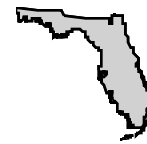


# Medicare A Bulletin

A Newsletter for Florida Medicare Part A Providers



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**T**he 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 website at [www.floridamedicare.com](http://www.floridamedicare.com).

#### Routing Suggestions :

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



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**Medicare A  
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The *Medicare A Bulletin* is published monthly by First Coast Service Options, Inc. Provider Outreach and Education division, to provide timely and useful information to Medicare Part A providers in Florida.

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

**Medicare Publications  
1-904-357-6702**

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## Have You Visited the FCSO Web Site Lately?

In response to feedback we received from you, our valued customers, we recently completed a redesign of the Florida and Connecticut Medicare Web sites. If you haven't visited our Web sites lately, here are some of the things you have missed, hot off the presses!

- A quick 15-second animation that shows you all the latest tips and tools at your disposal to help successfully complete the CMS-855 form (Provider Enrollment Application).
- Information about the latest enhancements and user tools for the provider automated customer service telephone lines.
- The latest list of final Local Coverage Determinations (LCDs).
- The latest information on the National Provider Identifier (NPI).

This information and much more are just a few clicks away! "You can access the Florida or Connecticut Medicare provider Web sites anytime by going to [www.fcsso.com](http://www.fcsso.com). Once there, select the Medicare Provider's pull-down menu and click on the Florida Part A or B." ❖

## 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  
1-904-357-6702

# PROVIDER ENROLLMENT

## New Extended Service Telephone Line Available

First Coast Service Options, Inc. strives to provide you, our customers, quick access to information and service to help you better manage your work. In keeping with our continuous service improvements, we are proud to announce a new extended service line to our providers is now available.

The extended service line will deliver comprehensive service specific to inquiries related to provider enrollment and debt collection activities. Representatives delivering service on this line receive extensive training and certification to ensure they can provide comprehensive support for non-general enrollment and debt collection inquiries.

### How Does It Work?

- Call FCSO's customer service toll-free line for assistance on all inquiries.
  - ♦ Part A – 1-888-664-4112
  - ♦ Part B – 1-866-454-9007
- When the FCSO representative determines your provider enrollment or debt collection issue requires more in-depth research and assistance, he or she will provide the new toll-free number for the extended service line and assign a referral number.
- Call the toll-free number and supply the assigned referral number.
- You work directly with a representative from the appropriate operational area within FCSO to resolve your issue.
- Hours of operation for the new extended service line are Monday – Friday (excluding holidays), 9 a.m. – 4 p.m. ET, closed for lunch from noon – 1 p.m.

### Once I Have the New Number, Can I Call the Extended Service Line Directly?

**No.** You must first contact FCSO through our general inquiries toll-free number to obtain the required referral number. The majority of inquiries can be managed through the general inquiries lines. This enables us to deliver the appropriate level of service to all customers, with only those that are more extensive in nature being referred to the extended service line.

### What Is Considered a General Enrollment or Debt Collection Inquiry?

Typically, a general enrollment inquiry would include such questions as:

1. What form to use when filling an enrollment application.
2. The Web site that provides information on how to file an application.
3. The status of a pending application.
4. General questions on Medicare participation and open enrollment.
5. General time frames for filing an application.
6. General questions regarding why an application was returned or rejected, including clarification on any development letters that a provider might have received.

General questions related to debt collection would include:

1. How to refund an overpayment to Medicare and the applicable form to use.
2. General questions about a demand letter that a provider received.
3. General questions regarding a HPSA check.
4. General questions related to a financial offset.

Because the Medicare customer service area can generally handle the majority of questions related to enrollment and debt collection, you are required to call the 1-888-664-4112 Part A service line and/or the 1-866-454-9007 Part B service line, before calling the extended service telephone number.

### What Will Happen if I Call the Extended Service Line Without a Referral Number?

We will redirect callers without a referral number to the appropriate general inquiries toll-free number. This ensures the specially trained representatives who support the extended service line focus their time and attention on those inquiries that require their level of expertise and knowledge. ❖

### 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 email notification when new or updated information is posted to the provider education Web site <http://www.floridamedicare.com>. It's very easy to do. Simply go to the Web site, click on the "eNews" link on the navigational menu and follow the prompts.



# GENERAL INFORMATION

## October 2007 Quarterly Average Sales Price Medicare Part B Drug Pricing File Update and Revisions to Prior Pricing Files

*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, durable medical equipment 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) 5710, which informs Medicare providers of the availability of the October 2007 average sales price (ASP) drug pricing file for Medicare Part B drugs as well as the revised January 2007, April 2007, July 2007 and October 2006 ASP payment files (**if the Centers for Medicare & Medicaid Services [CMS] determines that revisions are necessary to the latter files**). CR 5710 also advises Medicare providers that ASP not otherwise classified (NOC) files will be available for retrieval from the CMS ASP Web page as well as the revised January 2007, April 2007, July 2007 and October 2006 ASP NOC files (**if CMS determines that revisions are necessary to the latter files**). Providers should make certain that your billing staffs are aware of these changes.

### Background

The Medicare Modernization Act of 2003 (MMA; Section 303[c]) revised the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. Starting January 1, 2005, many of the 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 is performed by the local Medicare contractor. Additionally, beginning in 2006, all end-stage renal disease (ESRD) drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the outpatient prospective payment system (OPPS), will be paid based on the ASP methodology.

The ASP methodology is based on quarterly data submitted to the CMS by manufacturers, and CMS supplies Medicare contractors (carriers, DME MACs, FIs, A/B MACs, and/or RHHIs) with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. CMS also posts these files to its Web site at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>.

As announced in late 2006, CMS has been working further to ensure that more accurate and, as appropriate, separate payment is made for single source drugs and biologicals under Section 1847A of the Social Security Act. As part of this effort, CMS reviewed how the terms “single

source drug,” “multiple source drug,” and “biological product” are made operational in the context of payment under section 1847A. For the purposes of identifying “single source drugs” and “biological products” subject to payment under section 1847A, generally CMS (and its contractors) will use a multi-step process. CMS will consider:

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

For a biological product (as evidenced by a new FDA biologic license application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent *FDA Orange Book*) first sold in the United States after October 1, 2003, the payment limit under Section 1847A for that biological product or single source drug will be based on the pricing information for products produced or distributed under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may also be made operational through use of existing specific HCPCS codes or NOC HCPCS codes.

**For 2007, a separate fee of \$0.152 per international unit (I.U.) of blood-clotting factor furnished is payable when a separate payment for the blood clotting factor is made. The furnishing fee will be included in the payment amounts on the quarterly ASP pricing files.**

### Average Sale Price 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. 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), and
- Specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS.

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 will be updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department

*October 2007 Quarterly Average Sales Price Medicare Part B Drug Pricing File Update and Revisions to ... (continued)*

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 were not updated in 2007.** Payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment (DME) 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 and, then, is paid at reasonable cost.
- The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B drug pricing file or NOC pricing file, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the FDA, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPSS where the payment allowance limit is 95 percent of the published 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.
- 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 that were first sold on or after January 1, 2005.
- The payment allowance limits for radiopharmaceuticals are not subject to ASP. Medicare contractors determine payment limits for radiopharmaceuticals based on the methodology in place in 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 September 18, 2007, the October 2007 ASP file will be available for download from the CMS ASP Web site. If CMS determines that revisions are needed to the January 2007, April 2007, July 2007, and October 2006 ASP payment files, those revised files will also be available for retrieval from the CMS ASP Web page. The payment limits included in the revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document. The CMS ASP Web page is located at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>.

These quarterly files are applicable to claims based on dates of service as shown in the following table:

<b>Payment Allowance Limit Revision Date</b>	<b>Applicable Dates of Service for Claims Processed or Reprocessed on or after October 1, 2007</b>
October 2006	October 1, 2006 through December 31, 2006
January 2007	January 1, 2007 through March 31, 2007
April 2007	April 1, 2007 through June 30, 2007
July 2007	July 1, 2007 through September 30, 2007
October 2007	October 1, 2007 through December 31, 2007

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

**Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir**

Physicians (or a practitioner described in the Social Security Act (Section 1842(b) (18) (C); [http://www.ssa.gov/OP\\_Home/ssact/title18/1842.htm](http://www.ssa.gov/OP_Home/ssact/title18/1842.htm)) 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.

October 2007 Quarterly Average Sales Price Medicare Part B Drug Pricing Files Update and Revisions to ... (continued)

### Additional Information

CR 5710 is the official instruction issued to your Medicare carrier, FI, A/B MAC, DME MAC, or RHHI. That instruction may be viewed by going to the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1334CP.pdf>.

If you have questions, please contact your Medicare carrier, FI or A/B MAC, DME 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: MM5710

Related Change Request (CR) Number: 5710

Related CR Release Date: September 12, 2007

Effective Date: October 1, 2007

Related CR Transmittal Number: R1334CP

Implementation Date: October 1, 2007

Source: CMS Pub. 100-04, Transmittal 1334, CR 5710

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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## Payment Adjustment for CPT Code 85025

First Coast Service Options, Inc. (FCSO) has identified an overpayment in the Medicare allowances for CPT code 85025. This overpayment affects claims for dates of service **on or after January 1, 2007, with a processed date of June 30, 2007, through August 2, 2007.**

The correct allowance for CPT code 85025 is based on the 2007 clinical laboratory service fee schedule of \$10.86 (60% rate) and \$11.22 (62% rate).

Claims with receipt date **on or after August 3, 2007**, were not affected and were paid correctly.

### No Action Required by Providers

FCSO initiated the claim adjustments to correct the affected claims on September 17, 2007. Adjustments to all affected claims will be completed by October 5, 2007. ❖

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## CMS Issues Final Rule Prohibiting Physician Self-Referral

The Centers for Medicare & Medicaid Services (CMS) issued final regulations prohibiting physicians from referring Medicare patients for certain items, services and tests provided by businesses in which they or their immediate family members have a financial interest. This regulation is the third phase of the final regulations implementing the physician self-referral prohibition commonly referred to as the Stark law.

“These rules protect beneficiaries from receiving services they may not need and the Medicare program from paying potentially unnecessary costs,” said Herb Kuhn, CMS acting deputy administrator.

This third phase of rulemaking (phase III) responds to public comments on the phase II interim final rule published March 26, 2004, in the *Federal Register*. The rule does not establish any new exceptions to the self-referral prohibition, but rather makes certain refinements that could permit or, in some cases, require restructuring of some existing arrangements, CMS officials explained.

The final rule, was published in the September 5, 2007, *Federal Register*. To view the rule, go to: [http://www.cms.hhs.gov/PhysicianSelfReferral/04a\\_regphase3.asp](http://www.cms.hhs.gov/PhysicianSelfReferral/04a_regphase3.asp).

For more information, visit the following link on the CMS Web site: <http://www.cms.hhs.gov/PhysicianSelfReferral/>.

The entire press release is available on the CMS Web site at [http://www.cms.hhs.gov/apps/media/press\\_releases.asp](http://www.cms.hhs.gov/apps/media/press_releases.asp). ❖

Source: CMS Provider Education Resource 200708-18

**October Update to the 2007 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 other providers who bill Medicare contractors (carriers, fiscal intermediaries, or Medicare administrative contractors [MACs]) for professional services paid under the Medicare physician fee schedule (MPFS).

**What You Need to Know**

Change request (CR) 5714, from which this article was taken, amends the payment files previously issued to your Medicare contractor (based upon the December 1, 2006, MPFS final rule); and includes new codes for the Physician Quality Reporting Initiative.

**Background**

Section 1848(c)(4) of the Social Security Act authorizes the Secretary to establish ancillary policies necessary to implement relative values for physicians' services. Medicare contractors, in accordance with the *Medicare Claims Processing Manual*, Chapter 23, Section 30.1, give providers 30 days notice before implementing the revised payment amounts and the changes identified in CR 5714, which (unless otherwise stated in the CR 5714) will be retroactive to January 1, 2007.

You should be aware that carriers will adjust claims that you bring to their attention, but are not required to search their files to either retract payment for claims already paid or to retroactively pay claims. The changes made as a result of CR 5714 are as follows:

Changes included in the October update to the 2007 Medicare physician fee schedule database (MPFSDB) are as follows:

**The following changes are retroactive to January 1, 2007:**

**CPT/HCPCS ACTION**

- 16035 Global Period = 000
- Pre Op = 0.00
- Intra Op = 0.00
- Post Op = 0.00
- 20690 Bilateral Indicator = 0
- 38740 Bilateral Indicator = 1
- 38745 Bilateral Indicator = 1
- 54150 Transitional Non-Facility PE RVU = 3.38
- Transitional Facility PE RVU = 0.73
- 64412 Bilateral Indicator = 1
- 64418 Bilateral Indicator = 1
- 64613 Bilateral Indicator = 1

**As stated in Transmittal 1301, dated July 20, 2007, (CR 5665 – Revised Information on PET Scan Coding), effective January 28, 2005, CPT code 78609 became a noncovered service for Medicare purposes.**

<b>CPT Code</b>	<b>Procedure Status Indicator*</b>
78609	N
78609-TC (technical component)	N
78609-26 (professional component)	N

\*Effective for dates of service on or after January 28, 2005

**New Category II Codes for the Physician Quality Reporting Initiative (PQRI)**

**Effective for dates of service on or after October 1, 2007**, the following category II codes will be added to the MPFS with a status indicator of "M".



