Medicare A CONNECTION

FIRST COAST SERVICE OPTIONS, INC.

A Newsletter for MAC Jurisdiction 9 Providers June 2012

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This *MLN Matters*® article is intended for Medicare hospitals submitting claims to fiscal intermediaries (FIs) and A/B Medicare administrative contractors (MACs) for services to Medicare beneficiaries.

Provider action needed

This article, based on change request (CR) 7863, informs you that the Centers for Medicare & Medicaid Services (CMS) is providing its annual reminder of the ICD-9-CM update that is effective for the dates of service on and after October 1, 2012, (effective for discharges on or after October 1, 2012, for institutional providers).

You should note that the ICD-9-CM Coordination and Maintenance Committee implemented a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10.

- As a result of this partial code freeze, only one new ICD-9-CM procedure code is being added with this change request, i.e., 00.95 (Injection or infusion of glucarpidase).
- There are no new diagnosis codes for fiscal year (FY) 2013.

Please be sure to inform your staffs of these updates.

Background

ICD-9 information

The ICD-9-CM codes are updated annually. Effective since October 1, 2003, an ICD-9-CM code is required on all paper and electronic claims billed to Medicare contractors; including ambulance supplier claims submitted in the version 5010 electronic claim format. ICD-9-CM codes are not required on paper ambulance claims or on electronic ambulance claims submitted in earlier electronic claim formats.

An ICD-9-CM diagnosis code is required for all professional claims, e.g., physicians, non-physician practitioners, independent clinical diagnostic laboratories, occupational and physical therapists, independent diagnostic testing facilities, audiologist, ambulatory surgical centers (ASCs), ambulance (effective with 5010 implementation, for electronic claims only), and for all institutional claims. ICD-9-CM procedure codes are required for inpatient hospital Part A claims only.

CMS annually posts the new, revised, and discontinued ICD-9-CM diagnosis codes available at *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. The updated diagnosis and procedure codes are effective for dates of service/discharges on and after

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Register for free, hands-on Internet based PECOS class

Join First Coast Service Options, in Jacksonville, for a free, *interactive session* on using Internet-based PECOS to electronically create or update your Medicare enrollment. Select from the following session dates: July 17, August 21, or September 11, 2012.

The *Medicare A Connection* is published monthly by First Coast Service Options Inc.'s Provider Outreach & Education division to provide timely and useful information to Medicare Part A providers.

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Articles included in the *Medicare A Connection* represent formal notice of coverage policies. Policies have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined within to ensure compliance with Medicare coverage and payment guidelines.

Phase 2 of ordering and referring requirement

Provider types affected

This *MLN Matters*® special edition article is intended for:

- Physicians and non-physician practitioners (including interns, residents, fellows, and those who are employed by the Department of Veterans Affairs (DVA) or the Public Health Service (PHS)) who order or refer items or services for Medicare beneficiaries,
- Part B providers (including portable X-ray services) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) who submit claims to carriers, Part A/B Medicare administrative contractors (MACs), and DME MACs for items or services that they furnished as the result of an order or a referral, and
- Part A home health agency (HHA) services who submit claims to RHHIs, fiscal intermediaries (who still maintain an HHA workload), and Part A/B MACs.

Provider action needed

Stop – impact to you

CMS will soon begin denying Part B, DME, and Part A HHA claims that fail the ordering/referring provider edits. These edits ensure that physicians and others who are eligible to order and refer items or services have established their Medicare enrollment records and are of a specialty that is eligible to order and refer. CMS will provide 60 day advanced notice prior to turning on the ordering/referring edits. CMS does not have a date at this time.

Caution – what you need to know

CMS shall authorize A/B MACs and DME MACs to begin editing Medicare claims with phase 2 ordering/referring edits. This means that the billing provider will not be paid for the items or services that were furnished based on the order or referral from a provider who does not have a Medicare enrollment record.

Go – what you need to do

If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using Internet-based PECOS or by completing the paper enrollment application (CMS-855O).

