vaccine, im	150.27	30.05
J2820	0731	Sargramostim injection	25.02	5.00
J9010	9110	Alemtuzumab injection	549.29	109.86
J9015	0807	Aldesleukin/single use vial	764.56	151.47
J9226	1142	Supprelin LA implant	14694.12	2938.82

e. Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2008 through June 30, 2008

The payment rates for several HCPCS codes were incorrect in the April 2008 OPPS PRICER. The corrected payment rates are listed below and have been installed in the July 2008 OPPS PRICER, effective for services furnished on April 1, 2008, through implementation of the July 2008 update. Your Medicare contractor will adjust any claims that you bring to their attention that were not processed correctly due to the incorrect rates in the April 2008 OPPS PRICER.

Table 7 – Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2008 through June 30, 2008

HCPCS	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
J2323	9126	Natalizumab injection	7.51	1.49
J2778	9233	Ranibizumab inj	406.18	80.47
J3488	0951	Reclast injection	216.61	42.91

f. Correct Reporting of Drugs and Biologicals When Used As Implantable Devices

Hospitals are not to bill separately for drug and biological HCPCS codes, with the exception of drugs and biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPPS, hospitals are provided a packaged APC payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using drugs and biologicals during surgical procedures as implantable devices, hospitals may include the charges for these items in their charge for the procedure, report the charge on an uncoded revenue center line, or report the charge under a device HCPCS code (if one exists) so these costs would appropriately contribute to the future median setting for the associated surgical procedure.

g. Correct Reporting of Units for Drugs

Hospitals and providers are reminded to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in the HCPCS descriptor. For example, if the description for the drug code is 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. As another example, if the description for the drug code is 50 mg but 200 mg of the drug was administered to the patient, the units billed should be 4. Providers and hospitals should not bill the units based on the way the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, bill 10 units, even though only one vial

July 2008 Update to the Hospital Outpatient Prospective Payment System (continued)

was administered. HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

h. Changes to Payment for Therapeutic Radiopharmaceuticals for July 2008

The Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007, Pub. L. No. 110-173 amended the Medicare statute and provided a continuation of payment for therapeutic radiopharmaceuticals based on individual hospital charges adjusted to cost from January 1 through June 30, 2008. Therefore, in accordance with the statute, finalized CY 2008 prospective payment rates for therapeutic radiopharmaceuticals were not implemented in the OPPS during this time period. However, the statute expires on June 30, 2008, and, as such, the finalized payment prospective payment rates go into effect on July 1, 2008. Therefore, payment for separately payable therapeutic radiopharmaceuticals under the OPPS will be made on a prospective basis, with payment rates based upon mean costs from hospital claims data as set forth in the CY 2008 OPPS/ASC final rule (72 FR 66772), beginning on July 1, 2008.

Table 8 – Therapeutic Radiopharmaceuticals that are Separately Payable Effective July 1, 2008

HCPCS	Long Descriptor	SI	APC
A9517	Iodine I-131 sodium iodide capsule(s), therapeutic, per millicurie	K	1064
A9530	Iodine I-131 sodium iodide solution, therapeutic, per millicurie	K	1150
A9543	Yttrium Y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 millicuries	K	1643
A9545	Iodine I-131 tositumomab, therapeutic, per treatment dose	K	1645
A9563	Sodium phosphate P-32, therapeutic, per millicurie	K	1675
A9564	Chromic phosphate P-32 suspension, therapeutic, per millicurie	K	1676
A9600	Strontium Sr-89 chloride, therapeutic, per millicurie	K	0701
A9605	Samarium Sm-153 lexidronamm, therapeutic, per 50 millicuries	K	0702

i. Changes to Nuclear Medicine Procedure to Radiopharmaceutical Edits for July 2008

Effective January 1, 2008, under the OPPS, payment for diagnostic radiopharmaceuticals is packaged into payment for their associated nuclear medicine procedures. In order to ensure that appropriate diagnostic radiopharmaceutical costs for future rate setting purposes was captured, CMS implemented edits in the I/OCE effective January 2008 that required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure.