*October Update to the 2007 Medicare Physician Fee Schedule Database (continued)*

<b>Code</b>	<b>Long Descriptor</b>	<b>Short Descriptor</b>
1116F	<i>Auricular or periauricular pain assessed</i>	Auric/peri pain assessed
2035F	<i>Tympanic membrane mobility assessed with pneumatic otoscopy or tympanometry</i>	Tymp memb motion exam'd
3215F	<i>Patient has documented immunity to hepatitis A</i>	Pt immunity to hep a doc'd
3216F	<i>Patient has documented immunity to hepatitis B</i>	Pt immunity to hep b doc'd
3219F	<i>Hepatitis C genotype testing documented as performed prior to initiation of antiviral treatment for hepatitis C</i>	Hep c geno tstng doc'd - done
3220F	<i>Hepatitis C quantitative RNA testing documented as performed at 12 weeks from initiation of antiviral treatment</i>	Hep c quant rna tstng doc'd
3230F	<i>Documentation that hearing test was performed within 6 months prior to tympanostomy tube insertion</i>	Note hring tst w/in 6 mon
3260F	<i>pT category (primary tumor), pN category (regional lymph nodes), and histologic grade documented in pathology report</i>	Pt cat/pn cat/hist grd doc'd
4130F	<i>Topical preparations (including OTC) prescribed for acute otitis externa</i>	Topical prep rx, aoe
4131F	<i>Systemic antimicrobial therapy prescribed</i>	Syst antimicrobial thx rx
4132F	<i>Systemic antimicrobial therapy not prescribed</i>	No syst antimicrobial thx rx
4133F	<i>Antihistamines or decongestants prescribed or recommended</i>	Antihist/decong rx/recom
4134F	<i>Antihistamines or decongestants neither prescribed nor recommended</i>	No antihist/decong rx/recom
4135F	<i>Systemic corticosteroids prescribed</i>	Systemic corticosteroids rx
4136F	<i>Systemic corticosteroids not prescribed</i>	Syst corticosteroids not rx
4150F	<i>Patient receiving antiviral treatment for hepatitis C</i>	Pt recvng antivir txmnt hepc
4151F	<i>Patient not receiving antiviral treatment for hepatitis C</i>	Pt not recvng antiv hep c
4152F	<i>Documentation that combination peginterferon and ribavirin therapy considered</i>	Doc'd pegintf/rib thxy consid
4153F	<i>Combination peginterferon and ribavirin therapy prescribed</i>	Combo pegintf/rib rx
4154F	<i>Hepatitis A vaccine series recommended</i>	Hep a vac series recommended
4155F	<i>Hepatitis A vaccine series previously received</i>	Hep a vac series prev recvd
4156F	<i>Hepatitis B vaccine series recommended</i>	Hep b vac series recommended
4157F	<i>Hepatitis B vaccine series previously received</i>	Hep b vac series prev recvd
4158F	<i>Patient education regarding risk of alcohol consumption performed</i>	Pt edu re: alcoh drnkng done
4159F	<i>Counseling regarding contraception received prior to initiation of antiviral treatment</i>	Contrcp talk b/4 antiv txmnt

The payment indicators are identical for all of the above PQRI CPT codes and those indicators are as follows:

Procedure Status:	M
WRVU	0.00
Non-Facility PE RVU:	0.00
Facility PE RVU:	0.00
Malpractice RVU:	0.00
PC/TC:	9
Site of Service:	9
Global Surgery:	XXX
Multiple Procedure Indicator:	9
Bilateral Surgery Indicator:	9
Assistant at Surgery Indicator:	9
Co-Surgery Indicator:	9

## October Update to the 2007 Medicare Physician Fee Schedule Database (continued)

Team Surgery Indicator: 9  
Physician Supervision Diagnostic Indicator: 9  
Type of Service: 1  
Diagnostic Family Imaging Indicator: 99

*\*Effective for services performed on or after October 1, 2007.*

The short descriptor for G8370 was listed incorrectly in Transmittal 1258, dated May 29, 2007 (CR 5614 – July Update to the 2007 Medicare Physician Fee Schedule Database). The short descriptor has been corrected to read:

### HCPCS Revised Short Descriptor

G8370 Asthma pt w survey not docum

### Additional Information

You may find the official instruction about the October update to the 2007 Medicare physician fee schedule database by going to CR 5714, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1326CP.pdf>. If you have any questions, please contact your carrier, FI or 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: MM5714

Related Change Request (CR) Number: 5714

Related CR Release Date: August 30, 2007

Related CR Transmittal Number: R1326CP

Effective Date: January 1, 2007

Implementation Date: October 1, 2007

Source: CMS Pub. 100-04, Transmittal 1326, CR 5714

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## Medicare Clinical Trial Policy

*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 related to clinical trials to Medicare contractors (carriers, Medicare administrative contractors [A/B MACs], durable medical equipment Medicare administrative contractors [DME/MACs], fiscal intermediaries [FIs], and regional home health intermediaries [RHHIs]).

### Provider Action Needed

#### STOP – Impact to You

This article is based on change request (CR) 5719, which implements two changes to the 2000 clinical trial policy by: (1) modifying for clarity the language describing coverage of an investigational item/service in the context of a clinical trial, and, (2) adopting coverage with evidence development (CED). The remainder of the 2000 clinical trials policy continues without change.

CR 5719 states that for items and services furnished on and after July 9, 2007, the routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial. The investigational item or service itself is excluded, *unless otherwise covered outside of the clinical trial.*

### CAUTION – What You Need to Know

In addition, the national coverage determination (NCD) is revised to add coverage with evidence development (CED). CED is for items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination. CED is determined through the NCD process, and conditional upon meeting standards of patient safety and clinical evidence, items and services not otherwise covered would be considered “reasonable and necessary” in the context of a clinical trial. Coverage determined under CED is implemented via subsequent NCDs, CRs, and *MLN Matters* articles specific to the coverage issue.

### GO – What You Need to Do

Make certain your billing staff is aware of these changes. Medicare contractors will adjust claims processed prior to the implementation date of this change if you bring such claims to their attention.

### Background

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health & Human Services to “explicitly authorize [Medicare] payment for routine patient care costs and costs due to

**Medicare Clinical Trial Policy (continued)**

medical complications associated with participation in clinical trials.” In keeping with the President’s directive, the Centers for Medicare & Medicaid Services (CMS) engaged in defining the routine costs of clinical trials and identifying the clinical trials for which payment for such routine costs should be made. On September 19, 2000, CMS implemented its initial clinical trial policy through the NCD process. On July 10, 2006, CMS opened a reconsideration of its NCD on clinical trials in the *NCD Manual*, section 310.1. CR 5719 communicates the findings resulting from that analysis.

**Additional Information**

To see the official instruction (CR 5719) issued to your Medicare FI, carrier, DME/MAC, RHHI or A/B MAC, visit on the CMS Web site <http://www.cms.hhs.gov/transmittals/downloads/R74NCD.pdf>.

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

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

MLN Matters Number: MM5719

Related Change Request (CR) Number: 5719

Related CR Release Date: September 7, 2007

Related CR Transmittal Number: R74NCD

Effective Date: July 9, 2007

Implementation Date: October 9, 2007

Source: CMS Pub. 100-03, Transmittal 74, CR 5719

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## Ambulatory Surgical Center Payment Information for Value-Driven Health Care

President Bush directed the U.S. Department of Health & Human Services to make cost and quality data available to all Americans. As a first step in this initiative, on June 1, 2006, the Centers for Medicare & Medicaid Services (CMS) posted information about the payments made to hospitals in fiscal year 2005 for common elective procedures and other hospital admissions. Similar postings of Medicare payment data followed during the year for ambulatory surgery centers (ASCs), hospital outpatient departments, and physician services.

On June 20, 2007, CMS updated last year’s inpatient hospital data. CMS is now presenting an update to last year’s ASC data. The information is being displayed in the same format as last year, updated with calendar year 2006 data.

The ASC posting update is found on the CMS Web site at [http://www.cms.hhs.gov/HealthCareConInit/03\\_ASC.asp](http://www.cms.hhs.gov/HealthCareConInit/03_ASC.asp).

To obtain more information about the Health Care Consumer Initiative, go to the CMS Web site <http://www.cms.hhs.gov/HealthCareConInit/>. ❖

Source: CMS Provider Education Resource 200708-20

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## Discontinuance of the Unique Physician Identification Number Registry

*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 September 17, 2007, to reflect changes made to CR 5584, which CMS re-issued on September 14, 2007. The article was revised to show that the UPIN Registry Web site and lookup functionality will be available through May 23, 2008. Information was added regarding the release of information, including NPIs, via the National Plan and Provider Enumeration System (NPPES). The CR transmittal number, Web address for accessing CR 5584, and the CR release date were also changed. All other information remains the same. The *MLN Matters* article MM5584 was published in the July 2007 *Medicare A Bulletin* (pages 5-6).

**Provider Types Affected**

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, durable medical equipment 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****STOP – Impact to You**

This article is based on change request (CR) 5584 which announces that the Centers for Medicare & Medicaid Services (CMS) will discontinue assigning unique physician identification numbers (UPINs) on June 29, 2007.

## Discontinuance of the Unique Physician Identification Number Registry (continued)

### CAUTION – What You Need to Know

The national provider identifier (NPI) is a requirement of the Health Insurance Portability and Accountability (HIPAA) Act of 1996, and the NPI will replace the use of UPINs and other existing legacy identifiers. (However, CMS recently announced a contingency plan that allows for use of legacy numbers for some period of time beyond May 23, 2007. Under the Medicare fee-for-service [FFS] contingency plan, UPINs and surrogate UPINs may still be used to identify ordering and referring providers and suppliers until further notice.) Information on that contingency plan is on the CMS Web site at [http://www.cms.hhs.gov/NationalProvIdentStand/downloads/NPI\\_Contingency.pdf](http://www.cms.hhs.gov/NationalProvIdentStand/downloads/NPI_Contingency.pdf).

### GO – What You Need to Do

If you do not have an NPI, you should obtain one as soon as possible. Applying for an NPI is fast, easy and free by going to the NPPES Web site at <https://nppes.cms.hhs.gov/>.

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

### Background

CMS was required by law to establish an identifier that could be used in Medicare claims to uniquely identify providers/suppliers who order services for Medicare patients or who refer Medicare patients to physicians and certain other suppliers. The UPIN was established to meet this requirement. CMS assigns UPINs to those physicians and eligible suppliers who are permitted by Medicare to order or refer in the Medicare program. Medicare claims for services that were ordered or for services that resulted from referrals must include UPINs to identify the providers/suppliers who ordered the services or made the referral.

On January 23, 2004, the Secretary of Health & Human Services published a final rule in which the Secretary adopted a standard unique health identifier to identify health care providers in transactions for which the Secretary has adopted standards (known as HIPAA standard transactions). This identifier is the NPI. The NPI will replace all legacy provider identifiers that are used in HIPAA standard transactions, including the UPIN, to identify health care providers. All HIPAA covered entities (health plans, health care clearinghouses, and those health care providers who transmit any data electronically in connection with a HIPAA standard transaction) are required by that regulation to begin using NPIs in these transactions no later than May 23, 2007, (small health plans have until May 23, 2008). Medicare is also requiring the use of NPIs in paper claims no later than May 23, 2007, but see the note below regarding the May 23, 2007, implementation by Medicare.

**Note:** Effective May 23, 2007, Medicare FFS is establishing a contingency plan for implementing the NPI. In this plan, as soon as Medicare considers the number of claims submitted with an NPI for primary provid-

ers (billing, pay-to and rendering providers) is sufficient, Medicare (after advance notification to providers) will begin rejecting claims without an NPI for primary providers, perhaps as early as July 1, 2007. For more information on this contingency plan, please visit the NPI dedicated Web site at <http://www.cms.hhs.NationalProvIdentStand/>.

This contingency plan does not affect CMS plans to discontinue assigning UPINs on June 29, 2007, or to disable the UPIN “look-up” functionality as of September 30, 2007.

CMS discontinued assigning on June 29, 2007, but CMS will maintain its UPIN public “look-up” functionality and registry Web site (<http://www.upinregistry.com/>) through **May 23, 2008**.

In addition, CMS published the NPPES Data Dissemination Notice (CMS-6060-N) in the *Federal Register* on May 30, 2007. This notice describes the policy by which information, to include NPIs, may be disseminated by CMS from the NPPES.

### Additional Information

For additional information regarding NPI requirements and use, please see *MLN Matters* articles, MM4023 (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4023.pdf>) titled *Requirements for Use and Editing of National Provider Identifier (NPI) Numbers Received in Electronic Data Interchange Transactions, via Direct Data Entry Screens or Paper Claim Forms*, and MM4293 (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4293.pdf>) titled *Revised CMS-1500 Claim Form*, which describes the revision of CMS-1500 (12-90) to accommodate the reporting of the NPI and renamed CMS-1500 (08-05).

The official instruction (CR 5584) issued to your carrier, intermediary, RHHI, A/B MAC and DME MAC regarding this change may be viewed on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R222PI.pdf>.

If you have any questions, please contact your Medicare carrier, intermediary, 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: MM5584 – Revised  
Related Change Request (CR) Number: 5584  
Related CR Release Date: September 14, 2007  
Related CR Transmittal Number: R222PI  
Effective Date: May 29, 2007  
Implementation Date: June 29, 2007

Source: CMS Pub. 100-08, Transmittal 222, CR 5584

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## 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. ❖

# NATIONAL PROVIDER IDENTIFIER

## National Provider Identifier Data Dissemination Began September 4, 2007

### NPI Is Here. NPI Is Now. Are You Using It?

Health plans are progressing to transition to full national provider identifier (NPI) implementation. Be sure to stay informed about the steps you need to take to bill correctly and test your NPI with all of the health plans with whom you do business.

### National Plan and Provider Enumeration System FOIA-Disclosable Data To Be Available on September 4, 2007

The national plan and provider enumeration system (NPPES) health care provider data that are disclosable under the Freedom of Information Act (FOIA) will be disclosed to the public by the Centers for Medicare & Medicaid Services (CMS). In accordance with the e-FOIA Amendments, CMS will be disclosing these data via the Internet.

Data will be available in two forms:

1. A query-only database, known as the NPI registry.
2. A downloadable file.

CMS has extended the period of time in which enumerated health care providers can view their FOIA-disclosable NPPES data and make any edits they feel are necessary prior to our initial disclosure of the data. CMS will be making FOIA-disclosable NPPES health care provider data available beginning Tuesday, September 4, 2007. The NPI registry will become operational on September 4 and the downloadable file will be ready approximately one week later.

CMS has posted several documents to help providers understand what the downloadable file will look like, including a "Read Me" file, header file, and code value document for the downloadable file on the CMS NPI Web page at [http://www.cms.hhs.gov/NationalProvIdentStand/06a\\_DataDissemination.asp](http://www.cms.hhs.gov/NationalProvIdentStand/06a_DataDissemination.asp).

### Important Information for Medicare Providers Starting September 3, 2007, Medicare carriers and DME MACs will begin transitioning their systems to start rejecting claims when the NPI and legacy provider identifier cannot be found on the Medicare crosswalk.

Since May 29, 2007, Medicare fiscal intermediaries, as well as Part B CIGNA Idaho and Tennessee, have been validating NPIs and legacy provider identifier pairs submitted on claims against the Medicare NPI crosswalk. Between the period of **September 3, 2007, and October 29, 2007**, all other Part B carriers and DME MACS will begin to turn on edits to validate the NPI/legacy pairs submitted on claims. If the pair is not found on the Medicare NPI crosswalk, the claim will reject. Contractors have been instructed to inform providers at a minimum of seven days prior to turning on the edits to validate the NPI/legacy pairs against the crosswalk.

If you are receiving informational edits today, we strongly urge you to validate that the NPPES has **all** of the NPI and legacy numbers you intend to use on claims and for billing purposes. If NPPES is correct, and you continue to receive information edits, you should ask your contractor to validate the provider information in their system. If the contractor information is not correct, you may be instructed to submit a CMS-855 enrollment application. Please include **all** of your NPI/legacy numbers in NPPES **and all** of your NPIs that are to be used in place of your legacy on the CMS-855. If the information is different in the two systems, there is a very good chance your claim will reject. NPPES data may be verified on the Web at <https://nppes.cms.hhs.gov>.

### Medicare Efforts to Minimize Rejections and Suspensions

CMS change request (CR) 5649, transmittal number 1262, dated June 8, 2007, instructed Medicare contractors to identify providers with the highest volume of rejections (or

### *National Provider Identifier Data Dissemination Began September 4, 2007 (continued)*

potential rejections/informational edits) due to invalid NPI information. They were also instructed to identify providers who are not submitting their NPI. Contractors have begun calling providers that fit these categories. If you are contacted, you may be asked to validate your NPES information or confirm that the information in the contractor's provider file is correct. If you are not submitting your NPI at this time, your contractor will ask: why you are not submitting it, the date you plan to submit it, and will ask you to send a small batch of claims using your NPI only, if possible.

Additionally, all Medicare providers could receive phone calls and/or letters from their contractors in the event that a claim suspends due to problems with mapping a provider's NPI to a legacy provider identifier. This could happen in the instance where one NPI is tied to several legacy identifiers. If it is determined that the claim suspended due to incorrect data in the contractor's provider file or NPES, the provider will be requested to either update their information in NPES and/or submit an updated CMS-855 enrollment application.

If the provider does not respond within 14 calendar days to this communication, the contractor will return the claim as unprocessable. Conversely, if the provider does respond, it may furnish the legacy number over the phone; however, the contractor will ensure that it is in compliance with the *Medicare Program Integrity Manual* (Pub. 100-08), chapter 10, section 17.2 regarding the release of information.

#### **Reporting a Group Practice NPI on Claims**

Medicare has identified instances where the multi-carrier system (MCS) is correcting billing or pay-to provider data on Part B claims submitted by group practices. As of May 18, 2007, the MCS Part B claim processing systems no longer corrects claims submitted by group practices that are reporting the individual rendering provider identification number (PIN) or individual rendering NPI in either the billing or pay-to provider identifier fields. Groups should enter either their group NPI or group NPI and legacy PIN number pair in either of these fields.