Background

The Social Security Act (the Act) requires that all physicians and non-physician practitioners be uniquely identified for all claims for services that are ordered or referred. Effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the attending physician on the claim if that service or item was the result of an order or referral. Effective May 23, 2008, the unique identifier was determined to be the National Provider Identifier (NPI).

CMS began expanding the claims editing to meet the Act's requirements for ordering and referring providers as follows:

- **Phase 1:** Beginning October 5, 2009, if the billed Part B service requires an ordering/referring provider and the ordering/referring provider is not reported on the claim, the claim is not paid. If the ordering/referring provider is reported on the claim, but does not have a current Medicare enrollment record or is not of a specialty that is eligible to order and refer, the claim was paid, but the billing provider received an informational message in the remittance advice indicating that the claim failed the ordering/referring provider edits.

  Only physicians and certain types of non-physician practitioners are eligible to order or refer items or services for Medicare beneficiaries. They are as follows:

- Physician (doctor of medicine or osteopathy, doctor of dental medicine, doctor of dental surgery, doctor of podiatric medicine, doctor of optometry),
- Physician assistant,
- Certified clinical nurse specialist,

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Ordering *(continued)*

- Nurse practitioner,
- Clinical psychologist,
- Interns, residents, and fellows
- Certified nurse midwife, and
- Clinical social worker.

The informational message will indicate that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring Provider is not eligible to order or refer. The informational message on an adjustment claim that does not pass the edits will indicate that the claim/service lacks information that is needed for adjudication. The informational messages are identified below:

For Part B providers and suppliers who submit claims to carriers:

N264	Missing/incomplete/invalid ordering physician provider name
N265	Missing/incomplete/invalid ordering physician primary identifier

For adjusted claims CARC code 45 along with RARC codes N264 and N265 will be used. DME suppliers who submit claims to carriers (applicable to 5010 edits):

N544	Alert: Although this was paid you have billed with a referring/ordering provider that does not match our system record. Unless corrected this will not be paid in the future

For Part A HHA providers who order and refer, the claims system shall initially process the claim and add the following remark message:

N272	Missing/incomplete/invalid other payer attending provider identifier

For adjusted claims the CARC code 16 and/or the RARC code N272 shall be used.

Note: If the billed service requires an ordering/referring provider and the ordering/referring provider is not on the claim, the claim will not be paid.

Phase 2: CMS has not announced a date when the edits for phase 2 will become active. CMS will give the provider community at least 60 days notice prior to turning on these edits. During phase 2, Medicare will deny Part B, DME and Part A HHA claims that fail the ordering/referring provider edits. Physicians and others who are eligible to order and refer items or services need to be enrolled in Medicare and must be of a specialty that is eligible to order and refer. If the billed service requires an ordering/referring provider and the ordering/referring provider is not on the claim, the claim will not be paid. If the ordering/referring provider is on the claim, but is not enrolled in Medicare, the claim will not be paid. In addition, if the ordering/referring provider is on the claim, but is not of a specialty that is eligible to order and refer, the claim will not be paid. Below are the denial edits for Part B providers and suppliers who submit claims to carriers including DME:

254D	Referring/ordering provider not allowed to refer
255D	Referring/ordering provider mismatch
289D	Referring/ordering provider NPI required

CARC code 16 and/or the RARC code N264 and N265 shall be used for denied or adjusted claims. Following are the denial edits for Part A HHA providers who submit claims:

37236 – This reason code will assign when:

- The statement “From” date on the claim is on or after the date the phase 2 edits are turned on.
- The type of bill is “32” or “33”
- Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claim

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is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from PECOS or the specialty code is not a valid eligible code

37237 – This reason code will assign when:

- The statement "From" date on the claim is on or after the date the phase 2 edits are turned on.
- The type of bill is "32" or "33"
- The type of bill frequency code is "7" or "F-P"
- Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claims is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from PECOS or the specialty code is not a valid eligible code

CMS published the final rule, CMS-6010-F, RIN 0938-AQ01, "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements," on April 24, 2012, permitting phase 2 edits to be implemented.

