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To receive quick, automatic notification when new publications and other items of interest are posted to our provider education Web sites, subscribe to our *FCSO eNews* mailing list. It's very easy to do. Simply go to the Web site at <http://www.connecticutmedicare.com> or <http://www.floridamedicare.com>, click on the "eNews" link on the navigational menu and follow the prompts. The *FCSO eNews* is sent at least every week, more frequently as required.



The Medicare B Update! should be shared with all health care practitioners and managerial members of the provider/supplier staff. Publications issued beginning in 1997 are available at no cost from our provider education Web sites: <http://www.connecticutmedicare.com> and <http://www.floridamedicare.com>.

Routing Suggestions:

- ☐ Physician/Provider
- ☐ Office Manager
- ☐ Billing/Vendor
- ☐ Nursing Staff
- ☐ Other _____

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The *Medicare B Update!* is published monthly by First Coast Service Options, Inc. (FCSO) Provider Outreach and Education Division, to provide timely and useful information to Medicare Part B providers in Connecticut and Florida.

Questions concerning this publication or its contents may be faxed to (904) 361-0723.

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THE FCSO MEDICARE B UPDATE!

About the Connecticut and Florida Medicare B Update!

The *Medicare B Update!* is a comprehensive publication developed by First Coast Service Options, Inc. (FCSO) for Part B providers in Connecticut and Florida.

The Provider Outreach & Education Publications team distributes the *Medicare B Update!* on a monthly basis.

Important notifications that require communication in between publications will be posted to the FCSO Medicare provider education Web sites, <http://www.connecticutmedicare.com> and <http://www.floridamedicare.com>. In some cases, additional unscheduled special issues may be posted.

Who Receives the Update?

Anyone may view, print, or download the *Update!* from our provider education Web site(s). Providers who cannot obtain the *Update!* from the Internet are required to register with us to receive a complimentary hardcopy or CD-ROM.

Distribution of the *Update!* in hardcopy or CD-ROM format is limited to individual providers and professional association (PA) groups who have billed at least one Part B claim to either Connecticut or Florida Medicare for processing 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 registration form to us*. Registration forms must be submitted annually or when you experience a change in circumstances that impacts your electronic access.

For additional copies, providers may purchase a separate annual subscription in hardcopy or CD-ROM format (see order form in the back of this issue). All issues published since 1997 may be downloaded from the Internet, free of charge.

We use the same mailing address for *all* correspondence, and cannot designate that the *Update!* be sent to a specific person/department within a provider's office. 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 the appropriate CMS-855.

Clear Identification of State-Specific Content

Articles common to both states appear at the beginning of the publication. Within common articles, references to phone numbers, addresses, reimbursement amounts, past publications, etc., are state-specific as appropriate. Content specific to Connecticut is next, followed by content specific to Florida. Connecticut and Florida local coverage determination (LCD) summaries are combined into one section. Articles in this section applies to both Connecticut and Florida unless otherwise noted.

Publication Format

The *Update!* is arranged into distinct sections.

Following the table of contents, a letter from the carrier medical director (as needed), and an administrative information section, the *Update!* provides content applicable to both states, as noted previously. Within this section, information is categorized as follows.

- The **claims** section provides claim submission requirements and tips, plus correspondence (appeals and hearings) information.
- The **coverage/reimbursement** section discusses specific CPT and HCPCS procedure codes. It is arranged by specialty *categories* (not specialties). For example, "Mental Health" would present coverage information of interest to psychiatrists, clinical psychologists and clinical social workers, rather than listing articles separately under individual provider specialties. Also presented in this section are changes to the Medicare physician fee schedule, and other pricing issues.
- The section pertaining to **electronic data interchange** (EDI) submission also includes information pertaining to the Health Insurance Portability and Accountability Act (HIPAA).
- The **general information** section includes fraud and abuse, and Medicare Secondary Payer topics, plus additional topics not included elsewhere.

Educational resources. Important **addresses, phone numbers, and Web sites** will *always* be in state-specific sections.

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.

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. Once there, select the Medicare Provider's pull-down menu and click either Florida or Connecticut."

Advance Beneficiary Notices

Medicare Part B allows coverage for services and items deemed medically reasonable and necessary for treatment and diagnosis of the patient. For some services, to ensure that payment is made only for medically necessary services or items, coverage may be limited based on one or more of the following factors (this list is not inclusive):

- Coverage for a service or item may be allowed only for specific diagnoses/conditions. Always code to the highest level of specificity.
- Coverage for a service or item may be allowed only when documentation supports the medical need for the service or item.
- Coverage for a service or item may be allowed only when its frequency is within the accepted standards of medical practice (i.e., a specified number of services in a specified timeframe for which the service may be covered).

If the provider believes that the service or item may not be covered as medically reasonable and necessary, the patient must be given an acceptable advance notice of Medicare's possible denial of payment if the provider does not want to accept financial responsibility for the service or item. Advance beneficiary notices (ABNs) advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment.

Patient Liability Notice

The Centers for Medicare & Medicaid Services' (CMS) has developed the CMS-R131 form as part of the Beneficiary Notices Initiative (BNI). The ABNs are designed to be beneficiary-friendly, readable and understandable, with patient options clearly defined.

There are two ABN forms - the General Use form (CMS-R-131G) and the Laboratory Tests form (CMS-R-131L). Both are standard forms that *may not be modified*; however, both contain customizable boxes for the individual requirements of users. Reproducible copies of Form CMS-R-131 ABNs (in English and Spanish) and other BNI information may be found on CMS's BNI Web site at

http://www.cms.hhs.gov/BNI/01_overview.asp#TopOfPage.

ABN Modifiers

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting modifier **GA** (waiver of liability statement on file) or **GZ** (item or service expected to be denied as not reasonable and necessary) with the service or item.

Failure to report modifier **GA** in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Modifier **GZ** may be used in cases where a signed ABN is *not* obtained from the patient; however, when modifier **GZ** is billed, the provider assumes financial responsibility if the service or item is denied.

"GA" Modifier and Appeals

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting the modifier **GA** (waiver of liability statement on file).

Failure to report modifier **GA** in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Nonassigned claims containing the modifier **GA** in which the patient has been found liable **must** have the patient's **written consent** for an appeal. Written appeals requests should be sent to:

Connecticut

Medicare Part B Redeterminations Appeals
PO Box 45010
Jacksonville, FL 32232-5010

OR

Florida

Medicare Part B Redeterminations Appeals
PO Box 2360
Jacksonville, FL 32231-0018

PROVIDER ENROLLMENT

Medicare Provider Enrollment of Individuals

All individuals (physicians and non-physician practitioners[NPP]) who will be providing services to Medicare beneficiaries must complete the CMS-855I (Medicare Enrollment Application – Physicians and Non-Physician Practitioners) to enroll with Medicare. In some situations, the physician/NPP must also complete the CMS-855R (Medicare Enrollment Application – Reassignment of Medicare Benefits). The physician/NPP should refer to the documents entitled, “Tips to Facilitate the Medicare Enrollment Process for Physicians and Non-Physician Practitioners” and “CMS-855I Section Specific Tips” when completing the CMS-855I.

Physicians/NPP must obtain a national provider identifier (NPI) from the National Plan and Provider Enumeration System (NPPES) prior to completing the CMS-855I or CMS-855R enrollment applications because the NPI must be reported on the applications. If the NPI is not reported, the enrollment application will be rejected by the Medicare carrier and returned to the provider.

If a physician/NPP wants to opt out of Medicare, he/she should contact the Medicare contractor for instructions on the opt out process.

Physician/Nonphysician Practitioner Enrollment Scenarios

The following scenarios describe how the CMS 855I should be completed depending on how the physician/NPP will be providing services and billing Medicare. All appropriate sections of the CMS-855I are to be completed. We note below where the Medicare identification number (MIN) and national provider identifier (NPI) are to be reported for each scenario. We have also included other pertinent information, such as when a CMS-855R or a CMS-855B (Medicare Enrollment Application – Clinics/Group Practices and Certain Other Suppliers) is required.

Scenario 1: Physician assistant only.

A physician assistant furnishes his/her MIN (if assigned) and NPI in Section 1A, item 1, of the CMS-855I. Instructions included with the CMS 855I should be followed in completing the rest of the CMS-855I.

The following scenarios do not apply to a physician assistant.

Scenario 2a: A physician/NPP who has a sole proprietorship business.

***Note:** A sole proprietorship is a business whereby all of the business’ assets and liabilities are tied directly to the physician/NPP’s (the sole proprietor’s) social security account. The sole proprietor and the sole proprietorship are considered a single legal entity: an individual. The sole proprietor’s Social Security Number (SSN) serves as the taxpayer identification number (TIN) of the sole proprietorship. Often, the Internal Revenue Service (IRS) issues an employer identification number (EIN) to a sole proprietorship to protect the sole proprietor’s SSN from being disclosed on W-2 forms and in transactions, such as claims sent to health plans.*

Therefore, at the option of the sole proprietor, the EIN (if issued) instead of the SSN could be used as the TIN in submitting a sole proprietorship’s Medicare claims. The IRS links that EIN to the sole proprietor’s SSN for tax reporting purposes.

If a physician/NPP is enrolling in Medicare and will have a private practice operating as a sole proprietorship, he/she does not complete Section 4A of the CMS-855I. If the physician/NPP will have a private practice operating as a sole proprietorship and will also be working in a group/organization setting, a CMS-855R should be submitted for each group/organization to which the physician/NPP will be reassigning benefits. The physician/NPP completes Section 4B, item 2. The physician/NPP’s (i.e., the sole proprietor’s) MIN (if issued) and NPI are reported in Section 4C and the physician/NPP completes the information for his/her sole proprietorship business in Section 4C. [The NPI would be an Entity type 1- Individual.] The EIN of the sole proprietorship (if it has been issued an EIN) is reported in Section 4F.

Scenario 2b: A physician/NPP with no sole proprietorship business (i.e., physician/NPP who has no private practice and works only in a group/organization).

If the physician/NPP will be reassigning all of his/her benefits to a group or organization and will not have any private practice locations, he/she provides his/her MIN (if issued) and NPI in section 1A, item 2.

[The NPI would be an Entity type 1-Individual.] The physician/NPP completes all appropriate sections of the CMS-855I. Item 1 in Section 4B1 is checked YES and the physician/NPP enters the name(s) of the group(s)/organization(s). The physician/NPP then completes section 13, if applicable, and section 15. In addition to the CMS-855I, the physician/NPP must also submit a CMS-855R for each group/organization for which he/she will be working. In any scenario where a CMS-855R is required, the CMS-855I is not required if the physician/NPP has already enrolled with the Medicare contractor that would be processing that CMS-855I application.

Medicare Provider Enrollment of Individuals, continued

Scenario 3: A physician/NPP who is a sole owner of a PC, PA, or LLC.

A physician/NPP who is the sole owner of a professional corporation (PC), professional association (PA), or a limited liability company (LLC) and who will be billing Medicare through that business entity must furnish his/her NPI 3 (Entity type 1-Individual) and the NPI of the organization (PC, PA, LLC) (Entity type 2- Organization). The physician/NPP's MIN (if issued) and NPI are reported in section 1A, item 2. [The NPI would be an Entity type 1-Individual.] The group/organization's MIN (if issued) and NPI are reported in sections 4A and 4C. [The NPI would be an Entity type 2-Organization.] When a sole owner elects to bill Medicare through the group/organization, he/she must complete sections 1, 2 and 3 of the CMS-855I with his/her [individual] information. Section 4A captures information about the organization (including the organization's MIN and NPI [the NPI would be an Entity type 2-Organization]). The remainder of the CMS-855I is to be completed with the group/organization's information. When the CMS-855I is submitted by a sole owner, neither the CMS-855B nor the CMS-855R need to be completed.

