

# 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](http://www.fcso.com).

### Routing Suggestions :

- Medicare Manager
- Reimbursement Director
- Chief Financial Officer
- Compliance Officer
- DRG Coordinator
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_



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## Medicare A Bulletin

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### Publication Staff

Millie C. Pérez  
Terri Drury  
Mary Barnes  
Betty Alix

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Questions concerning this publication or its contents may be faxed to:

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## **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. ❖

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# ANNUAL *MEDICARE A BULLETIN* **HARDCOPY/CD-ROM** **REGISTRATION FORM**

To receive the *Medicare A Bulletin* in hardcopy, CD-ROM, or e-mail format, you must complete this registration form. **To receive a hardcopy, CD-ROM or e-mail of future issues of the *Medicare A Bulletin* your form must be faxed to the number below on or before June 30, 2008.** Providers currently receiving hardcopy publications that do not return this form by June 30, 2008, will not receive hardcopy versions after that date.

Please note that you are not obligated to complete this form to access information published in the *Medicare A Bulletin*. Issues published beginning in 1997 are available **free** on our provider education Web site at <http://www.fcso.com>, select Medicare Providers, Florida Part A or B, then select Medicare Part A, and then the News & Bulletins page on the left menu bar.

**Provider/Facility Name:**

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**Medicare Provider Identification Number (PIN):**

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**Address:**

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**City, State, ZIP Code:**

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**Contact Person/Title:**

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**Rationale for needing a hardcopy:**

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904-361-0723

Please share your questions and/or concerns regarding this initiative with us.

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Additional questions or concerns may be submitted via the Medicare provider education Web site at <http://www.fcso.com>, select Medicare Providers, Florida Part A or B, then *Contact* in the upper right corner of the page. You may also fax your questions or comments to 904-361-0723. **Our Provider Contact Center will not be able to respond to inquiries about this form.**

## GENERAL INFORMATION

### URGENT MESSAGE FOR MEDICARE FEE-FOR-SERVICE INSTITUTIONAL PROVIDERS WITH SUBPARTS

It has come to the Centers for Medicare & Medicaid Services (CMS) attention that the message of April 3, 2008, concerning the use of taxonomy codes to facilitate the national provider identification (NPI) matching with the Medicare NPI crosswalk, has caused both confusion and consternation. CMS regrets this unintended consequence. CMS believes that your claims will be successfully processed using your NPI, regardless of whether you enumerate your subparts with NPIs. **CMS continues to encourage you to test NPI-only claims before the May 23, 2008, deadline.**

Since February 2006, CMS has been encouraging providers with subparts (with separate OSCAR numbers attached to those subparts) to enumerate those subparts with an NPI. CMS believed then and now that such enumeration of subparts may be helpful towards ensuring Medicare crosswalk matches. This recommendation was not a mandated requirement nor is it mandated now (as some have assumed with the April 3, 2008, message).

In addition, while we originally thought that the taxonomy code would help facilitate matching a provider's NPI to the appropriate subpart OSCAR number, experience has shown that other data elements on the claim did a much better job of achieving this match. To be clear, this successful matching using claims data rather than the taxonomy code is working for those providers that did not enumerate their subparts.

In summary, providers with subparts do not need to do anything new or different as a result of the April 3, 2008, message. CMS continues to encourage you to enumerate your subparts, but CMS believe the data coming in on your claim will enable successful matches to the crosswalk, as is currently happening in most cases. While Medicare may not be using the taxonomy code, Medicare will pass it on to the trading partners on crossover claims, in the event they use it.

CMS hopes this clarification eases some of the concerns CMS is hearing.

**Again, you do not need to change your systems nor do anything new or different.**

**Note:** For more details see CMS message on April 3, 2008, on pages 28-29. ❖

Source: CMS Provider Education Resource 200804-16

### ANNOUNCING THE RELEASE OF THE REVISED CMS-855 MEDICARE ENROLLMENT APPLICATIONS

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

#### PROVIDER TYPES AFFECTED

All Medicare physicians, providers, and suppliers

#### BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) issued revised CMS-855 Medicare enrollment applications in March 2008. With the exception of providers enrolling as a specialty hospital on the CMS-855A, Medicare contractors will continue to accept the 2006 version of the Medicare enrollment application through June 2008. **Providers and suppliers should begin to use the new Medicare enrollment applications immediately.** Initially, these applications will be available only from the CMS provider enrollment Web site. The link for that CMS Web site is listed in the *Additional Information* section of this article.

Over the last year, CMS has received numerous comments and suggestions regarding the proposed revisions to the Medicare enrollment applications. CMS reviewed the comments and adopted many of the suggested revisions. Also, CMS incorporated a number of enhancements and changes (see *Key Points* below) to clarify the enrollment process and to reduce the burden imposed on the provider and supplier communities.

#### KEY POINTS

This special edition outlines the significant revisions to the Medicare enrollment applications and they are as follows:

#### Application-Specific Changes for Physicians and Nonphysician Practitioners (CMS-855I)

- Removed the requirement in section 17 that providers attached their national provider identifier (NPI) notification that is received from the National Plan and Provider Enumeration System.

#### Application-Specific Changes for Clinics/Group Practices and Certain Other Suppliers (CMS-855B)

- Removed the supplier type "Voluntary Health/Charitable Agency" from section 2A.
- Clarified reporting timeframes throughout the CMS-855B.
- Added additional information about the NPI-legacy association and expanded the number of NPI-legacy combinations that a provider may enter in section 4A from one to five.
- Removed the requirement in section 17 that providers attach their NPI notification that is received from the National Plan and Provider Enumeration System.

## Announcing the Release of the Revised CMS-855 Medicare Enrollment Applications (continued)

- Required that an independent diagnostic testing facility (IDTF) submit copies of its comprehensive liability insurance policy in section 17.
- Added a list of the new IDTF standards found in 42 CFR 410.33(g) on a separate page in attachment 2.
- Added instructions that explain the IDTF liability insurance requirements in 42 CFR 410.33(g)(6) to attachment 2.

### Application-Specific Changes for Institutional Providers (CMS-855A)

- Revised section 2A2 to include a specific box that specialty hospitals must check when completing the application. Instructions explaining the definition of a “specialty hospital” were also added to the form.
- Clarified the term “primary practice location” in the instructions in section 4. (The clarification did not change any data elements on the form.)
- Added additional information about the NPI-legacy association and expanded the number of NPI – legacy combinations that a provider may enter in section 4A from one to five.
- Removed the data element “Medicare Year-End Cost Report Date” from section 2.

- Removed the requirement in section 17 that providers attach their NPI notification that is received from the National Plan and Provider Enumeration System.

### Application-Specific Changes for DMEPOS Suppliers (CMS-855S)

- Added supplier standards 22 – 25 to the list of DMEPOS supplier standards found on page 31.

### ADDITIONAL INFORMATION

For additional information regarding the Medicare enrollment process, including the mailing address and telephone number for the carrier or FI serving your area, visit the CMS Web site

<http://www.cms.hhs.gov/MedicareProviderSupEnroll>.

MLN Matters special edition article SE0612 contains helpful information about the Medicare enrollment process. You may review that article on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0612.pdf>.

MLN Matters Number: SE0810

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 SE0810

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## WEB SITE FOR ADDITIONS AND DELETIONS OF ZIP CODES REQUIRING A PLUS FOUR ZIP CODE EXTENSION

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

### PROVIDER TYPES AFFECTED

Physicians, providers, and other health care providers submitting claims to Medicare fiscal intermediaries (FIs), carriers, Part A/B Medicare administrative contractors (A/B MACs) or regional home health intermediaries (RHHIs) for services paid under the Medicare physician fee schedule (MPFS) and for anesthesia services.

### PROVIDER ACTION NEEDED

#### STOP – IMPACT TO YOU

The ZIP code where services are rendered determines the payment locality for services paid under the MPFS and for anesthesia services. Certain ZIP codes fall into more than one payment locality and require a plus four ZIP code extension to ensure proper payment. (See the MLN Matters article on the Centers for Medicare & Medicaid Services [CMS] Web site for further details regarding ZIP code reporting at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5208.pdf>.)

### CAUTION – WHAT YOU NEED TO KNOW

The CMS will begin posting additions and deletions to the list of ZIP codes that require a plus four ZIP code extension on their Web site. A complete list of all ZIP codes requiring a plus four ZIP code extension will also be posted.

### GO – WHAT YOU NEED TO DO

Make certain your billing staffs are aware of these resources for checking plus four ZIP code extension requirements.

### KEY POINTS OF CHANGE REQUEST 5970

- To access a file containing the quarterly additions and deletions to the list of ZIP codes requiring a plus four extension refer to on the CMS Web site [http://www.cms.hhs.gov/prospmedicarefeesvcvcpmtgen/01\\_overview.asp](http://www.cms.hhs.gov/prospmedicarefeesvcvcpmtgen/01_overview.asp).

The file is named “ZIP Code to Carrier Locality” and may be found in the *Downloads* section of this Web page.

- To access a file containing all ZIP codes requiring a plus four extension, refer to on the CMS Web site [http://www.cms.hhs.gov/prospmedicarefeesvcvcpmtgen/01\\_overview.asp](http://www.cms.hhs.gov/prospmedicarefeesvcvcpmtgen/01_overview.asp).

The file is named “ZIP Codes Requiring +4 Ext” and may be found in the *Downloads* section of this Web page.

- Upon release of a new quarterly update, the previous quarter’s additions and deletions are incorporated into the file name “ZIP Codes Requiring +4 Ext” file and are not included in the “ZIP Code Changes” file.

**Web Site for Additions and Deletions of ZIP Codes Requiring a Plus Four ZIP Code Extension (continued)****ADDITIONAL INFORMATION**

To see the official instruction (CR 5970) issued to your Medicare FI, carrier, A/B MAC or RHHI refer to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1480CP.pdf>.

If you have questions, please contact your Medicare FI, carrier, A/B MAC or RHHI 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: MM5970  
Related Change Request (CR) Number: 5970  
Related CR Release Date: March 21, 2008  
Related CR Transmittal Number: R1480CP  
Effective Date: April 21, 2008  
Implementation Date: April 21, 2008

Source: CMS Pub. 100-04, Transmittal 1480, CR 5970

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## CLINICAL LABORATORY FEE SCHEDULE—SECTION 113 IMPLEMENTATION UNDER MMSCHIP ACT

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

**PROVIDER TYPES AFFECTED**

Clinical laboratories billing Medicare contractors (carriers, fiscal intermediaries, or Part A/B Medicare administrative contractors [A/B MACs]) for services to Medicare beneficiaries.

**PROVIDER ACTION NEEDED**

This article is based on change request (CR) 5987 which alerts clinical laboratories that, effective for tests furnished on or after April 1, 2008, the MMSCHIP Extension Act of 2007 sets payment for code 83037 and 83037QW (*Hemoglobin; glycosylated (A1c) by device*) by cross walking it to be the same as code 83036 [*glycosylated (A1c)*]. Make certain your billing staffs are aware of this change.

**BACKGROUND**

The Medicare, Medicaid and State Children's Health Insurance Program (MMSCHIP) Extension Act of 2007 passed in December 2007 and included section 113. Section 113 of the legislation set the price for any diagnostic test for HbA1C that is labeled by the Food and Drug Administration (FDA) for home use equal to the payment rate for a glycosylated hemoglobin test (identified as of October 1, 2007, by Healthcare Common Procedure Coding System (HCPCS) code 83036 [and any succeeding codes]). **The legislation is effective for tests furnished on or after April 1, 2008.**

- For calendar year (CY) 2006, the *Current Procedural Terminology (CPT)* established new code 83037 – *hemoglobin; glycosylated (A1C) by device* cleared by the Food and Drugs Administration (FDA) for home use. CPT code 83036, *glycosylated (A1c)*, already existed and was priced at \$13.56 on the clinical laboratory fee schedule.

- For CY 2006, CMS determined that CPT code 83037 should be paid via carrier gap filling.
- For CY 2007, CMS set the payment for CPT code 83037 by crosswalking it to CPT code 82985 (*Glycosylated protein*).
- For tests furnished on or after April 1, 2008, the payment for CPT code 83037 or 83037QW will be the same as the payment on the clinical laboratory fee schedule for CPT code 83036.

Your Medicare contractor will adjust claims for services on or after April 1, 2008, processed prior to implementation of this change if you bring such claims to the contractor's attention.

**ADDITIONAL INFORMATION**

To see the official instruction (CR 5987) issued to your Medicare contractor visit on the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R331OTN.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: MM5987  
Related Change Request (CR) Number: 5987  
Related CR Release Date: April 11, 2008  
Related CR Transmittal Number: R331OTN  
Effective Date: April 1, 2008  
Implementation Date: May 12, 2008

Source: CMS Pub. 100-20, Transmittal 331, CR 5987

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**NEW HCPCS CODES FOR THE APRIL 2008 UPDATE**

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

**PROVIDER TYPES AFFECTED**

Physicians, 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 services provided to Medicare beneficiaries.

**PROVIDER ACTION NEEDED**

This article is based on change request (CR) 5981, which instructs Medicare contractors to implement Healthcare Common Procedure Coding System (HCPCS) code changes effective April 1, 2008. Make sure that your billing staffs are aware of these changes.

**BACKGROUND**

The Centers for Medicare & Medicaid Services (CMS) updates the Healthcare Common Procedure Coding System (HCPCS) code set on a quarterly basis.

Effective for claims with dates of service on or after April 1, 2008, the following HCPCS codes will no longer be payable for Medicare:

| HCPCS Code | Short Description          | Long Description  |
|------------|----------------------------|---|
| J7602      | Albuterol inh non-comp con | Albuterol, all formulations including separated isomers, inhalation solution, FDA-approved final product, noncompounded, administered through DME, concentrated form, per 1 mg (albuterol) or per 0.5 mg (levalbuterol) |
| J7603      | Albuterol inh non-comp u d | Albuterol, all formulations including separated isomers, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, per 1 mg (albuterol) or per 0.5 mg (levalbuterol)        |
| J1751      | Iron dextran 165 injection | Injection, iron dextran 165, 50 mg  |
| J1752      | Iron dextran 267 injection | Injection, iron dextran 267, 50 mg  |

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

| HCPCS Code | Short Description          | Long Description   |
|------------|----------------------------|--|
| J7611      | Albuterol non-comp con     | Albuterol, inhalation solution, FDA-approved final product, noncompounded, administered through DME, concentrated form, 1mg                  |
| J7612      | Levalbuterol non-comp con  | Levalbuterol, inhalation solution, FDA-approved final product, noncompounded, administered through DME, concentrated form, 0.5 mg            |
| J7613      | Albuterol non-comp unit    | Albuterol, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, 1mg                         |
| J7614      | Levalbuterol non-comp unit | Levalbuterol, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose, 0.5 mg                    |
| Q4096      | VWF complex, NOS           | Injection, von Willebrand factor complex, human, ristocetin cofactor (not otherwise specified), per I.U. vWF:RCO                             |
| Q4097      | Inj IVIG Privigen 500 mg   | Injection, immune globulin (Privigen™), intravenous, nonlyophilized (e.g., liquid), 500 mg   |
| Q4098      | Inj iron dextran           | Injection, iron dextran, 50mg  |
| Q4099      | Formoterol fumarate, inh   | Formoretol fumarate, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, 20 micrograms |

Currently, Alphanate® is the only product that should be billed using HCPCS code Q4096. HCPCS code J7190 should continue to be billed when Alphanate® is furnished for purposes of administering factor VIII. The blood clotting furnishing fee is payable when payment is allowed for HCPCS code Q4096. When a payment allowance limit for HCPCS code Q4096 is included on the quarterly Part B drug pricing files, the payment allowance limit will include payment for the blood clotting furnishing fee.