CMS will announce the date via an updated article when it shall authorize Part A/B and DME MACs and Part A RHHIs to implement phase 2 edits.

Additional information

A note on terminology: Part B claims use the term "ordering/referring provider" to denote the person who ordered, referred or certified an item or service reported in that claim. CMS has used this term on its website and in educational products. The final rule uses technically correct terms: 1) a provider "orders" non-physician items or services for the beneficiary, such as DMEPOS, clinical laboratory services, or imaging services and 2) a provider "certifies" home health services for a beneficiary. The terms "ordered" "referred" and "certified" are often used interchangeably within the health care industry. Since it would be cumbersome to be technically correct, CMS will continue to use the term "ordered/referred" in materials directed to a broad provider audience.

For more information about the Medicare enrollment process, visit *http://www.cms.gov/Medicare/Provider-Enrollment-and- Certification/MedicareProviderSupEnroll/index.html*, or contact the designated Medicare contractor for your state. Medicare provider enrollment contact information for each state can be found at *http://www.cms.gov/Medicare/Provider-Enrollment-and- Certification/MedicareProviderSupEnroll/downloads/Contact_list.pdf*.

The *Medicare Learning Network*® fact sheet, "Medicare Enrollment Guidelines for Ordering/Referring Providers" provides information about the requirements for eligible ordering/referring providers and is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNProducts/downloads/MedEnroll_OrderReferProv_FactSheet_ICN906223.pdf*.

You may find the following articles helpful in understanding this matter:

- *MLN Matters*® article MM6417, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Claims Processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)," is available at *http://www.cms.gov/Outreach-and- Education/Medicare-Learning-Network- MLN/MLNMattersArticles/downloads/MM6417.pdf*.
- *MLN Matters*® article MM6421, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers' Claims Processed by Durable Medical Equipment Medicare Administrative Contractors (DME MACs)," is available at *http://www.cms.gov/Outreach- and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/downloads/MM6421.pdf*.
- *MLN Matters*® article MM6856, "Expansion of the Current Scope of Editing for Attending Physician Providers for free-standing and provider-based Home Health Agency (HHA) claims processed by Medicare Regional Home Health Intermediaries (RHHIs)", is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/downloads/MM6856.pdf*.
- *MLN Matters*® article MM7097, "Eligible Physicians and Non-Physician Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Items and Services for Medicare

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Beneficiaries," is available at *http://www.cms.gov/Outreach-and- Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7097.pdf*.

- *MLN Matters*® article MM6129, "New Requirement for Ordering/Referring Information on Ambulatory Surgical Center (ASC) Claims for Diagnostic Services," is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/downloads/MM6129.pdf*.
- *MLN Matters*® special edition article SE1011, "Edits on the Ordering/Referring Providers in Medicare Part B Claims (change requests 6417, 6421, and 6696)," is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/downloads/SE1011.pdf*.
- *MLN Matters*® article special edition article SE1201 "Important Reminder for Providers and Suppliers Who Provide Services and Items Ordered or Referred by Other Providers and Suppliers" is available at *http://www.cms.gov/Outreach-and-Education/Medicare- Learning-Network-MLN/MLNMattersArticles/downloads/SE1201.pdf*.
- *MLN Matters*® special edition article SE1208, "855-O Medicare Enrollment Application Ordering and Referring Physicians or Other Eligible Professionals," is available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/downloads/SE1208.pdf*.

If you have any questions, please contact your carrier, Part A/B MAC, RHHI, fiscal intermediary, or DME MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-%20Education/Medicare-Learning-Network-%20MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

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Delegated official signatures on CMS-855 revalidation applications

Effective with CMS-855 revalidation applications received on or after June 18, 2012, applications signed by the provider or supplier's delegated official will be accepted. Chapter 15 of the *Program Integrity Manual* will be updated to clarify that authorized and delegated officials may sign Form CMS-855 revalidation applications.

Note: This policy applies to paper and electronic applications and does not apply to initial applications, which must still be signed by an authorized official.