Scenario 4: A physician/NPP who is an owner, but not a sole owner, of a PC, PA, LLC, or a partner in a partnership.

A physician/NPP who is a part-owner of a PC, PA, LLC, or a partner in any type of partnership, and who will be rendering services through that group/organization or partnership, must complete the CMS-855I and/or the CMS-855R in accordance with the instructions in Scenario 2b. The PC, PA, LLC, or partnership is enrolled using the CMS-855B.

Source: Medicare Provider-Supplier Enrollment Section of the CMS Web site

INFORMATION FOR FLORIDA PROVIDERS

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.

The extended service line delivers 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 at 1-866-454-9007 for assistance on all inquiries.
- 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, and
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; and
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 1-866-454-9007 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.

CLAIMS

Quarterly Update to Correct Coding Initiative Edits, Version 13.3, Effective October 1, 2007

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

Provider Types Affected

Physicians who submit claims to Medicare carriers and Part A/B Medicare administrative contractors (A/B MACs).

Background

This article is based on change request (CR) 5703 that provides a reminder for physicians to take note of the quarterly updates to Correct Coding Initiative (CCI) edits. The latest package of CCI edits, Version 13.3, effective October 1, 2007, and the current Mutually Exclusive Code (MEC) edits will be available at <http://www.cms.hhs.gov/NationalCorrectCodInitEd/> on the Centers for Medicare & Medicaid Services (CMS) Web site.

The National Correct Coding Initiative developed by CMS helps promote national correct coding methodologies and controls improper coding. The coding policies developed are based on coding conventions defined in:

- The American Medical Association's (AMA's) *Current Procedural Terminology (CPT)* manual.
- National and local policies and edits.
- Coding guidelines developed by national societies.
- Analysis of standard medical and surgical practice.
- Review of current coding practice.

The latest package of CCI edits, version 13.3, includes all previous versions and updates from January 1, 1996, to the present and will be organized in two tables:

- Column 1/ Column 2 Correct Coding Edits.
- Mutually Exclusive Code (MEC) Edits.

Additional Information

The CCI and MEC file formats will be maintained in the *Medicare Claims Processing Manual* (Chapter 23, Section 20.9) which may be found at <http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage> on the CMS Web site.

The official instruction, CR 5703, issued to your carrier and A/B MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1330CP.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5703

Related Change Request (CR) #: 5703

Related CR Release Date: August 31, 2007

Effective Date: October 1, 2007

Related CR Transmittal #: R1330CP

Implementation Date: October 1, 2007

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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Join our eNews mailing list and receive urgent and other critical information issued by First Coast Service Options, Inc. (FCSO), your Connecticut and Florida Medicare carrier. By signing up, you will receive automatic email notification when new or updated information is posted to the provider education Web sites <http://www.connecticutmedicare.com> or <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.

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 (PSA).

Provider Action Needed

STOP – Impact to You

This article is based on change request (CR) 5711 that reminds physicians that the 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 *Background* 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 beneficiaries 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 <http://www.cms.hhs.gov/Transmittals/downloads/R1321CP.pdf> on the CMS Web site.

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

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5711
Related Change Request (CR) #: 5711
Related CR Release Date: August 24, 2007
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ANESTHESIA

Anesthesia Services Furnished by the Same Physician Providing the Medical and Surgical Service

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

Provider Types Affected

Physicians and other practitioners who bill Medicare carriers and/or Medicare administrative contractors (A/B MACs) for anesthesia services provided in conjunction with the performance of medical/surgical services.

Provider Action Needed

STOP – Impact to You

Physicians who both perform, and provide moderate sedation for, medical/surgical services will be paid for the conscious sedation consistent with CPT guidelines.

However, physicians who perform, and provide local or minimal sedation for, these procedures will not be paid separately for the sedation services.

CAUTION – What You Need to Know

The *Medicare Claims Processing Manual* (Publication 100-04) Chapter 12 (Physicians/Nonphysician Practitioners) Section 50A (General Payment) is being revised to be consistent with the pricing of the conscious sedation codes under the Medicare physician fee schedule payment system and CPT coding guidelines. In addition, a new section, 50L, explains the payment policy when the same physician performs both the medical/surgical service and the conscious sedation service, is added. Finally, Exhibit 1 that listed the base units by anesthesia code is deleted, because it is out of date and the material is communicated to carriers and Medicare administrative contractors (known as A/B MACs) annually via the HCPCS tape.

GO – What You Need to Do

Make sure that your billing staffs are aware of these new payment policies that address the same physician performing both the medical/surgical service and the conscious sedation service.

Background

The continuum of complexity in anesthesia services (from least intense to most intense) ranges from 1) local or topical anesthesia, 2) moderate (conscious) sedation, 3) regional anesthesia, to 4) general anesthesia. Moderate sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. It does not include minimal sedation, deep sedation or monitored anesthesia care.

CR 5618, from which this article is taken announces the revision of the anesthesia policy in the *Medicare Claims Processing Manual*, Chapter 12 (Physicians/Nonphysician Practitioners), Section 50A (General Payment), to be consistent with the pricing of conscious sedation codes under the Medicare physician fee schedule and CPT coding guidelines. It further announces:

- 1) The addition of a new Section (50L), that explains the payment policy if the same physician performs the medical/surgical service and the conscious sedation service; and
- 2) The deletion of Exhibit 1, that lists the base units by anesthesia code because it is out of date and the material is communicated to the carriers annually via the HCPCS tape.

Currently, section 50A instructs carriers and MACs not to allow separate payment for the anesthesia service performed by the same physician who furnishes the medical or surgical services (for example, there is no separate payment allowed for a surgeon's performance of a local or surgical anesthesia if the surgeon also performs the surgical procedure; or a psychiatrist's performance of the anesthesia service associated with the electroconvulsive therapy if the psychiatrist performs the electroconvulsive therapy).

The revised policy is: If the physician performing the procedure also provides moderate sedation for the procedure, then payment may be made for conscious sedation consistent with CPT guidelines; however, if the physician performing the procedure provides local or minimal sedation for the procedure, then no separate payment is made for the local or minimal sedation service.

Carriers and A/B MACs will not allow payment for codes 99148-99150 if any of these codes are performed on the same day with a medical/surgical service listed in Appendix G of CPT and the service is provided in a non-facility setting. A facility is defined in Chapter 23 Addendum of the *Medicare Claims Processing Manual* as one with a place of service code of 21, 22, 23, 24, 26, 31, 34, 41, 42, 51, 52, 53, 56, or 61.

Prior to 2006, Medicare did not recognize separate payment if the same physician both performed the medical or surgical procedure and provided the anesthesia needed for the procedure. The final physician fee schedule published in the *Federal Register* on November 21, 2005 included newly created codes (99143 to 99150) for moderate (conscious) sedation, which the CPT added in 2006.

Note: These codes have been assigned a status indicator of "C" under the Medicare physician fee schedule designating that these services are carrier priced. CMS has not established relative value units for these services.

Three of these codes (99143, 99144, and 99145) describe the scenario in which the same physician performing the diagnostic or therapeutic procedure provides the moderate sedation, and an independent trained observer's presence is required to assist in the monitoring of the patient's level of consciousness and physiological status.

Anesthesia Services Furnished by the Same Physician Providing the Medical and Surgical Service, continued

The other three codes (99148, 99149, and 99150) describe the scenario in which the moderate sedation is provided by a physician other than the one performing the diagnostic or therapeutic procedure.

CR 5618 presents some specific points that you should be aware of:

- CPT coding guidelines for conscious sedation codes instruct practices not to report codes 99143 to 99145 in conjunction with the codes listed in CPT Appendix G. Your carrier or A/B MAC will follow the National Correct Coding Initiative, which added edits in April 2006 that bundled CPT codes 99143 and 99144 into the procedures listed in Appendix G (There are no edits for code 99145; it is an add-on-code and it is not paid if the primary code is not paid.)
- In the unusual event that a second physician (other than the one performing the diagnostic or therapeutic services) provides moderate sedation in the facility setting for the procedures listed in CPT Appendix G, the second physician can bill 99148 to 99150, but cannot report these codes when the second physician performs these services (on the same day as a medical/surgical service) in the non-facility setting.
- If an anesthesiologist or certified registered nurse anesthetist (CRNA) provides anesthesia for diagnostic or therapeutic nerve blocks or injections, and a different provider performs the block or injection, then the anesthesiologist or CRNA may report the anesthesia service using CPT code 01991. In this case, the service must meet the criteria for monitored anesthesia care. If the anesthesiologist or CRNA provides both the anesthesia service and the block or injection, then the anesthesiologist or CRNA may report the anesthesia service using the conscious sedation code and the injection or block. However, the anesthesia service must meet the requirements for conscious sedation and if a lower level complexity anesthesia service is provided, then the conscious sedation code should not be reported.
- There is no CPT code for the performance of local anesthesia, and as such, payment for this service is considered to be part of the payment for the underlying medical or surgical service. Therefore, if the physician performing the medical or surgical procedure also provides a level of anesthesia lower in intensity than moderate or conscious sedation (such as a local or topical anesthesia), then the conscious sedation code

should not be reported and the carrier or A/B MAC will allow no payment.

- When denying claims, as appropriate under this policy, carriers and A/B MACs will use:
 - Medicare summary notice (MSN) message 16.8 when the service is bundled into the other service: "Payment is included in another service received on the same day;" In addition, the MSN (via MSN message 16.45) will note to the beneficiary that "You cannot be billed separately for this item or service. You do not have to pay this amount."
 - Claim adjustment reason code (CARC) 97: "Payment adjusted because the benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated;"
 - Remittance advice remark code (RARC) M80: "We cannot pay for this when performed during the same session as another approved service for this beneficiary." Carriers and A/B MACs will note that the beneficiary is not liable for payment for claims denied as noted in the above MSN message.
- Finally, carriers and A/B MACs will adjust claims, brought to their attention, that were not processed in accordance with the Medicare physician fee schedule data base indicators assigned to the conscious sedation codes.

Additional Information

You may find the official instruction, CR 5618, issued to your carrier or A/B MAC by visiting <http://www.cms.hhs.gov/Transmittals/downloads/R1324CP.pdf> on the CMS Web site. You will find updated *Medicare Claims Processing Manual* (100-04), Chapter 12 (Physicians/Non-physician Practitioners) as an attachment to that CR.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

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DRUGS AND BIOLOGICALS

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 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 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 Centers for Medicare & Medicaid Services (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 utilize 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.

ASP Methodology

Beginning January 1, 2005, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. 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 (95%) 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 are paid under OPPS at the amount specified for the ambulatory payment classification (APC) to which the product is assigned.
- Payment allowance limits for **infusion drugs furnished through a covered item of durable medical equipment**

October 2007 Quarterly ASP Part B Drug Pricing File Update and Revisions to Prior Pricing File, continued

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 OPPTS 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 OPPTS 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/> on the CMS Web site. These quarterly files are applicable to claims based on dates of service as shown in the following table:

Payment Allowance Limit Revision Date	Applicable Dates of Service for Claims Processed or Reprocessed on or after October 1, 2007
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 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 ASP Part B Drug Pricing File Update and Revisions to Prior Pricing File, continued***Additional Information**

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

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 at: <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS Web site.