Effective for dates of service on or after April 1, 2008, the requirements under CR 5713 (See the *MLN Matters* article for CR 5713, which is on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5713.pdf>) are being updated by CR 5981 to apply to claims that bill Intravenous Immune globulins (IVIG) using Q4097 as follows:

- Effective for dates of service on or after April 1, 2008, Medicare contractors will:
  - ♦ Only pay a claim for preadministration-related services (G0332) associated with IVIG administration if HCPCS code G0332, the drug (IVIG, HCPCS codes: J1566, J1568, J1569, J1561, J1572 and/or Q4097), and the drug administration service are all billed on the same claim for the same date of service.
  - ♦ Return institutional claims for G0332 to the provider if J1566, J1568, J1569, J1561, J1572 and/or Q4097 and a drug administration service are not also billed for the same date of service on the same claim.



**New HCPCS Codes for the April 2008 Update (continued)**

- ♦ Reject professional claims as unprocessable for G0332 if J1566, J1568, J1569, J1561, J1572 and/or Q4097 and a drug administration service are not billed for the same date of service on the same claim.
- ♦ Use the appropriate reason/remark messages such as: M67 "Missing other procedure codes" and/or 16 "Claim/service lacks information" which are needed for adjudication when claims are returned/rejected.

**ADDITIONAL INFORMATION**

The official instruction, CR 5981, issued to your carrier, FI, RHHI, A/B MAC, and DME MAC regarding these changes may be viewed on the CMS Web site at <http://www.cms.hhs.gov/transmittals/downloads/R1492CP.pdf>.

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.

MLN Matters Number: MM5981

Related Change Request (CR) Number: 5981

Related CR Release Date: April 18, 2008

Related CR Transmittal Number: R1492CP

Effective Date: April 1, 2008

Implementation Date: April 7, 2008

Source: CMS Pub. 100-04, Transmittal 1492, CR 5981

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## APRIL 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**

CR 5982, from which this article is taken, instructs Medicare contractors to download and implement the April 2008 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs; and if released by CMS, also the revised January 2008, January 2007, April 2007, July 2007, October 2007, and October 2006 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 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

## April 2008 Quarterly ASP Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files (continued)

- 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 OPSS.

Beginning January 1, 2008, under the OPSS, 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 OPSS 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 OPSS 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 will not be 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.
- 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 OPSS 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 Pub. 100-04, 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 OPSS 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 March 18, 2008, the April 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 March 18, 2008, the April 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 5982 for the dates of service noted in the following table:

**April 2008 Quarterly ASP Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files (continued)**

| <b>Payment Allowance Limit Revision Date</b> | <b>Applicable Dates of Service</b>         |
|--|--|
| 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    |
| October 2006 ASP and ASP NOC files           | October 1, 2006, through December 31, 2006 |

**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.

**ADDITIONAL INFORMATION**

To see the official instruction (CR 5982) issued to your Medicare contractor visit the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1484CP.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: MM5982

Related Change Request (CR) Number: 5982

Related CR Release Date: March 26, 2008

Related CR Transmittal Number: R1484CP

Effective Date: April 1, 2008

Implementation Date: April 7, 2008

Source: CMS Pub. 100-04, Transmittal 1484, CR 5982

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**NOTICE OF INTEREST RATE FOR MEDICARE OVERPAYMENTS AND UNDERPAYMENTS**

Medicare Regulation 42 CFR section 405.378 provides for the assessment of interest at the higher of the current value of funds rate (five percent for calendar year 2008) or the private consumer rate (PCR) as fixed by the Department of the Treasury.

The Department of the Treasury has notified the Department of Health & Human Services that the PCR has been changed to **11.375 percent, effective April 18, 2008**. The PCR will remain in effect until a new rate change is published. The following table lists previous interest rates.

| <b>Period</b>                       | <b>Interest Rate</b> |
|-------------------------------------|----------------------|
| January 18, 2008 – April 17, 2008   | 12.125%              |
| October 19, 2007 – January 17, 2007 | 12.5%                |
| July 20, 2007 – October 18, 2007    | 12.625%              |
| April 20, 2007 – July 19, 2007      | 12.375%              |
| January 19, 2007 – April 19, 2007   | 12.5%                |
| October 18, 2006 – January 18, 2007 | 12.375%. ❖           |

Source: CMS Pub. 100-06, Transmittal 138, CR 5752

**APRIL 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 submitting claims to Medicare contractors (carriers, fiscal intermediaries [FIs], and/or Part A/B Medicare administrative contractors [A/B MACs]) for professional services provided to Medicare beneficiaries that are paid under the Medicare physician fee schedule (MPFS).

**PROVIDER ACTION NEEDED**

This article is based on change request (CR) 5980 which amends payment files previously issued to Medicare contractors based upon the 2008 MPFS final rule. CR 5980 also includes new/revised codes for the physician quality reporting initiative (PQRI).

**BACKGROUND**

Attachment 1 of CR 5980 contains changes included in the April update to the 2008 MPFSDB, and CR 5980 may be reviewed on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1482CP.pdf>.

Specific changes are detailed in attachment 1 of CR 5980 and are summarized as follows:

**CPT/HCPCS Code Revisions**

A number of CPT/HCPCS codes have been modified to reflect revised bilateral indicators, relative value unit (RVU) revisions, or procedure status changes retroactive to January 1, 2008.

**Reinstated “J” Codes**

A number of “J” codes (J7611 through J7614) are reinstated with a status indicator of “E” and the reinstated codes are effective for dates of service on or after April 1, 2008. Descriptors and payment indicators for the reinstated codes are in attachment 1 of CR 5980.

**New “Q” Codes**

There are several new “Q” codes (Q4096 through Q4098) with a status indicator of “E” and which are effective for dates of service on or after April 1, 2008. The codes with their descriptors are in the following table:

| Code  | Long Descriptor   | Short Descriptor          |
|-------|---|---------------------------|
| Q4096 | Injection, Von Willebrand Factor Complex, Human, Ristocetin Cofactor (Not Otherwise Specified), per I.U. VWF:RCO                              | VWF complex, not Humate-P |
| Q4097 | Injection, Immune Globulin (Privigen), Intravenous, Non-Lyophilized (E.G., Liquid), 500 mg  | Inj IVIG Privigen 500 mg  |
| Q4098 | Injection, Iron Dextran, 50 mg  | Inj iron dextran          |
| Q4099 | Formoterol fumarate, inhalation solution, FDA approved final product, non-compounded, administered through DME, unit dose form, 20 micrograms | Formoterol fumarate, inh  |

**New Category II Codes for Physician Quality Reporting Initiative**

There are new category II codes for the PQRI for dates of service on or after April 1, 2008. These new codes and their descriptors are in the following table:

| Code  | Long Descriptor  | Short Descriptor            |
|-------|--|-----------------------------|
| 0525F | Initial visit for episode  | Initial visit for episode   |
| 0526F | Subsequent visit for episode   | Subs visit for episode      |
| 1130F | Back pain and function assessed, including all of the following: Pain assessment AND functional status AND patient history, including notation of presence or absence of “red flags” (warning signs) AND assessment of prior treatment and response, AND employment status | Bk pain + fxn assessed      |
| 1134F | Episode of back pain lasting six weeks or less   | Epsd bk pain for =< 6 wks   |
| 1135F | Episode of back pain lasting longer than six weeks   | Epsd bk pain for > 6 wks    |
| 1136F | Episode of back pain lasting 12 weeks or less  | Epsd bk pain for <= 12 wks  |
| 1137F | Episode of back pain lasting longer than 12 weeks  | Epsd bk pain for > 12 wks   |
| 2040F | Physical examination on the date of the initial visit for low back pain performed, in accordance with specifications   | Bk pn xm on init visit date |
| 2044F | Documentation of mental health assessment prior to intervention (back surgery or epidural steroid injection) or for back pain episode lasting longer than six weeks  | Doc mntl tst b/4 bk trxmnt  |
| 3330F | Imaging study ordered  | Imaging study ordered (bkp) |
| 3331F | Imaging study not ordered  | Bk imaging tst not ordered  |
| 3340F | Mammogram assessment category of “incomplete: need additional imaging evaluation”, documented  | Mammo assess inc xray docd  |
| 3341F | Mammogram assessment category of “negative”, documented  | Mammo assess negative docd  |
| 3342F | Mammogram assessment category of “benign”, documented  | Mammo assess bengn docd     |
| 3343F | Mammogram assessment category of “probably benign”, documented   | Mammo probably bengn docd   |
| 3344F | Mammogram assessment category of “suspicious”, documented  | Mammo assess susp docd      |
| 3345F | Mammogram assessment category of “highly suggestive of malignancy”, documented   | Mammo assess hghlymalig doc |

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

| <b>Code</b> | <b>Long Descriptor</b>   | <b>Short Descriptor</b>      |
|-------------|--|------------------------------|
| 3350F       | Mammogram assessment category of "known biopsy proven malignancy", documented  | Mammo bx proven malig docd   |
| 4240F       | Instruction in therapeutic exercise with follow-up by the physician provided to patients during episode of back pain lasting longer than 12 weeks  | Instr xrcz 4bk pn >12 weeks  |
| 4242F       | Counseling for supervised exercise program provided to patients during episode of back pain lasting longer than 12 weeks   | Sprvsd xrcz bk pn >12 weeks  |
| 4245F       | Patient counseled during the initial visit to maintain or resume normal activities   | Pt instr nrml lifest         |
| 4248F       | Patient counseled during the initial visit for an episode of back pain against bed rest lasting 4 days or longer   | Pt instr-no bd rest>= 4 days |
| 4250F       | Active warming used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) recorded within the 30 minutes immediately before or the 30 minutes immediately after anesthesia end time | Wrmng 4 surg - normothermia  |
| 5060F       | Findings from diagnostic mammogram communicated to practice managing patient's on-going care within 3 business days of exam interpretation   | Fndngs mammo 2pt w/in 3 days |
| 5062F       | Findings from diagnostic mammogram communicated to the patient within 5 days of exam interpretation  | Doc f2fmammo fndng in 3 days |
| 6040F       | Use of appropriate radiation dose reduction devices OR manual techniques for appropriate moderation of exposure, documented  | Appro rad ds dvcs techs docd |
| 6045F       | Radiation exposure or exposure time in final report for procedure using fluoroscopy, documented  | Radxps in end rpt4fluro pxd  |
| 7020F       | Mammogram assessment category [eg, Mammography Quality Standards Act (MQSA), Breast Imaging Reporting and Data System (BI-RADS®), or FDA approved equivalent categories] entered into an internal database to allow for analysis of abnormal interpretation (recall) rate                                | Mammo assess cat in dbase    |
| 7025F       | Patient information entered into a reminder system with a target due date for the next mammogram   | Pt infosys alarm 4 nxt mammo |

**Revised Descriptors for PQRI Codes**

Attachment 1 of CR 5980 also contains a list of editorial changes to the short and/or long descriptors for a number of PQRI codes.

**ADDITIONAL INFORMATION**

The official instruction, CR 5980, 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/R1482CP.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: MM5980

Related Change Request (CR) Number: 5980

Related CR Release Date: March 21, 2008

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Source: CMS Pub. 100-04, Transmittal 1482, CR 5980

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## SIGNATURE REQUIREMENTS—CHANGE REQUEST 5550 CLARIFICATION

*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, regional home health intermediaries, Part A/B Medicare administrative contractors, including durable medical equipment Medicare administrative contractors) for care provided to Medicare beneficiaries in hospice.

### WHAT YOU NEED TO KNOW

Change request (CR) 5971, from which this article is taken, clarifies the instructions on signature requirements for the certification of terminal illness for hospice. It provides that Medicare contractors will accept a facsimile of an original written or electronic signature in documenting the certification of terminal illness for hospice.

Make sure that your billing staffs are aware that, to document the certification of terminal illness for hospice, a facsimile of an original written or electronic signature is acceptable.

### BACKGROUND

CR 5971, from which this article is taken, clarifies the instructions in *Medicare Program Integrity Manual* Chapter 3 (Verifying Potential Errors and Taking Corrective Actions), subsection 3.4.1.1B (Signature Requirements) that address the signature requirements for the certification of terminal illness for hospice, that were provided in CR 5550 (Various Medical Review Clarifications).

Subsection 3.4.1.1B of the manual notes that Medicare contractors require a legible identifier for services provided/ordered. It further requires that when this documentation is for medical review purposes, the only acceptable method of documenting the provider signature is by written or an electronic signature. Stamp signatures are not acceptable to sign an order or other medical record documentation for medical review purposes.

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CR 5971 provides that there is an exception to this requirement.

It announces that a facsimile of an original written or electronic signature is acceptable for the certification of terminal illness for hospice. Please be sure to note however, that while a signature facsimile is acceptable in this instance, it and **hard copies of a physician's electronic signature** must be present in the patient's medical record.

### ADDITIONAL INFORMATION

You may find more information about the signature requirements for the certification of terminal illness for hospice by going to CR 5971, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R248PI.pdf>.

You will find updated *Medicare Program Integrity Manual* Chapter 3 (Verifying Potential Errors and Taking Corrective Actions), subsection 3.4.1.1B (Signature Requirements) as an attachment to this CR.

If you have any 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: MM5971  
Related Change Request (CR) Number: 5971  
Related CR Release Date: March 28, 2008  
Related CR Transmittal Number: R248PI  
Effective Date: September 3, 2007  
Implementation Date: April 28, 2008

Source: CMS Pub. 100-08, Transmittal 248, CR 5971

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## NEW MLN MATTERS ARTICLES NOW AVAILABLE ON DMEPOS

### COMPETITIVE BIDDING

**Note:** The Centers for Medicare & Medicaid Services (CMS) has issued *MLN Matters* special edition articles SE0806 and SE0807 since this provider education resource message was originated. The three in a series of articles, which are being published in the following pages, are intended to educate providers on the July 1, 2008, implementation of the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

**N**ow Available! The *Medicare Learning Network (MLN) Matters* special edition article SE0805 titled – “Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) – The first in a series of articles on the implementation of this program.” is now posted on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0805.pdf>.

This is the first in a series of educational articles that will assist you in understanding this new DMEPOS program and will help you interact with your patients. The new program begins July 1, 2008, and additional educational materials will be made available to you as this date approaches.

This series of articles will be of particular interest to any provider that that may order, refer, or supply durable medical equipment to a Medicare beneficiary affected by the new Medicare DMEPOS competitive bidding program.

The Centers for Medicare & Medicaid Services (CMS) has developed a fact sheet that explains the program for Medicare beneficiaries. This fact sheet, entitled, “What You Should Know if You Need Medicare-covered Equipment or Supplies” is available at, <http://www.medicare.gov/Publications/Pubs/pdf/11307.pdf>.

You may want to provide this fact sheet to your Medicare patients. ❖

Source: CMS Provider Education Resource 200804-01

## 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.*

### PROVIDER TYPES AFFECTED

Any Medicare fee-for-service (FFS) provider that may be in a position of ordering, referring, or supplying durable medical equipment, prosthetics, orthotics, and supplies (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.

## Overview of New Medicare Competitive Bidding Program for DMEPOS (continued)

### 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

[http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04\\_New\\_Quality\\_Standards.asp](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp).

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.
- **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://dmecompetitivebid.com/SPA>.

### 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.

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



**Overview of New Medicare Competitive Bidding Program for DMEPOS (continued)**

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:

| <b>If a beneficiary permanently lives in...</b>               | <b>And travels to...</b>                                      | <b>Type of supplier a beneficiary may go to...</b>  |
|---|---|---|
| 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 <b>not</b> 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 <b>not</b> 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 <b>not</b> covered by the competitive bidding program | An area <b>not</b> covered by the competitive bidding program | A beneficiary may get items from any Medicare-enrolled DMEPOS supplier.   |

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>.