Medicare has also reported instances of incorrect billing occurring with DME MACs. Providers must ensure that if they enumerate as individuals in the national supplier clearinghouse (NSC), they must enumerate as individuals in NPES. If they enumerate as organizations in NSC, they should do the same in NPES.

#### **Update to 835 Remittance Advice Changes in MLN Matters SE0725**

In *MLN Matters* special edition article SE0725, Medicare described the 835 changes that would occur for the 835 remittance advice and that those changes would

occur July 2, 2007 for DME MACS only. The article also went on to note that Medicare would notify providers when the Part A Institutional and Part B Professional 835 would be changing. Medicare 835 electronic remittance advices will reflect the noted changes on remittances for Part A and Part B, starting April 7, 2008.

#### **Transcript for August 2nd Roundtable Now Available**

The transcript for the August 2nd, Medicare fee-for-service (FFS) Q&A session: "Common Billing Errors, Roundtable" is now available on the CMS NPI page at [http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/aug\\_2\\_npi\\_transcript.pdf](http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/aug_2_npi_transcript.pdf).

#### **Reminder: Recent MLN Matters Articles**

Several recent special edition *MLN Matters* articles contain important billing information for Medicare providers and suppliers, including:

- How to use the NPI correctly on Part A and Part B claims <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0725.pdf>.
- Information on use of the NPI on the new CMS 1500 and UB-04 forms <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0729.pdf>.

#### **General Medicare Claims Processing Reminder**

Unrelated to the NPI, the contractors can reject Medicare FFS claims for a variety of reasons including:

- incorrect billing information
- the provider has been terminated from the program
- the beneficiary is not eligible for Medicare
- the claim was sent to the wrong contractor

If a provider has questions about a claim rejected by an FI/carrier or MAC, the provider should contact the contractor directly. It is never appropriate to direct the beneficiary, who received the service billed on the claim, to the 1-800-Medicare toll free line to resolve a claim rejection.

#### **Still Confused?**

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. ❖

Source: CMS Provider Education Resource 200708-17

### **Getting an NPI Is Free – Not Having One May Be Costly**

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## Medicare Fee-for-Service National Provider Identifier Implementation Contingency Plan

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 July 6, 2007, to provide a reference to *MLN Matters* article SE0721, regarding the provider authentication requirements for telephone and written inquires during the Medicare fee-for-service (FFS) national provider identifier (NPI) contingency plan. This was added to the *Additional Information* section. There was also an exception stating that NPI from the ordering/referring physician is not required on claims for ambulance services. The *MLN Matters* article MM5595 was published in the May 2007 *Medicare A Bulletin* (pages 17-18).

### Provider Types Affected

Physicians, providers, and suppliers who conduct HIPAA standard transactions, such as claims and eligibility inquiries, with Medicare contractors (carriers, fiscal intermediaries, [FIs], including regional home health intermediaries [RHHIs], Medicare administrative contractors [MACs], durable medical equipment regional carriers [DMERCs], and DME MACs).

### Provider Action Needed

#### STOP – Impact to You

As early as July 1, 2007, Medicare FFS contractors may begin rejecting claims that do not contain an NPI for the primary providers.

#### CAUTION – What You Need to Know

Change request (CR) 5595, from which this article is taken, announces that (effective May 23, 2007,) Medicare FFS is establishing a contingency plan for implementing the NPI. In this plan, as soon as Medicare considers the number of claims submitted with an NPI for primary providers (Billing, pay-to and rendering providers) is sufficient, Medicare (after advance notification to providers) will begin rejecting claims without an NPI for primary providers, perhaps as early as July 1, 2007.

#### GO – What You Need to Do

If you have not yet done so, you should obtain your NPI now. You may apply online on the CMS Web site at <https://nppes.cms.hhs.gov/>.

You should also make sure that your billing staffs begin to include your NPI on your claims as soon as possible.

### Background

The 1996 Health Insurance Portability and Accountability Act (HIPAA) required that each physician, supplier, and other health care provider conducting HIPAA standard electronic transactions, be issued a unique NPI. CMS began to issue NPIs on May 23, 2005; and to date, has been allowing transactions adopted under HIPAA to be submitted with a variety of identifiers, including:

- NPI only,
- Medicare legacy only, or
- An NPI and legacy combination.

On April 2, 2007, the Department of Health & Human Services (DHHS) provided guidance to covered entities regarding contingency planning for NPI implementation. **As long as covered entities, including health plans and covered health providers, continue to act in good faith to come into compliance, meaning they are working**

**towards being able to accept and send NPIs, they may establish contingency plans to facilitate the compliance of their trading partners.** You may find this guidance on the CMS Web site at [http://www.cms.hhs.gov/NationalProidentStand/Downloads/NPI\\_Contingency.pdf](http://www.cms.hhs.gov/NationalProidentStand/Downloads/NPI_Contingency.pdf).

In CR 5595, from which this article is taken, Medicare FFS announces that it is establishing a contingency plan that follows this DHHS guidance. For some period after May 23, 2007, Medicare FFS will:

- Allow continued use of legacy numbers on transactions.
- Accept transactions with only NPIs.
- Accept transactions with both legacy numbers and NPIs.

**After May 23, 2008, legacy numbers will NOT be permitted on ANY inbound or outbound transactions.**

As part of this plan, Medicare FFS has been assessing health care provider submission of NPIs on claims. As soon as the number of claims submitted with an NPI for primary providers (Billing, pay-to and rendering providers) is determined sufficient (and following appropriate notice to providers), Medicare will begin rejecting claims that do not contain an NPI for primary providers following appropriate notification. (See *Important Information* section below.)

In May 2007, Medicare FFS will evaluate the number of submitted claims containing a NPI. If this analysis demonstrates a sufficient number of submitted claims contain an NPI, Medicare will begin to reject claims without NPIs on July 1, 2007. If, however, there are not sufficient claims containing NPIs in the May analysis, Medicare FFS will assess compliance in June 2007 and determine whether to begin rejecting claims in August 2007.

CMS also recognizes that the National Council of Prescription Drug Programs (NCPDP) format only allows for reporting of one identifier. Thus, NCPDP claims may contain either the NPI or the legacy number, but not both, until May 23, 2008.

In addition, in regards to the 835 remittance advice transactions and 837 coordination of benefit (COB) transactions, Medicare FFS will do the following until May 23, 2008:

- If a claim is submitted with an NPI, the NPI will be sent on the associated 835 remittance advice; otherwise, the legacy number will be sent on the associated 835.
- If a claim is submitted with an NPI, the associated 837 COB transaction will be sent with both the NPI and the legacy number; otherwise, only the legacy number will be sent.

### *Medicare Fee-for-Service National Provider Identifier Implementation Contingency Plan (continued)*

By May 23, 2008, the X12 270/271 eligibility inquiry/response supported by CMS via the Extranet and Internet must contain the NPI.

#### **Important Information**

CR 5595 also provides specific important information that you should be aware of:

- Once a decision is made to require NPIs on claims, Medicare FFS will notify (in advance) providers and Medicare contractors about the date that claims without NPIs for primary providers will begin to be rejected. **That date will supersede all dates announced in previous CRs and MLN Matters articles.**
- In editing NPIs, Medicare considers billing, pay-to and rendering providers to be primary providers who must be identified by NPIs, or the claims will be rejected once the decision is made to reject.

All other providers (including referring, ordering, supervising, facility, care plan oversight, purchase service, attending, operating and “other” providers) are considered to be secondary providers. Legacy numbers are acceptable for secondary providers until May 23, 2008. If a secondary provider’s NPI is present, it will only be edited to assure it is a valid NPI. **There is an exception that the NPI from an ordering/referring physician is not required on claims for ambulance services. See the MLN Matters article MM5564 on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5564.pdf>.**

#### **Additional Information**

You can read CR 5595 by visiting the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1227CP.pdf>.

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You can also learn more about the NPI on the CMS Web site at <http://cms.hhs.gov/NationalProvIdentStand/>.

Due to the Medicare FFS NPI contingency plan, the NPI will not be a required authentication element for general provider telephone and written inquiries until the date that the CMS requires it to be on all claim transactions. In this contingency environment, the provider transaction access number (PTAN) will be the required authentication element for all inquiries to interactive voice response (IVR) systems, customer service representatives (CSRs), and the written inquiries units. Providers may find more information on the use of the PTAN by reading the *MLN Matters* article SE0721 on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0721.pdf>.

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found on the CMS website 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: MM5595 – Revised  
Related Change Request (CR) Number: 5595  
Related CR Release Date: April 24, 2007  
Related CR Transmittal Number: R1227CP  
Effective Date: May 23, 2007  
Implementation Date: May 23, 2007

Source: CMS Pub. 100-04, Transmittal 1227, CR 5595

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Join our *eNews* mailing list and receive urgent and other critical information issued by First Coast Service Options, Inc. (FCSO), your Florida Medicare intermediary. By signing up, you will receive automatic email notification when new or updated information is posted to the provider education Web site <http://www.floridamedicare.com>. It’s very easy to do. Simply go to the Web site, click on the “eNews” link on the navigational menu and follow the prompts.



## NPPES Data and New Data Dissemination Training Module now Available

### NPI Is Here. NPI Is Now. Are You Using It?

The national provider identifier (NPI) registry and the downloadable file are now available. To view the registry, visit on the Web <https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do>.

The downloadable file is available on the Web at [http://nppesdata.cms.hhs.gov/cms\\_NPI\\_files.html](http://nppesdata.cms.hhs.gov/cms_NPI_files.html).

Additionally, the final module (module 4) in the NPI training package is now available. This module describes the policy by which the Centers for Medicare & Medicaid Services (CMS) will make certain NPPES data available, as well as the data CMS is disclosing. Module 4, Data Dissemination, is now available on the CMS Web site at [http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI\\_Module4\\_Data\\_Dissemination.pdf](http://www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI_Module4_Data_Dissemination.pdf).

As always, more information and education on the NPI may be found through the CMS NPI page <http://www.cms.hhs.gov/NationalProvIdentStand>.

Providers can apply for an NPI online on the CMS Web site 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. ❖

### Getting an NPI Is Free – Not Having One May Be Costly

Source: CMS Provider Education Resource 200709-04

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## Trade Publication Issued Incorrect NPI Implementation Schedule

### NPI Is Here. NPI Is Now. Are You Using It?

The Centers for Medicare & Medicaid Services (CMS) has notified Medicare contractors that a trade publication recently published an incorrect schedule of NPI implementation dates, by contractor, for claim rejections based on the inability to locate an NPI/legacy identifier pair on the Medicare NPI crosswalk.

Medicare contractors have notified providers as to the particular timeframe for their transition. Providers are urged to only rely on information from their Medicare contractors. Any other published schedules are unofficial and may have inaccurate dates.

Providers may find the special edition *MLN Matters* article SE0725 helpful in determining how to use the NPI on Part A and Part B claims. You can view the article on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0725.pdf>.

As always, more information and education on the NPI may be found through the CMS NPI page <http://www.cms.hhs.gov/NationalProvIdentStand>.

Providers can apply for an NPI online on the CMS Web site 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. ❖

### Getting an NPI Is Free – Not Having One May Be Costly

Source: CMS Provider Education Resource 200709-01

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# GENERAL COVERAGE

## Ultrasound Diagnostic Procedures

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 carriers, fiscal intermediaries (FIs), and Medicare administrative contractors (MACs) for ultrasound diagnostic procedures.

### What Providers Need to Know

Change request (CR) 5608, from which this article is taken, announces that effective on and after May 22, 2007, the Centers for Medicare & Medicaid Services (CMS) will allow payment for the monitoring of cardiac output (esophageal Doppler) for ventilated patients in the intensive care unit (ICU) and for operative patients with a need for intra-operative fluid optimization.

Make sure that your billing staffs are aware of this change in the *National Coverage Determinations (NCD) Manual*, Chapter 1 (Coverage Determinations), Section 220.5 (Ultrasound Diagnostic Procedures) to allow coverage for this procedure.

### Background

CR 5608, from which this article is taken, announces:

- Effective for claims with dates of service on and after May 22, 2007, CMS has determined that esophageal Doppler monitoring of cardiac output for ventilated patients in the ICU and for operative patients with a need for intra-operative fluid optimization is reasonable and necessary; and
- The previous national noncoverage of cardiac output Doppler monitoring is therefore removed.

Specifically, in CR 5608, CMS amends the Medicare *NCD Manual*, Chapter 1 (Coverage Determinations), Section 220.5 (Ultrasound Diagnostic Procedures), by adding: “Monitoring of cardiac output (Esophageal Doppler) for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization” to category I (covered procedures), and deleting “Monitoring of cardiac output (Doppler)” from category II (noncovered procedures).

**Notes:** There is no specific *CPT* code for this service. *CPT* code 76999 is for unlisted ultrasound procedures. When performed in a hospital setting for ventilated patients in the ICU or for operative patients with a need for ultrasound diagnostic procedures, the professional services only are separately payable when billed using *CPT* code 76999 with modifier 26 to show professional component. Such services, when globally billed in a hospital setting with *CPT* code 76999, will be returned as unprocessable to the provider with a reason code

such as 58 denoting “Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.”

When such services are billed in a hospital setting as technical services with the *CPT* code 76999-TC, Medicare will deny the services with reason code 58 and remark code M77 to show “Missing/Incomplete/Invalid place of service.”

When performed in an ambulatory surgery center (ASC), ultrasound diagnostic procedures are covered when performed by an entity other than the ASC if globally billed using *CPT* code 76999, or the technical and professional components may be separately billed using *CPT* codes 76999-TC and 76999-26, respectively.

Ultrasound diagnostic procedures professional services billed using *CPT* codes 76999, 76999-TC, and 76999-26 are carrier-priced.

Medicare contractors will not search their files to identify and adjust claims processed prior to the implementation of this change, which are for services rendered on or after May 22, 2007. However, they will adjust such claims when you bring the claims to their attention.

### Additional Information

You may find more information about the coverage of esophageal Doppler monitoring of cardiac output by going to CR 5608, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R76NCD.pdf>.

You will find the amended *Medicare NCD Manual*, Chapter 1 (Coverage Determinations), Section 220.05 (Ultrasound Diagnostic Procedures), as an attachment to that CR.

If you have any questions, please contact your carrier, FI, or 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: MM5608  
 Related Change Request (CR) Number: 5608  
 Related CR Release Date: September 12, 2007  
 Related CR Transmittal Number: R76NCD  
 Effective Date: May 22, 2007  
 Implementation Date: September 28, 2007

Source: CMS Pub. 100-03, Transmittal 76, CR 5608

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## Clarification of Percutaneous Transluminal Angioplasty Billing Requirements

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, fiscal intermediaries [FIs], and/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) 5667, which adds ICD-9-CM diagnosis code 433.11, occlusion of the carotid artery with infarct, to the list of payable claims for percutaneous transluminal angioplasty (PTA) to ensure all eligible Medicare beneficiaries are covered.

### Background

On March 17, 2005, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) providing Medicare coverage for PTA of the carotid artery concurrent with placement of a Food and Drugs Administration (FDA)-approved carotid stent when beneficiaries are at high risk for carotid endarterectomy (CEA). (This was announced in CR 3811, effective March 17, 2005; see related *MLN Matters* article at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.pdf>.)

The NCD provides coverage for patients with symptomatic carotid artery stenosis who meet the coverage criteria specified in the policy. As stated in the NCD,

- Patients who experience non-disabling strokes (modified Rankin scale < 3) are considered to be symptomatic and therefore **are** eligible for coverage; however,
- Patients who experience disabling strokes (modified Rankin scale greater than 3) **are not** eligible for coverage.