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

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MEDICARE PHYSICIAN FEE SCHEDULE DATABASE

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, Medicare 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 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

October Update to the 2007 Medicare Physician Fee Schedule Database, continued

CPT/HCPCS	ACTION
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.

CPT Code	Procedure Status Indicator*
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”.

Code	Long Descriptor	Short Descriptor
1116F	Auricular or periauricular pain assessed	Auric/peri pain assessed
2035F	Tympanic membrane mobility assessed with pneumatic otoscopy or tympanometry	Tymp memb motion exam'd
3215F	Patient has documented immunity to hepatitis A	Pt immunity to hep a doc'd
3216F	Patient has documented immunity to hepatitis B	Pt immunity to hep b doc'd
3219F	Hepatitis C genotype testing documented as performed prior to initiation of antiviral treatment for hepatitis C	Hep c geno tstng doc'd - done
3220F	Hepatitis C quantitative RNA testing documented as performed at 12 weeks from initiation of antiviral treatment	Hep c quant rna tstng doc'd
3230F	Documentation that hearing test was performed within 6 months prior to tympanostomy tube insertion	Note hring tst w/in 6 mon
3260F	pT category (primary tumor), pN category (regional lymph nodes), and histologic grade documented in pathology report	Pt cat/pn cat/hist grd doc'd
4130F	Topical preparations (including OTC) prescribed for acute otitis externa	Topical prep rx, aoe
4131F	Systemic antimicrobial therapy prescribed	Syst antimicrobial thx rx
4132F	Systemic antimicrobial therapy not prescribed	No syst antimicrobial thx rx
4133F	Antihistamines or decongestants prescribed or recommended	Antihist/decong rx/recom
4134F	Antihistamines or decongestants neither prescribed nor recommended	No antihist/decong rx/recom
4135F	Systemic corticosteroids prescribed	Systemic corticosteroids rx
4136F	Systemic corticosteroids not prescribed	Syst corticosteroids not rx
4150F	Patient receiving antiviral treatment for hepatitis C	Pt recvng antivir txmnt hepc
4151F	Patient not receiving antiviral treatment for hepatitis C	Pt not recvng antiv hep c

October Update to the 2007 Medicare Physician Fee Schedule Database, continued

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

Procedure Status: M	Multiple Procedure Indicator: 9
WRVU: 0.00	Bilateral Surgery Indicator: 9
Non-Facility PE RVU: 0.00	Assistant at Surgery Indicator: 9
Facility PE RVU: 0.00	Co-Surgery Indicator: 9
Malpractice RVU: 0.00	Team Surgery Indicator: 9
PC/TC: 9	Physician Supervision Diagnostic Indicator: 9
Site of Service: 9	Type of Service: 1
Global Surgery: XXX	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 at <http://www.cms.hhs.gov/Transmittals/downloads/R1326CP.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

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Connecticut Fees

Code	Par	Non-Par	Limiting charge
54150	222.77	211.63	243.38
	105.06	99.81	114.78*

*Represents facility rate

Florida Fees

Code	Participating			Nonparticipating			Limiting Charge		
	Loc 01/02	Loc 03	Loc 04	Loc 01/02	Loc 03	Loc 04	Loc 01/02	Loc 03	Loc 04
54150	192.29	201.77	212.59	182.68	191.68	201.96	210.08	220.43	232.25
	98.28	102.35	107.34	93.37	97.23	101.97	107.37	111.82	117.27*

*Represents facility rate

RADIOLOGY

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 the modifier -26 to show professional component.

Such services, when globally billed in a hospital setting with 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 code 76999-TC, Medicare will deny the services with the 58 reason code and an M77 remark code 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 code 76999, or the technical and professional components may be separately billed using codes 76999-TC and 76999-26, respectively.

Ultrasound diagnostic procedures professional services billed using 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 at <http://www.cms.hhs.gov/Transmittals/downloads/R76NCD.pdf> on the CMS Web site. 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 at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS Web site.

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5608

Related Change Request (CR) #: 5608

Related CR Release Date: September 12, 2007

Effective Date: May 22, 2007

Related CR Transmittal #: R76NCD

Implementation Date: September 28, 2007

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SURGERY

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 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 an 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 \leq 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 at <http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage> on the CMS Web site.

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 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3489.pdf> on the CMS Web site.

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

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

The official instruction, CR 5667, issued to your carrier, FI, and A/B MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1315CP.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5667
Related Change Request (CR) #: 5667
Related CR Release Date: August 10, 2007
Effective Date: March 17, 2005
Related CR Transmittal #: R1315CP
Implementation Date: October 1, 2007

Clarification of Percutaneous Transluminal Angioplasty Billing Requirements Issued in CR 3811, continued

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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.

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 lumbar artificial disc replacement (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 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* at <http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf> on the CMS Web site. **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 and 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 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 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."

*Lumbar Artificial Disc Replacement, continued***Additional Information**

For complete details regarding this CR please see the official instruction (CR 5727) issued to your Medicare FI, carrier, or A/B MAC. That instruction may be viewed by going to <http://www.cms.hhs.gov/Transmittals/downloads/R75NCD.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5727

Related Change Request (CR) #: 5727

Related CR Release Date: September 11, 2007

Effective Date: August 14, 2007

Related CR Transmittal #: R75NCD and R1340CP

Implementation Date: October 1, 2007

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Percutaneous Transluminal Angioplasty

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals. This information was previously published in the August 2007 Medicare B Update! pages 38-40.

Note: This article was revised on September 13, 2007, to reflect that CMS revised and re-issued CR 5660. The CR release date, transmittal number, and the Web address for accessing CR 5660 were changed. All other information remains the same.

Provider Types Affected

Physicians and hospitals who 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 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 Centers for Medicare & Medicaid Services (CMS) issued change request (CR) 3811 providing Medicare coverage for PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent when beneficiaries are at high risk for carotid endarterectomy (CEA). This national coverage determination (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.
- 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.

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

Percutaneous Transluminal Angioplasty, continued

Note: 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 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 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 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*.

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.

Percutaneous Transluminal Angioplasty, continued

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 change request (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 <http://www.cms.hhs.gov/Transmittals/downloads/R77NCD.pdf> on the CMS Web site.

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 following link <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5660

Related Change Request (CR) #: 5660

Related CR Release Date: September 12, 2007

Effective Date: April 30, 2007

Related CR Transmittal #: R77NCD

Implementation Date: July 30, 2007

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GENERAL COVERAGE

New Remark Code for Denying Separately Billed Services

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals. This information was previously published in the September 2007 Medicare B Update! page 20.

Note: This article was revised on September 10, 2007, to reflect that change request (CR) 5659 was revised. The CR transmittal number and the Web address for accessing CR 5659 were revised. All other information remains the same.

Provider Types Affected

Medicare providers who submit claims to Medicare Part A/B Medicare administrative contractors (A/B MACs) or carriers for ambulance services rendered to Medicare beneficiaries.

Provider Action Needed

Be aware that contractors will use a new remittance advice remark code (RARC) message when denying ambulance claims submitted with a code(s) that is not separately billable and already included in the base rate. For claims submitted by ambulance suppliers that Medicare processes on or after October 1, 2007, and which Medicare denies because the code for the service does not appear on the ambulance fee schedule (AFS), Medicare will return the RARC of N390 to show "This service cannot be billed separately." See the remainder of this article for further details.

Key Points of Change Request 5659

- Effective October 1, 2007, the new RARC N390 and N185 with claim adjustment reason code (CARC) 97, group code CO, will be used when denying any codes on the ambulance claims that does not appear on the AFS.
- For such claims processed and denied on or after October 1, 2007, the following Medicare summary notice (MSN) message will be sent to Medicare beneficiaries: "16.45 - You cannot be billed separately for this item or service. You do not have to pay this amount."

Background

CR 5659 is the official document that announces these changes in Medicare processes and states that effective January 1, 2006, items and services which include but are not limited to oxygen, drugs, extra attendants, supplies, EKG, and night differential are no longer paid separately for ambulance services. This occurred when the Centers for Medicare & Medicaid Services (CMS) fully implemented the AFS. Therefore, payment is based solely on the AFS amount as cited in 42 CFR section 414.615 (e) and such payment represents payment in full for all services, supplies, and other costs for an ambulance service.

New Remark Code for Denying Separately Billed Services, continued

furnished to a Medicare beneficiary. CMS was made aware that some providers are submitting claims with ancillary services that are included in the base rate.

CMS decided that a clearer denial message was needed to explain the reason for the denial and that this service is not separately billable and as a result, these claims/services should not be resubmitted. This is true whether the primary transportation service is allowed or denied. Remember that when these services are denied, the services are not separately billable to the beneficiaries.

Additional Information

For complete details regarding this change request (CR) please see the official instruction (CR 5659) issued to your Medicare carrier or A/B MAC. That instruction may be viewed by going to <http://www.cms.hhs.gov/Transmittals/downloads/R1333CP.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5659

Related Change Request (CR) #: 5659

Related CR Release Date: September 6, 2007

Effective Date: October 1, 2007

Related CR Transmittal #: R1333CP

Implementation Date: October 1, 2007

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MEDIGAP/CROSSEVERS**Delay of Coordination of Benefits Agreement Medigap Identifiers**

The Centers for Medicare & Medicaid Services (CMS) has made a decision to delay the use of the new Coordination of Benefits Agreement (COBA) Medigap claim-based identifiers on incoming Part B claims or claims for durable medical equipment, prosthetics, orthotics, and medical supplies (DMEPOS) until October 1, 2007. This represents a change from previous CMS direction issued in accordance with transmittal 283, change request (CR) 5662, and the accompanying *MLN Matters* article.

Because of the CMS delay, physicians and other suppliers shall inform their billing vendors not to include any newly assigned 5-byte COBA Medigap claim-based identifiers, as referenced at <http://www.cms.hhs.gov/COBAgreement/Downloads/Medigap%20Claimbased%20COBA%20IDs%20for%20Billing%20Purpose.pdf>, on incoming Medicare claims before October 1, 2007. If participating providers or suppliers include the newly assigned COBA Medigap claim-based ID on incoming claims before October 1, 2007, Medicare will not cross the claims over to the Medigap insurer.

Providers that use PC-Ace or other free billing Medicare software need to ensure this product is updated to reflect the newly assigned 5-byte COBA Medigap claim-based IDs

but must ensure that the new identifiers will not be applied on incoming Medicare claims before October 1, 2007.

Effective with October 1, 2007, and as specified in transmittal 283, CR 5662, physicians and other suppliers that bill using paper forms, i.e., those granted an exception for billing electronically under the Administrative Simplification Compliance Act (ASCA), shall include the newly assigned 5-byte identifier (number will fall in the range 55000 through 59999) within item 9-D of incoming paper CMS-1500 claim forms. These providers should complete items 9A through 9D, in accordance with previous procedures, to ensure they will successfully trigger a Medigap claim-based crossover. Providers that are required to bill Medicare electronically using the Health Insurance Portability and Accountability Act (HIPAA) American National Standards Institute (ANSI) X12-N 837 professional claim shall include the newly assigned 5-byte only COBA Medigap claim-based ID (range=55000 to 59999) in field NM109 of the NM1 segment within the 2330B loop. Retail pharmacies that bill National Council for Prescription Drug Programs (NCPDP) batch claims to Medicare shall include the newly assigned Medigap identifier within field 301-C1 of the T04 segment of their incoming NCPDP claims.

Source: Joint Signature Memorandum 07535 dated September 21, 2007

Transitioning the Mandatory Medigap (“Claim-Based”) Crossover Process to the Coordination of Benefits Contractor

CMS has issued the following MLN Matters article. Information for Medicare Fee-for-Service Health Care Professionals. This information was previously published in the July 2007 Medicare B Update! pages 59-61.