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

As this is the first in a series of MLN Matters articles on this issue, further articles will be released in the very near future.

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## 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.

### PROVIDER TYPES AFFECTED

Any Medicare fee-for-service (FFS) provider supplying durable medical equipment, prosthetics, orthotics, and supplies (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 program's initial implementation.

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

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 non-contract 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 non-contract 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

#### 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 non-contract 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 non-contract 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.

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

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, email, 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**

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 advance beneficiary notice (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.

**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>.

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 may also visit the CMS Web site <http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/> or <http://www.dmecompetitivebid.com/> on the Internet for more details.

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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.*

### 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.

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.

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

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**

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.

**Skilled Nursing Facilities and Nursing Facilities Specialty Suppliers**

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**

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 may also visit <http://dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home> on the Internet and at <http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/> on the CMS Web site for more details.

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# PRE-BIDDING ACTIVITIES FOR THE MEDICARE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES COMPETITIVE BIDDING PROGRAM

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

## PROVIDER TYPES AFFECTED

Suppliers of durable medical equipment (DME) that wish to participate in the upcoming Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

## PROVIDER ACTION NEEDED

In order to participate in the second round of the DMEPOS competitive bidding program, suppliers will be required to register in the Centers for Medicare & Medicaid Services (CMS) security system known as the individuals authorized access to CMS computer services (IACS). This includes suppliers that bid in the first round of competition last year and are interested in competing in the second round. Although the bidding window for the second round of competition may not be announced before the issue date of this article, CMS urges suppliers planning to bid in the 2008 bidding cycle to make sure their provider enrollment record is current. Specifically, suppliers should verify their supplier number(s) and authorized official(s) information associated with that supplier number(s) on file with the national supplier clearinghouse (NSC). The accuracy of this data is critical for successful bid registration.

## BACKGROUND

In this year's bid cycle, suppliers who wish to bid will need to first register in IACS, before the bidding window opens. There will be three user roles available, which are described as follows:

- Authorized Official (AO) – Each supplier's organization will be allowed one AO. The AO role can approve all other users associated with their organization who are requesting access to the bidding system. The AO will be able to input bid data, approve Form A and certify Form B in the bidding system.
- Backup-Authorized Official (BAO) – Each supplier organization will be allowed to designate one or more BAOs. In this role, the BAO can approve the supplier's end user registration for access to the bidding system. Like the AO, the BAO can also input bid data, approve Form A and certify Form B in the bidding system.
- End User – Each supplier organization will be allowed one or more end user(s). The end user can input bid data, but cannot approve Form A or certify Form B.

## Save Time and Delay by Verifying NSC Information Prior to Registering to Bid

Only those AOs listed on the CMS-855S (Medicare Enrollment Application) as an AO may register in IACS to approve and certify as described above. As part of the CMS-855S, a supplier designates one or more AO(s). The

AO is an appointed official to whom the organization has granted the legal authority to enroll it in the Medicare program and to commit the organization to fully abide by the statutes, regulations and program instructions of the Medicare program.

End users do not need to be listed on the CMS-855S. However, the AO or BAO will need to approve an end user's request for access to the bidding system.

## Take Action Now

Be sure that the data you are submitting is current and in accordance with that submitted to the NSC. In particular, this concerns the AO's name, date of birth, social security number (SSN), and mailing address. If any of these data elements have changed since your last submission to the NSC, then you should **promptly** complete a change of information on the CMS 855-S.

**CMS urges that suppliers do it now.** The NSC processing time to complete a change of information on the CMS-855S is approximately 45 days and all submissions are processed in the order in which they are received.

## OVERVIEW OF AO IACS REGISTRATION PROCESS

For an AO, the verification of his/her last name, date of birth, and SSN must be validated against the data maintained by NSC. The NSC received this AO data when the supplier completed their most recent CMS-855S Medicare Enrollment Application. The AO's last name is listed in section 15 and the AO's date of birth and SSN in section 6A of the CMS-855S. If the data does not match, the registration will be rejected.

**Following successful registration, as an added measure of security, the AO's User ID and password is then mailed in a separate correspondence to the mailing address listed in section 2A2 of the CMS-855S Medicare Enrollment Application.**

The BAO goes through a similar process and an AO for the organization must approve a BAO's request for access before a User ID and password will be emailed to the BAO.

## Do I Need a Backup-Authorized Official Role?

The establishment of a BAO is highly recommended to avoid any disruption in the bidding process. The AO's role is instrumental to bidding, as the AO's role must be active to avoid all other users of the organization from losing access to the bidding system. If the AO leaves the organization, the BAO role can be changed to an AO role by the competitive bidding implementation contractor (CBIC).

You will want to verify that the CMS-855S Medicare Enrollment Application for your organization has two or more AOs listed.

**Pre-Bidding Activities for the Medicare DMEPOS Competitive Bidding Program (continued)****ADDITIONAL INFORMATION**

For more information on the DMEPOS competitive bidding program, visit the CMS Web site <http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/>.

MLN Matters Number: SE0811  
 Related Change Request (CR) Number: N/A  
 Related CR Release Date: N/A  
 Related CR Transmittal Number: N/A  
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 Implementation Date: N/A

Source: CMS Special Edition *MLN Matters* Article SE0811

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## USE OF PROFESSIONAL SOCIETY PRACTICE PARAMETERS IN PROPERLY PROVIDING ALLERGEN IMMUNOTHERAPY TO MEDICARE BENEFICIARIES

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

**PROVIDER TYPES AFFECTED**

All physicians and providers who submit Medicare claims for providing allergen immunotherapy to Medicare beneficiaries.

**PROVIDER ACTION NEEDED**

This special edition (SE) article SE0812 is in response to recommendations made by the Department of Health & Human Services (DHHS), Office of Inspector General (OIG) in its 2006 “Allergen Immunotherapy for Medicare Beneficiaries” report. This article provides guidance and resources, developed by professional societies, for Medicare contractors and providers in determining the most appropriate provisions of allergen immunotherapy to Medicare beneficiaries.

**BACKGROUND**

The Centers for Medicare & Medicaid Services (CMS) does not have a national coverage determination (NCD) that identifies national coverage criteria for allergen immunotherapy services. Currently coverage of allergen immunotherapy services is at the local Medicare contractor’s discretion. The February 2006 “Allergen Immunotherapy for Medicare Beneficiaries” report released by the DHHS, OIG identified areas of Medicare vulnerability due to insufficient available information regarding coverage, coding, and documentation requirements for physicians who provide allergen immunotherapy to Medicare beneficiaries.

**KEY POINTS**

- Because allergen immunotherapy may vary significantly based on geographical locations, CMS, with the support of the Joint Council of Allergy, Asthma, and Immunology (JCAAI), decided that an NCD was not the best

mechanism for providing coverage to beneficiaries throughout the nation.

- CMS determined that contractor discretion for coverage of allergen immunotherapy is most appropriate.
- Without an NCD, Medicare contractors may develop their own local coverage determinations (LCDs).
- While these policies may vary between contractors, **CMS strongly encourages physicians who provide allergen immunotherapy to closely follow practice parameters agreed upon and endorsed by the professional societies that represent allergy, asthma, and immunology practitioners** like the JCAAI, as long as those parameters fall within the coverage criteria of applicable LCDs.
- Specific practice parameters are provided on the JCAAI Web site at <http://www.jcaai.org/> and are important for all practitioners and providers to study and understand.

**ADDITIONAL INFORMATION**

The CMS website provides a searchable database of LCDs, which is available on the CMS Web site at <http://www.cms.hhs.gov/mcd/search.asp>.

Providers may also wish to review the *Medicare NCD Manual*, which is available on the CMS Web site at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>.

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Source: CMS Special Edition *MLN Matters* Article SE0812

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## LABORATORY COMPETITIVE BIDDING DEMONSTRATION

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 March 20, 2008, to reflect a change that was made to related change request (CR) 5389 on March 19, 2008. The CR was modified to delete a business requirement instructing carriers and A/B MACs to deny claims with dates of service between April 1, 2007 and March 31, 2010 inclusive and with modifier "90" submitted by laboratories for demonstration-covered services provided to beneficiaries residing in the competitive bidding demonstration area (CBA). Since that requirement was deleted, language regarding that denial requirement was deleted from the article. The CR release date, transmittal number and Web address for accessing CR 5389 were also changed. All other information remains the same. However, it is important to note that a more current article, MM5772, is now available regarding this demonstration at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5772.pdf> on the CMS Web site. Where there is disagreement between this article and related CR 5359 and MM5772 and related CR 5772, the information in CR 5772 is more current and takes precedence over CR 5359. The revised *MLN Matters* article MM5359 was published in the January 2007 *Medicare A Bulletin* (pages 14-16). The *MLN Matters* article MM5772 was published in the March 2008 *Medicare A Bulletin* (pages 7-10).

### PROVIDER TYPES AFFECTED

Physicians and hospitals (TOB 14x only) who bill Medicare carriers, fiscal intermediaries (FIs), or Part A/B Medicare administrative contractors (A/B MACs) for clinical laboratory tests performed for Medicare Part B beneficiaries who live within the competitive bidding demonstration area (CBA) sites.

### BACKGROUND

Section 302(b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) requires the Centers for Medicare & Medicaid Services (CMS) to conduct a demonstration project on the application of competitive acquisition for payment of most clinical laboratory services that would otherwise be payable under the Medicare Part B fee schedule.

Under this statute, Pap smears and colorectal cancer screening tests are excluded from this demonstration. Requirements under the Clinical Laboratory Improvement Amendments (CLIA), as mandated in section 353 of the Public Health Service Act, are applicable.

The payment basis determined for each CBA will be substituted for payment under the existing clinical laboratory fee schedule. Multiple winners are expected in each CBA.

### Key Points

This article and CR 5359 provides instructions for the implementation of a laboratory competitive bidding demonstration. The requirements specified in this article and CR 5359 are in preparation for the implementation of the demonstration in the first CBA on April 1, 2007.

- The project will cover demonstration tests for all Medicare Part B beneficiaries who live in the demonstration sites, as determined by the ZIP code of the beneficiary's residence.
- Hospital inpatient testing is covered by Medicare Part A and is therefore exempt from the demonstration.
- Physician office laboratory (POL) testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital laboratory functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital outpatient department.
- CMS will continue to pay POL patient and hospital outpatient laboratory services in accordance with the existing clinical laboratory fee schedule.

### Required Bidders

Laboratory firms with \$100,000 or more in annual Medicare Part B (fee-for-service) payments as of calendar year (CY) 2005 for "demonstration tests" provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) will be required to bid in the demonstration.

These laboratory firms will be referred to as "required bidders."

### Passive Laboratories

Small laboratories or laboratory firms with less than \$100,000 in annual Medicare Part B (fee-for-service) payments for demonstration tests provided to beneficiaries residing in the CBAs will not be required to bid in the demonstration. These laboratories are considered "passive" laboratories." Passive laboratories will be paid the laboratory competitive bidding demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBA.

During the demonstration period, CMS will monitor the volume of services performed by passive laboratories to ensure that their annual payments under Medicare Part B for demonstration tests provided to beneficiaries residing in the demonstration sites do not exceed the annual ceiling of \$100,000.

Passive laboratory firms exceeding the annual ceiling of \$100,000 by \$25,000 or more will be:

- Terminated from the demonstration project.
- Will not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.
- Laboratories or laboratory firms providing clinical laboratory services exclusively to beneficiaries with end stage renal disease (ESRD) residing in the CBA will not be required to bid in the demonstration. These laboratories are considered "passive-ESRD" laboratories. Passive-ESRD laboratories will be paid the laboratory competitive bidding demonstration fee schedule for Part B demonstration tests provided to ESRD beneficiaries residing in the CBA. During the demonstration period (April 1, 2007 through March 31, 2010, inclusive), passive-ESRD laboratories that expand their business to provide clinical laboratory services to non-ESRD beneficiaries residing in the CBA will be terminated from the competitive bidding demonstration.



**Laboratory Competitive Bidding Demonstration (continued)****Winners**

Both required and non-required bidders that bid and win will be paid the laboratory competitive bidding demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located). These laboratories will be labeled "winners."

**Non-Winners**

Both required and non-required bidders that bid and do not win will not be paid anything by Medicare (neither under the Part B clinical laboratory fee schedule nor under the competitively bid price) for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration. These laboratories will be labeled "non-winners."

Similarly, required bidders that do not bid will not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.

Non-winner laboratories that furnish a demonstration test to a Medicare beneficiary residing in the CBA during the demonstration have no appeal rights when Medicare payment for the test is denied. Moreover, non-winner laboratories may not charge the beneficiary for Part B laboratory services.

**Demonstration-Covered Laboratory Tests**

Only the laboratory that performs the test may bill for the service and only winning or passive laboratories are eligible to receive the laboratory competitive bidding demonstration fee schedule payment for services covered under the demonstration.

Although non-winner laboratories may not bill either Medicare or the beneficiary for any demonstration-covered services, such laboratories may refer such services to a winner laboratory or a passive laboratory.

For all other tests (i.e., those not covered under the demonstration or for tests for beneficiaries not residing in the service area), all laboratories will be paid according to the clinical laboratory fee schedule and in accordance with Medicare payment policies.

**Demonstration Sites**

There are two demonstration sites and each site runs for three years with a staggered start of one year. The demonstration uses metropolitan statistical areas (MSAs) to define the CBAs.

The residence status of beneficiaries will be determined by information in the Medicare system as of the date the claim is processed. The residence of the beneficiary receiving services must be in the same CBA as determined by review of a beneficiary's zip code of residence.

CMS will provide the contractors with a list of zip codes included in each MSA, which will be used to determine whether a beneficiary's residence is included in one of the CBAs.

The demonstration will set (competitively bid) fees in the demonstration areas for all tests paid under the Medicare Part B clinical laboratory fee schedule, with the exception of pap smears, colorectal cancer screening tests, and new tests

added to the Medicare Part B clinical laboratory fee schedule during the course of the demonstration. Demonstration fees will be set for each service payable under the demonstration in each of the CBAs.

Only CLIA-certified laboratories will be allowed to participate in the demonstration.

**Implementation**

CR 5359 is being implemented in multiple phases. The requirements specified in this instruction are for the implementation of the demonstration in the first CBA (CBA1).

During the first quarter of 2007, CMS will provide Medicare carriers, FIs, and A/B MACs with a national ZIP code pricing file identifying the zip codes included in the first CBA. Also, in that same timeframe, CMS will provide to the carriers, FIs, and A/B MACs a list of the laboratories eligible to participate in the first CBA demonstration ("winners" and passive laboratories) and a list of those laboratories not selected to participate in CBA1.

For covered demonstration laboratory services in CBA1 with dates of service between April 1, 2007 and March 31, 2010, Medicare will pay the laboratory competitive bidding demonstration fee schedule amounts for laboratory services on that schedule. For services not on the demonstration schedule, Medicare will pay based on the clinical laboratory fee schedule.

Claims submitted by non-winner laboratories for dates of service of April 1, 2007 through March 31, 2010, for Medicare beneficiaries in CBA1 will be denied using:

- Reason code 96 (non-covered charges)
- Remark code M114 (*This service was processed in accordance with rules and guidelines under the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project. If you would like more information regarding this project, you may contact your local contractor.*)
- Remark code N83 (No appeal rights. Administrative decision based on the provisions of a demonstration project).

Medicare will pay claims during the demonstration period submitted by non-demonstration laboratories for beneficiaries residing in the CBA who receive services outside of those areas (e.g., "snow birds") according to the laboratory competitive bidding demonstration.

Non-winning laboratories should know that advance beneficiary notices (ABNs) and notices of beneficiary exclusion from Medicare benefits (NEMBs) are not to be used to transfer liability to beneficiaries when services under the demonstration are obtained at non-winner laboratories.