As is the standard process for edit lists under the OPPS, CMS reviews the appropriateness of the edits and considers modifying the edits quarterly as issues are brought to their attention. In April 2008, in response to several descriptions of specific clinical scenarios provided to CMS by members of the public, CMS added HCPCS code A9517 (Iodine I-131 sodium iodide capsule(s), therapeutic, per millicurie) to their list of radiopharmaceuticals that would be accepted for a nuclear medicine procedure claim to process.

Since the change to the edit list was adopted for the April update, CMS has received several descriptions of clinical scenarios where a therapeutic radiopharmaceutical or a brachytherapy source is provided to a patient by a hospital and a nuclear medicine procedure follows, without administration of a diagnostic radiopharmaceutical. Members of the public bringing these situations to the attention of CMS state that situations where these radiolabeled products would be used without a diagnostic radiopharmaceutical would be rare, but are sufficiently common that hospitals require a methodology to appropriately bill and be paid for the associated nuclear medicine procedures. As a result of these requests, for the July 2008 update CMS has included the HCPCS codes for all diagnostic radiopharmaceuticals, therapeutic radiopharmaceuticals, and brachytherapy sources as radiolabeled products that may be reported on a claim with nuclear medicine procedures to satisfy the edit requirements. CMS expects that the majority of nuclear medicine procedures will be performed with diagnostic radiopharmaceuticals, and that it will be only in uncommon circumstances that hospitals would report nuclear medicine procedures with therapeutic radiopharmaceuticals or brachytherapy sources. CMS will be monitoring claims to ensure that this is the case.

Therefore, beginning in July 2008, claims for nuclear imaging procedures reported with any of the HCPCS codes for diagnostic radiopharmaceuticals, therapeutic radiopharmaceuticals, or brachytherapy sources will not be returned to the provider as the nuclear medicine procedure and radiolabeled product are included on the same claim.

Note: Hospitals are only to report HCPCS codes for products they administer and should not be reporting a token charge for a radiolabeled product on the edit list solely for the purpose of bypassing edits present in the I/OCE.

The complete list of updated edits may be found on the CMS Web site at

http://www.cms.hhs.gov/HospitalOutpatientPPS/02_device_procedure.asp#TopOfPage.

Hospital Services for Patients with End-Stage Renal Disease

CMS is revising the *Medicare Claims Processing Manual*, chapter 4, section 200.2 to expand the circumstances under which payment may be made to a hospital for unscheduled outpatient dialysis provided to an end-stage renal disease (ESRD) patient. The first circumstance listed is "dialysis performed following or in connection with a vascular access procedure". CMS is expanding this to include any dialysis related procedure such as vascular access procedures or blood transfusions, and the revised chapter 4, section 200.2 of the *Medicare Claims Processing Manual* is included as an attachment to CR 6094.

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

July 2008 Update to the Hospital Outpatient Prospective Payment System (continued)

Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000

CMS is revising the *Medicare Benefit Policy Manual*, chapter 6, section 20.5.1 to remove language stating that services furnished in provider-based departments of hospitals must be rendered under the direct supervision of a physician "who is treating the patient." While this "treating the patient" language has been a part of the manual for several years, recent revisions made to section 20.5.1 in Transmittal 82/CR 5946 (February 8, 2008) have caused confusion related to the context and application of this phrase in relation to the requirements of the *Code of Federal Regulations*. The revised chapter 6, section 20.5.1 of the *Medicare Benefit Policy Manual* is included as an attachment to CR 6094.

Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPTS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. FIs/AB MACS will determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, FI/MACs will determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

ADDITIONAL INFORMATION

The official instruction, CR 6094, issued to your FI, RHHI, and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1536CP.pdf>.