Source: TDL 12396

Appeals for denied claims submitted by ordering and referring opt-out physicians/non-physician practitioners who are excluded by the OIG

Provider types affected

This *MLN Matters*® special edition article is intended for opt-out physicians/non-physician practitioners who elect to order and refer and are excluded by the Office of Inspector General (OIG) and who are listed as an eligible professional on a provider submitted claim to Medicare contractors (carriers, fiscal intermediaries (who maintain an HHA workload, RHHIs, and/or A/B Medicare administrative contractors (A/B MACs)) for services provided to Medicare beneficiaries which meet exceptions described at 42 CFR 1001.1901(c).

Provider action needed

Stop – impact to you

The Centers for Medicare & Medicaid Services (CMS) is issuing this article to inform opt-out physicians/non-physician practitioners who elect to order and refer and have been excluded by the OIG that Medicare will soon begin denying Part B, durable medical equipment (DME), and Part A HHA claims that fail the ordering/referring provider edits. Opt-out physicians/non-physician practitioners who elect to order and refer and have been excluded by the OIG should file an appeal for any claim denials to their carriers and A/B MACs that they believe meets one of the exceptions described at 42 CFR 1001.1901(c).

Caution – what you need to know

The claims appeal should follow guidelines contained in the *Medicare Claims Processing Manual*, Chapter 29, Section 290. The appeal should include documentation that proves one of the exceptions described at 42 CFR 1001.1901(c) has been met.

Go – what you need to do

See the *Background* and *Additional information* sections of this article for more details.

Background

Medicare requirements for opting out can be found in the *Medicare Benefit Policy Manual*, Chapter 15, Section 40, which is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*. Opt-out affidavit requirements can be found in the *Medicare Benefit Policy Manual*, Chapter 15, Section 40.9, which is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*.

The OIG exclusion does not prohibit a physician/non-physician practitioner from opting out of the Medicare program. This includes exclusions under the following sections of the Social Security Act:

- Section 1128, Exclusion of Certain Individuals and Entities from Participation in Medicare and State Health Care Programs, which is available at *http://www.ssa.gov/OP_Home/ssact/title11/1128.htm*;
- Section 1156, Obligations of Health Care Practitioners and Providers of Health Care Services, Sanctions, and Penalties, Hearings and Review, which is available at *http://www.ssa.gov/OP_Home/ssact/title11/1156.htm*; or
- Section 1892, Offset of Payments to Individuals to Collect Past Due Obligations Arising from Breach of Scholarship and Loan Contract, which is available at *http://www.ssa.gov/OP_Home/ssact/title18/1892.htm*.

However, if the opt out physician/non-physician practitioner elects to order and refer services, then 42 CFR 405.425(j) would be applicable. It states that:

"The physician or practitioner who is excluded under sections 1128, 1156, or 1892 of the Social Security Act may not order, prescribe, or certify the need for Medicare-covered items and services except as provided in §1001.1901 of this title, and must otherwise comply with the terms of the exclusion in accordance with §1001.1901 effective with the date of the exclusion."

This article informs opt-out physicians/non-physician practitioners who elect to order and refer and have been excluded by the OIG that they should file an appeal for any claim denials to their carriers and/or A/B MACs. That is, if they believe it meets one of the exceptions described at 42 CFR 1001.1901(c).

- 42 CFR 1001.1901(c) is available at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr1001_main_02.tpl*.
- The claims appeal should follow the guidelines found in the *Medicare Claims Processing Manual*, Chapter 29, Section 290. It should also include documentation that proves one of the exceptions described at 42 CFR 1001.1901(c) has been met. The *Medicare Claims Processing Manual*, Chapter 29, Section 290, is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c29.pdf*.

Additional information

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.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

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Helpful tips for successful submission of electronic medical documentation

Currently, Medicare contractors request medical documentation by sending a letter to the provider. The provider's only option to submit records is via the U.S. Postal Service. Effective September 2011, providers were given the opportunity to participate in Medicare's electronic submission of medical documentation (esMD) pilot project, which allows for the electronic transmission of documentation. This article provides a list of questions and answers to assist providers in this process and to alleviate current processing issues associated with electronic submission of records.