Line items for demonstration services and for non-demonstration services may be submitted on the same claim.

A subsequent CR will be issued with requirements to implement the demonstration in the second CBA (CBA2).

Medicare contractors will be prepared to begin processing claims under the laboratory competitive bidding demonstration in the first CBA on April 1, 2007. The tentative start date for the demonstration in the second CBA is April 1, 2008.

## GENERAL INFORMATION

### Laboratory Competitive Bidding Demonstration (continued)

**Note:** Remember that required and non-required bidders that bid and lose will be paid nothing under the Part B clinical laboratory fee schedule and will have no appeal rights for demonstration tests provided to beneficiaries residing in the CBAs, regardless of the location of the laboratory itself.

### IMPLEMENTATION

The implementation date for this instruction is April 2, 2007.

### ADDITIONAL INFORMATION

The official instructions issued to your Medicare carrier, FI, or A/B MAC regarding this change may be found on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R57DEMO.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: MM5359 – Revised  
Related Change Request (CR) Number: 5359  
Related CR Release Date: March 19, 2008  
Related CR Transmittal Number: R57DEMO  
Effective Date: April 1, 2007  
Implementation Date: April 2, 2007

Source: CMS Pub. 100-19, Transmittal 57, CR 5359

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## NATIONAL PROVIDER IDENTIFIER

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### VISIT THE NPI MLN MATTERS WEB PAGE AND QUARTERLY JOURNAL

#### ADVERTISEMENT

As Medicare May 23rd national provider identifier (NPI) implementation approaches, the Centers for Medicare & Medicaid Services (CMS) reminds providers to visit the NPI *MLN Matters* national provider education articles, courtesy of the **Medicare Learning Network**.

The national provider identifier (NPI) is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification standard. The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses will use the NPIs in the administrative and financial transactions adopted under HIPAA.

The NPI is a 10-position, intelligence-free numeric identifier (10-digit number). This means that the numbers do not carry other information about health care providers, such as the state in which they live or their medical specialty.

The **Medicare Learning Network** has created many *MLN Matters* articles on the various aspects of Medicare's NPI implementation. A comprehensive list of the NPI articles is available on the CMS Web site at [http://www.cms.hhs.gov/NationalProvidentStand/Downloads/MMArticles\\_NPI.pdf](http://www.cms.hhs.gov/NationalProvidentStand/Downloads/MMArticles_NPI.pdf).

**New MLN Quarterly Journal Ad—NPI MLN Matters Articles** – This quarterly journal ad features the *MLN Matters* articles available regarding Medicare's implementation of the national provider identifier (NPI).

Each calendar quarter, the **Medicare Learning Network** creates a journal advertisement based on an initiative or new product of particular importance during that time frame. National, state and local associations are encouraged to use this journal ad in their publications and/or newsletters and Web sites, as appropriate.

The files for this quarter's ad, as well as future ads, may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNGenInfo/>. ❖

Source: CMS Provider Education Resource 200804-14

## MAY 23<sup>RD</sup> IS ONLY TWO WEEKS AWAY—ARE YOU PREPARED?

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

#### INFORMATION FOR ALL HEALTH CARE PROVIDERS MEDICARE AND NON-MEDICARE

The Centers for Medicare & Medicaid Services (CMS) encourages all health care providers to contact other health plans with which you interact in order to ensure you fully understand their expectations for May 23, 2008.

#### IMPORTANT INFORMATION FOR MEDICARE FEE-FOR-SERVICE PROVIDERS

##### Clarification of April 3, 2008, Statement “Institutional Providers Submitting Taxonomy Codes to Identify Subparts – What Medicare Is Using to Obtain NPI/OSCAR Match”

Providers who submit Medicare claims may continue to send their Medicare provider taxonomy codes. However, Medicare fee-for-service claim processing systems will not use this data to adjudicate claims. The taxonomy codes will be crossed over to the secondary payers as CMS understands that some payers may use this information to adjudicate claims.

##### When to Update NPPES if an Update to Medicare Enrollment Information Is Also Needed

The NPI final rule requires covered providers to update their required NPPES data within 30 days of the change. If a Medicare provider needs to update information in NPPES, it will also need to update the corresponding information in its Medicare enrollment record via the CMS-855. Providers should not make updates to NPPES data until after their CMS-855s are processed and those updates are effective in the Medicare enrollment system (PECOS, or the NSC for Medicare DMEPOS suppliers). After the update is effective in PECOS or the NSC (whichever is appropriate), providers have up to 30 days to make the corresponding updates in NPPES. In a change of ownership (CHOW) situation, for example, the new owner would not make changes in the NPPES record of the provider that is being sold until after the CMS-855 is processed and its changes are effective in the Medicare enrollment system. If a new NPI is to be obtained as part of the CHOW and an existing NPI is to be deactivated (those decisions are up to the buyer and the seller), the NPI should not be deactivated until after all claims using that NPI reach final settlement (this could involve health plans in addition to Medicare).

##### May 23rd Is Only Two Weeks Away, Are You Prepared?

**URGENT:** CMS continues to be concerned about the low percentage of claims being submitted with an NPI alone in the primary provider identifier fields. See below for specific steps to begin using the NPI alone in the primary provider identifier fields.

##### Don't Be Surprised on May 23...Try NPI-only Now

Now that the NPI is required on all Medicare claims in the primary provider fields, if your claims are being successfully processed with NPI/legacy pairs (and most are) now is the time to begin sending a small batch of claims with NPI alone. If the Medicare NPI crosswalk cannot match your

NPI to your Medicare legacy number, the claim with an NPI-only will reject. You can and should try sending NPI-only now! If the claim is processed and you are paid, continue to increase the volume of claims sent with only your NPI. If the claims reject, go into your NPPES record and validate that the information you are sending on the claim is consistent with the information in NPPES. If it is different, make the updates in NPPES and resend a small batch of claims three-four days later. If your claims are still rejecting, you may need to update your Medicare enrollment information to correct this problem. Call the Customer Service Representative at your Medicare carrier, FI, or A/B MAC or at your DME MAC to discuss your situation and, if necessary, have it investigated. Have a copy of your NPPES record or your NPI registry record available. The contractor telephone numbers are likely to be quite busy, so don't wait.

If you bill Medicare using a billing service or clearinghouse, you should work with them to establish a way to try sending NPI-only claims. It may be difficult for some of these third party vendors to send small batches of your NPI-only claims and continue sending NPI and legacy claims as well, so contact them and develop an alternative solution so you can try NPI-only.

Sending a sample of NPI-only claims will allow time for any needed corrections prior to May 23, 2008, the date when only the NPI will be accepted in all provider fields.

##### NPIs in Secondary Provider Fields

May 23, 2008, is also the deadline for using the NPI-only in the secondary provider identifier fields on a claim transaction. This includes the prescriber field in a Medicare fee-for-service retail pharmacy drug claim submitted in an NCPDP 5.1 transaction. CMS will be providing guidance with respect to the reporting of NPIs in the Service Facility Location loop in the X12 N 837 claim transactions.

##### NPIs on ALL HIPAA Standard Transactions

May 23, 2008, is also the deadline for the use of NPI on ALL HIPAA standard transactions (e.g., 837I, 837P, NCPDP, DDE, 276/277, 270/271 and 835).

##### 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 200804-13

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## STEPS TO FACILITATE A SMOOTH TRANSITION TO NPI-ONLY MEDICARE BILLING AND MORE

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

#### INFORMATION FOR ALL HEALTH CARE PROVIDERS MEDICARE AND NON-MEDICARE

The Centers for Medicare & Medicaid Services (CMS) encourages all health care providers to ensure they understand the readiness of other health plans with which they interact, especially if those health plans may be primary or secondary to Medicare. Medicare will only accept/send NPI-only transactions beginning May 23, 2008, and providers need to understand from these other plans what will happen if they are unable to send/receive **NPI-only** transactions.

#### IMPORTANT INFORMATION FOR MEDICARE FEE-FOR-SERVICE PROVIDERS

CMS is pleased to announce that Medicare is receiving more than 98 percent of claims with an NPI. The next milestone – May 23<sup>rd</sup> – requires providers to take the next step so they do not risk disruption in cash flow. Begin billing with **NPI-only** now to test how May 23<sup>rd</sup> will impact you. CMS is concerned that the percentage of Medicare claims with **NPI-only** is not growing fast enough.

#### Steps to Facilitate a Smooth Transition to NPI-Only

- 1) Bill with Medicare legacy ID & NPI
  - Once claims are successfully processed, move to Step 2.
- 2) Bill with NPI-only
  - Start with a small batch of claims. If, or when, the results are positive, begin sending a greater volume and move to Step 3.
  - Billing with NPI-only also tests the ability to receive the NPI on 835 transactions.
- 3) Test NPI-only on other HIPAA transactions
  - CMS will require use of the NPI on the 270/271, 276/277 and NCPDP transactions. Providers should begin testing the use of the NPI on these transactions, in small quantities, prior to May 23<sup>rd</sup> to ensure a smooth transition. Also, be prepared to accept the NPI-only on the 835-remittance advice transaction.

#### INSTITUTIONAL PROVIDERS SUBMITTING TAXONOMY CODES TO IDENTIFY SUBPARTS

##### Update: Medicare is Using Alternative Data to Obtain NPI/OSCAR Match

On January 1, 2007, Medicare implemented change request (CR) 5243, which required the submission of taxonomy codes all claims submitted by institutional Medicare providers who submit claims for their primary facility and its subparts (such as psychiatric unit, rehabilitation unit, etc.).

The intent of CR 5243 was to enable Medicare to appropriately crosswalk a provider NPI to each of the provider's subparts through the reporting of taxonomy codes in the claims.

Medicare has found that using taxonomy codes has been unsuccessful in obtaining a one-to-one match on the crosswalk for those providers having one NPI tied to multiple OSCAR/certification numbers. As a result, the taxonomy code is no longer used as part of the crosswalk criteria that are used to attempt to match an NPI with an OSCAR/certification number. Currently, the fiscal intermediary shared system (FISS) uses these matching criteria to obtain a one-to-one match between an institutional Medicare provider's NPI and its OSCAR/certification number:

- **First level of match: Type of bill (TOB) to OSCAR/certification number.**  
If the system is unable to identify a valid match, the search will continue with the next level of match.
- **Second level of match: Revenue code to OSCAR/certification number.**  
If the system is unable to identify a valid match, the search will continue with the next level of match.
- **Third and final level of match: Facility ZIP code on the claim.**  
This final level prompts the systems logic to limit the list of appropriate OSCAR numbers by matching the facility ZIP code on the claim against the ZIP code of the master address in the FISS provider address file.

**Note:** If the system is unable to make a valid match, the claim will suspend with reason code 32105, and the provider will receive an additional development letter (ADR) requesting the OSCAR number.

#### ACTION REQUIRED BY INSTITUTIONAL PROVIDERS WITH SUBPARTS

Providers are strongly encouraged to enumerate their subparts. The following documents may assist providers in answering additional questions on this subject.

- CMS Medicare Subpart Expectations paper may be accessed on the CMS Web site at <http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/Medsubparts01252006.pdf>
- Read NPI Fact Sheet titled "For Health Care Providers Who Are Organizations" at [http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI\\_FactSheet\\_-03-07.pdf](http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI_FactSheet_-03-07.pdf)
- Review the article titled "Information Regarding National Plan and Provider Enumeration System Errors, Using the NPI on Medicare Claims and 835 Remittance Advice Changes" available in the August 2007 Medicare A Bulletin at [http://www.floridamedicare.com/Part\\_A/Medicare\\_A\\_Bulletins/Archive/110043.pdf](http://www.floridamedicare.com/Part_A/Medicare_A_Bulletins/Archive/110043.pdf)
- Review Special Edition article <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0608.pdf>
- National Plan and Provider Enumeration System (NPPES) <https://nppes.cms.hhs.gov/NPPES>.

### **Steps to Facilitate a Smooth Transition to NPI-Only Medicare Billing and More (continued)**

#### **ENCOURAGE CLEARINGHOUSES TO ALLOW TESTING OF NPI-ONLY**

It has come to CMS' attention that some clearinghouses may not allow important NPI-only testing prior to May 23rd. CMS encourages Medicare providers to work with their clearinghouses to allow use of the NPI-only to facilitate this testing. If you do not test, you will not be aware, in advance, of any problems that could prohibit Medicare from processing and paying claims.

#### **NEED MORE INFORMATION?**

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>.

#### **Visit The Medicare Learning Network – It's Free! ❖**

Source: CMS Provider Education Resource 200804-02

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## GENERAL COVERAGE

## ERYTHROPOIESIS STIMULATING AGENTS IN CANCER AND RELATED NEOPLASTIC CONDITIONS

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 April 25, 2008, the third bullet under *Reasonable and Necessary ESA Use* regarding the "Maintenance of ESA therapy" (See bullet in bold). It should have stated that the "starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is < 30 percent) four weeks after initiation of therapy and the rise in hemoglobin is  $\geq$  1g/dL (hematocrit  $\geq$  3 percent)." All other information remains the same. The revised MLN Matters article MM5818 was published in the April 2008 *Medicare A Bulletin* (pages 18-20).

## PROVIDER TYPES AFFECTED

Providers and suppliers who bill Medicare contractors (carriers, fiscal intermediaries [FI], regional home health intermediaries [RHHI], Medicare administrative contractors [A/B MAC] and durable medical equipment Medicare administrative contractors [DME MAC]) for administering or supplying erythropoiesis stimulating agents (ESAs) for cancer and related neoplastic conditions to Medicare beneficiaries.

## WHAT YOU NEED TO KNOW

Following a national coverage analysis (NCA) to evaluate the uses ESAs in non-renal disease applications, the Centers for Medicare & Medicaid Services (CMS), on July 30, 2007, issued a decision memorandum (DM) that addressed ESA use in non-renal disease applications (specifically in cancer and other neoplastic conditions).

Change request (CR) 5818 communicates the NCA findings and the coverage policy in the national coverage determination (NCD). Specifically, CMS determines that ESA treatment is reasonable and necessary for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia under specified conditions; and not reasonable and necessary for beneficiaries with certain other clinical conditions, as listed below.

The HCPCS codes specific to non-end-stage renal disease (ESRD) ESA use are J0881 and J0885. Claims processed with dates of service July 30, 2007, through December 31, 2007, do not have to include the ESA modifiers, as the modifiers are not effective until January 1, 2008. However, providers are to begin using the modifiers as of January 1, 2008, even though full implementation of related system edits are not effective until April 7, 2008.

Make sure that your billing staffs are aware of this guidance regarding ESA use.

## BACKGROUND

Emerging safety concerns (thrombosis, cardiovascular events, tumor progression, and reduced survival) derived from clinical trials in several cancer and non-cancer populations prompted CMS to review its coverage of ESAs. In so doing, on March 14, 2007, CMS opened an NCA to evaluate the uses of ESAs in non-renal disease applications, and on July 30, 2007, issued a DM specifically narrowed to the use of ESAs in cancer and other neoplastic conditions.