Note: This article was revised on September 3, 2007, to reflect changes CMS made to change request (CR) 5601, which was re-issued on August 31, 2007. The CR transmittal number, release date, and the Web address for accessing CR 5601 were revised in this article. All other information remains the same.

Provider Types Affected

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

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

This article is based on change request (CR) 5601, which outlines the Centers for Medicare & Medicaid Services (CMS) systematic requirements for the transitioning of its mandatory Medigap (“claim-based”) crossover process from its Part B contractors to the coordination of benefits contractor (COBC). During the period from June through September 2007, CMS’ (COBC) will sign national crossover agreements with Medigap claim-based crossover insurers and will assign new 5-digit Coordination of Benefits Agreement (COBA) Medigap claim-based crossover identifiers to these entities for inclusion on incoming Medicare claims. CMS is also preparing a separate CR (5662) that includes the Web site where provider billing staffs may go to obtain the listing of new COBA Medigap claim-based identifiers for purposes of initiating Medigap claim-based crossovers. Within the next few weeks, following the issuance of CR 5662, providers will also receive more detailed information regarding this change via their Medicare contractors’ provider newsletters/bulletins and Web sites.

CAUTION – What You Need to Know

October 1, 2007, is the effective date for completing the transition of the Medigap crossover process to the COBC. At that time, CMS will then only support the Health Insurance Portability and Accountability Act (HIPAA) American National Standards Institute (ANSI) X-12N 837 professional COB (version 4010-A1) claim format and National Council for Prescription Drug

Transitioning the Mandatory Medigap Crossover Process to the Coordination of Benefits Contractor, continued

Programs (NCPDP) version 5.1 batch standard 1.1 claim format for such crossovers. As CMS' COBC assigns the new COBA Medigap claim-based ID to the Medigap insurers, it will populate this information on its COB Web site so that provider billing staffs may access it for purposes of including the new identifiers on incoming Medicare Part B claims, claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and NCPDP Part B drug claims. By October 1, 2007, providers will exclusively be including the new identifiers on incoming claims to initiate Medigap claim-based crossovers.

GO – What You Need to Do

During June through September 2007, CMS will gradually be moving Medigap insurers to the new process. Be certain that your billing staffs are aware of these changes and that claims are sent to Medicare contractors in a timely and correct manner.

Background

Currently, in accordance with section 1842(h)(3)(B) of the Social Security Act and §4081(a)(B) of Public Law 100-203 (the Omnibus Budget Reconciliation Act of 1987), Part B contractors, including carriers and MACs, and DME MACs transfer participating provider claims to Medigap insurers if the beneficiary has assigned rights to payment to the provider and if other claims filing requirements are met. This form of claims transfer is commonly termed “Medigap claim-based crossover.” One of the “other” claims filing requirements for Medigap claim-based crossover is that the participating provider must include an other carrier name and address (OCNA) or N-key identification number on the incoming electronic claim to trigger the crossing over of the claim.

Key Points of CR 5601

- Be aware that during the transition period from June through September 2007, the COBC will assign new 5-byte claim-based COBA IDs to the Medigap insurers on a graduated basis throughout the three month period prior to the actual transition. Until CMS' COBC assigns a new 5-digit COBA Medigap claim-based ID to a Medigap insurer, Medicare will continue to accept the older contractor-assigned OCNA or N-key identifiers for purposes of initiating Medigap claim-based crossovers. During June through September 2007, the affected contractors will also continue to cross claims over as normal to their Medigap claim-based crossover recipients. CMS will be regularly apprising the affected Medicare contractors when the COBC has assigned new COBA Medigap claim-based IDs to the Medigap insurers and will post this information on its COB Web site so that contractors **may direct providers to that link for purposes of obtaining regular updates.**
- Effective with claims filed to Medicare on October 1, 2007:
 - All participating providers that have been granted a billing exception under the Administrative Simplification Compliance Act (ASCA) should enter CMS' newly assigned COBA Medigap claim-based identifier (ID) within block 9d of the incoming CMS-1500 for purposes of triggering Medigap claim-based crossovers.

- All other participating providers shall enter the newly assigned COBA Medigap claim-based ID, left-justified and followed by spaces, within the NM109 portion of the 2330B loop of the incoming HIPAA ANSI X12-N 837 professional claim **and** within field 301-C1 of the T04 segment on incoming National Council for Prescription Drug Programs (NCPDP) claims for purposes of triggering Medigap claim-based crossovers.
- Providers will need to make certain that claims are submitted with the appropriate identifier that begins with a “5” and contains five numeric digits.
- Be mindful that claims for Medigap claim-based crossovers shall feature a syntactic editing of the incoming COBA claim-based Medigap ID to ensure that the identifier begins with a “5” and contains five numeric digits. If your claim does not follow the appropriate format, Medicare will continue to adjudicate your claim as normal but will notify you via the electronic remittance advice (ERA) and the beneficiary via the Medicare summary notice (MSN) that the information reported was insufficient to cause the claim to be crossed over.
- Your Medicare contractor's screening process will also continue to verify that you participate with Medicare and that the beneficiary has assigned benefits to you as the provider.
- If the claim submitted to the Medicare contractor indicates that (1) the claim contained an invalid claim-based Medigap crossover ID, **the Medicare contractor** will send the following standard message to you, the provider.
 - “Information was **not** sent to the Medigap insurer due to incorrect/invalid information you submitted concerning the insurer. **Please verify your information and submit your secondary claim directly to that insurer.”**
- In addition, in these cases, if CMS common working file (CWF) system determines that the beneficiary was identified for crossover on a Medigap insurer's eligibility file, the CWF system will suppress crossover to the Medigap insurer whose information was entered on the incoming claim.
- Also, the Medicare contractor will include the following message on the beneficiary's MSN in association with the claim: (MSN #35.3):
 - “A copy of this notice will not be forwarded to your Medigap insurer because the Medigap information submitted on the claim was incomplete or invalid. Please submit a copy of this notice to your Medigap insurer.”

Remember: As CMS' COBC assigns new five digit COBA Medigap claim-based identifiers to Medigap insurers, participating providers will be expected to include the new five digit identifier on incoming crossover claims for purposes of triggering claim-based Medigap crossovers. Additionally, effective with **October 1, 2007, Medigap claim-based crossovers will occur exclusively through the COBC in the HIPAA ANSI X12-N 837 professional claim format (version 4010A1 or more current standard) and NCPDP claim format.**

GENERAL INFORMATION

Transitioning the Mandatory Medigap Crossover Process to the Coordination of Benefits Contractor, continued

Additional Information

For complete details regarding this CR please see the official instruction (CR 5601) issued to your Medicare carrier, A/B MAC, or DME MAC. That instruction may be viewed by going to <http://www.cms.hhs.gov/Transmittals/downloads/R1332CP.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5601 *Revised*
Related CR Release Date: August 31, 2007
Related CR Transmittal #: R1332CP

Related Change Request (CR) #: 5601
Effective Date: October 1, 2007
Implementation Date: October 1, 2007

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NATIONAL PROVIDER IDENTIFIER

Delete References to Required Reporting of the National Provider Identifier on or after May 23, 2007 and Revise to a “When Effective” Date

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

Provider Types Affected

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

Provider Action Needed

This article is informational in nature and is based on change request (CR) 5678, which updates Chapter 80 of the *Medicare Claims Processing Manual* to delete references to the May 23, 2007 mandatory date for entry of the national provider identifier (NPI) on claims. The effective date for providers to use only the NPI on Medicare claims will be officially announced at a later date, as previously communicated to providers in the *MLN Matters* article corresponding to CR 5595. That article is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5595.pdf> on the CMS Web site.

Background

The national provider identifier (NPI) final rule, published in the *Federal Register* on January 23, 2004 (http://www.access.gpo.gov/su_docs/fedreg/a040123c.html; Health and Human Services Department Rules), established the standard for a unique identifier for each health care provider for use in health care transactions. Medicare contractors were to be required to enter NPI in certain items and fields of paper claim forms and electronic equivalents on or after May 23, 2007.

However, on April 2, 2007, the Department of Health & Human Services (DHHS) provided guidance regarding contingency planning for the implementation of the NPI. For some time after May 23, 2007, Medicare fee-for-service (FFS) will allow continued use of legacy numbers (unique physician identification numbers (UPINs) and provider identification numbers (PINs), as well as accepting transactions with

only NPIs. The effective date for providers to use only the NPI only on claims and to cease entering UPINs and PINs will be officially announced at a later date, as previously communicated to providers in the *MLN Matters* article corresponding to CR 5595. That article is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5595.pdf> on the CMS Web site. This article reflects CR 5678, which simply amends Chapter 80 of the *Medicare Claims Processing Manual* to reflect that the use of the NPI will be mandated for Medicare FFS claims at a future date.

Additional Information

The official instruction, CR 5678, issued to your carrier, A/B MAC, or DME MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1328CP.pdf> on the CMS Web site.

If you have any questions, please contact your Medicare carrier, DMERCs, 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> on the CMS Web site.

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5678
Related Change Request (CR) #: 5678
Related CR Release Date: August 31, 2007
Effective Date: October 1, 2007
Related CR Transmittal #: R1328CP
Implementation Date: October 1, 2007

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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. This information was previously published in the July 2007 Medicare B Update! pages 45-46.

Note: This article was revised on September 17, 2007, to reflect changes made to change request (CR) 5584, which the Center for Medicare & Medicaid Services (CMS) re-issued on September 14, 2007. The article was revised to show that the unique physician identification number (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 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.

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 CMS discontinued assigning UPINs on June 29, 2007.

CAUTION – What You Need to Know

The national provider identifier (NPI) is a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 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 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 at http://www.cms.hhs.gov/NationalProvIdentStand/downloads/NPI_Contingency.pdf on the CMS site.)

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 National Plan and Provider Enumeration System (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 following note regarding the May 23, 2007, implementation by Medicare.

Important 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 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. For more information on this contingency plan, please visit the NPI dedicated Web site at <http://www.cms.hhs.gov/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 May 23, 2008.

CMS discontinued assigning UPINs 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

GENERAL INFORMATION

Discontinuance of the Unique Physician Identification Number Registry, continued

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 the 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 at <http://www.cms.hhs.gov/Transmittals/downloads/R222PI.pdf> on the CMS Web site.

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 B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5584 *Revised*
Related CR Release Date: September 14, 2007
Related CR Transmittal #: R222PI

Related Change Request (CR) #: 5584
Effective Date: May 29, 2007
Implementation Date: June 29, 2007

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Do Your Claims Need a Rendering Provider?

First Coast Service Options, Inc. (FCSO) is experiencing a high volume of pending claims and denials because of national provider identifier (NPI) billing issues when the same NPI is submitted as the billing and rendering provider. To avoid future delays in claim processing, additional development letters, or claim denials, please ensure that claims submitted conform to the following:

If the billing provider is an independent laboratory, ambulatory surgical center (ASC), independent diagnostic testing facility (IDTF), ambulance supplier, or solo practitioner, then a rendering provider identifier is not required.

For paper claims submitted on the CMS-1500 (08/05) that means:

- Enter the billing provider's NPI in item 33A.
- If submitted, enter the billing provider's Medicare legacy number (also referred to as the provider identification number [PIN]), in item 33B; it should correspond to the NPI in item 33A.
- Leave item 24J blank.