The modified section of the Medicare Benefit Policy Manual regarding coverage of outpatient therapeutic services incident to physician's services is available on the same site at <http://www.cms.hhs.gov/Transmittals/downloads/R90BP.pdf>.

If you have any questions, please contact your FI, RHHI, or A/B MAC at their toll-free number, which may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip>.

The toll-free number for First Coast Service Options Inc. Medicare Part A Customer Service Center is 1-888-664-4112.

MLN Matters Number: MM6094

Related Change Request (CR) Number: 6094

Related CR Release Date: June 19, 2008

Related CR Transmittal Number: R1536CP and R90BP

Effective Date: July 1, 2008

Implementation Date: July 7, 2008

Source: CMS Pub. 100-04, Transmittal 1536, CR 6094

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FRAUD AND ABUSE

OFFICE OF INSPECTOR GENERAL REFINES SELF-DISCLOSURE PROTOCOL

Inspector General Daniel R. Levinson issued an open letter to health care providers on April 15, 2008, announcing that the Office of Inspector General (OIG) for the Department of Health & Human Services has refined the requirements of the OIG provider self-disclosure protocol, under which health care providers can voluntarily report fraudulent conduct affecting Medicare, Medicaid, and other federal health care programs.

The self-disclosure protocol provides guidance to health care providers who voluntarily disclose federal health care program compliance issues that the provider believes potentially violate federal criminal, civil, or administrative laws for which exclusion or civil monetary penalties are authorized. According to the open letter, providers who disclose in good faith, fully cooperate with OIG, and provide requested information in a timely manner will generally not be required to enter into corporate integrity or certification of compliance agreements with OIG.

Source: OIG News, April 15, 2008

AN OPEN LETTER TO HEALTH CARE PROVIDERS

Since the inception of the Office of Inspector General (OIG) Provider Self-Disclosure Protocol (SDP) in 1998, OIG has encouraged the health care provider community to help ensure the integrity of the federal health care programs by voluntarily disclosing self-discovered evidence of potential fraud. In this spirit of collaboration, we have responded to the provider community's suggestions in the past for ways to improve the SDP. In my 2006 Open Letter, for example, I encouraged providers to disclose improper arrangements under the physician self-referral (Stark) law (42 D.S.C. section 1395nn) and committed to settling liability under OIG's authorities generally for an amount near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred.

The SDP has been an important component of our shared commitment to promote integrity in the federal health care programs through effective compliance programs. To date, OIG has returned approximately \$120 million to the Medicare trust fund through the SDP and participating providers have avoided the costs and disruptions often associated with a Government-directed investigation. However, we have identified additional opportunities to improve the SDP process. This open letter discusses certain refinements and clarifications to OIG's policies that we believe will increase the efficiency of the SDP and benefit providers who self-disclose.

To improve the disclosure process, we have concluded that the initial submission must contain the following information: (1) a complete description of the conduct being disclosed; (2) a description of the provider's internal investigation or a commitment regarding when it will be completed; (3) an estimate of the damages to the federal health care programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate; and (4) a statement of the laws potentially violated by the conduct. This information must be included in addition to the basic information described in the SDP. The provider must be in a position to complete the investigation and damages assessment within three months after acceptance into the SDP.

In addition, we have found from experience that the success of the SDP is contingent on OIG responding to the self-disclosure promptly and making resolution of the matter a priority. To that end, we have streamlined our internal process for resolving these cases. In turn, we expect full cooperation from disclosing providers during the verification of the matter disclosed. As I advised in my prior open letter, we will remove providers from participation in the SDP unless they disclose in good faith and timely respond to OIG's requests for additional information.