## Reasonable and Necessary ESA Use

CMS has determined that ESA treatment for the anemia secondary to a regimen of myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is reasonable and necessary only under the following specified conditions:

- The hemoglobin level immediately prior to the first administration is < 10 g/dL (or the hematocrit is < 30 percent) and the hemoglobin level prior to any maintenance administration is < 10g/dL (or the hematocrit is < 30 percent).
- The starting dose for ESA treatment is up to either of the recommended Food and Drug Administration (FDA) approved label starting doses for cancer patients receiving chemotherapy, which includes the, 150 U/kg/3 times weekly or the 40,000 U weekly doses for epoetin alfa and the 2.25 mcg/kg/weekly or the 500 mcg once every three week dose for darbepoetin alpha.
- **Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is < 30 percent) four weeks after initiation of therapy and the rise in hemoglobin is  $\geq$  1g/dL (hematocrit  $\geq$  3 percent).**
- For patients whose hemoglobin rises < 1 g/dl (hematocrit rise < 3 percent) compared to pretreatment baseline over four weeks of treatment and whose hemoglobin level remains < 10 g/dL after four weeks of treatment (or the hematocrit is < 30 percent), the recommended FDA label starting dose may be increased once by 25 percent. Continued use of the drug is not reasonable and necessary if the hemoglobin rises < 1 g/dl (hematocrit rise < 3 percent) compared to pretreatment baseline by 8 weeks of treatment.
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin > 1 g/dl (hematocrit > 3 percent) over any two week period of treatment unless the hemoglobin remains below or subsequently falls to < 10 g/dL (or the hematocrit is < 30 percent). Continuation and reinstatement of ESA therapy must include a dose reduction of 25 percent from the previously administered dose.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

**Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (continued)****Not Reasonable and Necessary ESA Use**

Either because of a deleterious effect of ESAs on the underlying disease, or because the underlying disease increases the risk of adverse effects related to ESA use, CMS has also determined that ESA treatment is not reasonable and necessary for beneficiaries with the following clinical conditions:

- Any anemia in cancer or cancer treatment patients due to folate deficiency (diagnosis code 281.2), B-12 deficiency (281.1 or 281.3), iron deficiency (280.0-280.9), hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9, 283.10, 283.19), bleeding (280.0 or 285.1), or bone marrow fibrosis.
- Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91), or erythroid cancers (207.00-207.81).
- Anemia of cancer not related to cancer treatment.
- Any anemia associated only with radiotherapy.
- Prophylactic use to prevent chemotherapy-induced anemia.
- Prophylactic use to reduce tumor hypoxia.
- Erythropoietin-type resistance due to neutralizing antibodies.
- Anemia due to cancer treatment if patients have uncontrolled hypertension.

**Claim Processing**

Effective for claims with dates of service on or after January 1, 2008, Medicare will deny non-ESRD ESA services for J0881 or J0885 when:

- Billed with modifier **EC** (ESA, anemia, non-chemo/radio) when a diagnosis on the claim is present for any anemia in cancer or cancer treatment patients due to folate deficiency (diagnosis code 281.2), B-12 deficiency (281.1 or 281.3), iron deficiency (280.0-280.9), hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9, 283.10, 283.19), bleeding (280.0 or 285.1), anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91), or erythroid cancers (207.00-207.81).
- Billed with modifier **EC** for any anemia in cancer or cancer treatment patients due to bone marrow fibrosis, anemia of cancer not related to cancer treatment, prophylactic use to prevent cancer-induced anemia, prophylactic use to reduce tumor hypoxia, erythropoietin-type resistance due to neutralizing antibodies, and anemia due to cancer treatment if patients have uncontrolled hypertension.
- Billed with modifier **EA** (ESA, anemia, chemo-induced) for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia when a hemoglobin 10.0g/dL or greater or hematocrit 30.0 percent or greater is reported.

- Billed with modifier **EB** (ESA, anemia, radio-induced).

**Note:** Denial of claims for non-ESRD ESAs for cancer and related neoplastic indications as outlined in NCD 110.21 are based on reasonable and necessary determinations. A provider may have the beneficiary sign an advance beneficiary notice (ABN), making the beneficiary liable for services not covered by Medicare. When denying ESA claims, contractors will use Medicare Summary Notice 15.20, The following policies [NCD 110.21] were used when we made this decision, and remittance reason code 50, These are noncovered services because this is not deemed a 'medical necessity' by the payer. However, standard systems shall assign liability for the denied charges to the provider unless documentation of the ABN is present on the claim. Denials are subject to appeal and standard systems shall allow for medical review override of denials. Contractors may reverse the denial if the review results in a determination of clinical necessity.

Medicare contractors have discretion to establish local coverage policies for those indications not included in NCD 110.21. Medicare contractors will not search files to retract payment for claims paid prior to April 7, 2008. However, contractors shall adjust claims brought to their attention.

**ADDITIONAL INFORMATION**

This addition/revision of section 110.21 of Pub.100-03 is an NCD. NCDs are binding on all carriers, FIs, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060[a][4] [2005]). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869[f][1][A][I] of the Social Security Act.)

The official instruction, CR 5818, was issued to your contractor in two transmittals. The first is the NCD transmittal and that is available at <http://www.cms.hhs.gov/Transmittals/downloads/R80NCD.pdf> on the CMS Web site. The second transmittal revises the *Medicare Claims Processing Manual* and it is on the same site at <http://www.cms.hhs.gov/Transmittals/downloads/R1413CP.pdf>.

If you have any 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: MM5818 – Revised  
 Related Change Request (CR) Number: 5818  
 Related CR Release Date: January 14, 2008  
 Related CR Transmittal Number: R80NCD and R1413CP  
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 Implementation Date: April 7, 2008

Source: CMS Pub. 100-04, Transmittal 1413, CR 5818

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**ASTIGMATISM-CORRECTING INTRAOCULAR LENS—CMS-1536 RULING**

**IMPLEMENTATION**

*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 April 10, 2008, to add a reference to *MLN Matters* article MM5853 (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5853.pdf>), which provides instructions regarding the use of HCPCS code V2787 when billing for intraocular lens procedures and services involving recognized astigmatism-correcting intraocular lenses (A-C IOLs) that take place in ambulatory surgery centers (ASCs), physician offices, or hospital outpatient departments (HOPDs). The *MLN Matters* article MM5527 was published in the August 2007 *Medicare A Bulletin* (pages 34-37).

**PROVIDER TYPES AFFECTED**

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

**PROVIDER ACTION NEEDED**

This article is based on change request (CR) 5527, which discusses a recent administrator ruling from the Centers for Medicare & Medicaid Services (CMS) regarding astigmatism-correcting intraocular lenses (A-C IOLs) following cataract surgery (CMS-1536-R). **The new policy is effective for dates of service on and after January 22, 2007. Physicians and providers need to be aware that effective January 22, 2007:**

- Medicare will pay the same amount for cataract extraction with A-C IOL insertion that it pays for cataract extraction with conventional IOL insertion.
- **The beneficiary is responsible for payment of that portion of the hospital or ambulatory surgery center (ASC) charge for the procedure that exceeds the facility's usual charge for cataract extraction and insertion of a conventional IOL following cataract surgery, as well as any fees that exceed the physician's usual charge to perform a cataract extraction with insertion of a conventional IOL.**

In addition, CMS reminds physicians that they can be reimbursed for the conventional or A-C IOL (V2632) only when the service is performed in a physician's office. Also, when physicians perform cataract surgery in an ASC or hospital outpatient setting, the physician may only bill for the professional service because payment for the lens is bundled into the facility payment for the cataract extraction.

**BACKGROUND**

The Centers for Medicare & Medicaid Services (CMS) Administrator rulings serve as 1) precedent final opinions and orders and 2) statements of policy and interpretation. The Administrator rulings provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, utilization and peer review by quality improvement organizations, private health insurance, and related matters. These rulings also promote consistency in interpretation of policy and adjudication of disputes, and they are binding on all CMS components, Medicare contractors, the Provider

Reimbursement Review Board, the Medicare Geographic Classification Review Board, and administrative law judges who hear Medicare appeals.

CR 5527 discusses a recent CMS administrator ruling concerning requirements for determining payment for insertion of intraocular lenses (IOLs) that replace beneficiaries' natural lenses and correct pre-existing astigmatism following cataract surgery under the Social Security Act:

**Note:** CR 5527 basically restates CMS policy provided in CR 3927 (*MLN Matters* article MM3927), except that CR 3927 focused on presbyopia-correcting IOLs and this article focuses on A-C IOLs.

**Coverage Policy**

In general, an item or service covered by Medicare must satisfy the following three basic requirements:

- Fall within a statutorily-defined benefit category.
- Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part.
- Not be excluded from coverage.

The Social Security Act specifically excludes eyeglasses and contact lenses from coverage, with an exception for one pair of eyeglasses or contact lenses covered as a prosthetic device furnished after each cataract surgery with insertion of an IOL. In addition, there is no Medicare benefit category to allow payment for the surgical correction or cylindrical lenses of eyeglasses or contact lenses that may be required to compensate for the imperfect curvature of the cornea (astigmatism).

An A-C IOL is intended to provide what is otherwise achieved by two separate items:

- An implantable conventional IOL (one that is not astigmatism -correcting) that is covered by Medicare
- The surgical correction, eyeglasses, or contact lenses that are not covered by Medicare.

Although A-C IOLs may serve the same function as eyeglasses or contact lenses furnished following removal of a cataract, A-C IOLs are neither eyeglasses nor contact lenses. The following table is a summary of benefits for which Medicare makes payment, and services for which Medicare does not pay (no benefit category):



**Astigmatism-Correcting Intraocular Lens—CMS-1536 Ruling Implementation (continued)**

| <b>Benefits for Which Medicare Makes Payment</b>  | <b>Services for Which Medicare Does NOT Pay – No Benefit Category</b>   |
|---|---|
| A conventional intraocular lens (IOL) implanted following cataract surgery.   | The astigmatism-correcting functionality of an IOL implanted following cataract surgery.  |
| Facility or physician services and supplies required inserting a conventional IOL following cataract surgery.                   | Facility or physician services and resources required inserting and adjusting an AC-IOL following cataract surgery that exceeds the services and resources furnished for insertion of a conventional IOL.   |
| One pair of eyeglasses or contact lenses as a prosthetic device furnished after each cataract surgery with insertion of an IOL. | The surgical correction of cylindrical lenses of eyeglasses or contact lenses that may be required to compensate for imperfect curvature of the cornea (astigmatism).<br><br>Eye examinations performed to determine the refractive state of the eyes specifically associated with insertion of an AC-IOL (including subsequent monitoring services), that exceed the one-time eye examination following cataract surgery with insertion of a conventional IOL. |

Currently, there is one NTIOL class approved for special payment when furnished by an ASC, and this currently active NTIOL category for “Reduced Spherical Aberration” was established on February 27, 2006, and expires on February 26, 2011.

Effective for services furnished on or after January 22, 2007, CMS now recognizes the following as A-C IOLs:

- Acrysof® Toric IOL (models: SN60T3, SN60T4, and SN60T5), manufactured by Alcon Laboratories, Inc
- Silicon 1P Toric IOL (models: AA4203TF and AA4203TL), manufactured by STAAR Surgical.

**Payment Policy for Facility Services and Supplies**

The following applies to an IOL inserted following removal of a cataract in a hospital (on either an outpatient or inpatient basis) that is paid under 1) the hospital outpatient prospective payment system (OPPS) or 2) the inpatient prospective payment system (IPPS), respectively (or in a Medicare-approved ASC that is paid under the ASC fee schedule):

- Medicare does not make separate payment to the hospital or the ASC for an IOL inserted subsequent to extraction of a cataract. Payment for the IOL is packaged into the payment for the surgical cataract extraction/lens replacement procedure
- Any person or ASC, who presents or causes to be presented a bill or request for payment for an IOL inserted during or subsequent to cataract surgery for which payment is made under the ASC fee schedule, is subject to a civil money penalty.

For an A-C IOL inserted subsequent to removal of a cataract in a hospital (on either an outpatient or inpatient basis) that is paid under the OPPS or the IPPS, respectively (or in a Medicare-approved ASC that is paid under the ASC fee schedule):

- The facility should bill for removal of a cataract with insertion of a conventional IOL, regardless of whether a conventional or A-C IOL is inserted. When a beneficiary receives an A-C IOL following removal of a cataract, hospitals and ASCs should report the same CPT code that is used to report removal of a cataract with insertion of a conventional IOL (see “Coding” below)
- There is no Medicare benefit category that allows payment of facility charges for services and supplies required to insert and adjust an A-C IOL following removal of a cataract that exceed the facility charges for

services and supplies required for the insertion and adjustment of a conventional IOL

- There is no Medicare benefit category that allows payment of facility charges for subsequent treatments, services and supplies required to examine and monitor the beneficiary who receives an AC-IOL following removal of a cataract that exceed the facility charges for subsequent treatments, services, and supplies required to examine and monitor a beneficiary after cataract surgery followed by insertion of a conventional IOL.

**Payment Policy for Physician Services and Supplies**

For an IOL inserted following removal of a cataract in a physician’s office Medicare makes separate payment, based on reasonable charges, for an IOL inserted subsequent to extraction of a cataract that is performed at a physician’s office.

For an A-C IOL inserted following removal of a cataract in a physician’s office:

- A physician should bill for a conventional IOL, regardless of whether a conventional or A-C IOL is inserted (see “Coding,” below)
- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust an A-C IOL following removal of a cataract that exceed the physician charges for services and supplies for the insertion and adjustment of a conventional IOL
- There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, services, and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of an AC-IOL that exceed the physician charges for services and supplies to examine and monitor a beneficiary following removal of a cataract with insertion of a conventional IOL.

For an A-C IOL inserted following removal of a cataract in a hospital or ASC:

- A physician may not bill Medicare for the A-C IOL inserted during a cataract procedure performed in those settings because payment for the lens is included in the payment made to the facility for the entire procedure.
- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust an A-C IOL following removal of a cataract that exceed physician charges for

## ***Astigmatism-Correcting Intraocular Lens—CMS-1536 Ruling Implementation (continued)***

services and supplies required for the insertion of a conventional IOL.

- There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, services, and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of an A-C IOL that exceed the physician charges for services and supplies required to examine and monitor a beneficiary following cataract surgery with insertion of a conventional IOL.

### **Coding**

No new codes are being established at this time to identify an A-C IOL or procedures and services related to an A-C IOL, and hospitals, ASCs, and physicians should report one of the following CPT codes to bill Medicare for removal of a cataract with IOL insertion:

- 66982 *Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage*
- 66983 *Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure)*
- 66984 *Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification).*

Physicians inserting an IOL or an A-C IOL in an office setting may bill HCPCS code V2632 (posterior chamber intraocular lens) for the IOL or the A-C IOL, which is paid on a reasonable charge basis.

If appropriate, hospitals and physicians may use the proper CPT code(s) to bill Medicare for evaluation and management services usually associated with services following cataract extraction surgery, if appropriate.

### **Beneficiary Liability**

When a beneficiary requests insertion of an A-C IOL instead of a conventional IOL following removal of a cataract and that procedure is performed, the beneficiary is responsible for payment of facility charges for services and supplies attributable to the astigmatism-correcting functionality of the A-C IOL:

- In determining the beneficiary's liability, the facility and physician may take into account any additional work and resources required for insertion, fitting, vision acuity testing, and monitoring of the AC-IOL that exceeds the work and resources attributable to insertion of a conventional IOL.

- The physician and the facility may not charge for cataract extraction with insertion of an A-C IOL unless the beneficiary requests this service.
- The physician and the facility may not require the beneficiary to request an A-C IOL as a condition of performing a cataract extraction with IOL insertion.

### **Provider Notification Requirements**

When a beneficiary requests insertion of an A-C IOL instead of a conventional IOL following removal of a cataract:

- Prior to the procedure to remove a cataractous lens and insert an A-C IOL, the facility and the physician must inform the beneficiary that Medicare will not make payment for services that are specific to the insertion, adjustment, or other subsequent treatments related to the astigmatism-correcting functionality of the IOL
- The correcting functionality of an A-C IOL does not fall into a Medicare benefit category and, therefore, is not covered. Therefore, the facility and physician are not required to provide an advanced beneficiary notice to beneficiaries who request an A-C IOL
- Although not required, CMS strongly encourages facilities and physicians to issue a notice of exclusion from Medicare benefits to beneficiaries in order to identify clearly the non-payable aspects of an A-C IOL insertion. This notice may be found on the CMS Web site at:

For the English language version  
<http://www.cms.hhs.gov/BNI/downloads/CMS20007English.pdf>.