For EMC claims that means:

- Enter the billing provider's NPI in the 2010AA Billing Provider loop, NM1 segment.
- Enter the billing provider's Medicare legacy number in the 2010AA loop, REF segment; it should correspond to the NPI in the NM1 segment.
- Do not use loops 2310B and 2420A.

If the billing provider is a group, limited liability corporation (LLC), professional association (PA), or other corporate entity, identify the billing and rendering providers.

For paper claims submitted on the CMS-1500 (08/05) that means:

- Enter the billing provider's NPI in item 33A.
- If submitted, enter the billing provider's Medicare legacy number (also referred to as the provider identification number [PIN]), in item 33B; it should correspond with the NPI in item 33A.
- Enter the individual physician/nonphysician practitioner's NPI in the unshaded lower portion of item 24J.
- If submitted, enter the individual physician/nonphysician practitioner's Medicare legacy number in the shaded upper portion of item 24J; should correspond with the NPI in the lower portion of item 24J.

For EMC claims that means:

- Enter the billing provider's NPI in the 2010AA Billing Provider loop, NM1 segment.
- If submitted, enter the billing provider's Medicare legacy number in the 2010 AA loop, REF segment; it should correspond to the NPI in the NM1 segment
- Enter the individual physician/nonphysician practitioner's NPI in 2310B Rendering Provider loop, NM1 segment.
- If submitted, enter the individual physician/nonphysician practitioner's Medicare legacy number in the 2310B loop, REF segment; it should correspond to the NPI in the NM1 segment.

Source: Pub 100-04, #1227, Change Request 5595

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. This information was previously published in the May 2007 Medicare B Update! pages 21-22.

Note: This article was revised on July 6, 2007, to provide a reference to *MLN Matters* article SE0721, regarding the provider authentication requirements for telephone and written inquiries during the Medicare fee-for-service (FFS) national provider identifier (NPI) contingency plan. This was added to the *Additional Information* section below. There was also an exception added to the *Important Information* section, stating that ordering/referring physician's NPI is not required on claims for ambulance services.

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 Medicare administrative contractors [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 at <https://nppes.cms.hhs.gov/> on the Center for Medicare & Medicaid Services (CMS) Web site. You should also make sure that your billing staff begins 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/NationalProvIdentStand/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; and
- 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* 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 a 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 can 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 Benefits (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.

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

GENERAL INFORMATION

Medicare Fee-For-Service National Provider Identifier Implementation Contingency Plan, continued

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 ordering/referring physician’s NPI is not required on claims for ambulance services. See the MLN Matters article MM5564 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5564.pdf> on the CMS Web site.**

Additional Information

You may read CR 5595 by visiting <http://www.cms.hhs.gov/Transmittals/downloads/R1227CP.pdf> on the CMS Web site. You may also learn more about the NPI at <http://cms.hhs.gov/NationalProvIdentStand/> on the CMS Web site.

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 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0721.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5595 *Revised*

Related Change Request (CR) #: 5595

Related CR Release Date: April 24, 2007

Effective Date: May 23, 2007

Related CR Transmittal #: R1227CP

Implementation Date: May 23, 2007

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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 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 began making FOIA-disclosable NPPES health care provider data available Tuesday, September 4, 2007. The NPI registry became operational on September 4 and the downloadable file was

ready approximately one week later.

CMS has posted several documents to help providers understand what the downloadable file looks 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.

Important Information for Medicare Providers

September 3, 2007, Medicare carriers and DME MACs began 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

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

NPI and legacy numbers you intend to use on claims and for billing purposes. If NPES 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 NPES **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. NPES data may be verified on the Web at <https://npes.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 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 contractors 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.

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://npes.cms.hhs.gov> or can call the NPI enumerator to request a paper application at 1-800-465-3203.

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

Source: CMS Provider Education Resource 200708-17

NPPES Data and New Data Dissemination Training Module now Available NPI Is Here. NPI Is Now. Are You Using It?

The 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.

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/NationalProviderStand/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/NationalProviderStand>.

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

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/NationalProviderStand>.

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

GENERAL

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.

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

Source: Provider Education Resources Listserv, Message 200708-20

Competitive Acquisition Program 2008 Physician Election Period

The 2008 Physician Election Period for the Medicare Part B Drug Competitive Acquisition Program (CAP) will begin on October 1, 2007, and concludes on November 15, 2007. The CAP is a voluntary program that offers physicians the option to acquire many drugs they use in their practice from an approved CAP vendor, thus reducing the time they spend buying and billing for drugs. The 2008 CAP program period will run from January 1, 2008, to December 31, 2008.

Physicians are instructed to submit their CAP election forms to their local carrier. As per change request (CR) 4064, local carriers are required to forward a list to the CAP designated carrier of all physicians and practitioners who have elected to participate in the CAP. This list is due on November 22, 2007.

Participating CAP physicians are required to use CAP-specific modifier codes on their billing claims, which will affect how local carriers process these claims. The following CRs pertain to the Part B Drug CAP and may be found on the "Transmittals" page at <http://www.cms.hhs.gov/transmittals>.

2007: R1239CP, R1207CP
2006: R841CP, R839CP, R1034CP, R57MSP, R1088CP, R1076CP, R1055CP, R1313CP
2005: R777CP, R761CP, R715CP, R699CP

Additional information about the CAP is available at the following Web site: http://www.cms.hhs.gov/CompetitiveAcquisforBios/01_overview.asp

The list of drugs supplied by the CAP vendor, including national drug code is in the Downloads section at http://www.cms.hhs.gov/CompetitiveAcquisforBios/15_Approved_Vendor.asp

To view and download the billing instructions for CAP physicians, see "CAP Physician Billing Tips" in the Downloads section of the "Information for Physicians" page at http://www.cms.hhs.gov/CompetitiveAcquisforBios/02_infophys.asp

Source: Provider Education Resources Listserv, Message 200709-06 & 200709-15

CMS Issues Final Rule Prohibiting Physician Self-Referral

The Center 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, which was put on display Monday, will be published in the September 5, 2007, *Federal Register*. To view the rule, go to: http://www.cms.hhs.gov/PhysicianSelfReferral/04a_regphase3.asp.

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

To view the entire press release, please click here: http://www.cms.hhs.gov/apps/media/press_releases.asp.

Source: Provider Education Resources Listserv, Message 200708-18

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.

Medicare Clinical Trial Policy, continued

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 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.

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.

Additional Information

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

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 at: <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS Web site.

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5719

Related Change Request (CR) #: 5719

Related CR Release Date: September 7, 2007

Effective Date: July 9, 2007

Related CR Transmittal #: R74NCD

Implementation Date: October 9, 2007

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).

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

Source: CMS Provider Education Resource 200709-12

Requirement for Billing Components of a Purchased Diagnostic Service

Background
Effective for claims with dates of service on or after October 1, 2007, carriers/MACS will use the MPFS national abstract file for purchased diagnostic tests/interpretations to price all claims for purchased diagnostic services based on the ZIP code of the location where the service was rendered, including those submitted by physicians for purchased diagnostic services performed outside of the local carrier’s jurisdiction, in accordance with the carrier jurisdictional pricing rules specified in Chapter 1, Section 10.1.1 of the *Medicare Claims Processing Manual*.

Reminder

Paper claim submissions for purchased diagnostic tests require separate claims for the professional and technical components, since only one rendering location address may be entered in item 32 of the CMS 1500 claim form (version 08-05). Failure to submit separate claims will result in the claim being returned unprocessable. This separate claims requirement does not apply to electronic claim submission.

Source: CMS Publication 100-04, Transmittal 1250, Change Request 5543

Physician Quality Reporting Initiative Clarification on Recent Claim Issues

Centers for Medicare & Medicaid Services (CMS) has notified contractors that due to the way that some edits and audits are placed in the Medicare claim processing system, some codes eligible for the Physician Quality Reporting Initiative (PQRI) may be denying with denial messages other than the designated message for PQRI codes.

CMS has confirmed that PQRI codes that have finalized with messages other than the designated PQRI messages will be part of the CMS PQRI analysis. Therefore, these codes will be included in the 1.5 percent final bonus.

Maintenance to the claim processing system is scheduled for October 4, 2007, to allow claims filed after that date to finalize with the correct denial message.

Source: CMS Joint Signature Memorandum 07525, September 6, 2007

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).

Important 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.
- For information to share with your Medicare patients, please visit 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.nhlbi.nih.gov/cholesterol/>.

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

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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/DiabetesSvc.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
- **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

GENERAL INFORMATION

Update on Medicare Preventive Service Educational Materials, continued

- **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
- **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
- **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

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 and 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 at http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp#TopOfPage on the CMS Web site.
- 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 <http://www.cms.hhs.gov/Transmittals/downloads/R1341CP.pdf> on the CMS Web site.

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

The toll-free number for First Coast Service Options, Inc. Medicare Part B Customer Service Center is 1-866-454-9007 (FL) or 1-888-760-6950 (CT).

MLN Matters Number: MM5724

Related Change Request (CR) #: 5724

Related CR Release Date: September 21, 2007

Effective Date: June 28, 2007

Related CR Transmittal #: R1341CP

Implementation Date: October 22, 2007

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LOCAL COVERAGE DETERMINATIONS

Unless otherwise indicated, articles apply to both Connecticut and Florida.

This section of the *Medicare B Update!* features summaries of new and revised local coverage determinations 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 that the carrier's medical policies and review guidelines are consistent with accepted standards of medical practice.

In accordance with publication requirements specified by the Centers for Medicare & Medicaid Services (CMS), carriers no longer include full-text local coverage determinations (LCDs) to providers in the *Update!* Summaries of revised and new LCDs are provided instead. Providers may obtain full-text LCDs on our provider education Web sites, <http://www.connecticutmedicare.com> or <http://www.floridamedicare.com>. Final LCDs, draft LCDs available for comment, LCD statuses, and LCD comment/response summaries may be printed from the Part B Medical Policy section.

Effective and Notice Dates

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

Electronic Notification

To receive quick, automatic notification when new LCDs are posted to the Web site, subscribe to our *FCSO eNews* mailing list. It's very easy to do; go to <http://www.connecticutmedicare.com> or <http://www.floridamedicare.com>, click on the "eNews" link on the navigational menu and follow the prompts.

More Information

For more information, or, if you do not have Internet access, to obtain a hardcopy of a specific LCD, contact Medical Policy at:

Medical Policy and Procedures
PO Box 2078
Jacksonville, FL 32231-0048

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Advance Beneficiary Notice

Modifier GZ must be used when 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 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 must append the billed service with modifier GA or GZ.

ADDITIONAL INFORMATION

Billing Compounded Drugs, Service Date on/after March 20, 2006

This information was previously published in the Third Quarter 2006 Medicare B Update! page 143.

This article addresses and provides clarification for the billing and reimbursement of compounded drugs. There continues to be a pattern of inconsistent billing and handling of these type claims resulting in an increase in appeals and hearings.

Background

Compounded medications created/processed by a pharmacist in accordance with the Federal Food, Drug, and Cosmetic Act may be covered under Medicare when their use meets all other criteria for services incident to a physician's service. Since the compounded medications do not have an individual NDC number, the specific HCPCS Level II "J" codes may not be used. Instead, providers should use J3490 (unclassified drug) as appropriate for reimbursement of the drug (s). The use of compounded medications has been especially prevalent in the filling of implantable infusion pumps, (CPT codes 95990 or 95991). Whether a single agent or a combination of agents is used, the compounded medication must be billed under HCPCS code J3490 with the KD modifier even though the compound was similar to a specific HCPCS code (e.g., J2275 for preservative free morphine). Of course, providers who document and use the true "off-the-shelf" product from their office supply may continue to use the specific HCPCS code.