Currently, there are no codes that distinguish between non-disabling and disabling strokes. In order to ensure that claims for all eligible patients can be paid, CR 5667 adds the following International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code of 433.11 (Occlusion and stenosis of carotid artery, with cerebral infarction) to the list of payable claims for carotid artery stenting (CAS).

Patients who experience disabling strokes remain ineligible for coverage.

Note that Medicare contractors will not search their files to reprocess claims already processed. However, they will adjust such claims if you bring the claims to their attention. Also, since the Centers for Medicare & Medicaid Services (CMS) considers this an administrative error, your Medicare contractor will follow the guidelines in the *Medicare Claims Processing Manual* (Chapter 1, Section 70.7.1) for allowing an extension to the timely filing limits. In essence, this allows your contractor to accept claims with 433.11 outside the timely filing limitations, since such

claims were not previously payable due to the administrative error. Medicare manuals are available on the CMS Web site at <http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage>.

CR 5667 also advises providers that they can correctly bill covered bilateral carotid services by coding both 433.30 (Occlusion and stenosis of multiple and bilateral arteries, without mention of cerebral infarction) or 433.31 (Occlusion and stenosis of multiple and bilateral arteries, with cerebral infarction) and 433.10 (Occlusion and stenosis of carotid artery, without mention of cerebral infarction) or 433.11 in any order on the same claim. Providers would code 433.30 with 433.10 or 433.31 with 433.11 to identify the multiple and bilateral condition and 433.10 or 433.11 to specifically identify the carotid artery.

Claims submitted by physicians to carriers or MACs may also contain a CPT code of 37215 (*Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection*), 0075T (*Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel*), or 0076T (*Each additional vessel*).

**Claims submitted by institutional providers to FIs or MACs should contain the appropriate procedure codes of 00.61 (Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessels) and 00.63 (Percutaneous insertion of carotid artery stent(s)).**

### Additional Information

MM3489, Percutaneous Transluminal Angioplasty (PTA), may be found on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3489.pdf>.

MM3811, Expansion of Coverage for Percutaneous Transluminal Angioplasty (PTA), is located on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.pdf>.

MM5022, Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent with the Placement of an FDA-approved Carotid Stent, is located on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM.pdf5022>.

The official instruction, CR 5667, 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/R1315CP.pdf>.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which is 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.

## Clarification of Percutaneous Transluminal Angioplasty Billing Requirements (continued)

MLN Matters Number: MM5667

Related Change Request (CR) Number: 5667

Related CR Release Date: August 10, 2007

Related CR Transmittal Number: R1315CP

Effective Date: March 17, 2005

Implementation Date: October 1, 2007

Source: CMS Pub. 100-04, Transmittal 1315, CR 5667

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## Lumbar Artificial Disc Replacement

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

**Note:** Hospitals must ensure that a beneficiary over 60 years of age who chooses to have a lumbar artificial disc replacement signs a hospital issued notice of noncoverage.

### Provider Types Affected

All physicians, hospitals, and providers who submit claims to Medicare contractors (carriers, Medicare administrative contractors (A/B MACs), or Medicare fiscal intermediaries (FIs)) for LADR provided to Medicare beneficiaries.

### Provider Action Needed

#### STOP – Impact to You

This article is based on change request (CR) 5727 that summarizes a national coverage analysis for the reconsideration of the national coverage determination (NCD) for lumbar artificial disc replacement (LADR).

#### CAUTION – What You Need to Know

**Effective for dates of service on or after August 14, 2007, LADR is NOT COVERED for Medicare beneficiaries over 60 years of age.**

#### GO – What You Need to Do

Make certain your billing staffs are aware of this change and that you issue the appropriate liability notices to beneficiaries in advance of the procedure consistent with Chapter 30 of the *Medicare Claims Processing Manual* on the CMS Web site at <http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf>.

**Providers should make certain to issue the advanced beneficiary notice (ABN) and/or (as appropriate) the hospital issued notice of noncoverage (HINN) to the beneficiary over the age of 60 years who chooses to have LADR.**

#### Background

On November 28, 2006, the Centers for Medicare & Medicaid Services (CMS) initiated a national coverage analysis for the reconsideration of the NCD on LADR. The original NCD for LADR was focused on a specific lumbar artificial disc implant (Charite™) because it was the only one with the Food and Drug Administration (FDA)-approval at that time. In the original decision memorandum for LADR, CMS stated that when another lumbar artificial disc received FDA-approval CMS would reconsider the policy. Subsequently, another lumbar artificial disc,

ProDisc®-L, received FDA-approval, which initiated the reconsideration of the NCD on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the over age 60 populations; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacture's implant.

#### Key Points

- For services performed on or after August 14, 2007, Medicare contractors will consider LADR a noncovered service for Medicare beneficiaries over 60 years of age as indicated in the Medicare NCD Manual, section 150.10 (see the *Additional Information* section of this article for information on accessing the NCD manual section attached to CR 5727).

**Note:** For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination, leaving such determinations to continue to be made by local Medicare contractors.

- Medicare contractors will deny claims submitted with category III codes 22857 and 0163T for Medicare beneficiaries over 60 years of age, (**i.e. on or after a beneficiary's 61st birthday**).
- Medicare contractors will deny claims submitted with ICD-9-CM procedure code 84.65 for Medicare beneficiaries over 60 years of age.
- Where claims are denied:
  - Associated Medicare summary notices to beneficiaries will contain a message (21.24) indicating "This service is not covered for patients over age 60."
  - The associated remittance advice will reflect claim adjustment reason code 96 "Non-covered charge(s)" and remittance advice remark code N386 ("This decision was based on a national coverage determination (NCD). An NCD provides



**Lumbar Artificial Disc Replacement (continued)**

a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>.

If you do not have Web access, you may contact the contractor to request a copy of the NCD.”

**Additional Information**

For complete details regarding this change request (CR) please see the official instruction (CR 5727) issued to your Medicare FI, carrier, or A/B MAC. CR 5727 contains two transmittals, one for the *National Coverage Determination Manual* and one for the revised *Medicare Claims Processing Manual* instructions. These two transmittals may be viewed by going respectively, to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R75NCD.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R1340CP.pdf>.

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

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

MLN Matters Number: MM5727

Related Change Request (CR) Number: 5727

Related CR Release Date: September 21, 2007

Related CR Transmittal Number: R75NCD and R1340CP

Effective Date: August 14, 2007

Implementation Date: October 1, 2007

Source: CMS Pub. 100-03, Transmittal 75, CR 5727

CMS Pub. 100-04, Transmittal 1340, CR 5727

**Percutaneous Transluminal Angioplasty**

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 September 13, 2007, to reflect the revision and reissue of change request (CR) 5660. The CR release date, transmittal number, and the Web address for accessing CR 5660 were changed. All other information remains the same. The MLN Matters article MM5660 was published in the August 2007 *Medicare A Bulletin* (pages 29-31).

**Provider Types Affected**

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

**Provider Action Needed****STOP – Impact to You**

On August 02, 2006, a request to reconsider the national coverage determination (NCD) for PTA and stenting of the carotid arteries initiated a national coverage analysis. Change request (CR) 5660 communicates the findings resulting from that analysis.

**CAUTION – What You Need to Know**

Effective for dates of service performed on and after April 30, 2007, be aware of:

- Clarifications regarding the use of PTA and stenting of the carotid arteries for patients at high risk for carotid endarterectomy (CEA).
- **Note the process that facilities must follow for certification and recertification** that is specified in section 20.7 of Publication 100-03, the *Medicare National Coverage Determinations Manual*.

**GO – What You Need to Do**

If you are a provider of PTA and stenting of the carotid arteries services be aware that the Centers for Medicare &

Medicaid Services (CMS) has reviewed the evidence and determined that **coverage for this NCD is unchanged** and that **facilities should follow the certification/recertification guidelines in CR 5660**. See the *Background and Additional Information* sections of this Medicare Modernization Act (MMA) update.

**Background**

On April 22, 2005, the CMS issued CR 3811 providing Medicare coverage for PTA of the carotid artery concurrent with placement of a Food and Drugs Administration (FDA)-approved carotid stent when beneficiaries are at high risk for CEA. This NCD is contained in section 20.7 of the *Medicare National Coverage Determinations Manual* and the **changes in the NCD are listed below**. To read more about this NCD, click on the article issued with this change request that may be found in the *Additional Information* section of this article.

**PTA is covered when used under the following conditions:**

- Treatment of atherosclerotic obstructive lesions:
  - In the lower extremities, i.e. the iliac, femoral, and popliteal arteries.
  - In the upper extremities, i.e. the innominate, subclavian, axillary, and brachial arteries, but not head or neck vessels.
  - Of a single coronary artery.

## Percutaneous Transluminal Angioplasty (continued)

- Concurrent with carotid stent placement:
  - Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trials, effective July 1, 2001.
  - FDA-approved post approval studies, effective October 12, 2004.
  - Patients at high risk for carotid endarterectomy (CEA), effective March 17, 2005.

**Notes:** Coverage is limited to procedures performed using FDA approved carotid artery stents and embolic protection devices.

The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of carotid artery stenting (CAS) without distal embolic protection.

- Concurrent with intracranial stent placement.
- FDA-approved category B IDE clinical trials, effective November 6, 2006.

CAS for patients who are not at high risk for CEA remains covered only in FDA-approved category B IDE clinical trials under 42 CFR 405.201.

CMS has determined that PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent is not reasonable and necessary for all other patients.

### Facilities Certification

Facilities must be certified for Medicare to cover the CAS procedures and must recertify every two (2) years in order to maintain Medicare coverage of CAS procedures. Recertification will occur when the facility documents that and describes how it continues to meet the CMS standards. The new recertification guidelines are as follows:

#### At 23 months after initial certification:

- Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed in Section 20.7 of the *Medicare National Coverage Determinations Manual*. (See the *Additional Information* section of this article for the Web link to the NCD within CR 5660)

#### At 27 months after initial certification:

- Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.
- Required data elements:
  - Patients' Medicare identification number if a Medicare beneficiary
  - Patients' date of birth
  - Date of procedure
  - Does the patient meet high surgical risk criteria (defined below)?
    - Age =80
    - Recent (< 30 days) myocardial infarction (MI)

- Left ventricle ejection fraction (LVEF) < 30%
- Contralateral carotid occlusion
- New York Heart Association (NYHA) class III or IV congestive heart failure
- Unstable angina: Canadian cardiovascular society (CCS) class III/IV
- Renal failure: end stage renal disease on dialysis
- Common carotid artery (CCA) lesion(s) below clavicle
- Severe chronic lung disease
- Previous neck radiation
- High cervical internal carotid artery (ICA) lesion(s)
- Restenosis of prior carotid endarterectomy (CEA)
- Tracheostomy
- Contralateral laryngeal nerve palsy.

### Is the patient symptomatic (defined below)?

- Carotid transient ischemic attack (TIA) persisting less than 24 hours
  - Non-disabling stroke: modified Rankin scale <3 with symptoms for 24 hours or more
  - Transient monocular blindness: amaurosis fugax
- Modified Rankin Scale score if the patient experienced a stroke
- Percent stenosis of stented lesion(s) by angiography

### Was embolic protection used?

Were there any complications during hospitalization (defined below)?

- Stroke: an ischemic neurologic deficit that persisted more than 24 hours
- MI
- Death

Recertification is effective for two (2) additional years during which facilities will be required to submit the requested data every April 1 and October 1.

CMS will consider the approval of national carotid artery stenting registries that provide CMS with a comprehensive overview of the registry and its capabilities, and the manner in which the registry meets CMS data collection and evaluation requirements. Specific standards for CMS approval are listed below. Facilities enrolled in a CMS approved national CAS registry will automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the registry to submit required data to CMS for the hospital. A list of approved registries will be made available on the CMS coverage Web site. In addition, CMS will publish a list of approved facilities in the *Federal Register*.

*Percutaneous Transluminal Angioplasty (continued)***National Registries**

As noted above, CMS will approve national registries developed by professional societies and other organizations and allow these entities to collect and submit data to CMS on behalf of participating facilities to meet facility certification and recertification requirements. To be eligible to perform these functions and become a CMS-approved registry, the national registry, at a minimum, must be able to:

1. Enroll facilities in every US state and territory.
2. Assure data confidentiality and compliance with HIPAA.
3. Collect the required CMS data elements as listed above.
4. Assure data quality and data completeness.
5. Address deficiencies in the facility data collection, quality, and submission.
6. Validate the data submitted by facilities, as needed.
7. Track long term outcomes such as stroke and death.
8. Conduct data analyses and produce facility specific data reports and summaries.
9. Submit data to CMS on behalf of the individual facilities.
10. Provide quarterly reports to CMS on facilities that do not meet or no longer meet the CMS facility certification and recertification requirements pertaining to data collection and analysis.

Registries wishing to receive this designation from CMS must submit evidence that they meet or exceed these 10 requirements. Though the registry requirements pertain

to CAS, CMS strongly encourages all national registries to establish a similar mechanism to collect comparable data on CEA. Having both CAS and CEA data will help answer questions about carotid revascularization, in general, in the Medicare population.

**Additional Information**

For complete details regarding this CR please see the official instruction (CR 5660) issued to your Medicare carrier, or A/B MAC. That instruction may be viewed by going to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R77NCD.pdf>.

The *MLN Matters* article related to CR 3811, which is referenced in the *Background Section* of this article, may be reviewed by clicking on the CMS Web site at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.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: MM5660 – Revised  
 Related Change Request (CR) Number: 5660  
 Related CR Release Date: September 12, 2007  
 Related CR Transmittal Number: R77NCD  
 Effective Date: April 30, 2007  
 Implementation Date: July 30, 2007

Source: CMS Pub. 100-03, Transmittal 77, CR 5660

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.

**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 email notification when new or updated information is posted to the provider education Web site <http://www.floridamedicare.com>. It's very easy to do. Simply go to the Web site, click on the "eNews" link on the navigational menu and follow the prompts.

# LOCAL COVERAGE DETERMINATIONS

In accordance with publications specified by LCMS, Medicare contractors no longer distribute full-text local coverage determinations (LCDs) to providers in hardcopy format. Providers may obtain full-text LCDs from the provider education Web site <http://www.floridamedicare.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 sign on to the provider education Web site, <http://www.floridamedicare.com>; click on the *eNews* link on the navigational menu 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.floridamedicare.com>.**

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# ADDITIONS/REVISIONS TO EXISTING LCDs

## 2008 ICD-9-CM Changes

The 2008 update to the ICD-9-CM diagnosis coding structure is effective October 1, 2007. Providers are required to use the 2008-updated ICD-9-CM coding effective for all hospital discharges and outpatient services occurring **on or after October 1, 2007**.

Due to the direct relationship between coding and reimbursement, it is particularly important that providers reimbursed under the outpatient prospective payment system (OPPS) used the appropriate ICD-9-CM coding. Other providers that code diagnoses and procedures (non-OPPS providers) are also affected. In addition, the new diagnosis coding is used in hospital outpatient billing.