- For the Spanish language version  
<http://www.cms.hhs.gov/BNI/downloads/CMS20007Spanish.pdf>.

### **ADDITIONAL INFORMATION**

The official instruction, CR 5527, issued to your Medicare carrier, intermediary, and A/B MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1228CP.pdf>.

If you have any questions, please contact your Medicare carrier, intermediary, or A/B MAC at their toll-free number, which may be found on the CMS Web site 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: MM5527 – Revised  
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Implementation Date: May 29, 2007  
Source: CMS Pub. 100-04, Transmittal 1228, CR 5527

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## PSYCHOLOGICAL AND NEUROPSYCHOLOGICAL TESTS

*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 March 3, 2008, to reflect a revision made to change request (CR) 5204.

The article was changed to correct a reference in the first paragraph of the *Background* section to the section 1861(s)(2)(c) of the Social Security Act. The correct section number is 1861(s)(3). Also, the CR release date, transmittal number, and Web address for accessing CR 5204 were changed. All other information remains the same. The *MLN Matters* article MM5204 was published in the November 2006 *Medicare A Bulletin* (pages 11-12).

### PROVIDER TYPES AFFECTED

Providers who bill Medicare carriers or fiscal intermediaries (FIs) for the provision of diagnostic psychological and neuropsychological tests

### PROVIDER ACTION NEEDED

#### STOP – IMPACT TO YOU

Effective January 1, 2006, carriers and FIs will pay (under the Medicare physician fee schedule (MPFS) database) for diagnostic psychological and neuropsychological tests that are within the *CPT* code range of 96101 through 96120.

#### CAUTION – WHAT YOU NEED TO KNOW

The Centers for Medicare & Medicaid Services (CMS) announces the revision of the *CPT* codes for psychological and neuropsychological tests (codes 96101 through 96120) to include tests performed by technicians and computers (*CPT* codes 96102, 96103, 96119 and 96120) in addition to those performed by physicians, clinical psychologists, independently practicing psychologists and other qualified nonphysician practitioners (as described in *Background*, below).

#### GO – WHAT YOU NEED TO DO

Make sure that your billing staffs are aware of the *CPT* code changes.

### BACKGROUND

Medicare Part B coverage of psychological tests and neuropsychological tests is authorized under section 1861(s)(3) of the Social Security Act, and payment for these tests is authorized under section 1842(b)(2)(A) of the Social Security Act.

The *CPT* codes for these tests are included in the range of codes from 96101 to 96120. The appropriate codes when billing for psychological tests are: 96101, 96102, 96103, 96105, 96110, and 96111; and when billing for neuropsychological tests are: 96116, 96118, 96119 and 96120. All of the tests under this *CPT* code range 96101-96120 are covered and indicated as active codes under the MPFS database.

More specifically, CR 5204, from which this article is taken, provides that (effective January 1, 2006) the *CPT* codes for psychological and neuropsychological tests include tests performed by technicians and computers (*CPT* codes 96102, 96103, 96119 and 96120) in addition to tests performed by physicians, clinical psychologists, independently practicing psychologists and other qualified nonphysician practitioners.

These changes, made in accordance with the final physician fee schedule regulation, were published in the *Federal Register* on November 21, 2005, at 70 FR 70279 and 70280 under Table 29 (AMA, Relative Value Update Committee (RUC) and Health Care Professional Advisory

Committee (HCPAC) Recommendations and CMS Decisions for New and Revised 2006 *CPT* Codes).

You should be aware of some supervision requirements for diagnostic psychological and neuropsychological tests. First, under the diagnostic tests provision, all diagnostic tests are assigned a certain level of supervision. Generally, regulations governing the diagnostic tests provision allow only physicians to provide the assigned level of supervision for such tests; however, for diagnostic psychological and neuropsychological tests, there is a regulatory exception that allows either a clinical psychologist (CP) or a physician to perform the assigned general supervision.

Moreover, nonphysician practitioners such as nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs), who personally perform diagnostic psychological and neuropsychological tests are excluded from having to perform these tests under the supervision requirements of the diagnostic psychological and neuropsychological tests benefit, that is, under the general supervision of a physician or a CP.

In fact, rather than providing them under the requirements for diagnostic psychological and neuropsychological tests, NPs and CNSs must perform such tests under the requirements of their respective benefit. Therefore, NPs and CNSs must perform them in collaboration (as defined under Medicare law at section 1861(aa)(6) of the Act) with a physician. Likewise, PAs must perform these tests under the general supervision of a physician as required for services furnished under the PA benefit.

To continue, physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) are authorized to bill three test *CPT* codes (96105, 96110, and 96111) as "sometimes therapy" codes. However, when PTs, OTs and SLPs perform these three tests, they must do so under the general supervision of a physician or a CP.

You should also note that expenses for diagnostic psychological and neuropsychological tests are not subject to the outpatient mental health treatment limitation, which is the payment limitation on treatment services for mental, psychoneurotic and personality disorders as authorized under section 1833(c) of the Social Security Act. Further, the payment amounts that are billed for tests performed by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings.

Remember that CPs, NPs, CNSs and PAs are required by law to accept assigned payment for psychological and neuropsychological tests. And although independently practicing psychologists (IPPs) are not required to accept assigned payment for these tests, they must report the name and address of the physician who ordered the test on the claim form when billing for tests. (An IPP is any psychologist who is licensed (or certified) to practice psychology in the state or jurisdiction where furnishing services or, if the jurisdiction does not issue licenses, if provided by any

## **Psychological and Neuropsychological Tests (continued)**

practicing psychologist. Examples of psychologists (other than CPs) whose psychological and neuropsychological tests are covered under the diagnostic tests provision include, but are not limited to, educational psychologists and counseling psychologists.) Additionally, there is no authorization under Medicare law for payment for diagnostic tests when performed on an "incident to" basis.

Following is a summary of who may bill for diagnostic psychological and neuropsychological tests, and references for the review of qualifications, when appropriate.

### **Providers that May Bill for Diagnostic Psychological and Neuropsychological Tests**

#### **Clinical Psychologist**

See qualifications under chapter 15, section 160 of the *Medicare Benefits Policy Manual*.

**Nurse Practitioners** – to the extent authorized under state scope of practice.,

See qualifications under chapter 15, section 200 of the *Medicare Benefits Policy Manual*.

**Clinical Nurse Specialists** – to the extent authorized under state scope of practice.

See qualifications under chapter 15, section 210 of the *Medicare Benefits Policy Manual*.

**Physician Assistants** – to the extent authorized under state scope of practice.

#### **Independently Practicing Psychologists**

See qualifications under chapter 15, section 190 of the *Medicare Benefits Policy Manual*.

#### **Physical Therapists, Occupational Therapists and Speech-Language Pathologists**

See qualifications under chapter 15, sections 220-230.6 of the *Medicare Benefits Policy Manual*.

The *Medicare Benefits Policy Manual* is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage> on the CMS Web site.

#### **Here are some other important things that you should know:**

- The technician and computer CPT codes for psychological and neuropsychological tests include practice expense, malpractice expense and professional work relative value units. Therefore, CPT psychological test code 96101 will not be paid if you include it in the bill for the same tests or services performed under psychological test codes 96102 or 96103. Similarly, CPT neuropsychological test code 96118 will not be paid when included in the bill for the same tests or services performed under neuropsychological test codes 96119 or 96120. Note, however, CPT codes

96101 and 96118 can sometimes be paid separately, when billed on the same date of service for different and separate tests from 96102, 96103, 96119 and 96120.

- Under the MPFS, there is no payment for services performed by students or trainees. Accordingly, Medicare does not pay for services represented by CPT codes 96102 and 96119, when performed by a student or a trainee. However, the presence of a student or a trainee while the test is being administered does not prevent a physician, CP, IPP, NP, CNS or PA from performing and being paid for the psychological test under 96102 or the neuropsychological test under 96119.
- Fiscal intermediaries will continue to pay claims from providers of outpatient Part B therapy services (including physical therapy, occupational therapy, and speech-language pathology) for CPT codes 96105, 96110 and 96111 with revenue codes and corresponding therapy modifiers (42x with GP, 43x with GO, and 44x with GN, respectively).
- Finally, your carriers and fiscal intermediaries do not have to search their files to either retract payment for claims already paid, or to retroactively pay claims to January 1, 2006; they will adjust claims that you bring to their attention.

#### **ADDITIONAL INFORMATION**

You may find more information about psychological and neuropsychological tests by reading CR 5204, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R85BP.pdf>.

As an attachment to this CR, you will find updated relevant portions of Publication 100.02 (*Medicare Benefit Policy Manual*), chapter 15 (Covered Medical and Other Health Services), section 80.2 (Psychological Tests and Neuropsychological Tests).

If you have any questions, please contact your carrier or FI 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: MM5204 – Revised  
Related Change Request (CR) Number: 5204  
Related CR Release Date: February 29, 2008  
Related CR Transmittal Number: R85BP  
Effective Date: January 1, 2006  
Implementation Date: December 28, 2006

Source: CMS Pub. 100-02, Transmittal 55, CR 5204

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.

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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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## NEW LCD IMPLEMENTATION

### A51784: ANORECTAL MANOMETRY AND EMG OF THE URINARY AND ANAL SPHINCTERS—NEW LCD

This new local coverage determination (LCD) for anorectal manometry and EMG of the urinary and anal sphincters was developed to outline the indications and limitations for these diagnostic tests. Medical review of claims showed that providers were performing these diagnostic tests on a frequent basis for patients who were receiving “pelvic floor therapy” or “pelvic floor rehabilitation” for services that are more appropriately described by CPT code 90911 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry*) or for services that fall under the physical therapy benefit. This new LCD applies to CPT codes 51784 (*Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique*), 51785 (*Needle electromyography studies (EMG) of anal or urethral sphincter, any technique*) and 91122 (*Anorectal manometry*) and includes indications, limitations, utilization guidelines and documentation requirements. The LCD also outlines the ICD-9-CM codes that support medical necessity for CPT codes 51784/51785 and for CPT code 91122.

EMG of the anal or urinary sphincters (CPT code 51784 or 51785) are diagnostic tests that measure muscle activity and are used to assist in evaluating a diagnosis of fecal or urinary incontinence, dysfunctional elimination of the bowel and bladder and neurogenic bladder dysfunction leading to functional abnormalities of the muscular sphincter. Anorectal manometry (91122) is a diagnostic test that measures the anal sphincter pressures and provides assessment of rectal sensation, rectoanal reflexes and rectal compliance. It is used to help evaluate a diagnosis of fecal incontinence or anorectal elimination dysfunction.

#### EFFECTIVE DATE

This new LCD is effective for services provided **on or after June 30, 2008**. The full text of this LCD (L26914) is available through our provider education Web site <http://www.fcso.com>. ❖

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### A87181: SUSCEPTIBILITY STUDIES—NEW LCD

Susceptibility testing is performed by growing the pure bacterial isolate in the presence of varying concentrations of several antimicrobials and then examining the amount of growth to determine which antimicrobials at which concentrations inhibit the growth of the bacteria. If there is more than one pathogen, the laboratory will report results for each one. The test results of antimicrobial susceptibility testing should be combined with clinical information and experience when selecting the most appropriate antibiotic for the patient.

The new local coverage determination (LCD) for susceptibility studies was developed to define indications and limitations of coverage and/or medical necessity, documentation requirements, ICD-9-CM codes that support medical necessity, and coding guidelines for CPT codes 87181 through 87190. The diagnoses listed under the “ICD-9 Codes that Support Medical Necessity” section of the LCD represent payable diagnosis codes added by First Coast Service Options, Inc. (FCSO). In addition, diagnosis codes listed in the “Covered Code List” of the “CMS Medicare National Coverage Determinations (NCD), Section 190.12 – Urine Culture, Bacterial” that include CPT codes 87184 and 87186 are listed in the “Coding Guidelines” attachment of the LCD. These ICD-9-CM codes are also payable for CPT codes 87181 – 87190 when indicated.

#### EFFECTIVE DATE

This new LCD is effective for services provided **on or after June 30, 2008**. The full text of this LCD (L26916) is available through our provider education Web site <http://www.fcso.com>. ❖

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#### SIGN UP TO OUR eNEWS ELECTRONIC MAILING LIST

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.

## ADDITIONS/REVISIONS TO EXISTING LCDs

### AJ1561: INTRAVENOUS IMMUNE GLOBULIN—REVISION TO THE LCD

The local coverage determination (LCD) for intravenous immune globulin (IVIG) was last revised January 5, 2008. Since that time, the Centers for Medicare & Medicaid Services (CMS) issued change request 5980 (April Update to the 2008 Medicare Physician Fee Schedule Database [MPFSDB]), transmittal 1482, dated March 21, 2008, which included the addition of HCPCS code Q4097 (Injection, immune globulin (Privigen™), intravenous, non-lyophilized (e.g., liquid), 500 mg). Therefore, the LCD has been revised to include the addition of HCPCS code Q4097 to the “CPT/HCPCS Codes” section of the LCD.

#### EFFECTIVE DATE

This revision to the LCD is effective for claims processed **on or after April 7, 2008**, for services provided **on or after April 1, 2008**. The full text of this LCD (L1405) is available through our provider education Web site <http://www.fcso.com>. ❖

### AJ9310: RITUXIMAB (RITUXAN®)—REVISION TO THE LCD

The local coverage determination (LCD) for rituximab (Rituxan®) was last updated on January 24, 2008. Since that time, a revision was made to update language for approved indications based on the Food and Drug Administration (FDA) drug label, for rituximab – J9310.

Language was updated for Non-Hodgkin’s lymphoma, and a new indication concerning progression of structural damage was added to rheumatoid arthritis (RA) under the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD. The indication for RA now states Rituximab (Rituxan®) is FDA approved “*In combination with methotrexate to reduce signs and symptoms and to slow the progression of structural damage in adult patients with moderately-to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.*” In addition, the “Sources of Information and Basis for Decision” section of the LCD was updated, and drug information was added under the “Utilization Guidelines” section of the LCD.

#### EFFECTIVE DATE

This revision to the LCD is effective for services provided **on or after January 25, 2008**. The full text of this LCD (L25125) is available through our provider education Web site <http://www.fcso.com>. ❖

### ANCSVCS: THE LIST OF MEDICARE NONCOVERED SERVICES—REVISION TO THE LCD

The local coverage determination (LCD) for the list of Medicare noncovered services was last updated on February 29, 2008. Since that time, the LCD has been revised to add the following CPT codes to the list of procedures under the “CPT/HCPCS Codes,” “Local Noncoverage Decisions, Procedures” section of the LCD, as these procedures are considered experimental and investigational.

- 0042T *Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time*
- 0088T *Submucosal radiofrequency tissue volume reduction of tongue base, one or more sites, per session (ie, for treatment of obstructive sleep apnea syndrome)*
- 0170T *Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])*
- 0181T *Corneal hysteresis determination, by air impulse stimulation, bilateral, with interpretation and report*
- 64999 *Percutaneous neuromodulation using a percutaneous electrode array (PER) (eg, BioWave)*

In addition, CPT code 97799 (*Vertebral Axial Decompression/Intervertebral Differential Dynamics [IDD]*) has been added to the list of procedures under the “CPT/HCPCS Codes, ‘National Noncoverage Decisions, Procedures’ section of the LCD, as this procedure is also considered experimental and investigational.