Definition

Compounded Drug: A compounded drug is a blend of drugs mixed (compounded) by a pharmacist. This mixture is delivered to the physician or qualified non-physician provider ready to instill into an implantable pump. At times, the pharmacist may reconstitute only one substance and deliver it to the provider in a ready to instill form. An example of reconstituting is adding saline solution to a medication that is supplied as a powder and then turning it into a liquid. For purposes of this billing instruction, a drug that is reconstituted outside the provider's office and is delivered to her/him for instillation into an implantable pump is a compounded drug. In summary, any agent that has been processed by a pharmacist outside the provider's office is a compounded drug.

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Of note, drug compounding by the physician and/or office staff should be billed with the unlisted code (J3490) given that the compound drug does not have a unique NDC number. Also, compounding or reconstituting of drugs by the physician and/or office staff solely for economic gain is not medically necessary or reasonable.

Procedure Codes

HCPCS J3490: Unclassified drugs.

CPT 95990: Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural), or brain (intraventricular).

CPT 95991: Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular); administered by physician. Effective for services rendered on or after March 20, 2006, the guidelines below should be followed.

EMC/Paper Claims

The following information should be reported in block 19 of the CMS 1500 claim form or the electronic equivalent field for EMC claim submitters:

- Name(s) and dose (s) of drug(s) administered into the implantable pump
- Volume of refill in ml
- Pump reservoir size (ml)
- Exact invoice price for that individual patient claim for infusion drugs furnished via implanted DME, with dates of service on or after January 1, 2004, shall be identified using the modifier KD. Units billed should be (1) in the days/units field (Item 24G) on the CMS 1500 claim form.

Note: If any of the above information is omitted from the initial claim, the claim will have to be developed. In that situation, First Coast Service Options, Inc. will request specific documentation by means of an additional documentation request (ADR) letter. This will slow down processing and payment.

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

LOCAL COVERAGE DETERMINATIONS

Humanitarian Use Device and Humanitarian Device Exemptions, continued

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.
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

0145T: Computed Tomographic Angiography of the Chest, Heart and Coronary Arteries—Coding Guideline Revision

The local coverage determination (LCD) for computed tomographic angiography of the chest, heart and coronary arteries was last revised on April 23, 2007. Since that time, the coding guideline attachment has been revised to include the addition of language clarifying the split billing for the physician interpretation.

This revision to the coding guideline attachment is effective for services rendered on or after September 11, 2007. The full text of this LCD is available through our provider education Web site at <http://www.connecticutmedicare.com> or <http://www.floridamedicare.com> on or after this effective date.

CONNECTICUT ONLY - REVISIONS TO THE LCDs

2008 ICD-9-CM Coding Changes

The 2008 update to the ICD-9-CM diagnosis coding structure became effective October 1, 2007. Updated diagnosis codes must be used for all services billed on or after October 1, 2007. Physicians, practitioners, and suppliers must bill using the diagnosis code that is valid for that date of service. Carriers will no longer be able to accept discontinued diagnosis codes for dates of service after the date on which the diagnosis code is discontinued. Connecticut Medicare has reviewed all 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
BEXXAR Tositumomab and Iodine I 131 Tositumomab (BEXXAR®) Therapy	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes A9544, A9545, and G3001.
EPO Epoetin alfa	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0885.
J2505 Pegfilgrastim (Neulasta™)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J2505. Added diagnosis range 202.70-202.78 for HCPCS code J2505.
J7504 ATGAM (Lymphocyte Immune Globulin, Antithymocyte Globulin [Equine])	Removed diagnosis 284.8 for HCPCS code J7504. Added diagnosis range 284.81-284.89 for HCPCS code J7504.
J9000 Doxorubicin HCl	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9000.
J9041 Bortezomib (Velcade®)	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
J9045 Carboplatin (Paraplatin®, Paraplatin-AQ®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9045.
J9160 Denileukin Diftitox (Ontak®)	Added diagnosis range 202.70-202.78 for HCPCS code J9160.
J9178 Epirubicin Hydrochloride (Ellence™)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9178.
J9181 Etoposide	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes J9181 and J9182.
J9185 Fludarabine (Fludara®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9185.
J9201 Gemcitabine (Gemzar®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9201.
J9208 Ifosfamide (Ifex®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9208.
J9212 Interferon	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes J9214 and J9215.
J9293 Mitoxantrone Hydrochloride	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9293.
J9310 Rituximab (Rituxan®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9310.
NESP Darbepoetin alfa (Aranesp®) (novel erythropoiesis stimulating protein [NESP])	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0881.
ZEVALIN Ibritumomab Tiuxetan (Zevalin™) Therapy	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes A9542 and A9543.
0145T Computed Tomographic Angiography of the Chest, Heart, and Coronary Arteries	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.

LOCAL COVERAGE DETERMINATIONS

2008 ICD-9-CM Coding Changes, continued

LCD Title	2008 Changes
31525 Diagnostic Laryngoscopy	Removed diagnosis 787.2 for CPT codes 31525 and 31575. Added diagnosis range 787.20-787.29 for CPT codes 31525 and 31575.
70544 Magnetic Resonance Angiography (MRA)	Added diagnosis 440.4 for CPT code 73725.
84155 Serum Protein	Removed diagnosis 284.8 for CPT code 84155. Added diagnosis range 284.81-284.89 for CPT code 84155. Changed descriptor for diagnosis range 200.00-200.88 for CPT code 84155.
88182 Flow Cytometry and Morphometric Analysis	Removed diagnosis 789.5 for CPT codes 88184-88189. Added diagnoses 789.51 and 789.59 for CPT codes 88184-88189. Changed descriptor for diagnosis range 200.00-200.88 for CPT codes 88182 and 88184-88189.
92552 Audiometry	Removed diagnosis 389.2 for CPT codes 92552, 92553, and 92557. Added diagnosis range 389.20-389.22 for CPT codes 92552, 92553, and 92557. Changed descriptor for diagnosis 389.7 for CPT codes 92552, 92553, and 92557.
92567 Tympanometry	Removed diagnosis 389.2 for CPT code 92567. Added diagnosis range 389.20-389.22 for CPT code 92567.
93922 Noninvasive Physiologic Studies of Upper or Lower Extremity Arteries	Added diagnoses 440.4 and 449 for CPT codes 93922, 93923, and 93924.
93965 Non-Invasive Evaluation of Extremity Veins	Added diagnosis 415.12 for CPT codes 93965, 93970, and 93971.
93975 Duplex Scanning	Removed diagnosis 789.5 for CPT codes 93975 and 93976. Added diagnoses 789.51 and 789.59 for CPT codes 93975 and 93976.
95860 Electromyography and Nerve Conduction Studies	Removed diagnosis 787.2 for CPT codes 95860, 95861, 95863, 95864, 95867, 95868, 95869, 95870, 95872, 95900, 95903, 95904, 95934, 95936, and 95937. 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.

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Source: CMS Publication 100-04, Transmittal 1260, Change Request 5643

CONNECTICUT ONLY - ADDITIONAL INFORMATION

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.

Investigational Device Exemptions, continued

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.
6. 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

1. 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.
2. 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.
3. Providers should not bill Medicare for services, supplies or other costs, which are paid for, or provided by, another party.
4. 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.
5. Medicare contractors have discretion for the approval of coverage of devices and associated services under an IDE.
6. Approval by the contractor for an IDE should not be construed as prior authorization for specific services for specific Medicare beneficiaries.
7. If a hospital is the place of service, the FI may have other requirements for approval. (See billing information for Part A listed below).

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.

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.

LOCAL COVERAGE DETERMINATIONS

Investigational Device Exemptions, continued

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).

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

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>

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 Connecticut and Florida Medicare carrier. By signing up, you will receive automatic email notification when new or updated information is posted to the provider education Web sites <http://www.connecticutmedicare.com> or <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.

Investigational Device Exemptions, continued

**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.

(To be signed by IDE investigator or proxy)

Please submit this document with the above requested materials to:

First Coast Service Options, Inc.
Attn: Neil Sandler, MD
Office of the Medical Director
321 Research Parkway
Meriden, CT 06450

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

FLORIDA ONLY - REVISIONS TO THE LCDs

2008 ICD-9-CM Coding Changes

The 2008 update to the ICD-9-CM diagnosis coding structure became effective October 1, 2007. Updated diagnosis codes must be used for all services billed on or after October 1, 2007. Physicians, practitioners, and suppliers must bill using the diagnosis code that is valid for that date of service. Carriers will no longer be able to accept discontinued diagnosis codes for dates of service after the date on which the diagnosis code is discontinued. Florida Medicare has reviewed all 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
BEXXAR Tositumomab and Iodine I 131 Tositumomab (BEXXAR®) Therapy	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes A9544, A9545, and G3001.
EPO Epoetin alfa	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0885.
J0640 Leucovorin (Wellcovorin®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0640.
J2355 Oprelvekin (Neumega®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J2355.
J2505 Pegfilgrastim (Neulasta™)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J2505. Added diagnosis range 202.70-202.78 for HCPCS code J2505.
J7504 ATGAM (Lymphocyte Immune Globulin, Antithymocyte Globulin [Equine])	Removed diagnosis 284.8 for HCPCS code J7504. Added diagnosis range 284.81-284.89 for HCPCS code J7504.
J9000 Doxorubicin HCl	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9000.
J9041 Bortezomib (Velcade®)	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
J9045 Carboplatin (Paraplatin®, Paraplatin-AQ®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9045.
J9160 Denileukin Diftitox (Ontak®)	Added diagnosis range 202.70-202.78 for HCPCS code J9160.
J9178 Epirubicin Hydrochloride (Ellence™)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9178.
J9181 Etoposide	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes J9181 and J9182.
J9185 Fludarabine (Fludara®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9185.
J9201 Gemcitabine (Gemzar®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9201.
J9212 Interferon	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes J9214 and J9215.
J9293 Mitoxantrone Hydrochloride	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9293.
J9310 Rituximab (Rituxan®)	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J9310.
NESP Darbepoetin alfa (Aranesp®) (novel erythropoiesis stimulating protein [NESP])	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS code J0881.
ZEVALIN Ibritumomab Tiuxetan (Zevalin™) Therapy	Changed descriptor for diagnosis range 200.00-200.88 for HCPCS codes A9542 and A9543.