Florida Medicare has revised the local coverage determinations (LCDs), for procedure codes with specific diagnosis criteria that are affected by the 2008 ICD-9-CM update. The following table lists the LCDs affected and the specific conditions revised as a result of the 2008 ICD-9-CM update:

LCD Title	2008 Changes
ABEXXAR – Tositumomab and Iodine I 131 Tositumomab (BEXXAR <sup>®</sup> ) Therapy	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes A9544, A9545, and G3001.</li> </ul>
AEPO – Epoetin alfa	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0885.</li> </ul>
AJ0640 – Leucovorin (Wellcovorin <sup>®</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0640.</li> </ul>
AJ2505 – Pegfilgrastim (Neulasta <sup>™</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J2505.</li> <li>Added diagnosis range 202.70-202.78 for HCPCS code J2505.</li> </ul>
AJ7504 – ATGAM (Lymphocyte Immune Globulin, Antithymocyte Globulin [Equine])	<ul style="list-style-type: none"> <li>Removed diagnosis 284.8 for HCPCS code J7504.</li> <li>Added diagnosis range 284.81-284.89 for HCPCS code J7504.</li> </ul>
AJ9000 – Doxorubicin HCl	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9000.</li> </ul>
AJ9041 – Bortezomib (Velcade <sup>®</sup> )	<ul style="list-style-type: none"> <li>Added diagnoses 200.40, 200.41, 200.42, 200.43, 200.44, 200.45, 200.46, 200.47, 200.48, and 202.70-202.78 for HCPCS code J9041</li> </ul>
AJ9045 – Carboplatin (Paraplatin <sup>®</sup> , Paraplatin-AQ <sup>®</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9045.</li> </ul>
AJ9160 – Denileukin Diftitox (Ontak <sup>®</sup> )	<ul style="list-style-type: none"> <li>Added diagnosis range 202.70-202.78 for HCPCS code J9160.</li> </ul>
AJ9178 – Epirubicin Hydrochloride (Ellence <sup>™</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9178.</li> </ul>
AJ9181 – Etoposide (Etopophos <sup>®</sup> Toposar <sup>®</sup> Vepeside <sup>®</sup> , VP-16)	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes J9181 and J9182.</li> </ul>
AJ9185 – Fludarabine (Fludara <sup>®</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9185.</li> </ul>
AJ9201 – Gemcitabine (Gemzar <sup>®</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9201.</li> </ul>
AJ9293 – Mitoxantrone Hydrochloride	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9293.</li> </ul>
AJ9310 – Rituximab (Rituxan <sup>®</sup> )	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9310.</li> </ul>
ANESP – Darbepoetin alfa (Aranesp <sup>®</sup> ) (novel erythropoiesis stimulating protein [NESP])	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0881.</li> </ul>
AZEVALIN – Ibritumomab Tiuxetan (Zevalin <sup>™</sup> ) Therapy	<ul style="list-style-type: none"> <li>Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes A9542 and A9543.</li> </ul>

## LOCAL COVERAGE DETERMINATIONS

### 2008 ICD-9-CM Changes (continued)

LCD Title	2008 Changes
A0145T – Computed Tomographic Angiography of the Chest, Heart, and Coronary Arteries	<ul style="list-style-type: none"> <li>Removed new diagnosis 414.2 from diagnosis range 414.00-414.9 and replaced diagnosis range 414.00-414.9 with diagnosis codes 414.00-414.07, 414.10, 414.11, 414.12, 414.19, 414.8, and 414.9 for CPT codes 0145T, 0146T, 0147T, 0148T, 0149T, 0150T, and 0151T.</li> </ul>
A43235 – Diagnostic and Therapeutic Esophagogastroduodenoscopy	<ul style="list-style-type: none"> <li>Added diagnosis range 789.51-789.59 for CPT codes 43235, 43236, 43237, 43238, 43239, 43241, 43243, 43244, 43245, 43246, 43247, 43248, 43249, 43250, 43251, 43255, and 43258.</li> </ul>
A44388 – Diagnostic Colonoscopy	<ul style="list-style-type: none"> <li>Added diagnosis 569.43 for CPT codes 44388, 44389, 44390, 44391, 44392, 44393, 44394, 44397, 45355, 45378, 45379, 45380, 45381, 45382, 45383, 45384, 45385, 45386, 45387, 45391, and 45392.</li> </ul>
A70540 – Magnetic Resonance Imaging of the Orbit, Face, and Neck	<ul style="list-style-type: none"> <li>Added diagnoses 200.31, 200.41, 200.51, 200.61, 200.71, and 202.71 for CPT codes 70540, 70542, and 70543.</li> </ul>
A70544 – Magnetic Resonance Angiography (MRA)	<ul style="list-style-type: none"> <li>Added diagnosis 440.4 for CPT codes 73725, C8912, C8913, and C8914.</li> </ul>
A73218 – Magnetic Resonance Imaging of Upper Extremity	<ul style="list-style-type: none"> <li>Removed diagnosis 359.2 for CPT codes 73218, 73219, 73220, 73221, 73222, and 73223.</li> <li>Added diagnoses 359.21-359.29, 999.31, and 999.39 for CPT codes 73218, 73219, 73220, 73221, 73222, and 73223.</li> <li>Changed descriptor for diagnoses 200.00-200.88 and 359.3 for CPT codes 73218, 73219, 73220, 73221, 73222, and 73223.</li> </ul>
A76536 – Ultrasound, Soft Tissues of Head and Neck	<ul style="list-style-type: none"> <li>Added diagnoses 200.31, 200.41, 200.51, 200.61, 200.71, and 202.71 for CPT code 76536.</li> </ul>
A78460 – Myocardial Perfusion Imaging	<ul style="list-style-type: none"> <li>Added diagnosis 440.4 for CPT codes 78460, 78461, 78464, 78465, 78478, and 78480.</li> </ul>
A82310 – Total Calcium	<ul style="list-style-type: none"> <li>Removed diagnoses 255.4 and 787.2 for CPT code 82310.</li> <li>Added diagnoses 255.41, 255.42, and 787.20-787.29 for CPT code 82310.</li> </ul>
A82330 – Ionized Calcium	<ul style="list-style-type: none"> <li>Removed diagnosis 787.2 for CPT code 82330.</li> <li>Added diagnosis range 787.20-787.29 for CPT code 82330.</li> </ul>
A83735 – Magnesium	<ul style="list-style-type: none"> <li>Removed diagnosis 255.4 for CPT code 83735.</li> <li>Added diagnoses 255.41 and 255.42 for CPT code 83735.</li> </ul>
A83970 – Parathormone (Parathyroid Hormone)	<ul style="list-style-type: none"> <li>Removed diagnosis 787.2 for CPT code 83970.</li> <li>Added diagnosis range 787.20-787.29 for CPT code 83970.</li> </ul>
A93303 – Transthoracic Echocardiogram (TTE)	<ul style="list-style-type: none"> <li>Removed diagnosis 999.3 for CPT codes 93307 and 93308.</li> <li>Added diagnoses 415.12, 999.31 and 999.39 for CPT codes 93307 and 93308.</li> </ul>
A93922 – Noninvasive Physiologic Studies of Upper or Lower Extremity Arteries	<ul style="list-style-type: none"> <li>Added diagnoses 440.4 and 449 for CPT codes 93922, 93923, and 93924.</li> </ul>
A93925 – Duplex Scan of Lower Extremity Arteries	<ul style="list-style-type: none"> <li>Added diagnoses 440.4 and 449 for CPT codes 93925 and 93926.</li> </ul>
A93965 – Non-Invasive Evaluation of Extremity Veins	<ul style="list-style-type: none"> <li>Added diagnosis 415.12 for CPT codes 93965, 93970, and 93971.</li> </ul>
A93975 – Duplex Scanning	<ul style="list-style-type: none"> <li>Removed diagnosis 789.5 for CPT codes 93975 and 93976.</li> <li>Added diagnoses 789.51 and 789.59 for CPT codes 93975 and 93976.</li> </ul>

*2008 ICD-9-CM Changes (continued)*

LCD Title	2008 Changes
A95860 – Electromyography and Nerve Conduction Studies	<ul style="list-style-type: none"> <li>Removed diagnosis 787.2 for CPT codes 95860, 95861, 95863, 95864, 95867, 95868, 95869, 95870, 95872, 95900, 95903, 95904, 95934, 95936, and 95937.</li> <li>Added diagnosis range 787.20-787.29 for CPT codes 95860, 95861, 95863, 95864, 95867, 95868, 95869, 95870, 95872, 95900, 95903, 95904, 95934, 95936, and 95937.</li> </ul>

Source: CMS Pub. 100-04, Transmittal 1260, CR 5643

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## **ADDITIONAL MEDICAL INFORMATION**

### **Humanitarian Use Device and Humanitarian Device Exemptions**

A humanitarian use device (HUD) is a device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4000 individuals in the United States per year. The costs of research and development for such devices could exceed the returns when treating such small populations. The HUD provision of the regulations is intended to provide an incentive for the development of devices, which might provide benefit to these small populations of individuals. To obtain approval for marketing of a HUD, the manufacturer submits a humanitarian device exemption (HDE) application to the Food and Drug Administration (FDA). Such applications are exempt from the “effectiveness” requirement outlined in the Food, Drug and Cosmetic Act (Ch. 5, Sub. Ch. A, Sec. 514-515). In short, the HDE need not demonstrate that the device is effective for its intended use, but instead must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health, outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. FDA decisions regarding a device’s classification as a HUD and its use under an HDE relate to **marketing** of the device. The Centers for Medicare & Medicaid Services (CMS) and/or its contractor determine **coverage** of such devices.

Currently, CMS does not have a national coverage determination (NCD) for HDEs. The Social Security Act [Title XVIII, Sec 1862(a)(1)(a)] precludes Medicare program payment for any and all services not reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member. Contractors have offered only limited coverage, if any, for HDEs, as a device whose effectiveness is questionable, may not meet the requirements of the provisions of section 1862(a)(1)(a).

First Coast Service Options, Inc. (FCSO) will consider coverage for a humanitarian use device when:

1. The FDA has designated the device as a humanitarian use device (HUD).
2. The FDA has approved the device for marketing under an HDE.
3. The device has local IRB (Institutional Review Board) approval in the setting in which it is proposed to be used.
4. Appropriate informed consent has been obtained from the patient.
5. There exists a benefit category and the device is not statutorily excluded from coverage.
6. There is no national or local coverage determination (NCD/LCD), which prohibits coverage.
7. If there is a national or local coverage determination applicable to the device and/or its proposed use, the criteria noted in the NCD/LCD are met.
8. The device is used in an episode of care that is reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve the function of a malformed body member.

FCSO requires providers seeking to use a HUD in the diagnosis and treatment of Medicare beneficiaries to submit the following information:

1. Details about the specific device, including documentation that the device is classified by the FDA as a HUD and has been approved by the FDA under an HDE.
2. A description of the clinical scenario(s) in which the device will be used.

## Humanitarian Use Device and Humanitarian Device Exemptions (continued)

3. A list of expected CPT/HCPCS codes expected to be billed in conjunction with the use of the device. In the event that an unlisted code will be used, the service to which it will apply must be described.
4. A copy of the local IRB approval. The FDA requires that a HUD be used only in facilities that have established an IRB approval process responsible for supervising the use of the device and related services.

Upon receipt of the required documentation, FCSO will review your submission and respond as soon as possible. Though there is no prior approval process in traditional Medicare, this process will help ensure Medicare beneficiaries are receiving covered services and have adequate access to care. Given the complexities of determining whether a device is reasonable and necessary when it has

not been proven effective for its intended use, providers may wish to discuss this issue with their patients and consider the use of an advanced beneficiary notice (ABN). Additional information on the CMS beneficiary notice initiative may be found at <http://www.cms.hhs.gov/bni/>. All coverage/payment decisions are made at the time of claims submission. Do not submit clinical records unless specifically asked to do so. Medical records, when submitted, should document why the benefits of use of the device outweigh the risks, considering both other available devices and other available therapies.

### FDA Links to Humanitarian Device Exemption Information

<http://www.fda.gov/cdrh/ode/guidance/1381.html>

[http://www.fda.gov/cdrh/devadvice/pma/app\\_methods.html](http://www.fda.gov/cdrh/devadvice/pma/app_methods.html)

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## Investigational Device Exemptions

Medicare may provide coverage and reimbursement for certain investigational devices and services related to the use of those devices. Such services may be covered when they are necessary to the use of the device, as part of the preparation for the use of the device or for the follow-up care after device use. Coverage is contingent upon meeting regulatory criteria (listed below) and upon the Medicare contractor's approval of the application for reimbursement.

### Background

Title XVIII of the Social Security Act prohibits Medicare from providing coverage for the use of devices that are not "reasonable and necessary for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member" [1862(a)(1)(A)]. Consequently, Medicare denied any and all reimbursement for experimental devices and associated costs due to the absence of medical necessity that could not be established when the safety and effectiveness of a device was unknown. A device the Food and Drug Administration (FDA) categorized as investigational was presumed to be experimental, including devices being studied under investigational device exemptions (IDEs). A medical device required FDA-approval for marketing (post-marketing approval or "PMA"), the device's safety and effectiveness having been established, to qualify for payment consideration.

On November 1, 1995, Congress enacted legislation that now permits coverage of some investigational devices. That legislation directed Medicare to cover the use of certain devices classified by the FDA as category B investigational devices, under the auspices of an IDE. In 2003, Congress passed the Medicare Modernization Act which directed Medicare to provide limited coverage for the use of certain category A devices. Coverage for both categories of devices is contingent upon meeting certain criteria.

**Category A** consists of novel, first-of-a-kind technologies.

These are innovative devices for which initial questions of safety and effectiveness have not been resolved and the absolute risk of the device type has not been

established. The FDA has insufficient evidence to determine whether these device types can be safe and effective.

**Category B** devices are newer generation devices of already proven technologies where the initial questions of safety and effectiveness of these devices have been resolved.

### Investigational Device Exemption Coverage Criteria

1. The device must be used in the context of an *FDA and IRB (Institutional Review Board) approved study*. Coverage is limited to a predetermined number of patients and a predetermined number of sites as specified in the FDA-approval letter and/or the study protocol.
2. The device must be used according to the clinical trial's approved patient protocols.
3. The device must have an assigned IDE number. This identification number allows the Medicare contractor to establish the special claims processing procedures associated with the study.
4. The device must meet all Medicare's coverage requirements.
  - a. It must fall within a benefit category.
  - b. In the event that the device itself and/or the associated services fall within the scope of a national or local coverage determination (NCD/LCD) it must meet the criteria set forth in the NCD/LCD.
  - c. In the absence of an NCD/LCD, it must be considered reasonable and necessary in accordance with section 1862(a)(1)(a) of the Act.
5. Use of the device and the provision of associated services must be furnished in a setting appropriate to the patient's medical needs and condition.



*Investigational Device Exemptions (continued)*

- Category A devices are covered only to the extent that they are used in the diagnosis, treatment or monitoring of a life-threatening disease or condition. Only the related routine care costs are covered. The device itself is not subject to reimbursement. Category B devices are covered in addition to the routine care costs.

**Notes**

- Current statutes and regulations are not a guarantee of coverage for a device and associated services. Assignment of an IDE number, in and of itself, is also not a guarantee of coverage.
- It is the responsibility of the provider participating in the IDE protocol to furnish any and all information about the device, the associated services, the protocol and participating Medicare beneficiaries that the contractor deems necessary to make a coverage determination and to properly process claims.
- Providers should not bill Medicare for services, supplies or other costs, which are paid for, or provided by, another party.
- Providers should not bill Medicare for services or costs associated with data collection, data analysis, coordinator time or any cost not considered by the contractor as a routine clinical care cost.
- Medicare contractors have discretion for the approval of coverage of devices and associated services under an IDE.
- Approval by the contractor for an IDE should not be construed as prior authorization for specific services for specific Medicare beneficiaries.

**Billing Guidelines**

**Medicare Part A**

The UB-04 (CMS-1450) claim form contains form locators (FLs) that must be specifically coded for IDE trial claims according to the Centers for Medicare & Medicaid Services (CMS) instructions, including:

**Device Line FL 42: Revenue Code.** Bill all IDE devices and procedures under revenue code 624. This code was specifically created by CMS to identify IDE devices, and is only applicable to investigational devices and procedures with FDA and IRB-approved IDE.