Please note that CPT code 97799 (*Unlisted physical medicine/rehabilitation service or procedure*) for ‘vertebral axial decompression (VAX-D)/intervertebral differential dynamics (IDD)’ is performed for symptomatic relief of pain associated with lumbar disk problems. This treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, Medicare does not cover VAX-D (CMS Manual System, Pub. 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 2, Section 160.16, Vertebral Axial Decompression [VAX-D]).

## LOCAL COVERAGE DETERMINATIONS

### **ANCSVCS: The List of Medicare Noncovered Services (continued)**

Because this NCD specifically refers to a treatment which “combines pelvic and/or cervical traction connected to a special table that permits the traction application”, any similar device would fall under this category of a noncovered benefit. Therapeutic Tables (e.g., VAX-D, Decompression Reduction Stabilization (DRS) System, Accu-Spina System, DRX-3000, DRX9000, SpineMED Decompression Table, and Lordex Traction Unit) are used for this service and are motorized traction devices used to stretch the lower back.

#### **EFFECTIVE DATE**

This revision to the LCD is effective for services provided **on or after June 30, 2008**. The full text of this LCD (L24028) is available through our provider education Web site <http://www.fcso.com>. ❖

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### **AVISCO: VISCOSUPPLEMENTATION THERAPY FOR KNEE—REVISION TO THE LCD**

The local coverage determination (LCD) for viscosupplementation therapy for knee was last revised January 1, 2008. Since that time, it has come to the attention of First Coast Service Options, Inc. (FCSO) that the LCD required clarification regarding the number of allowable courses of treatment. Therefore, the statement located at the third bullet under the “Limitations” section of the LCD has been revised to indicate the following:

- If the first course of treatment produces relief, a subsequent course of treatment may be reasonable if symptoms return. A second course of treatment will be allowed six (6) months after the last injection of a previous course of treatment.

The revision of this verbiage clarifies the conditions under which a second course of treatment will be allowed. It is also intended to remove the impression that FCSO will allow multiple courses of treatment.

#### **EFFECTIVE DATE**

This revision to the LCD is effective for services provided **on or after March 20, 2008**. The full text of this LCD (L1600) is available through our provider education Web site <http://www.fcso.com>. ❖

## ADDITIONAL MEDICAL INFORMATION

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### **A77371: STEREOTACTIC RADIOSURGERY (SRS)—DRAFT LCD**

The draft local coverage determination (LCD) for stereotactic radiosurgery (SRS) was posted for comment on January 22, 2007. During the comment period, First Coast Services Options, Inc. (FCSO) received a large number of comments related to the coverage and coding of these services. Since that time, it has been determined that FCSO will not be finalizing this draft. A new draft LCD will be considered in the future. ❖

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### **AG0173: STEREOTACTIC BODY RADIATION THERAPY (SBRT)—DRAFT LCD**

The draft local coverage determination (LCD) for stereotactic body radiation therapy (SBRT) was posted for comment on January 22, 2007. During the comment period, First Coast Services Options, Inc. (FCSO) received a large number of comments related to the coverage and coding of these services. Since that time, it has been determined that FCSO will not be finalizing this draft. A new draft LCD will be considered in the future. ❖

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### **ATHERSVCS: THERAPY AND REHABILITATION SERVICES—REVISION TO THE CODING GUIDELINES**

The “Coding Guidelines” attachment for the therapy and rehabilitation services local coverage determination (LCD) was last revised on January 1, 2008. Since that time, the coding guideline has been revised. Language has been added based on change request 5717, transmittals 84 and 1470, dated February 29, 2008. This change request outlines updated audiology policies. Language regarding speech-language pathology services has been added according to the revised manual language for this change request. A complete discussion of the updated audiology policies may be found in Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80.3 and in Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 12, Section 30.3.

#### **EFFECTIVE DATE**

This revision to the “Coding Guidelines” attachment of the LCD is effective for claims processed **on or after April 7, 2008**, for services provided **on or after April 1, 2008**. The full text of this LCD (L1125) is available through our provider education Web site <http://www.fcso.com>. ❖



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## **ABOTULINUM TOXINS: BOTULINUM TOXINS—REVISION TO THE CODING GUIDELINES**

The “Coding Guidelines” attachment for the botulinum toxins local coverage determination (LCD) were last updated on May 11, 2006. Since that time, the “Other Comments” section of the “Coding Guidelines” attachment for this LCD has been revised to add the following language:

Botulinum toxins are best described as a family of toxins produced by the anaerobic organism *Clostridia botulinum*. There are seven distinct serotypes designated as type A, B, C-1, D, E, F and G. Each serotype is produced by a specific strain of clostridium botulinum. In this country two preparations of botulinum are available and they are manufactured from two different strains of bacteria: Type A (BOTOX®) is made from the Hall strain and has been used for more than two decades and, Type B (Myobloc®) is made from the bean strain and was approved by the FDA in December 2000.

Whether a botulinum toxin is produced from the same or a different serotype producing strain, they undergo different manufacturing processes that yield differences in the size and weight of the molecules. Because of this, botulinum toxin A and B, as well as other type A products available internationally, are not interchangeable. They are chemically, pharmacologically and clinically distinct.

Please note the FDA labeling in each product's package insert states: “Units of biological activity cannot be converted into units of any other botulinum toxin or any toxin assessed with any other specific assay method.”

### **EFFECTIVE DATE**

This revision to the “Coding Guidelines” attachment to the LCD is effective for services provided **on or after April 17, 2008**. The full text of this LCD (L1382) is available through our provider education Web site <http://www.fcso.com>. ❖

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## **AJ1440: G-CSF (FILGRASTIM, NEUPOGEN®): CLARIFICATION ON CORRECT ADMINISTRATION OF NEUPOGEN—REVISION TO ARTICLE**

First Coast Service Options, Inc. (FCSO) has discovered, through medical review and subsequent data analysis, that providers are inappropriately administering Neupogen (J1440 and J1441) to patients who are receiving a chemotherapeutic agent.

Neupogen is not a cancer chemotherapy agent. It is a class II hematopoietic growth factor that acts on progenitor cells. Because Neupogen acts only on progenitor cells that are already committed to one pathway, it increases only the neutrophil count. The local coverage determination (LCD) for Neupogen outlines the Food and Drug Administration (FDA)-approved indications and the off-label indications FCSO will cover when the medical necessity criteria are met.

Under the “limitations” section of the LCD, it is outlined that Neupogen should not be given within 24 hours before or after a dose of a chemotherapeutic agent, as rapidly dividing myeloid cells are potentially sensitive to these agents. This instruction is also outlined in the FDA approved label. This rule applies to any indication in the LCD that requires the administration of a chemotherapeutic agent.

An example of inappropriate administration found during medical review of claims shows that providers are administering Neupogen the day before, the day of and the day after chemotherapy administration. In the cases reviewed, patients received one injection of Neupogen less than 12 hours before chemotherapy, then received an injection immediately following chemotherapy infusion and received a Neupogen injection, the next day, less than 12 hours after the chemotherapy infusion.

FCSO would like to reiterate to providers that the continued practice of inappropriate administration of Neupogen may lead to medical review. FCSO does not expect to see Neupogen billed the day before, the day of or the day after chemotherapy administration. If providers bill Neupogen the day before or the day after chemotherapy administration, the medical record must show that Neupogen was not given less than 24 hours before and/or less than 24 hours after chemotherapy and that this requirement is documented in the medical record. Claims that cannot support this requirement may be denied as not medically necessary.

FCSO strongly encourages providers to review the current LCD for Neupogen to ensure their patients meet the coverage criteria outlined for each indication and that all other documentation and utilization requirements are met. The LCD can be located on our Web site at <http://www.fcso.com>. Questions regarding coverage or the appropriate administration of Neupogen may be forwarded to [medical.policy@fcso.com](mailto:medical.policy@fcso.com). Providers who feel the language in the LCD is not appropriate may refer to FCSO's reconsideration process located on our Web site. ❖

## HOSPITAL SERVICES

### EXTENSION OF REASONABLE COST PAYMENT FOR CLINICAL LABORATORY TESTS FURNISHED BY HOSPITALS WITH FEWER THAN 50 BEDS IN QUALIFIED RURAL AREAS

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

#### PROVIDER TYPES AFFECTED

Hospitals with fewer than 50 beds in qualified rural areas submitting claims to Medicare contractors (fiscal intermediaries [FIs] or Part A/B Medicare administrative contractors [A/B MACs]) for outpatient clinical laboratory tests provided to Medicare beneficiaries.

#### IMPACT ON PROVIDERS

This article is based on change request (CR) 5961 which instructs that payment for outpatient clinical laboratory tests to hospitals (with fewer than 50 beds in qualified rural areas) will be made on a reasonable cost basis for cost reporting periods beginning on or after July 1, 2004 through June 30, 2008. Currently, section 107 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 extends reasonable cost payment for clinical laboratory tests performed by hospitals with fewer than 50 beds in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2004 through June 30, 2008. Thus, this can apply to services performed as late as June 30, 2009, depending upon the provider's cost reporting period.

- Providers should note that Medicare contractors will adjust any claims that were not previously paid according to reasonable cost, but should have been paid as such, per section 107 of the Medicare, Medicaid and SCHIP Extension Act of 2007.
- Beneficiaries are not liable for any deductible, coinsurance, or any other cost-sharing amount.

#### BACKGROUND

A provision in Section 416 of the Medicare Modernization Act (MMA) of 2003 provided for payment on a reasonable cost basis for outpatient clinical laboratory tests to hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning during the two-year period beginning on July 1, 2004. At that time the Centers for Medicare & Medicaid Services (CMS) issued CR 3301 on February 13, 2004, to implement procedures to provide for such payment.

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.

Based on section 105 of the Tax Relief and Health Care Act (TRHCA) of 2006, CMS issued CR 5493, on February 2, 2007, to extend the two-year provision outlined within CR 3301 for an additional cost-reporting year. Because CR 5493 was implemented beyond the original sun-setting date outlined in CR 3301, Medicare contractors were instructed to adjust any claims for laboratory services that should have received reasonable cost payment under TRHCA. You may review the MLN Matters article related to CR 5493 on the CMS Web site at

<http://www.cms.hhs.gov/MLNMattersArticles/Downloads/mm5493.pdf>.

#### ADDITIONAL INFORMATION

To see the official instruction (CR 5961) issued to your Medicare FI or A/B MAC, refer to the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R3300TN.pdf>.

If you have questions, please contact your Medicare 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: MM5961

Related Change Request (CR) Number: 5961

Related CR Release Date: April 4, 2008

Related CR Transmittal Number: R3300TN

Effective Date: Cost report periods beginning July 1, 2007 through June 30, 2008

Implementation Date: July 7, 2008

Source: CMS Pub. 100-20, Transmittal 330, CR 5961

## HEMOPHILIA CLOTTING FACTOR—NEW HCPCS CODE Q4096

Effective for claims with dates of service on or after April 1, 2008, the following new Health Care Procedure Code System (HCPCS) 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. The earliest FISS can make the changes is the October 2008 quarterly release. Until then, CMS is asking providers to omit HCPCS code Q4096 from the inpatient hospital claims. Once the 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 October 6, 2008.

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 October 6, 2008, will be returned to the provider (RTP). ❖

Source: CMS JSM 08264, April 7, 2008

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**HOSPITAL OUTPATIENT  
PROSPECTIVE PAYMENT SYSTEM**

**APRIL 2008 INTEGRATED OUTPATIENT CODE EDITOR SPECIFICATIONS VERSION 9.1**

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

**PROVIDER TYPES AFFECTED**

All providers who submit institutional outpatient claims (including non-OPPS hospitals) to Medicare administrative contractors (A/B MACs), fiscal intermediaries (FIs), or regional home health intermediaries (RHHIs) for services provided to Medicare beneficiaries.

**IMPACT ON PROVIDERS**

This article is based on change request (CR) 5969 and notifies providers that integrated outpatient code editor (I/OCE) specifications version 9.1, is effective April 1, 2008. Claims with dates of service prior to July 1, 2007 are routed through the non-integrated versions of the outpatient code editor (OCE) software that coincide with the versions in effect for the date of service on the claim.

**BACKGROUND**

This article is based on CR 5969 and informs providers that the I/OCE routes all institutional outpatient claims (including non-outpatient prospective payment system hospital claims) through a single integrated OCE eliminating the need to update, install, and maintain two separate OCE software packages on a quarterly basis. **This integration does not change the current logic that is applied to outpatient bill types that already pass through the outpatient prospective payment system (OPPS) OCE software.** It expands the software usage to include non-OPPS hospitals. The full specifications for the I/OCE as well as detailed lists of the APC (ambulatory payment classifications), HCPCS (Health Care Common Procedure Coding Systems), CPT (*Current Procedural Terminology*) code changes, additions, and deletions are attached to CR 5969. The Web address for accessing CR 5969 is in the *Additional Information* section of this article. Thus, we will not repeat all of those changes in this article. However, the key changes in the version 9.1 of I/OCE are as follows:

| Effective Date | Edit                 | Description of Change  |
|----------------|----------------------|--|
| 4/1/08         | 24                   | Modify the software to maintain/retain 28 prior quarters (7 years) of programs & codes in each release. Remove older versions with each release.<br><br>(The earliest version date included in the April 2008 release will be 1/1/01). |
| 4/1/08         |                      | Modify appendix D of I/OCE Specifications (attached to CR 5969) to exempt codes with SI of "S" and "X" from the conditional bilateral discounting.   |
| 1/1/08         |                      | Change HCPCS APC to "0" in the APC/ASC Return Buffer for all PH services on PHP claims.  |
| 4/1/02         |                      | Add code 29086 to the list of cast procedures (code list for Antigens, splints & Casts)  |
| 1/1/08         |                      | Modify/correct list of codes identified as partial hospitalization services for PHP claims   |
| 1/1/08         |                      | Bypass edit 48 for rev code 0637. Assign edit 50 when submitted without a HCPCS code. Apply to OPPS & Non-OPPS claims.   |
|                |                      | Make HCPCS/APC/SI changes as specified by CMS  |
|                | 19,<br>20,<br>39, 40 | Implement version 14.0 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).                                     |
| 1/1/07         | 22                   | Add new (genetic testing) modifier (8C) to the valid modifier list.  |
|                |                      | Modify description of PHP code lists in appendix C – to include all PH services in list B, and make list A a subset of list B.   |
| 1/1/08         | 78                   | Update nuclear medicine/radiopharmaceutical edit requirements.   |
| 1/1/08         | 71                   | Update procedure/device edit requirements.   |
| 1/1/08         |                      | Remove ASC procedure list – no longer needed to identify claims to be processed as 83x TOB.  |
|                |                      | Added explanatory paragraphs, re antigens/splints/casts & CCI editing to the specifications document. Add appendix N, for requested code listings.   |

## April 2008 Integrated Outpatient Code Editor Specifications Version 9.1 (continued)

### ADDITIONAL INFORMATION

For complete details regarding this CR please see the official instruction (CR 5969) issued to your Medicare FI, A/B MAC, or RHHI. That instruction may be viewed by going to the Centers for Medicare & Medicaid Services (CMS) Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1483CP.pdf>.

To review the OCE Web site you may refer to the CMS Web site at <http://www.cms.hhs.gov/OutpatientCodeEdit/>.

If you have questions, please contact your Medicare FI, A/B MAC, or RHHI 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: MM5969

Related Change Request (CR) Number: 5969

Related CR Release Date: March 25, 2008

Related CR Transmittal Number: R1483CP

Effective Date: April 1, 2008

Implementation Date: April 7, 2008

Source: CMS Pub. 100-04, Transmittal 1483, CR 5969

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## APRIL 2008 UPDATE OF 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 and suppliers 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 paid under the OPSS provided to Medicare beneficiaries.

### PROVIDER ACTION NEEDED

#### STOP – IMPACT TO YOU

This article is based on change request (CR) 5999, which describes changes to, and billing instructions for various payment policies implemented in the April 2008 hospital outpatient prospective payment system (OPSS) update.