LOCAL COVERAGE DETERMINATIONS

2008 ICD-9-CM Coding Changes, continued

LCD Title	2008 Changes
0145T Computed Tomographic Angiography of the Chest, Heart, and Coronary Arteries	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.
11600 Excision of Malignant Skin Lesions	Removed diagnosis 233.3 for CPT code range 11620-11626. Added diagnosis range 233.30-233.39 for CPT code range 11620-11626.
31231 Diagnostic Nasal Endoscopy	Removed diagnosis 787.2 for CPT codes 31231, 31233, 31235, and 92511. Added diagnosis range 787.20-787.29 for CPT codes 31231, 31233, 31235 and 92511.
31525 Diagnostic Laryngoscopy	Removed diagnosis 787.2 for CPT codes 31525 and 31575. Added diagnosis range 787.20-787.29 for CPT codes 31525 and 31575.
43235 Diagnostic and Therapeutic Esophagogastroduodenoscopy	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.
44388 Diagnostic Colonoscopy	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.
69220 Mastoidectomy Cavity Debridement	Removed diagnosis 389.2 for CPT codes 69220 and 69222. Added diagnoses 389.05, 389.06, 389.13, 389.17, and 389.20-389.22 for CPT codes 69220 and 69222. Changed descriptor for diagnosis 389.18 for CPT codes 69220 and 69222.
70540 Magnetic Resonance Imaging of the Orbit, Face, and Neck	Added diagnoses 200.31, 200.41, 200.51, 200.61, 200.71, and 202.71 for CPT codes 70540, 70542, and 70543.
70544 Magnetic Resonance Angiography (MRA)	Added diagnosis 440.4 for CPT code 73725.
70551 Magnetic Resonance Imaging of the Brain	Removed diagnosis 389.2 for CPT codes 70551, 70552, and 70553. Added diagnosis range 389.20-389.22 for CPT codes 70551, 70552, and 70553.
73218 Magnetic Resonance Imaging of Upper Extremity	Removed diagnosis 359.2 for CPT codes 73218, 73219, 73220, 73221, 73222, and 73223. Added diagnoses 359.21-359.29, 999.31, and 999.39 for CPT codes 73218, 73219, 73220, 73221, 73222, and 73223. Changed descriptor for diagnoses 200.00-200.88 and 359.3 for CPT codes 73218, 73219, 73220, 73221, 73222, and 73223.
76536 Ultrasound, Soft Tissues of Head and Neck	Added diagnoses 200.31, 200.41, 200.51, 200.61, 200.71, and 202.71 for CPT code 76536.
78460 Cardiovascular Nuclear Imaging Studies	Added diagnosis 414.2 for CPT codes 78460, 78461, 78464, 78465, 78472, 78473, 78478, 78480, 78481, 78483, 78494, and 78496. Added diagnosis 440.4 for CPT codes 78460, 78461, 78464, 78465, 78478, and 78480.
82310 Total Calcium	Removed diagnoses 255.4 and 787.2 for CPT code 82310. Added diagnoses 255.41, 255.42, and 787.20-787.29 for CPT code 82310.
82330 Ionized Calcium	Removed diagnosis 787.2 for CPT code 82330. Added diagnosis range 787.20-787.29 for CPT code 82330.
83735 Magnesium	Removed diagnosis 255.4 for CPT code 83735. Added diagnoses 255.41 and 255.42 for CPT code 83735.
83970 Parathormone (Parathyroid Hormone)	Removed diagnosis 787.2 for CPT code 83970. Added diagnosis range 787.20-787.29 for CPT code 83970.
92015 Ophthalmological Diagnostic Services	Removed diagnosis 364.8 for CPT code 92287. Changed diagnosis range 364.00-364.8 to 364.00-364.89 for CPT code 92287.
92567 Tympanometry	Removed diagnosis 389.2 for CPT code 92567.

LOCAL COVERAGE DETERMINATIONS

2008 ICD-9-CM Coding Changes, continued

LCD Title	2008 Changes
93303 Transthoracic Echocardiogram	Removed diagnosis 999.3 for CPT codes 93307 and 93308. Added diagnoses 415.12, 999.31 and 999.39 for CPT codes 93307 and 93308.
93922 Noninvasive Physiologic Studies of Upper or Lower Extremity Arteries	Added diagnoses 440.4 and 449 for CPT codes 93922, 93923, and 93924.
93925 Duplex Scan of Lower Extremity Arteries	Added diagnoses 440.4 and 449 for CPT codes 93925 and 93926.
93965 Non-Invasive Evaluation of Extremity Veins	Added diagnosis 415.12 for CPT codes 93965, 93970, and 93971.
93975 Duplex Scanning	Removed diagnosis 789.5 for CPT codes 93975 and 93976. Added diagnoses 789.51 and 789.59 for CPT codes 93975 and 93976.
95860 Electromyography and Nerve Conduction Studies	Removed diagnosis 787.2 for CPT codes 95860, 95861, 95863, 95864, 95867, 95868, 95869, 95870, 95872, 95900, 95903, 95904, 95934, 95936, and 95937. 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.

Italicized and/or quoted material is excerpted from the American Medical Association *Current Procedural Terminology*. CPT codes, descriptions and other data only are copyrighted 2006 American Medical Association (or other such date of publication of CPT). All rights reserved. Applicable FARS/DFARS apply.

Source: CMS Publication 100-04, Transmittal 1260, Change Request 5643

64400: Peripheral Nerve Blocks—Revision to the LCD

This local coverage determination (LCD) was last revised on October 30, 2006. Since that time, the following ICD-9-CM codes have been added to the LCD:

338.18 Other acute postoperative pain
355.1 Meralgia paresthetica

This revision is effective for services rendered on or after September 4, 2007. The full text of this LCD is available through our provider education Web site at <http://www.floridamedicare.com> on or after this effective date.

FLORIDA ONLY - ADDITIONAL INFORMATION

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.

Investigational Device Exemptions, continued

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.
6. 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

1. 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.
2. 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.
3. Providers should not bill Medicare for services, supplies or other costs, which are paid for, or provided by, another party.
4. 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.
5. Medicare contractors have discretion for the approval of coverage of devices and associated services under an IDE.
6. 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.

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.

LOCAL COVERAGE DETERMINATIONS

Investigational Device Exemptions, continued

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).

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

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>

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 Connecticut and Florida Medicare carrier. By signing up, you will receive automatic email notification when new or updated information is posted to the provider education Web sites <http://www.connecticutmedicare.com> or <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.

Investigational Device Exemptions, continued

**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.

(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.

CONNECTICUT EDUCATIONAL RESOURCES

Upcoming Provider Outreach and Education Events

October 2007 – November 2007

Medicare Executive Circle (MEC) Meeting

For membership information, please leave a message on our registration hotline at 203-634-5527.

When: October 22, 2007

Time: 11:30 a.m. – 3:30 p.m.

Type of Event: In-person

Hot Topics Teleconference

Topics based on data analysis; session includes discussion of changes in the Medicare program.

When: November 14, 2007

Time: 11:30 a.m. – 1:00 p.m.

Type of Event: Teleconference

***Note:** Dates and times are subject to change prior to event advertisement.*

Two Easy Ways To Register!

Online - Simply log on to your account on our provider training Web site at www.fcsomedicaretraining.com and select the course you wish to register for. Class materials will be available under “My Courses” no later than one day before the event.

First-time user? Please set up an account using the instructions located at www.connecticutmedicare.com/Education/108651.asp in order to register for a class and obtain materials.

Fax - Providers without Internet access can leave a message on our Registration Hotline at 203-634-5527 requesting a fax registration form. Class materials will be faxed to you the day of the event.

Tips for Using the FCSO Provider Training Web Site

The best way to search and register for Connecticut events on www.fcsomedicaretraining.com is by clicking on the following links in this order:

- “Course Catalog” from top navigation bar
- “Catalog” in the middle of the page
- “Browse Catalog” on the right of the search box
- “J13 – CT – Part B” from list in the middle of the page.

Select the specific session you’re interested in, click the “Preview Schedule” button at the bottom of the page. On the Instructor-Led Training (ILT) Schedule page, locate the line that has the course you are interested in and click the “Register” link in the Options column.

If you need assistance, please contact our FCSO Medicare training help desk by calling 866-756-9160 or sending an email to fcsohelp@geolearning.com.

Registrant’s Name: _____

Registrant’s Title: _____

Provider’s Name: _____

Telephone Number: _____ Fax Number: _____

Email Address: _____

Provider Address: _____

City, State, ZIP Code: _____

FLORIDA EDUCATIONAL RESOURCES

Upcoming Provider Outreach and Education Events November 2007 – December 2007

Hot Topics Teleconference – Topics to be determined

When: November 15, 2007
Time: 11:30 a.m. – 12:30 p.m.
Type of Event: Teleconference

Ask the Contractor Teleconference – Topics to be determined

When: December 13, 2007
Time: 11:30 a.m. – 1:00 p.m.
Type of Event: Teleconference

Two Easy Ways To Register

Online – To register for this seminar, please visit our new training Web site at <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!

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!

CONNECTICUT MEDICARE PART B MAIL DIRECTORY

Connecticut Medicare Part B welcomes any questions that you may have regarding the Medicare Part B program. Always be sure to clearly explain your question or concern. This will help our staff to know exactly what issues to address when developing a response to your inquiry.

Please submit your questions to the appropriate department. This will ensure that your concerns are handled in a proper and timely manner. This can be achieved by including an Attention Line below the address on the envelope. Listed below is a directory of departments that includes the issues that you would address to their attention.

With the exception of Redeterminations and Medicare EDI, please submit all correspondence with the appropriate attention line to:

Attention: (insert dept name)
Medicare Part B CT
P.O. Box 45010
Jacksonville, FL 32232-5010

Attention: Correspondence

The Correspondence attention line is used for inquiries pertaining to general issues regarding Medicare Part B. Some examples of these issues are deductibles, assignment, and beneficiary address changes. Do not use words such as *REVIEW* or *RECHECK* when sending general correspondence.

Attention: Financial Services

Use this attention line to return duplicate payments or overpayment refunds.

Attention: Fraud and Abuse

If you encounter what you believe is suspected, potential, or possible fraud or abuse of the Medicare program, we encourage you to contact this department.

Attention: Freedom of Information (FOIA)

This department handles requests for information available under the Freedom of Information Act.

Attention: Medical Review

Questions regarding LMRPs/LCDs and correct documentation for evaluation and management services are handled by this department. Documentation for off-label chemotherapy use should also be submitted to the Medical Review Department.

Attention: MSP

Write to the Medicare Secondary Payer (MSP) department when submitting an Explanation of Benefits from a primary insurance, Exhaust letters from Auto Liability claims, and MSP calculation review requests.

Attention: Pricing/ Provider Maintenance

Address your envelope to this department to apply for a new provider number, change a business or billing address of a provider, or to make any changes in the status of a provider. This department also handles fee schedule requests and inquiries, participation requests, and UPIN requests.

Attention: Resolutions

Use the Resolutions attention line when inquiring or submitting information regarding dates of death, incorrect Medicare (HIC) numbers, incorrect beneficiary information, etc.

MAILING ADDRESS EXCEPTIONS

We have established special P.O. boxes to use when mailing your redeterminations and hearings requests, paper claims, or to contact Medicare EDI:

Redeterminations/Appeals

Please mail only your requests for redeterminations to this P.O. Box. *DO NOT* send new claims, general correspondence, or other documents to this location; doing so will cause a delay in the processing of that item.

If you believe the payment or determination is incorrect and want a claim to be reconsidered, then send it to the attention of the review department. Requests for redeterminations must be made within 120 days of the date of the Medicare Summary Notice. These requests should not include redetermination requests on Medicare Secondary Pay calculations. Claims that are denied for return/reject need to be resubmitted and should **not** be sent as a redetermination. These resubmitted claims should be sent in as new claims.

Post Office Box for Appeals:

Medicare Part B CT Appeals
First Coast Service Options, Inc.
P.O. Box 45041
Jacksonville, FL 32232-5041

Post Office Box for EDI:

Electronic Media Claims/EDI

The Electronic Data Interchange department handles questions and provides information on electronic claims submission (EMC).