**Medicare Coverage and Billing Requirements**

Coverage and Billing Requirements	Clinical Trial	Category A IDE	Category B IDE
Device or Drug Payable?	NO	NO	YES
Associated Routine Costs Payable?	YES	YES	YES
Life Threatening Dx Required?	NO	YES	NO
IDE # in Item 23 Required on CMS-1500?	NO	YES	YES
IDE # in FL 43 Required on CMS-1450?	NO	YES	YES
Primary Dx V70.7 Required?	CMS-1500 only	NO	NO
Secondary Dx V70.7 Required?	CMS-1450 only	YES	YES
Modifier QV per Line Required?	YES	YES	NO
Modifier QA per Line Required?	NO	NO	YES
Revenue Code 624?	NO	YES	YES

**FL 43: IDE Number, “G prefix field”.** For claims submitted via paper, enter the 7-digit IDE number for the trial in form locator 43. For electronic claims, enter the IDE number on the bottom of page 4. Look for “ID” and a two-digit field (for entering the line number that corresponds to revenue code 624) and then the seven-digit field for the IDE number. If using DDE and entering a new claim, the IDE field is on page 3, identified as “IDE”.

**FL 44: If exists, HCPCS or “C” code.** In FL 44, opposite the 624 revenue code, list the appropriate HCPCS or “C” code for the device/procedure. May be xxx99. The ICD-9-CM diagnosis codes listed on the claim must be consistent with IDE trial indications.

**Procedure Line FL 42:** Rev CD for site of service **FL 43:** Description **FL 44:** HCPCS/CPT; use closest appropriate HCPCS section or group; may be xxx99.

**Medicare Part B**

The CMS-1500 (08-05) claim form (or the electronic equivalent) must be specifically coded for IDE claims in accordance with CMS instructions, as follows:

**ICD-9-CM Diagnosis Codes:** The ICD-9-CM diagnosis codes listed on the claim must be consistent with the IDE trial indications. Category A IDE coverage requires an immediately life-threatening disease or condition. The ICD-9-CM code must reflect this. Additionally, V70.7, “examination of a participant in clinical trial”, must be reported as a secondary diagnosis.

**IDE Number:** The IDE number is reported in **item 23** (or the electronic equivalent) when an investigational device is used in an FDA-approved clinical trial. Claims for services associated with a Category A IDE must report **modifier QV** (item or service provided as routine in a Medicare qualifying clinical trial) for each line item. Claims for services associated with Category B IDE investigations must report **modifier QA** (FDA investigational device exemption) for each line item. These modifiers are reported in **item 24D** (or the electronic equivalent).

## Investigational Device Exemptions (continued)

### Useful Links

Medicare Benefit Policy Manual (Pub. 100-02, Ch. 14), Medical Devices  
<http://www.cms.hhs.gov/manuals/Downloads/bp102c14.pdf>

FDA Clinical Trial and Investigational Device Exemption Web page  
<http://www.fda.gov/cdrh/devadvice/ide/index.shtml>

## INVESTIGATIONAL DEVICE EXEMPTION (IDE) APPROVAL REQUIREMENTS

- The name and description of device
- A copy of the study protocol. Summaries and abbreviated versions are not acceptable.
- Identification of the sponsor of the trial
- Identification of the funding agency/organization, if different from sponsor.
- A copy of the Food and Drug Administration-approval letter (conditional approvals not sufficient).
- Identification of lead investigator
- Identification of assigned IDE #
- A copy of local/hospital/institutional IRB-approval
- Stipulation as to the anticipated place of service (initial device implantation/attachment)
- Notification of any and all costs by code to be billed in association with the study. Identification of all services as either routine care costs or data acquisition/study related costs, by code, including the anticipated frequency of billing. **Note:** *Data acquisition/study related costs are **not** billable to Medicare*
- An outline of a typical claim identifying codes to be billed on the initial date of service (implantation/attachment of device) to include:
  - Physician services (CPT/HCPCS) codes submitted to the carrier.
  - Facility services [(CPT/HCPCS) (APC; ICD-9: DRG)] submitted to the fiscal intermediary.
  - If unlisted code is used a complete description of the procedure and estimate of appropriate RVUs based upon similar CPT/HCPCS codes.
- A copy of the informed consent document and/or protocol for obtaining informed consent.
- Pertinent articles in the form of at least two publications in the peer reviewed literature.
- A copy of all agreements between the sponsor and the provider, especially, but not limited to, financial agreement.

*I certify the above is accurate and complete and understand that it is my responsibility to ensure that claims are submitted to Medicare in compliance with Medicare guidelines.*

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(To be signed by IDE investigator or proxy)

Please submit this document with the above requested materials to:

First Coast Service Options, Inc.  
Attn: James J. Corcoran, MD, MPH  
Office of the Medical Director, 20T  
532 Riverside Avenue  
Jacksonville, FL 32202

First Coast Service Options will make a coverage determination within 45 days of submission of all the required documentation.

# HOSPITAL SERVICES

## Inpatient Rehabilitation Facility Annual Update: Prospective Payment System PRICER Changes for Fiscal Year 2008

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

### Provider Types Affected

Providers submitting claims to Medicare fiscal intermediaries (FIs) and Part A/B Medicare Administrative Contractors (A/B MACs) for inpatient rehabilitation facility (IRF) prospective payment system (PPS) services provided to Medicare beneficiaries.

### Provider Action Needed

#### STOP – Impact to You

This article is based on change request (CR) 5694, which provides details about the annual IRF PPS rate updates for fiscal year (FY) 2008.

#### CAUTION – What You Need to Know

Updated rates are effective for claims with **discharges** that fall **on or after October 1, 2007**, and on or before September 30, 2008.

#### GO – What You Need to Do

See the *Background* section of this article for further details regarding this IRF annual update.

### Background

On August 7, 2001, the Centers for Medicare & Medicaid Services (CMS) published a final rule in the *Federal Register* ([http://www.access.gpo.gov/su\\_docs/fedreg/a010807c.html](http://www.access.gpo.gov/su_docs/fedreg/a010807c.html)) that established the PPS for IRFs as authorized under the Social Security Act (Section 1886(j)). In that final rule, CMS set forth per discharge federal rates for federal FY 2002. These IRF PPS payment rates became effective for cost reporting periods beginning on or after January 1, 2002, and annual updates to the IRF PPS rates are required by the Social Security Act (Section 1886(j)(3)(C)).

On August 7, 2007, CMS published the FY 2008 IRF PPS final rule in the *Federal Register* (<http://www.cms.hhs.gov/inpatientrehabfacpps/downloads/cms1551f.pdf>), which provides the prospective payment rates applicable for IRFs for FY 2008.

A new IRF PRICER software package will be released prior to October 1, 2007, that will contain the updated rates that are effective for claims with **discharges** that fall **on or**

**after October 1, 2007, through September 30, 2008.**

Your FI or Part A/B MAC will install the new revised PRICER program in a timely fashion to ensure you receive accurate payments for IRF PPS claims with discharges occurring on or after October 1, 2007, through September 30, 2008.

The IRF PPS FY 2008 rates applicable to discharges on or after October 1, 2007, through September 30, 2008, are as shown in the following table:

Standard federal rate	\$13,451
Fixed loss amount	\$7,362
Labor-related share	75.818%
Non-labor related share	24.182%
Urban national average cost-to-charge ration (CCR)	0.476
Rural national average CCR	0.596

### Additional Information

The official instruction, CR 5694, issued to your Medicare FI or A/B MAC regarding this change may be found on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1323CP.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: MM5694

Related Change Request (CR) Number: 5694

Related CR Release Date: August 24, 2007

Related CR Transmittal Number: R1323CP

Effective Date: October 1, 2007

Implementation Date: October 1, 2007

Source: CMS Pub. 100-04, Transmittal 1323, CR 5694

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## New Web Site for Approved Transplant Centers

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

### Provider Types Affected

All hospital transplant programs that submit claims to Medicare administrative contractors (A/B MACs), carriers or fiscal intermediaries (FIs), for organ transplants provided to Medicare beneficiaries.

### Provider Action Needed STOP – Impact to You

This article is based on change request (CR) 5724, which states that on March 30, 2007, the Department of Health & Human Services (DHHS) established a regulation authorizing the survey and certification of transplant programs.

### CAUTION – What You Need to Know

All hospital transplant programs covered by the regulation, whether currently approved by the Centers for Medicare & Medicaid Services (CMS) or seeking initial approval, must submit a request for approval under the new regulations to CMS by December 26, 2007 (180 days from the effective date of the regulation). **Those programs that were already Medicare approved for participation at the time of the effective date (June 28, 2007) of the regulation will continue to be covered under national coverage determination (NCD) or end-stage renal disease (ESRD) conditions for coverage (as applicable) until they are notified in writing by CMS of their approval or denial under the new regulations.**

### GO – What You Need to Do

**Be sure to submit** your request for approval by December 26, 2007, and see the *Background/Key Points* section of this article for further details. The specific manual sections that relate to this article are attached to CR 5724, which is available at the Web address listed in the *Additional Information* section of this article.

### Background/Key Items

CMS is the federal agency responsible for monitoring compliance with the Medicare conditions of participation for transplant hospitals. CMS will review the information transplant hospitals submit and conduct onsite surveys as necessary to determine compliance with the conditions of participation. Transplant programs must be in compliance with the conditions of participation to continue Medicare approval or to receive initial approval for participation.

- On or about September 1, 2007, Medicare approved transplant centers for all Medicare approved transplant

programs will be listed on the CMS Web site at [http://www.cms.hhs.gov/CertificationandCompliance/20\\_Transplant.asp#TopOfPage](http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage).

- Transplant hospitals should review the above Web site and send applications to the following address:  
Centers for Medicare & Medicaid Services  
Survey and Certification Group  
7500 Security Blvd. Mailstop: S2-12-25  
Baltimore, MD 21244
- Medicare providers should be aware that the new CMS certification number (CCN) series 9800-9899, established via transmittal 25 (CR 5490) on April 20, 2007 is **not for billing**. **Providers are not to bill with the CCN number.**
- CR 5724 will not change the way your Medicare contractors process your claims. Your contractor will, however, continue to check to determine if you are an approved transplant center **and** check the effective approval date.
- Your Medicare contractor will also check to determine if your facility is certified for adults and/or pediatric transplants dependent upon the patient's age.

### Additional Information

For complete details regarding this change request (CR) please see the official instruction (CR 5724) issued to your Medicare FI, carrier, or A/B MAC. That instruction may be viewed by going to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1341CP.pdf>.

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

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

MLN Matters Number: MM5724

Related Change Request (CR) Number: 5724

Related CR Release Date: September 21, 2007

Related CR Transmittal Number: R1341CP

Effective Date: June 28, 2007

Implementation Date: October 22, 2007

Source: CMS Pub. 100-04, Transmittal 1341, CR 5724

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## Submission of Claims for Pancreas Transplantation Alone

During 2006, the Centers for Medicare & Medicaid Services (CMS) instructed fiscal intermediaries to hold any pancreas transplantation alone claims with discharge dates on or after April 26, 2006. In addition, CMS requested from Part A providers **not** to submit to their fiscal intermediaries claims for pancreas transplantation alone until further notice.

Effective October 1, 2007, with the installation of the fiscal year 2008 Medicare code editor (MCE) software, fiscal intermediaries will release for processing all claims for pancreas transplantation alone with discharge dates of on or after April 26, 2006.

### Action Required by Providers

Effective October 1, 2007, providers holding claims for pancreas transplantation alone with discharge dates of April 26, 2006, or after can submit these claims for processing. ❖

Source: CMS JSM-07512, August 21, 2007

## Delay in the Crossover of 837-Institutional Claims Containing Reason Code 42

The Centers for Medicare & Medicaid Services (CMS) has notified fiscal intermediaries that certain 837-institutional claims that were crossed over to the coordination of benefit contractor (COBC) have been rejected because the claims contained claim adjustment reason code (CARC) 42, which should have been deactivated and replaced with CARC 45.

The Fiscal Intermediary Shared System (FISS) is in the process of installing the deactivation of CARC 42 and replacing it with CARC 45. The implementation is anticipated by the weekend of August 25, 2007. Claims rejected since August 4, 2007, will be corrected approximately two weeks later.

### No Action Required by Providers

CMS requests that, to the extent possible, providers refrain from billing Medicare beneficiaries' supplemental insurer for outstanding balances on recently billed inpatient and outpatient-oriented claims until FISS has completed the installation process.

Source: CMS Provider Education Resource 200708-15

## Present on Admission Indicator

*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 September 11, 2007, to clarify the timeframes for reporting the present on admission indicator (POA). The revised *MLN Matters* article MM5499 was published in the September 2007 *Medicare A Bulletin* (pages 35-37).

### Provider Types Affected

Hospitals who submit claims to fiscal intermediaries (FI) or Part A/B Medicare administrative contractors (A/B MACs) for Medicare beneficiary inpatient services.

### Provider Action Needed

#### STOP – Impact to You

**Effective October 1, 2007**, Medicare providers should begin to submit a present on admission (POA) indicator for every diagnosis on your inpatient acute care hospital claims. Critical access hospitals, Maryland waiver hospitals, long-term care hospitals, cancer hospitals, psychiatric hospital, inpatient rehabilitation facilities, and children's inpatient facilities are exempt from this requirement.

#### CAUTION – What You Need to Know

CR 5499, from which this article is taken, announces the requirement for completing a POA indicator for every diagnosis on an inpatient acute care hospital claim beginning with discharges **on or after October 1, 2007**, and provides your FI and A/B MACs with the coding and editing requirements, and software modifications needed to successfully implement this indicator.

### GO – What You Need to Do

You should make sure that your billing staffs are aware of this requirement, and that your physicians and other practitioners and coders are collaborating to ensure complete and accurate documentation, code assignment and reporting of diagnoses and procedures. Please refer to the *Background* section for more details.

#### Background

Section 5001(c) of the Deficit Reduction Act of 2005 requires hospitals to begin reporting the secondary diagnoses that are present on the admission of patients **effective for discharges on or after October 1, 2007**. By October 1, 2007, the Centers for Medicare & Medicaid Services (CMS) will have selected at least two high cost or high volume (or both) diagnosis codes that:

- Represent conditions (including certain hospital acquired infections) that could reasonably have been prevented through the application of evidence-based guidelines; and
- When present on a claim along with other (secondary) diagnoses, have a diagnosis related group (DRG) assignment with a higher payment weight.

## Present on Admission Indicator (continued)

Then, for acute care inpatient PPS discharges on or after October 1, 2008, while the presence of these diagnosis codes on claims **could** allow the assignment of a higher paying DRG, when they are present at the time of discharge, but not at the time of admission, the DRG that must be assigned to the claim will be the one that does **not** result in the higher payment.

Beginning for discharges on or after October 1, 2007, hospitals should begin reporting the POA indicator for acute care inpatient PPS discharges. **There is one exception, i.e., claims submitted via direct data entry (DDE) should not report the POA indicators until January 1, 2008, as the DDE screens will not be able to accommodate the codes until that date.**

Between October 1, 2007, and December 31, 2007, CMS will collect the information on the hospital claim, but does not intend to provide any remittance or other information to hospitals if the information is not submitted correctly for each diagnosis on the claim. Hospitals that fail to provide the POA indicator **for discharges on or after January 1, 2008**, will receive a remittance advice remark code informing them that they failed to report a valid POA indicator. However, **beginning with discharges on or after April 1, 2008**, Medicare will return claims to the hospital if the POA indicator is not reported and the hospital will have to supply the correct POA code and resubmit the claim.

In order to be able to group these diagnoses into the proper DRG, CMS needs to capture a POA indicator for all claims involving inpatient admissions to general acute care hospitals. CR 5499, from which this article is taken, announces this requirement and provides your FIs and A/B MACs with the coding and editing requirements, and software modifications needed to successfully implement this indicator.