Note: The most important aspect of electronic transmission of records to Medicare is to ensure that the first page of the transmission is a copy of the automatic development request (ADR) letter. The ADR contains vital information that allows the contractor to match your records to the corresponding claims pending in the Medicare system that are awaiting the records.

Questions and answers

Q1. How can providers sign up for the esMD initiative?

A1. The provider would need to sign up to submit esMD transactions by a third-party vendor. A complete list of vendors is located at *http://go.usa.gov/kr4*. Instructions are also available in *special edition article SE1110*.

Q2. If records are submitted through the esMD portal, should paper documentation also be submitted?

A2. No. If the documentation has been sent electronically, do not submit paper documentation separately.

Q3. Should a copy of the ADR letter be submitted with the electronic documentation?

A3. First Coast Service Options (FCSO) strongly encourages the provider to include the ADR letter at the beginning of the transmission. This allows the contractor to match the documentation with the claims.

Q4. When should an electronic document be submitted?

A4. An electronic document should only be returned when an ADR is received from the contractor.

Q5. Are there plans for providers to be able to submit redetermination requests via the esMD portal in the future?

A5. Yes, but at this time there has not been a date established. More information on this will be provided as it becomes available.

Q6. If a provider submits a redetermination request via the esMD portal, will it be accepted?

A6. No, it will not be accepted. The provider will not receive any type of response on the request. It will be rejected through the portal.

Additional information

Refer to *special edition article SE1110* for a list of contractors participating in the pilot as well as health information handlers (HIHs) that offer esMD gateway services.

Additional information is also available on the esMD Web page at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/index.html*. You might also try the Twitter link, which is @ CMSGov (Look for #CMS_esMD).

Appeals *(continued)*

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Advanced beneficiary notice of noncoverage (ABN), Form CMS-R-131, updated manual instructions

Provider types affected

This *MLN Matters*® article is intended for physicians, providers and suppliers that submit claims to Medicare contractors (carriers, fiscal intermediaries (FIs), regional home health intermediaries (RHHIs), durable medical equipment Medicare administrative contractors (DME MACs), and Part A/B Medicare administrative contractors (A/B MACs)) for services provided to beneficiaries enrolled in original Medicare.

What you need to know

This article is based on CR 7821 which clarifies the currently published instructions on advance beneficiary notice of noncoverage (ABN) use in the *Medicare Claims Processing Manual* (Chapter 30, Section 50). Make sure that your billing staff is aware of these ABN policy updates and clarifications that are summarized in this article.

Background

ABNs are issued by providers and suppliers to inform beneficiaries in original Medicare about possible charges for items or services that are not covered by Medicare. issuance of the ABN is required in certain situations when limitation of liability (LOL) applies. You may review that information in the Social Security Act (Section 1879; see *http://www.ssa.gov/OP_Home/ssact/title18/1879.htm*). In 2008 CMS revised the notice and its instructions to streamline and simplify the notice process.

Change request (CR) 7821 revises the current manual instructions on ABN use in the *Medicare Claims Processing Manual*, Chapter 30 (Financial Liability Protections), Section 50 (Form CMS-R-131 Advance Beneficiary Notice of Noncoverage (ABN)). The revised Chapter 30, Section 50 is included as an attachment to CR 7821. The last page of this article contains a *Quick Glance Guide* from the revised manual section, that may help you and your staff comply with ABN issuance requirements.

Key points from the updated Chapter 30 Section 50

General information

Section 50 of the *Medicare Claims Processing Manual* establishes the standards for use by providers and suppliers (including laboratories) in implementing the advance beneficiary notice of noncoverage (ABN), Form CMS-R-131, formerly the "Advance Beneficiary Notice."

Since March 1, 2009, the ABN-G (general) and ABN-L (laboratory) are no longer valid notices and have been replaced with the ABN.