The efficiency of the SDP also depends on the provider's good faith determination that the matter implicates potential fraud against the federal health care programs, rather than merely an overpayment. The SDP is intended to facilitate resolution of matters that potentially violate federal criminal law, civil law, or administrative laws for which exclusion or civil monetary penalties are authorized. Disclosures that are characterized as mere billing errors or overpayments are not appropriately addressed by the SDP and should be submitted directly by the provider to the appropriate claims-processing entity, such as the Medicare contractor.

A provider's submission of a complete and informative disclosure, quick response to OIG's requests for further information, and performance of an accurate audit are indications that the provider has adopted effective compliance measures. Accordingly, when we negotiate the resolution of OIG's applicable administrative monetary and permissive exclusion authorities in exchange for an appropriate monetary payment, we generally will not require the provider to enter into a Corporate Integrity Agreement or Certification of Compliance Agreement. We believe that this presumption in favor of not requiring a compliance agreement appropriately recognizes the provider's commitment to integrity and also advances our goal of expediting the resolution of self-disclosures.

An Open Letter to Health Care Providers (continued)

These refinements to OIG's SDP process are intended to provide an opportunity for providers to work with OIG to more efficiently and fairly resolve matters appropriately disclosed under the SDP. I believe that this approach benefits both disclosing providers and the Government and furthers our efforts to strengthen the integrity of the federal health care programs. I look forward to continuing our mutual efforts to promote compliance.

Source: Daniel R. Levinson, Inspector General, April 15, 2008

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EDUCATIONAL EVENTS

UPCOMING PROVIDER OUTREACH AND EDUCATION EVENTS

JULY 2008 – AUGUST 2008

Hot Topics – Medicare Updates

When: Tuesday, July 15, 2008
 Time: 11:30 a.m. – 12:30 p.m. Eastern Standard Time
 Type of Event: Teleconference

Recovery Audit Contractor (RAC) – Topics: RAC Permanent Program

When: Wednesday, July 23, 2008
 Time: 11:30 a.m. – 1:00 p.m. Eastern Standard Time
 Type of Event: Webcast

Ask the Contractor – Topics: Community Mental Health Center/Psychiatric Partial Hospitalization Program

When: Tuesday, August 12, 2008
 Time: 11:30 a.m. – 1:00 p.m. Eastern Standard Time
 Type of Event: Teleconference

TWO EASY WAYS TO REGISTER

ONLINE – Log on to your account on our provider training Web site at www.fcsomedicaretraining.com and select the course you wish to register. Class materials are available under “My Courses” no later than one day before the event. **First-time User?** Set up an account using the instructions at www.floridamedicare.com/Education/108651.asp to register for a class and obtain materials.

FAX – Providers without Internet access may request a fax registration form through our Registration Hotline at 1-904-791-8103. Class materials will be faxed to you the day of the event.

Keep checking our Web site, www.floridamedicare.com, or listening to information on the FCSO Provider Education Registration Hotline, 1-904-791-8103, for details and newly scheduled educational events (teleconferences, webcasts, etc.).

TIPS FOR USING THE FCSO PROVIDER TRAINING WEB SITE

To search and register for Florida events on www.fcsomedicaretraining.com click on the following links:

- “Course Catalog” from top navigation bar
- “Catalog” in the middle of the page
- “Browse Catalog” on the right of the search box
- “FL – Part B or FL – Part A” from list in the middle of the page.

Select the specific session you’re interested in, click the “Preview Schedule” button at the bottom of the page. On the Instructor-Led Training (ILT) Schedule page, locate the line that has the course you are interested in and click the “Register” link in the Options column.

If you need assistance, please contact our FCSO Medicare training help desk by calling 866-756-9160 or sending an email to fcsohelp@geolearning.com.

Please Note:

- Pre-registration is required for all teleconferences, webcasts and in-person educational seminars.
- Dates and times are subject to change prior to opening of event registration.