**Note:** Adjustments to the relative weight that occur because of this action are not budget neutral. Specifically, aggregate payments for discharges in a fiscal year could be changed as a result of these adjustments.

These POA guidelines are not intended to replace any found in the ICD-9-CM *Official Guidelines for Coding and Reporting*, nor are they intended to provide guidance on when a condition should be coded. Rather, you should use them in conjunction with the *UB-04 Data Specifications Manual* and the ICD-9-CM *Official Guidelines for Coding and Reporting* to facilitate the assignment of the POA indicator for each “principal” diagnosis and “other” diagnosis codes reported on claim forms (UB-04 and 837 Institutional). Information regarding the UB-04 data specifications may be found at <http://www.nubc.org/become.html>.

**Note:** Critical access hospitals, Maryland waiver hospitals, long-term care hospitals, cancer hospitals, and children’s inpatient facilities are exempt from this requirement. Also, as noted in CR 5679 (<http://www.cms.hhs.gov/Transmittals/downloads/R2890TN.pdf>), hospitals paid under a prospective payment system (PPS) other than the acute care hospital PPS are exempt. Thus psychiatric and rehabilitation hospitals are exempt.

The following information, from the *UB-04 Data Specifications Manual*, is provided to help you understand how and when to code POA indicators:

### 1. General Reporting Requirements

- Pertain to all claims involving inpatient admissions to general acute care hospitals or other facilities that are subject to a law or regulation mandating collection of present on admission information.
- Present on admission is defined as present at the time the order for inpatient admission occurs – conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are considered as present on admission.
- POA indicator is assigned to principal and secondary diagnoses (as defined in Section II of the *Official Guidelines for Coding and Reporting*) and the external cause of injury codes.
- The provider must still resolve issues related to inconsistent, missing, conflicting, or unclear documentation.
- If a condition would not be coded and reported based on UHDDS definitions and current official coding guidelines, then the POA indicator would not be reported.
- CMS does not require a POA indicator for the external cause of injury code unless it is being reported as an “other diagnosis.”

### 2. Reporting Options and Definitions

**Y** – Yes (present at the time of inpatient admission)

**N** – No (not present at the time of inpatient admission)

**U** – Unknown (documentation is insufficient to determine if condition is present at time of inpatient admission)

**W** – Clinically undetermined (provider is unable to clinically determine whether condition was present at time of inpatient admission or not)

**1** – Unreported/Not used – Exempt from POA reporting (This code is the equivalent of a blank on the UB-04, but blanks are not desirable when submitting data via the 4010A1.

The POA data element on your electronic claims must contain the letters “POA” followed by a single POA indicator for every diagnosis that you report. The POA indicator for the principal diagnosis should be the first indicator after “POA,” and (when applicable) the POA indicators for secondary diagnoses would follow. The last POA indicator must be followed by the letter “Z” to indicate the end of the data element (or FIs and A/B MACs will allow the letter “X” which CMS may use to identify special data processing situations in the future).

Note that on paper claims the POA indicator is the eighth digit of the principal diagnosis field (FL 67), and the eighth digit of each of the secondary diagnosis fields (FL 67

**Present on Admission Indicator (continued)**

A-Q); and on claims submitted electronically via 837, 4010 format, you must use segment K3 in the 2300 loop, data element K301.

Below is an example of what this coding should look like on an electronic claim:

*If segment K3 read as follows: "POAYNUWIYZ," it would represent the POA indicators for a claim with 1 principal and five secondary diagnoses. The principal diagnosis was POA (Y), the first secondary diagnosis was not POA (N), it was unknown if the second secondary diagnosis was POA (U), it is clinically undetermined if the third secondary diagnosis was POA (W), the fourth secondary diagnosis was exempt from reporting for POA (I), and the fifth secondary diagnosis was POA (Y).*

As of January 1, 2008, all DDE screens will allow for the entry of POA data and POA data will also be included with any secondary claims sent by Medicare for coordination of benefits purposes.

See the complete instructions in the *UB-04 Data Specifications Manual* for more specific instructions and examples.

**Note:** CMS, in consultation with the Centers for Disease Control and Prevention and other appropriate entities, may revise the list of selected diagnoses from time to time, but there will always be at least two conditions selected for discharges occurring during any fiscal year. Further, this list of diagnosis codes and DRGs is not subject to judicial review.

Finally, you should keep in mind that achieving complete and accurate documentation, code assignment, and reporting of diagnoses and procedures requires a joint effort between the health care provider and the coder. Medical

record documentation from any provider (a physician or any qualified health care practitioner who is legally accountable for establishing the patient's diagnosis) involved in the patient's care and treatment may be used to support the determination of whether a condition was present on admission or not; and the importance of consistent, complete documentation in the medical record cannot be overemphasized.

**Note:** You, your billing office, third party billing agents and anyone else involved in the transmission of this data must insure that any resequencing of diagnosis codes prior to their transmission to CMS, also includes a resequencing of the POA indicators.

**Additional Information**

You can find the official instruction, CR 5499, issued to your FI or A/B MAC by visiting the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1240CP.pdf>.

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

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

MLN Matters Number: MM5499 – Revised  
Related Change Request (CR) Number: 5499  
Related CR Release Date: May 11, 2007  
Related CR Transmittal Number: R1240CP  
Effective Date: October 1, 2007  
Implementation Date: October 1, 2007

Source: CMS Pub. 100-04, Transmittal 1240, CR 5499

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# CRITICAL ACCESS HOSPITAL SERVICES

## Sunset of the Physician Scarcity Area Bonus Payment

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

### Provider Types Affected

Providers billing a Medicare carrier, fiscal intermediary (FI), or Medicare administrative contractor (A/B MAC) for services provided to Medicare beneficiaries in physician scarcity areas.

### Provider Action Needed

#### STOP – Impact to You

This article is based on change request (CR) 5711 that reminds physicians that the physician scarcity area (PSA) bonus under section 413(a) of the Medicare Modernization Act (MMA) will sunset after December 31, 2007.

#### CAUTION – What You Need to Know

The PSA bonus is payable for dates of service January 1, 2005 through December 31, 2007. The PSA bonus is **not payable for dates of service after December 31, 2007.**

#### GO – What You Need to Do

Make certain that your billing staffs are aware of these changes as listed in the section below and in the revisions to the *Medicare Claims Processing Manual* chapter 4, sections 250.2.1, 250.2.2 and 250.3.2. The revised manual sections are attached to the official instruction in CR 5711. The Web address for accessing CR 5711 is in the *Additional Information* section of this article.

### Background

Section 413(a) of the Medicare Modernization Act (MMA) requires Medicare to pay an additional five percent bonus to physicians rendering service in a designated PSA. Physician scarcity designations are based on the lowest primary care and specialty care ratios of Medicare beneficiaries to active physicians in every county or the lowest primary care and specialty care ratios of Medicare benefi-

ciaries to active physicians in each identified rural census tract. The bonus payment is based on the amount actually paid, not the amount Medicare approved for each service.

**The key point of CR 5711 is that the PSA termination date is December 31, 2007 and is not payable for dates of service after that date.**

### Additional Information

For complete details regarding this issue, see the official instruction (CR 5711) issued to your Medicare carrier, FI, or A/B MAC. That instruction may be viewed by going to the CMS Web site <http://www.cms.hhs.gov/Transmittals/downloads/R1321CP.pdf>.

For the CMS Web site with information about HPSA/PSA (physician bonuses) and ZIP code downloadable files you may visit on the CMS Web site <http://www.cms.hhs.gov/HPSAPSAPhysicianBonuses/>.

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: MM5711

Related Change Request (CR) Number: 5711

Related CR Release Date: August 24, 2007

Related CR Transmittal Number: R1321CP

Effective Date: January 1, 2008

Implementation Date: January 7, 2008

Source: CMS Pub. 100-04, Transmittal 1321, CR 5711

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# HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

## October 2007 Integrated Outpatient Code Editor Specifications

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-outpatient prospective payment system (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) 5723 and notifies providers that the integrated outpatient code editor (I/OCE) specifications, version 8.3, is effective October 1, 2007. Claims with dates of service **prior to July 1, 2007**, are routed through the non-integrated versions of the OCE software that **coincide with the versions in effect for the date of service on the claim.**

### Background

This article is based on CR 5723 and informs providers that the I/OCE routes all institutional outpatient claims (including non-OPPS hospital claims) through a single integrated OCE eliminating the need to update, install, and maintain two separate OCE software **logic that is applied to outpatient bill types that already pass through the OPPS OCE software.** It expands the software usage to include non-OPPS hospitals.

There are numerous changes/additions/deletions to diagnosis codes, ambulatory payment classification (APC) codes, and Health Care Common Procedure Codes (HCPCS) in the October 2007, the changes will not be detailed in this article. Instead, please see CR 5723 for those details. CR 5723 is available on the Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1342CP.pdf>.

The key changes for the October 2007 I/OCE are as follows: (Some I/OCE modifications in the release may also be retroactively added to prior releases. If so, the retroactive date will appear in the 'Effective Date' column.)

### Effective Date Modification

- January 1, 2006** Modify the program logic to return edit 47 for codes that have SI changed from Q to N, if there is no other service on the claim (e.g., if G0378 is the only code reported on a claim).
- October 1, 2007** Modify the program to exclude bill type 12x from edits 71 and 77.

- July 1, 2007** Modify the program to assign ASC group numbers only on claims from non-OPPS hospitals (OPPS flag = 2) with bill type 83x, and only in the PC program/interface. Make HCPCS/APC/SI changes as specified by CMS. Implement version 13.2 of the NCCI file, removing all code pairs, which include anesthesia (00100-01999), E&M (92002-92014, 99201-99499), or MH (90804-90911).

- October 1, 2007** Update the valid diagnosis code lists with ICD-9-CM changes.

- October 1, 2007** Update diagnosis/age and diagnosis/sex conflict edits with MCE changes.

- April 1, 2007** Remove codes 0599, 0709, 0749, 0759, 0779, 0789 & 0799 from the list of valid revenue codes.

- October 1, 2007** Remove code 0719 from the list of valid revenue codes.

**Note:** Readers should also read through the specifications attached to CR 5723 and note the highlighted sections, which also indicate change from the prior release of the software.

### Additional Information

For complete details regarding CR 5723, please see the official instruction (CR 5723) issued to your Medicare A/B MAC, RHHI, or FI. That instruction may be viewed by going to the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1342CP.pdf>.

If you have questions, please contact your Medicare A/B MAC, RHHI, 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: MM5723  
 Related Change Request (CR) Number: 5723  
 Related CR Release Date: September 21, 2007  
 Related CR Transmittal Number: R1342CP  
 Effective Date: October 1, 2007  
 Implementation Date: October 1, 2007  
 Source: CMS Pub. 100-04, Transmittal 1342, CR 5723

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**October 2007 Update of the Hospital Outpatient Prospective Payment System: Summary of Payment Policy Changes**

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

**Provider Types Affected**

Providers submitting claims to Medicare contractors (fiscal intermediaries [FIs], regional home health intermediaries [RHHIs], and/or Medicare administrative contractors [A/B MACs]) for outpatient services furnished under the outpatient prospective payment system (OPPS).

**Impact On Providers**

This article is based on change request (CR) 5718, which describes changes to the OPPS to be implemented in the October 2007 OPPS update. Be sure billing staff are aware of these changes.

**Background**

CR 5718 describes changes to, and billing instructions for, various payment policies implemented in the October 2007 OPPS update. The October 2007 integrated code editor (I/OCE) and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), ambulatory payment classification (APC), HCPCS modifier, and revenue code additions, changes, and deletions identified in this notification.

October 2007 revisions to I/OCE data files, instructions, and specifications will be provided in change request (CR) 5723, "October 2007 integrated outpatient code editor (I/OCE) specifications version 8.3."

Key changes in CR 5718 are as follows:

**Changes to Procedure to Device Edits**

The effective dates for the previously existing procedure to device edits for the following procedures are changed from January 1, 2007, to October 1, 2005, in the October 2007 I/OCE:

- 19296** Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy.
- 19297** Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy concurrent with partial mastectomy (List in addition to code for primary procedure)
- 93651** Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connection or other atrial foci, singly or in combination.

**Correction to the Offset Percentages for APCs 0315 and 0385**

The Centers for Medicare & Medicaid Services (CMS) reduces the payment for selected APC when specified devices are furnished to the hospital without cost or with a full credit for the cost of the device being replaced. The tables that contain the devices and APCs to which the policy applies may be found on the CMS Web site under supporting documentation for CMS-1506 FC at <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/>.

There were errors in the entries for two APCs in the table of adjustment percentages and adjustment amounts that were posted before October 1, 2007. The table containing the corrected amounts is now posted at <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/> under supporting documentation for CMS-1506 FC and is titled: "2007 OPPS Without Cost or With Credit Device Information; corrected 10/01/2007".

Table 1, below, shows both the incorrect and correct offset percentages and adjustment amounts for APC 0315 (Level II implantation of neurostimulator) and APC 0385 (Level I prosthetic urological procedures). The OPPS PRICER for October 2007 contains the corrected amounts with an effective date of January 1, 2007. Your Medicare contractors will adjust claims previously processed for APCs 0315 and 0385 where the modifier **FB** was reported on the line with the 0315 or 0385, if you bring such claims to their attention.

<b>APC</b>	<b>0315</b>	<b>0385</b>
APC Group Title	Level II Implantation of Neurostimulator	Level I Prosthetic Urological Procedures
SI	T	S
Calendar year (CY) 2007 Payment	\$14,932.81	\$4,868.83
Incorrect CY 2007 Adjustment Percent	76.03%	83.19%
Incorrect CY 2007 Adjustment Amount	\$11,353.42	\$4050.38
Correct CY 2007 Adjustment Percent	83.19%	46.86%
Correct CY 2007 Adjustment Amount	\$12,422.60	\$2,281.53

*October 2007 Update of the Hospital OPSS: Summary of Payment Policy Changes (continued)*

**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 very important 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 caring for the patient.

We remind 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 code (J9999 or J3490). In these situations, we remind 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.

**Drugs and Biologicals with Payments Based on Average Sales Price Effective October 1, 2007**

In the CY 2007 OPSS final rule, it was stated that payments for separately payable drugs and biologicals based on average sale price (ASP) 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, changes to the payment rates will be incorporated in the October 2007 release of the OPSS PRICER. The updated payment rates effective October 1, 2007, will be included in the October 2007 update of the OPSS Addendum A and Addendum B, which was posted on the CMS Web site at the end of September at <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>.

**Updated Payment Rate for Selected Drugs and Biologicals Effective January 1, 2007 through March 31, 2007**

The payment rates for the HCPCS codes in Table 2 below were incorrect in the January 2007 OPSS PRICER. The corrected payment rates listed in Table 2 are in the October 2007 OPSS PRICER, effective for services furnished on January 1, 2007, through implementation of the April 2007 update. Note that your FI, RHHI, or A/B MAC will adjust claims that you bring to their attention when the claims have dates of service that fall on or after January 1, 2007, but prior to April 1, 2007, contain a HCPCS code listed in Table 2, and were originally processed prior to the installation of the October 2007 OPSS PRICER.