ABN scope

The ABN is an Office of Management and Budget (OMB) approved written notice issued by providers and suppliers for items and services provided under Medicare Part B, including hospital outpatient services, and certain care provided under Part A (hospice and religious non-medical health care institutes only).

The ABN is given to beneficiaries enrolled in the Medicare fee-for-service (FFS) program. It is not used for items or services provided under the Medicare Advantage (MA) program or for prescription drugs provided under the Medicare prescription drug program (Part D). The ABN is used to fulfill both mandatory and voluntary notice functions.

Skilled nursing facilities (SNFs) issue the ABN for Part B services only. The skilled nursing facility advance beneficiary notice of noncoverage (SNFABN), Form 10055, is issued for Part A SNF items and services.

Home health agencies (HHAs) do not issue the ABN. HHAs issue the home health advance beneficiary notice of noncoverage (HHABN), Form CMS-R-296.

Mandatory ABN uses

The following provisions of the Social Security Act necessitate delivery of the ABN:

- Section1862(a)(1) of the Social Security Act (not reasonable and necessary); *http://www.ssa.gov/OP_Home/ssact/title18/1862.htm*;
- Section 1834(a)(17)(B) of the Social Security Act (violation of the prohibition on unsolicited telephone contacts); *http://www.ssa.gov/OP_Home/ssact/title18/1834.htm*;
- Section 1834(j)(1) of the Social Security Act (medical equipment and supplies supplier number requirements not met),
- Section 1834(a)(15) of the Social Security Act (medical equipment and/or supplies denied in advance),
- Section 1862(a)(9) of the Social Security Act (custodial care); (*http://www.ssa.gov/OP_Home/ssact/title18/1862.htm*),
- Section 1879(g)(2) of the Social Security Act (hospice patient who is not terminally ill); see *http://www.ssa.gov/OP_Home/ssact/title18/1879.htm*.

Expanded mandatory ABN use in 2011

In addition, delivery of an ABN is mandatory under 42 CFR §414.408(e)(3)(ii) (*http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr414_main_02.tpl)* when a noncontract supplier furnishes

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ABN *(continued)*

an item included in the durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) competitive bidding program (CBP) for a competitive bidding area (CBA) unless the beneficiary has signed an ABN. Although all other denial reasons triggering mandatory use of the ABN are found in Section 1879 of the Social Security Act, in this situation, Section 1847(b)(5)(D) (*http://www.ssa.gov/OP_Home/ssact/title18/1847.htm*) of the Social Security Act permits use of the ABN with respect to these items and services.

The Affordable Care Act, P.L. 111-148, Section 4103(d)(1)(C) added a new subparagraph (P) to 1862(a)(1) of the Act. Per Section 1862(a)(1)(P), Medicare covered personalized prevention plan services (as defined in Section *1861(hhh)(1)*) that are performed more frequently than covered are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The limitation of liability (LOL) provisions of Section1879 apply to this new subparagraph; thus, providers must issue an ABN prior to providing a preventative service that is usually covered by Medicare but will not be covered in this instance because frequency limitations have been exceeded.

Voluntary ABN uses

ABN issuance is not required for care that is either statutorily excluded from coverage under Medicare (i.e. care that is never covered) or most care that fails to meet a technical benefit requirement (i.e. lacks required certification). However, the ABN can be issued voluntarily.

The voluntary ABN serves as a courtesy to the beneficiary in forewarning him/her of impending financial obligation. When an ABN is used as a voluntary notice, the beneficiary should not be asked to choose an option box or sign the notice. The provider or supplier is not required to adhere to the issuance guidelines for the mandatory notice (as set forth below) when using the ABN for voluntary notification.

Note: Certain DME items/services that fail to meet a technical requirement may require an ABN as outlined in the mandatory use section above.

ABN triggering events

Notifiers are required to issue the ABN when an item or service is expected to be denied based on one of the provisions in the *Mandatory use* section above. This may occur at any one of three points during a course of treatment which are initiation, reduction, and termination, also known as “triggering events.”