Registrant's Name: _____
 Registrant's Title: _____
 Provider's Name: _____
 Telephone Number: _____ Fax Number: _____
 E-mail Address: _____
 Provider Address: _____
 City, State, ZIP Code: _____

More educational events (teleconferences, webcasts, etc.) are being planned to help providers with hot issues. Keep checking our Web site <http://www.floridamedicare.com> or listening to information on the FCSO Provider Education Registration Hotline, 1-904-791-8103, for details and newly scheduled events. ❖

OTHER EDUCATIONAL RESOURCES

MEDICARE DISPROPORTIONATE SHARE HOSPITAL FACT SHEET

The April 2008 version of the *Medicare Disproportionate Share Hospital Fact Sheet* is now available in downloadable format from the Centers for Medicare & Medicaid Services *Medicare Learning Network* at http://www.cms.hhs.gov/MLNProducts/downloads/2008_mdsh.pdf.

This fact sheet provides information about methods to qualify for the Medicare disproportionate share hospital (DSH) adjustment; Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Deficit Reduction Act of 2005; number of beds in hospital determination; and Medicare DSH payment adjustment formulas. ❖

Source: CMS Provider Education Resource 200805-26

CRITICAL ACCESS HOSPITAL FACT SHEET NOW AVAILABLE

The April 2008 version of the *Critical Access Hospital Fact Sheet* is now available in downloadable format from the Centers for Medicare & Medicaid Services *Medicare Learning Network* at <http://www.cms.hhs.gov/MLNProducts/downloads/CritAccessHospfctsh.pdf>.

If this hyperlink does not take you directly to the fact sheet, please copy and paste the URL in your Internet browser.

The fact sheet provides information about eligible critical access hospital (CAH) providers; CAH designation; CAH payments; reasonable cost payment principles that do not apply to CAHs; election of standard method or optional (elective) payment method; Medicare rural pass-through funding for certain anesthesia services; health professional shortage area incentive payments; physician scarcity area bonus payments; Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and grants to states under the Medicare rural hospital flexibility program. ❖

Source: CMS Provider Education Resource 200806-07

SOLE COMMUNITY HOSPITAL FACT SHEET

The April 2008 version of the *Sole Community Hospital Fact Sheet*, which provides information about the sole community hospital classification and payments, is now available in print format from the Centers for Medicare & Medicaid Services *Medicare Learning Network*. To place your order, visit <http://www.cms.hhs.gov/mlngeninfo/>, scroll down to "Related Links Inside CMS" and select "MLN Product Ordering Page." ❖

Source: CMS Provider Education Resource 200806-10

RURAL REFERRAL CENTER FACT SHEET

The April 2008 version *Rural Referral Center Fact Sheet*, which provides information about rural referral center program requirements, is now available in downloadable format Centers for Medicare & Medicaid Services *Medicare Learning Network* at <http://www.cms.hhs.gov/MLNProducts/downloads/RuralRefCtrfctsh2008.pdf>. ❖

Source: CMS Provider Education Resource 200806-02

MEDICARE REMIT EASY PRINT BROCHURE NOW AVAILABLE

The *Medicare Remit Easy Print* brochure has been updated and is now available to order print copies or to download as a PDF file. This brochure provides an overview of free software that enables physicians and suppliers to view and print remittance information. To view the PDF file, go to http://www.cms.hhs.gov/MLNProducts/downloads/MedicareRemit_0408.pdf.

Print copies may be ordered by visiting the MLN Product Ordering page on the CMS Web site at http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5.

Visit the Medicare Learning Network – It's Free! ❖

Source: CMS Provider Education Resource 200805-19

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Addresses

CLAIMS STATUS

Coverage Guidelines

Billing Issues Regarding

Outpatient Services, CORF, ORF, PHP

Medicare Part A Customer Service
P. O. Box 2711
Jacksonville, FL 32231-0021

PART A REDETERMINATION

Medicare Part A Redetermination and Appeals
P. O. Box 45053
Jacksonville, FL 32232-5053

MEDICARE SECONDARY PAYER (MSP)