#### CAUTION – WHAT YOU NEED TO KNOW

CR 5999 announces that the April 2008 integrated code editor (I/OCE) and OPSS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), ambulatory payment classification (APC), HCPCS modifier, and revenue code additions, changes, and deletions. The specific I/OCE updates for April 2008 are in CR 5969.

#### GO – WHAT YOU NEED TO DO

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

### BACKGROUND

CR 5999 describes changes to, and billing instructions for various payment policies implemented in the April 2008 OPSS update. The April 2008 I/OCE and OPSS 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.

April 2008 revisions to I/OCE data files, instructions, and specifications are provided in CR 5969, "April 2008 Integrated Outpatient Code Editor (I/OCE) Specifications Version 9.1". A related *MLN Matters* article is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5969.pdf>.

The key OPSS changes are as follows:

#### 1. Changes to Procedure to Device Edits for April 2008

Procedures to device edits require 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. CMS deleted the procedure to device edits for *Current Procedural Terminology (CPT)* code 36815, retroactive to their original implementation date of 10/1/2005. The complete list of updated edits may be found under downloads on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

#### 2. Modification of Methodology for Calculation of Hospital Overall Cost-to-Charge Ratio for Hospitals that Have Nursing and Paramedical Education Programs

CMS is updating Section 10.11.8 of the *Medicare Claims Processing Manual*, chapter 4, to further refine the methodology of the calculation of the hospital overall cost-to-charge ratio (CCR) for hospitals that have nursing and paramedical education programs. Specifically, the instructions for calculating the CCR for cost center 6200 (non-distinct unit observation beds) are being modified. This is a prospective change that is effective April 1, 2008. It is unnecessary to retroactively re-calculate CCRs that are affected by CR 5999.

## April 2008 Update of the Hospital Outpatient Prospective Payment System (continued)

### 3. 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 OPSS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug HCPCS code (J9999 or J3490). In these situations, CMS reminds hospitals 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 FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.

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

In the calendar year (CY) 2008 OPSS 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, we will incorporate changes to the payment rates in the April 2008 release of the OPSS PRICER. The updated payment rates effective April 1, 2008, will be included in the April 2008 update of the OPSS addendum A and addendum B, which will be posted on the CMS Web site at the end of March.

#### b. Drugs and Biologicals with OPSS Pass-Through Status Effective April 1, 2008

Four drugs have been granted OPSS pass-through status effective April 1, 2008. These drugs, their descriptors and APC assignments are identified in the Table 1 below.

**Table 1 – Drugs and Biologicals with OPSS Pass-Through Status Effective April 1, 2008**

| HCPCS Code | Long Descriptor                         | APC  | Status Indicator Effective 4/1/08 |
|------------|---|------|-----------------------------------|
| C9241      | Injection, doripenem, 10 mg             | 9241 | G                                 |
| C9240      | Injection, ixabepilone, 1 mg            | 9240 | G                                 |
| C9238      | Injection, levetiracetam, 10 mg         | 9238 | G                                 |
| J9226      | Histrelin implant (Supprelin La), 50 mg | 1142 | G                                 |

#### c. New HCPCS Codes for Drugs and Biologicals Effective April 1, 2008

Three new HCPCS codes have been created effective April 1, 2008. These new HCPCS codes, their descriptors, OPSS status indicators and APC assignments are listed in Table 2 below.

**Table 2 – New HCPCS Codes for Drugs and Biologicals Effective April 1, 2008**

| HCPCS Code | Long Descriptor  | APC  | Status Indicator |
|------------|--|------|------------------|
| Q4096      | Injection, von Willebrand factor complex, human, ristocetin cofactor (not otherwise specified), per I.U. VWF:RCO | 1213 | K                |
| Q4097      | Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg                       | 1214 | K                |
| Q4098      | Injection, iron dextran, 50 mg   | 1215 | K                |

#### d. Revised Long and Short HCPCS Code Descriptors for Cardiac Echocardiography Services:

- **Cardiac Echocardiography With Contrast**

In the January 2008 Update to the OPSS (CR 5912, dated January 18, 2008; see related *MLN Matters* article on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5912.pdf>), CMS listed eight new C-codes in Table 14 of CR 5912 for cardiac echocardiography with contrast services. To ensure appropriate reporting of these services, CMS revised the short and long descriptors for C8921 through C8928, which are reflected in Table 3 below, to appropriately reflect those services that either use contrast or are performed without contrast followed by with contrast. Hospitals are reminded that these codes should be reported for echocardiograms with contrast, and hospitals are advised to report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms. The contrast HCPCS Q-codes associated with these services should be reported separately.

April 2008 Update of the Hospital Outpatient Prospective Payment System (continued)

**Table 3 – Revised Long and Short HCPCS Code Descriptors for Cardiac Echocardiography Services**

| HCPCS Codes | Revised Short Descriptor     | Revised Long Descriptor  |
|-------------|------------------------------|--|
| C8921       | TTE w or w/o fol w/cont, com | Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete  |
| C8922       | TTE w or w/o fol w/cont, f/u | Transthoracic echocardiography with contrast, or without contrast followed by with contrast; follow-up or limited study  |
| C8923       | 2D TTE w or w/o fol w/con,co | Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d) with or without m-mode recording; complete  |
| C8924       | 2D TTE w or w/o fol w/con,fu | Transthoracic echocardiography with contrast, or without contrast followed by with contrast, material real-time with image documentation (2d) with or without m-mode recording; follow-up or limited study   |
| C8925       | 2D TEE w or w/o fol w/con,in | Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, real time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report   |
| C8926       | TEE w or w/o fol w/cont,cong | Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report   |
| C8927       | TEE w or w/o fol w/cont, mon | Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis |
| C8928       | TEE w or w/o fol w/con,stres | Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), with or without m-mode recording, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report   |

**• Cardiac Echocardiography Without Contrast**

Hospitals are reminded to bill for echocardiograms without contrast in accordance with the CPT code descriptors and guidelines associated with the applicable Level I CPT code(s) (93303-93350).

**e. Recognition of Multiple HCPCS Codes for Drugs**

Prior to January 1, 2008, the OPPS generally recognized only the lowest available administrative dose of a drug if multiple HCPCS codes existed for the drug; for the remainder of the doses, the OPPS assigned a status indicator “B” indicating that another code existed for OPPS purposes. For example, if drug X has two HCPCS codes, the first for a 1 ml dose and a second for a 5 ml dose, the OPPS would assign a payable status indicator to the 1 ml dose and status indicator “B” to the 5 ml dose. Hospitals then were required to bill the appropriate number of units for the 1 ml dose in order to receive payment under the OPPS. However, beginning January 1, 2008, the OPPS has recognized each HCPCS code for a Part B drug, regardless of the units identified in the drug descriptor. Hospitals may choose to report multiple HCPCS codes for a single drug, or to continue billing the HCPCS code with the lowest dosage descriptor available.

**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

## April 2008 Update of the Hospital Outpatient Prospective Payment System (continued)

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 1 vial 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.

### 4. HCPCS Code G0377

HCPCS code G0377 (Administration of vaccine for Part D drug) that was in effect for 2007 is discontinued for CY 2008. The April 2008 OCE will implement this change effective January 1, 2008. Hospitals should no longer be reporting this service under OPSS, as this service is covered under the Part D benefit beginning in 2008.

### 5. Use of HCPCS Modifiers

CMS updated the *Medicare Claims Processing Manual*, chapter 4, section 20.6 to reflect the addition of HCPCS modifiers **FB** and **FC** effective, January 1, 2007, and January 1, 2008, respectively. CMS added section 20.6.10, which includes the definition of the modifier **FC** ("Partial credit received for replaced device"). This manual revision is attached to CR 5999. OPSS hospitals must report the modifier **FC** for cases in which the hospital receives a partial credit of 50 percent or more of the cost of a new replacement device under warranty, recall, or field action. The hospital must append the modifier **FC** to the procedure code (not the device code) that reports the services provided to replace the device.

### 6. Clarification of HCPCS Code to Revenue Code Reporting

CMS updated the *Medicare Claims Processing Manual*, chapter 4, section 20.5 to reflect that, generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPSS since hospitals' assignments of costs vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report. Previous language providing guidance on HCPCS code and revenue code billing was deleted.

### 7. Clarification of Manual Instructions Regarding Billing and Payment for Blood and Blood Products Under the OPSS

CMS updated the *Medicare Claims Processing Manual*, chapter 4, section 231 to provide important clarifications regarding billing for blood and blood products. In

section 231.2, CMS specifies that the requirement that the same line item date of service, the same number of units, the same HCPCS code, and HCPCS modifier **BL** must be reported on **both** lines, applies to all OPSS providers that transfuse blood. CMS also clarifies that, in order to ensure correct application of the Medicare blood deductible, providers should report charges for whole units of packed red cells using revenue code 381 (Packed red cells), and should report charges for whole units of whole blood using revenue code 382 (Whole blood). Revenue codes 381 and 382 should be used only to report charges for packed red cells and whole blood, respectively. The blood coding requirements discussed in section 231.2 do not apply to blood and blood products carrying only a processing and storage fee; when billing only for blood processing and storage, OPSS providers should follow the coding requirements outlined in section 231.1. Revenue code 380 is not a valid revenue code for Medicare billing.

In a revised section 231.4, chapter 4 of the *Medicare Claims Processing Manual*, CMS clarifies that providers should bill split units of packed red cells and whole blood using revenue code 389 (Other blood), and should not use revenue codes 381 (Packed red cells) or 382 (Whole blood). Providers should bill split units of other blood products using the applicable revenue codes for the blood product type, such as 383 (Plasma) or 384 (Platelets), rather than 389. Reporting revenue codes according to these specifications will ensure the Medicare beneficiary's blood deductible is applied correctly. In revised Section 231.6, CMS provides a chart of blood and blood products indicating whether providers should bill separately for freezing and thawing using the available *CPT* codes.

In revised section 231.7 of chapter 4, CMS specifies that where blood or a blood product is split or irradiated specifically with the intent of transfusion to a beneficiary but is not then used, the hospital may bill for the services of splitting or irradiating the unit of blood but may not bill for the HCPCS code for the blood product that was not transfused. The date of service must be the date on which the decision not to use the blood was made and indicated in the patient's medical record. Where the unit of blood is split or irradiated and stored without specific intention to administer it to a Medicare beneficiary at the time of splitting or irradiation and is not subsequently transfused, there is no service to be reported.

All of the revised sections referenced above are attached to CR 5999.

### 8. Outpatient Partial Hospitalization Program Services

With CR 5999, CMS is updating the *Medicare Claims Processing Manual*, chapter 4, sections 260.1 and 260.1.1 to reflect the current policies for outpatient partial hospitalization program services. Once again, the revised manual section is attached to CR 5999.



## April 2008 Update of the Hospital Outpatient Prospective Payment System (continued)

### 9. Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPSS 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 and Medicare administrative contractors determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, FIs 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 5999, 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/R1487CP.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: MM5999

Related Change Request (CR) Number: 5999

Related CR Release Date: April 8, 2008

Related CR Transmittal Number: R1487CP

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Implementation Date: April 7, 2008

Source: CMS Pub. 100-04, Transmittal 1487, CR 5999

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**EDUCATIONAL EVENTS**

**UPCOMING PROVIDER OUTREACH AND EDUCATION EVENTS**

**MAY 2008 – JULY 2008**

**Hot Topics – Medicare Updates**

When: Tuesday, May 13, 2008  
Time: 11:30 a.m. – 12:30 p.m. Eastern Standard Time  
Type of Event: Teleconference

**Ask the Contractor – Topic: Overview of the New Medicare Competitive Bidding Program for DMEPOS**

When: Tuesday, June 10, 2008  
Time: 11:00 a.m. – 1:00 p.m. Eastern Standard Time  
Type of Event: Teleconference

**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

**TWO EASY WAYS TO REGISTER**

**ONLINE** – Log on to your account on our provider training Web site at [www.fcsomedicaretraining.com](http://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](http://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](http://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](http://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](mailto: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

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### OUTPATIENT MAINTENANCE DIALYSIS—END-STAGE RENAL DISEASE FACT SHEET

The *Outpatient Maintenance Dialysis – End-Stage Renal Disease Fact Sheet*, which provides general information about outpatient maintenance dialysis for end-stage renal disease, the composite payment rate system, and separately billable items and services, is now available in downloadable format from the Centers for Medicare & Medicaid Services *Medicare Learning Network* at <http://www.cms.hhs.gov/MLNProducts/downloads/ESRDpaymfctsh08-508.pdf>.

Visit the Medicare Learning Network - It's Free! ❖

Source: CMS Provider Education Resource 200804-04

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### AMBULANCE FEE SCHEDULE FACT SHEET NOW AVAILABLE

The *Ambulance Fee Schedule Fact Sheet*, which provides general information about the ambulance fee schedule, 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 200803-14

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### MEDICARE PHYSICIAN FEE SCHEDULE FACT SHEET NOW AVAILABLE

The revised *Medicare Physician Fee Schedule Fact Sheet* (January 2008), which provides general information about the Medicare physician fee schedule, 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 200803-13

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### CMS ONLINE MANUAL SYSTEM BROCHURE UPDATED

The *CMS Online Manual System: A Web-based Manual System for Medicare Contractors, Providers and State Agencies* brochure has been updated and is now available to order print copies or to download as a PDF file. This brochure explains how to navigate the CMS Online Manual System. To view the PDF file, go to <http://www.cms.hhs.gov/MLNProducts/downloads/on-linebrochure.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](http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5). ❖

Source: CMS Provider Education Resource 200804-09

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### CLINICAL LABORATORY FEE SCHEDULE FACT SHEET NOW AVAILABLE

The *Clinical Laboratory Fee Schedule Fact Sheet*, which provides general information about the clinical laboratory fee schedule, coverage of clinical laboratory services, and how payment rates are set, is now available in downloadable format from the Centers for Medicare & Medicaid Services *Medicare Learning Network* at [http://www.cms.hhs.gov/MLNProducts/downloads/clinical\\_lab\\_fee\\_schedule\\_fact\\_sheet.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/clinical_lab_fee_schedule_fact_sheet.pdf). ❖

Source: CMS Provider Education Resource 200804-06

### MEDICARE LEARNING NETWORK BOOKMARK NOW AVAILABLE

The MLN bookmark lists: the topics covered by the educational products and services of the MLN, the various product types available to the learner, as well as the Web address for the MLN. This product is appropriate for distribution at health care professional conferences, provider outreach and education activities and other appropriate types of provider/supplier events.

The MLN bookmark is available for download on the CMS Web site at <http://www.cms.hhs.gov/MLNProducts/downloads/MLNBookmrk-006960.pdf>.

You can also order hard copies of the bookmark through the MLN Product Ordering page on the Web at [http://cms.meridianksi.com/kc/main/kc\\_frame.asp?kc\\_ident=kc0001&loc=5](http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5).

A version of the MLN bookmark is also available for distribution to Indian health care professionals. To view this bookmark, go to <http://www.cms.hhs.gov/MLNProducts/downloads/MLN-AIANBookmrk006954.pdf> or to order hard copies go to [http://cms.meridianksi.com/kc/main/kc\\_frame.asp?kc\\_ident=kc0001&loc=5](http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5) on the Web. ❖

Source: CMS Provider Education Resource 200804-14

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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](http://www.floridamedicare.com)

#### **Centers for Medicare & Medicaid Services**

[www.cms.hhs.gov](http://www.cms.hhs.gov)

### **BENEFICIARIES**

#### **Centers for Medicare & Medicaid Services**

[www.medicare.gov](http://www.medicare.gov)



WHEN EXPERIENCE COUNTS & QUALITY MATTERS

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