Medicare Part B CT Medicare EDI
P.O. Box 44071
Jacksonville, FL 32231-4071

Claims

The Health Insurance Portability and Accountability Act (HIPAA) requires electronic submission of most types of Medicare claims. We realize, however, that on occasion it is necessary to submit a paper claim. When this happens, submit your claims on the approved red-and-white Form CMS-1500 to:

Medicare Part B CT Claims
P.O. Box 44234
Jacksonville, FL 32231-4234

CONNECTICUT MEDICARE PHONE NUMBERS

Beneficiary Services

1-800-MEDICARE (toll-free)
1-866-359-3614 (hearing impaired)
First Coast Service Options, Inc.
Provider Services
Medicare Part B
1-888-760-6950

Appeals

1-866-535-6790, option 1

Medicare Secondary Payer
1-866-535-6790, option 2

Provider Enrollment

1-866-535-6790, option 4

Interactive Voice Response
1-866-419-9455

Electronic Data Interchange (EDI) Enrollment

1-203-639-3160, option 1

PC-ACE® PRO-32

1-203-639-3160, option 2

Marketing and Reject Report Issues

1-203-639-3160, option 4

Format, Testing, and Remittance Issues

1-203-639-3160, option 5

Electronic Funds Transfer Information

1-203-639-3219

Hospital Services

National Government Services
Medicare Part A
1-888-855-4356

Durable Medical Equipment

NHIC
DME MAC Medicare Part B
1-866-419-9458

Railroad Retirees

Palmetto GBA
Medicare Part B
1-877-288-7600

Quality of Care

Qualidign (Peer Review Organization)
1-800-553-7590

OTHER HELPFUL NUMBERS

Social Security Administration
1-800-772-1213

**To Report Lost or
Stolen Medicare Cards**
1-800-772-1213

**Health Insurance Counseling Program
(CHOICES)/Area Agency on Aging**
1-800-994-9422

Department of Social Services/ConnMap
1-800-842-1508

**ConnPACE/
Assistance with Prescription Drugs**
**1-800-423-5026 or 1-860-832-9265 (Hartford
area or from out of state)**

MEDICARE WEB SITES

PROVIDER

Connecticut
<http://www.connecticutmedicare.com>
**Centers for Medicare & Medicaid
Services**
<http://www.cms.hhs.gov>

BENEFICIARIES

**Centers for Medicare & Medicaid
Services**
<http://www.medicare.gov>

Florida Medicare Part B Mail Directory

CLAIMS SUBMISSIONS

Routine Paper Claims

Medicare Part B
P. O. Box 2525
Jacksonville, FL 32231-0019

Participating Providers

Medicare Part B Participating Providers
P. O. Box 44117
Jacksonville, FL 32231-4117

Chiropractic Claims

Medicare Part B Chiropractic Unit
P. O. Box 44067
Jacksonville, FL 32231-4067

Ambulance Claims

Medicare Part B Ambulance Dept.
P. O. Box 44099
Jacksonville, FL 32231-4099

Medicare Secondary Payer

Medicare Part B Secondary Payer Dept.
P. O. Box 44078
Jacksonville, FL 32231-4078

ESRD Claims

Medicare Part B ESRD Claims
P. O. Box 45236
Jacksonville, FL 32232-5236

COMMUNICATIONS

Redetermination Requests

Medicare Part B Claims Review
P.O. Box 2360
Jacksonville, FL 32231-0018

Fair Hearing Requests

Medicare Hearings
Post Office Box 45156
Jacksonville FL 32232-5156

Administrative Law Judge Hearing

Q2 Administrators, LLC
Part B QIC South Operations
P.O. Box 183092
Columbus, Ohio 43218-3092
Attn: Administration Manager

Status/General Inquiries

Medicare Part B Correspondence
P. O. Box 2360
Jacksonville, FL 32231-0018

Overpayments

Medicare Part B Financial Services
P. O. Box 44141
Jacksonville, FL 32231-4141

DURABLE MEDICAL EQUIPMENT (DME)

DME, Orthotic or Prosthetic Claims

Cigna Government Services
P.O. Box 20010
Nashville, Tennessee 37202

ELECTRONIC MEDIA CLAIMS (EMC)

EMC Claims, Agreements and Inquiries

Medicare EDI
P. O. Box 44071
Jacksonville, FL 32231-4071

MEDICARE PART B ADDITIONAL DEVELOPMENT

Within 40 days of initial request:

Medicare Part B Claims
P. O. Box 2537
Jacksonville, FL 32231-0020

Over 40 days of initial request:

Submit the charge(s) in question, including information requested, as you would a new claim, to:

Medicare Part B Claims
P.O. Box 2525
Jacksonville, FL 32231-0019

MISCELLANEOUS

Provider Participation and Group Membership Issues; Written Requests for UPINs, Profiles & Fee Schedules:

Medicare Enrollment
P. O. Box 44021
Jacksonville, FL 32231-4021

Provider Change of Address:

Medicare Registration
P. O. Box 44021
Jacksonville, FL 32231-4021
and

Provider Enrollment Department
Blue Cross Blue Shield of Florida
P. O. Box 41109
Jacksonville, FL 32203-1109

Provider Education:

For Educational Purposes and Review of Customary/Prevailing Charges or Fee Schedule:

Medicare Part B
Provider Outreach and Education
P. O. Box 2078
Jacksonville, FL 32231-0048

For Education Event Registration:

Medicare Part B
Medicare Education and Outreach
P. O. Box 45157
Jacksonville, FL 32232-5157

Limiting Charge Issues:

For Processing Errors:

Medicare Part B
P. O. Box 2360
Jacksonville, FL 32231-0048

For Refund Verification:

Medicare Part B
Compliance Monitoring
P. O. Box 2078
Jacksonville, FL 32231-0048

Medicare Claims for Railroad

Retirees:

MetraHealth RRB Medicare
P. O. Box 10066
Augusta, GA 30999-0001

Fraud and Abuse

First Coast Service Options, Inc.
Complaint Processing Unit
P. O. Box 45087
Jacksonville, FL 32232-5087

Florida Medicare Phone Numbers

PROVIDERS

Toll-Free

Customer Service:
1-866-454-9007
Interactive Voice Response (IVR):
1-877-847-4992

BENEFICIARY

Toll-Free:

1-800-MEDICARE

Hearing Impaired:

1-800-754-7820

Note: The toll-free customer service lines are reserved for Medicare beneficiaries only. Use of this line by providers is not permitted and may be considered program abuse.

For Education Event Registration (not toll-free):

1-904-791-8103

EMC

Format Issues & Testing:

1-904-354-5977 option 4

Start-Up & Front-End Edits/Rejects:

1-904-791-8767 option 1

Electronic Funds Transfer

1-904-791-8016

Electronic Remittance Advice, Electronic Claim Status, & Electronic Eligibility:

1-904-791-6895

PC-ACE Support:

1-904-355-0313

Marketing:

1-904-791-8767 option 1

New Installations:

(new electronic senders; change of address or phone number for senders):
1-904-791-8608

Help Desk:

(Confirmation/Transmission):
1-904-905-8880 option 1

DME, ORTHOTIC OR PROSTHETIC CLAIMS

Cigna Government Services

1-866-270-4909

MEDICARE PART A

Toll-Free:

1-866-270-4909

Medicare Web sites

PROVIDERS

Florida Medicare Contractor

www.floridamedicare.com

Centers for Medicare & Medicaid Services

www.cms.hhs.gov

BENEFICIARIES

Centers for Medicare & Medicaid Services

www.medicare.gov

ORDER FORM**ORDER FORM — 2008 PART B MATERIALS**

The following materials are available for purchase. To order these items, please complete and **submit this form along with your check/money order** payable to FCSO with the designated account number indicated below.

Note: Payment for fee schedules cannot be combined with payment for other items; separate payments are required for purchases of items from different accounts.

ITEM	ACCOUNT NUMBER	COST PER ITEM	QUANTITY	TOTAL	
Medicare B Update! Subscription — The <i>Medicare B Update!</i> is available free of charge online at http://www.fcsso.com (click on “Medicare Providers”). Non-provider entities or providers who need additional copies may purchase an annual subscription. This subscription includes all issues published from October 2007 through September 2008.	700395	Hardcopy \$60.00			
		CD-ROM \$20.00			
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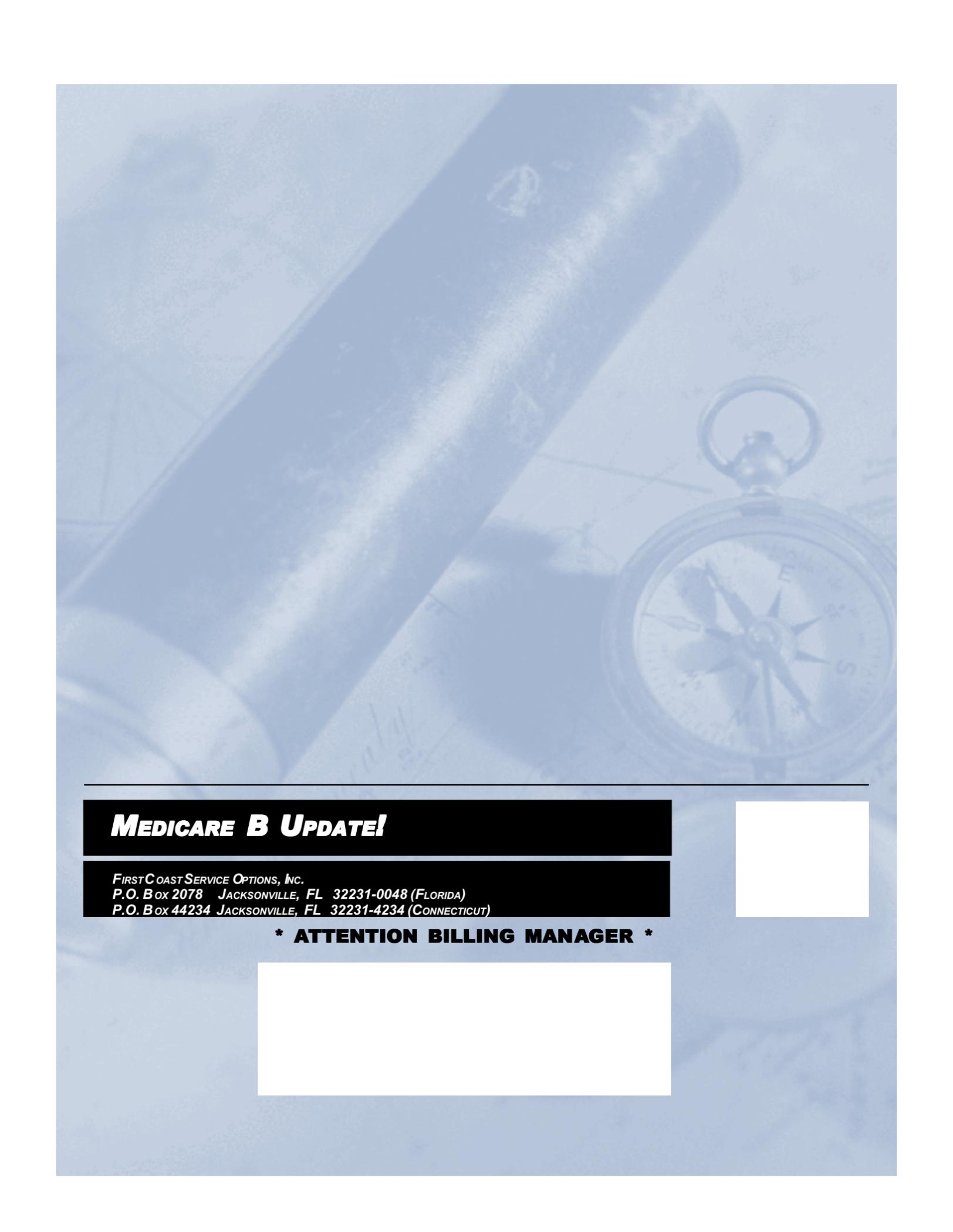
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