**Table 2 – Updated Payment Rate for HCPCS Code Q3025 Effective January 1, 2007, through March 31, 2007**

HCPCS Code	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
Q3025	9022	IM inj interferon beta 1-a	\$115.13	\$23.03
J0152	0917	Adenosine injection	\$69.20	\$13.84
J0215	1633	Alefacept	\$26.28	\$5.26
J0289	0736	Ampho b cholesteryl sulfate	\$16.66	\$3.33
J7342	9054	Metabolically active tissue	\$31.66	\$6.33
J8560	0802	Etoposide oral 50 mg	\$30.53	\$6.11
J9268	0844	Pentostatin injection	\$1,828.98	\$365.80

**Updated Payment Rates for Selected Drugs and Biologicals Effective April 1, 2007 through June 30, 2007**

In the April 2007 OPSS PRICER, the payment rate for APC 9022 was incorrect and the payment rate for APC 0767 was not updated (as the APC 0767 rate did not change from the January rate). The corrected payment rates are listed in Table 3, below, and have been installed in the October 2007 OPSS PRICER, effective for services furnished on April 1, 2007, through June 30, 2007. Note that your FI, RHHI, or A/B MAC will adjust claims that you bring to their attention when the claims have dates of service that fall on or after April 1, 2007, but prior to July 1, 2007; contain at least one of the HCPCS codes listed in Table 3; and were originally processed prior to the installation of the October 2007 OPSS PRICER.

**Table 3 – Updated Payment Rates for Selected Drugs and Biologicals Effective April 1, 2007 through June 30, 2007**

HCPCS Code	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
Q3025	9022	IM inj interferon beta 1-a	\$114.50	\$22.90
J1324	0767	Enfuvirtide injection	\$0.38	\$0.08

**New HCPCS Drug Code Separately Payable Under OPSS as of October 1, 2007**

The drug shown in Table 4, below, has been designated as eligible for separate payment under the OPSS effective October 1, 2007.

**Table 4– New Drug Separately Payable under OPSS as of October 1, 2007**

HCPCS Code	APC	SI	Long Descriptor
C9236	9236	K	Injection, eculizumab, 10 mg

## October 2007 Update of the Hospital OPSS: Summary of Payment Policy Changes (continued)

The payment rate for this drug may be found in the October 2007 update of OPSS Addendum A and Addendum B which was posted on the CMS Web site at the end of September at

<http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>.

### Correct Reporting of Drugs and Biologicals When Used As Implantable Devices

Hospitals should not bill separately for drug and biological HCPCS codes except when using drugs and biologicals with pass-through status 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 OPSS, 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 as implantable devices during surgical procedures, 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 contribute to the future median setting for the associated surgical procedure.

### Correct Reporting of Units for Drugs

Hospitals and providers need to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in the HCPCS descriptor. For example, if the description for the drug code is 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. Similarly, 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 bill the units based on the way the drug is administered, not on the way that it 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, you should 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.

### 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. Fiscal intermediaries determine whether a drug, device, procedure, or other service meets all program requirements for coverage; such as whether a drug is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from 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.

### Revisions to Medicare Claims Processing Manual

CR 5718 also includes several changes to sections in Chapter 4 (Part B Hospital Including Inpatient Hospital Part B and OPSS) of the *Medicare Claims Processing Manual*. You may want to review these updated manual sections.

### Additional Information

You can find more information about the October 2007 update of the hospital OPSS summary of payment policy changes by going to CR 5718, located on the CMS Web site at <http://www.cms.hhs.gov/Transmittals/downloads/R1336CP.pdf>.

You will find the amended *Medicare Claims Processing Manual*, Chapter 4 (Part B Hospital Including Inpatient Hospital Part B and OPSS) as an attachment to that CR.

The list of devices eligible for transitional pass-through payments changes as 1) New device categories are approved for pass-through payment status on an ongoing basis, and 2) Device categories expire from transitional pass-through payment; and their costs are included in APC rates for associated surgical procedures. To view or download the latest complete list of currently payable and previously payable pass-through device categories, refer to the CMS Web site

[http://www.cms.hhs.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage).

Remember that the OCE will return to the provider any claim that reports a HCPCS code for a procedure listed in the table of device edits that does not also report at least one device HCPCS code required for that procedure as listed on the CMS Web site at

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

The OCE will also return to the provider claims for which specified devices are billed without the procedure code that is necessary for the device to have therapeutic benefit to the patient. These edits are also listed on the CMS Web site at

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

This table shows the effective date for each edit. If the claim is returned to the provider for failure to pass the edits, the hospital will need to modify the claim by either correcting the device code or ensuring that one of the required procedure codes is on the claim before resubmission.

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

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

MLN Matters Number: MM5718

Related Change Request (CR) Number: 5718

Related CR Release Date: September 14, 2007

Related CR Transmittal Number: R1336CP

Effective Date: October 1, 2007

Implementation Date: October 1, 2007

Source: CMS Pub. 100-04, Transmittal 1336, CR 5718



# EDUCATIONAL EVENTS

## Upcoming Provider Outreach and Education Events

*October 2007 – December 2007*

### Ask the Contractor – Topics To Be Determined

**When:** Tuesday, October 9, 2007  
**Time:** 11:30 a.m. – 1:00 p.m. Eastern Standard Time  
**Type of Event:** Teleconference

### Hot Topics – Medicare Updates

**When:** Tuesday, November 13, 2007  
**Time:** 11:30 a.m. – 12:30 p.m. Eastern Standard Time  
**Type of Event:** Teleconference

### Ask the Contractor – Topics To Be Determined

**When:** Tuesday, December 11, 2007  
**Time:** 11:30 a.m. – 1:00 p.m. Eastern Standard Time  
**Type of Event:** Teleconference

### Two Easy Ways To Register

**Online** – To register for this seminar, please visit our new training Web site at [www.fcsomedicaretraining.com](http://www.fcsomedicaretraining.com).

- If you are already a registered user of FCSO's Learning Management System (LMS), simply log on, select the specific session you are interested in, and click the "Register" button.
- If you are a **first-time user** of the LMS, you will need to set up an account. To do so, follow these steps:
  - From the welcome page, click on "I need to request an account" just above the log on button.
  - Complete the Request User Account form. (**Note:** Providers who do not yet have an NPI may use 9999.) You will receive your log on information within 72 hours of requesting an account.
  - Once your registration is complete, log on and select "Course Catalog," then select "Catalog." Select the specific session you are interested in, and then click the "Register" button.

**Fax** – If you would like to participate in any of these events, please complete the registration section, circle your selection(s) and fax to (904) 361-0407. Keep listening to information on the FCSO Provider Education Registration Hotline, 1-904-791-8103, for details and newly scheduled events. Providers without Internet access may leave a message on our FCSO Provider Education and Outreach Registration Hotline 1-904-791-8103 requesting a fax registration form.

#### Please Note:

- Pre-registration is required for all teleconferences, webcasts and in-person educational seminars.
- Dates and times are subject to change prior to event advertisement.

Registrant's Name: \_\_\_\_\_

Registrant's Title: \_\_\_\_\_

Provider's Name: \_\_\_\_\_

Telephone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Provider Address: \_\_\_\_\_

City, State, ZIP Code: \_\_\_\_\_

More educational events (teleconferences, webcasts, etc.) will be 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.

## PREVENTIVE SERVICES

### September is National Cholesterol Education Month

The Centers for Medicare & Medicaid Services (CMS) reminds health care professionals that Medicare provides coverage of cardiovascular screening blood tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk of heart disease and stroke. This benefit presents an excellent opportunity for health care professionals to help their eligible Medicare patients check their cholesterol status, know their risk for heart disease and the steps they can take toward following a heart-healthy lifestyle that can lower their risk for heart disease and keep it down.

Medicare provides cardiovascular screening blood tests for all asymptomatic beneficiaries every **five** years.

The beneficiary must have no apparent signs or symptoms of cardiovascular disease. Covered screening tests include:

- Total cholesterol test
- Cholesterol test for high-density lipoproteins
- Triglycerides test

Coverage of cardiovascular screening blood tests is provided as a Medicare Part B benefit. The beneficiary will pay nothing for the blood tests (there is no coinsurance or copayment and no deductible for this benefit).

**Note:** The cardiovascular screening benefit covered by Medicare is a stand alone billable service separate

from the initial preventive physical examination also known as the “Welcome to Medicare” visit and does not have to be obtained within the first six months of a beneficiary’s Medicare Part B coverage.

#### For More Information

- For more information about Medicare’s coverage of cardiovascular screening blood tests, including coverage, coding, billing and reimbursement, please visit the following CMS Web site:
  - The MLN Preventive Services Educational Products Web page [http://www.cms.hhs.gov/MLNProducts/35\\_PreventiveServices.asp#TopOfPage](http://www.cms.hhs.gov/MLNProducts/35_PreventiveServices.asp#TopOfPage).
- For information to share with your Medicare patients, please visit [www.medicare.gov](http://www.medicare.gov).
- To learn more about National Cholesterol Education Month, please refer to the National Heart, Lung, and Blood Institute’s 2007 National Cholesterol Education Month Kit <http://hp2010.nhlbihin.net/cholmonth/>.

Thank you for helping CMS ensure that all eligible people with Medicare take full advantage of this preventive screening service. ❖

Source: CMS Provider Education Resource 200708-23

### National Adult Immunization Awareness Week

**September 23 – 29, 2007 is National Adult Immunization Awareness Week.** This annual health observance is a great opportunity to promote the importance of adult immunizations. The Centers for Medicare & Medicaid Services (CMS) reminds health care professionals that Medicare provides coverage for flu, pneumococcal, and hepatitis B vaccines and their administration. All adults 65 and older should get flu and pneumococcal shots. People with Medicare who are under 65 but have chronic illness, including heart disease, lung disease, diabetes or end-stage renal disease should get a flu shot.

People at medium to high risk for hepatitis B should get hepatitis B shots. CMS needs your help to ensure that people with Medicare take full advantage of these vital preventive benefits. You can help by talking with your Medicare patients about their risk for these vaccine-preventable diseases covered by Medicare and the steps they can take to help reduce their risk of contracting these diseases, including getting vaccinated.

For more information about Medicare’s coverage of adult immunizations and a list of related educational resources, please visit CMS Medicare Learning Network Preventive Services Educational Products on the CMS Web page ([http://www.cms.hhs.gov/MLNProducts/35\\_PreventiveServices.asp#TopOfPage](http://www.cms.hhs.gov/MLNProducts/35_PreventiveServices.asp#TopOfPage)).

For information about National Adult Immunization Awareness Week, go to <http://www.cdc.gov/vaccines/events/naiaw/default.htm#kit>. ❖

Source: CMS Provider Education Resource 200709-12

## Update on Medicare Preventive Service Educational Materials

A new preventive service brochure entitled *Diabetes-Related Services* (ICN# 006840) is now available from the Centers for Medicare & Medicaid Services (CMS), Medicare Learning Network (MLN). This tri-fold brochure provides health care professionals with an overview of Medicare coverage of diabetes screening tests, diabetes self-management training, medical nutrition therapy, and supplies and other services for Medicare beneficiaries with diabetes. The new brochure is available as a downloadable PDF file on the CMS MLN publication Web page at <http://www.cms.hhs.gov/MLNProducts/downloads/DiabetesSvcs.pdf>.

The following preventive service brochures have recently been updated:

- **Adult Immunizations**, ICN# 006435. This tri-fold brochure provides health care professionals with an overview of Medicare coverage of influenza, pneumococcal, and hepatitis B vaccines and their administration.  
[http://www.cms.hhs.gov/MLNProducts/downloads/Adult\\_Immunization.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/Adult_Immunization.pdf)
- **Bone Mass Measurements**, ICN# 006437. This tri-fold brochure provides health care professionals with an overview of Medicare coverage of bone mass measurement services.  
[http://www.cms.hhs.gov/MLNProducts/downloads/Bone\\_Mass.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/Bone_Mass.pdf)
- **Cancer Screenings**, ICN# 006434. This tri-fold brochure provides health care professionals with an overview of Medicare coverage of the following screening services: mammography, colorectal, prostate, Pap test, and pelvic exam.  
[http://www.cms.hhs.gov/MLNProducts/downloads/Cancer\\_Screening.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/Cancer_Screening.pdf)
- **Expanded Benefits**, ICN# 006433. This tri-fold brochure provides health care professionals with an overview of Medicare coverage of three preventive services: the initial preventive physical examination (IPPE), also known as the “Welcome to Medicare physical exam” or the “Welcome to Medicare visit,” ultrasound screening for abdominal aortic aneurysms, and cardiovascular screening blood tests.  
[http://www.cms.hhs.gov/MLNProducts/downloads/Expanded\\_Benefits.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/Expanded_Benefits.pdf)
- **Glaucoma Screening**, ICN# 006436. This tri-fold brochure provides health care professionals with an overview of Medicare’s coverage of glaucoma screening services.  
<http://www.cms.hhs.gov/MLNProducts/downloads/Glaucoma.pdf>
- **Smoking and Tobacco-Use Cessation Counseling Services**, ICN# 006767. This tri-fold brochure provides health care professionals with an overview of Medicare coverage of smoking cessation services.  
<http://www.cms.hhs.gov/MLNproducts/downloads/smoking.pdf>

These seven national provider education brochures are available for download on the MLN Publications Web page as PDF files. Print copies of these brochures will be available in approximately four to six weeks. ❖

Source: CMS Provider Education Resource 200709-02

### 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 email notification when new or updated information is posted to the provider education Web site <http://www.floridamedicare.com>. It’s very easy to do. Simply go to the Web site, click on the “eNews” link on the navigational menu and follow the prompts.

**ORDER FORM – PART A MATERIALS**

The following materials are available for purchase. To order, please complete and submit this form along with your check/money order (PAYABLE TO: FCSO – account number 700284).

NUMBER ORDERED	ITEM	ACCOUNT NUMBER	COST PER ITEM
_____	<p><b>Medicare A Bulletin Subscriptions</b> – The <i>Medicare A Bulletin</i> is available free of charge online at <a href="http://www.floridamedicare.com">http://www.floridamedicare.com</a>. Hardcopy or CD-ROM distribution is limited to one copy per medical facility that has billed at least one Part A claim to the fiscal intermediary in Florida for processing during the twelve months prior to the release of each issue.</p> <p><b>Beginning with publications issued after June 1, 2003</b>, providers that meet the above criteria must register with our office (see Third Quarter 2006 <i>Medicare A Bulletin</i> page 8-9) to receive the <i>Bulletin</i> in hardcopy or CD-ROM format. Qualifying providers will be eligible to receive one hardcopy or CD-ROM of each issue, if a valid reason is giving indicating why the electronic publication available free-of-charge on the Internet cannot be used. Non-Medicare providers (e.g., billing agencies, consultants, software vendors, etc.) or providers that need additional copies at other office-facility locations may purchase an annual subscription. This subscription includes all Medicare bulletins published during October 2006 through September 2007 (back issues sent upon receipt of the order). Please check here if this will be a:  <input type="checkbox"/> Subscription Renewal or  <input type="checkbox"/> New Subscription</p>	700284	<p>\$250.00 (Hardcopy)</p> <p>\$20.00 (CD-ROM)</p>

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**Medicare Publications**  
**P.O. Box 406443**  
**Atlanta, GA 30384-6443**

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City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Attention: \_\_\_\_\_ Area Code/Telephone Number: \_\_\_\_\_

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**(CHECKS MADE TO “PURCHASE ORDERS” NOT ACCEPTED)**

**ALL ORDERS MUST BE PREPAID –**  
**DO NOT FAX - PLEASE PRINT**

*NOTE: The Medicare A Bulletin is available free of charge online at [www.floridamedicare.com](http://www.floridamedicare.com).*



## Addresses

### **CLAIMS STATUS**

#### **Coverage Guidelines**

#### **Billing Issues Regarding**

#### **Outpatient Services, CORE, 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

### **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 the 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)  
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

## 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)

## 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

### **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



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***MEDICARE A BULLETIN***

*FIRST COAST SERVICE OPTIONS, INC. ✦ P.O. Box 2078 ✦ JACKSONVILLE, FL 32231-0048*

**\* ATTENTION BILLING MANAGER \***