Information on Hospital Protocols

Admission Questionnaires

Audits

Medicare Secondary Payer
Hospital Review
P. O. Box 45267
Jacksonville, FL 32232-5267

General MSP Information

Completion of UB-04 (MSP Related)

Conditional Payment

Medicare Secondary Payer
P. O. Box 2711
Jacksonville, FL 32231-0021

Automobile Accident Cases

Settlements/Lawsuits

Other Liabilities

Auto/Liability Department – 17T
P. O. Box 44179
Jacksonville, FL 32231-4179

PROVIDER EDUCATION

Medicare Outreach and Education
P. O. Box 45157
Jacksonville, FL 32232-5157

Seminar Registration Hotline

1-904-791-8103

Seminar Registration Fax Number

1-904-361-0407

Other Important Addresses

REGIONAL HOME HEALTH &

HOSPICE INTERMEDIARY

Home Health Agency Claims

Hospice Claims

Palmetto Government Benefit Administrators – Gulf Coast
34650 US Highway 19 North,
Suite 202
Palm Harbour, FL 34684-2156

RAILROAD MEDICARE

Railroad Retiree Medical Claims

Palmetto Government Benefit Administrators
P. O. Box 10066
Augusta, GA 30999-0001

ELECTRONIC CLAIM FILING

“DDE Startup”

Direct Data Entry (DDE)
P. O. Box 44071
Jacksonville, FL 32231-4071

FRAUD AND ABUSE

Complaint Processing Unit
P. O. Box 45087
Jacksonville, FL 32232-5087

PART A RECONSIDERATION

Claims Denied at Redetermination Level

MAXIMUS
QIC Part A East Project
Eastgate Square
50 Square Drive
Victor, NY 14564-1099

OVERPAYMENT COLLECTIONS

Repayment Plans for Part A

Participating Providers

Cost Reports (original and amended)

Receipts and Acceptances

Tentative Settlement Determinations

Provider Statistical and Reimbursement (PS&R) Reports

Cost Report Settlement (payments due to provider or program)

Interim Rate Determinations

TEFRA Target Limit and Skilled

Nursing Facility Routine Cost Limit

Exceptions

Freedom of Information Act Requests

(relative to cost reports and audits)

Provider Audit and Reimbursement Department (PARD)
Attn: FOIA PARD – 16T
P.O. Box 45268
Jacksonville, FL 32232-5268
1-904-791-8430

PROVIDER ENROLLMENT

American Diabetes Association

Certificates

Medicare Provider Enrollment – ADA
P. O. Box 2078
Jacksonville, FL 32231-0048

DURABLE MEDICAL EQUIPMENT

REGIONAL CARRIER (DMERC)

Durable Medical Equipment Claims

Orthotic and Prosthetic Device Claims

Take Home Supplies

Oral Anti-Cancer Drugs

CIGNA Government Services
P. O. Box 20010
Nashville, Tennessee 37202

Telephone Numbers

PROVIDERS

Customer Service Center Toll-Free

1-888-664-4112
Speech and Hearing Impaired
1-877-660-1759

BENEFICIARY

Customer Service Center Toll-Free

1-800-MEDICARE
1-800-633-4227
Speech and Hearing Impaired
1-800-754-7820

ELECTRONIC MEDIA CLAIMS

EMC Start-Up

1-904-791-8767, option 4

Electronic Eligibility

1-904-791-8131

Electronic Remittance Advice

1-904-791-6865

Direct Data Entry (DDE) Support

1-904-791-8131

PC-ACE Support

1-904-355-0313

Testing

1-904-791-6865

Help Desk

(Confirmation/Transmission)
1-904-905-8880

Medicare Web sites

PROVIDERS

Florida Medicare Contractor

www.floridamedicare.com

Centers for Medicare & Medicaid Services

www.cms.hhs.gov

BENEFICIARIES

Centers for Medicare & Medicaid Services

www.medicare.gov



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