An initiation is the beginning of a new patient encounter, start of a plan of care, or beginning of treatment. If a notifier believes that certain otherwise covered items or services will be noncovered (e.g. not reasonable and necessary) at initiation, an ABN must be issued prior to the beneficiary receiving the non-covered care.

A. Initiations

Example: Mrs. S. asks her physician for an EKG because her sister was recently diagnosed with atrial fibrillation. Mrs. S. has no diagnosis that warrants medical necessity of an EKG but insists on having an EKG even if she has to pay out of pocket for it. The physician’s office personnel issue an ABN to Mrs. S. before the EKG is done.

A reduction occurs when there is a decrease in a component of care (i.e. frequency, duration, etc.). The ABN is not issued every time an item or service is reduced. But, if a reduction occurs and the beneficiary wants to receive care that is no longer considered medically reasonable and necessary, the ABN must be issued prior to delivery of this noncovered care.

B. Reductions

Example: Mr. T is receiving outpatient physical therapy five days a week, and after meeting several goals, therapy is reduced to three days per week. Mr. T wants to achieve a higher level of proficiency in performing goal related activities and wants to continue with therapy five days a week. He is willing to take financial responsibility for the costs of the two days of therapy per week that are no longer medically reasonable and necessary. An ABN would be issued prior to providing the additional days of therapy weekly.

A termination is the discontinuation of certain items or services. The ABN is only issued at termination if the beneficiary wants to continue receiving care that is no longer medically reasonable and necessary.

C. Terminations

Example: Ms. X has been receiving covered outpatient speech therapy services, has met her treatment goals, and has been given speech exercises to do at home that do not require therapist intervention. Ms. X wants her speech therapist to continue to work with her even though continued therapy is not medically reasonable or necessary. Ms. X is issued an ABN prior to her speech therapist resuming therapy that is no longer considered medically reasonable and necessary.

Completing the ABN

The ABN and step by step instructions for notice completion are posted on the CMS website at

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ABN *(continued)*

http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html. Notifiers must follow the instructions posted on the CMS website to construct a valid notice.

Retention requirements

Retention periods for the ABN are five years from discharge/completion of delivery of care when there are no other applicable requirements under state law. Retention is required in all cases, including those cases in which the beneficiary declined the care, refused to choose an option, or refused to sign the notice. Electronic retention of the signed paper document is acceptable. Notifiers may scan the signed paper or "wet" version of the ABN for electronic medical record retention and if desired, give the paper copy to the beneficiary.

Clarification of period of effectiveness/repetitive or continuous noncovered care

An ABN can remain effective for up to one year. Notifiers may give a beneficiary a single ABN describing an extended or repetitive course of noncovered treatment provided that the ABN lists all items and services that the notifier believes Medicare will not cover. If applicable, the ABN must also specify the duration of the period of treatment. If there is any change in care from what is described on the ABN within the one-year period, a new ABN must be given. If during the course of treatment additional noncovered items or services are needed, the notifier must give the beneficiary another ABN. The limit for use of a single ABN for an extended course of treatment is one year. A new ABN is required when the specified treatment extends beyond one year.

If a beneficiary is receiving repetitive non-covered care, but the provider or supplier failed to issue an ABN before the first or the first few episodes of care were provided, the ABN may be issued at any time during the course of treatment. However, if the ABN is issued after repetitive treatment has been initiated; the ABN cannot be retroactively dated or used to shift liability to the beneficiary for care that had been provided before ABN issuance.

Electronic issuance of the ABN

Electronic issuance of ABNs is not prohibited. If a provider elects to issue an ABN that is viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic if that is what she/he prefers. Also, regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the signed ABN to keep for his/her own records. Electronic retention of the signed ABN is permitted.

ABN standards for upgraded durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)

Notifiers must give an ABN before a beneficiary receives a Medicare covered item containing upgrade components that are not medically reasonable and necessary and not paid for by the supplier. For example, an ABN must be issued when a notifier expects that Medicare will not pay for additional parts or features of a usually covered item because those parts and/or features are not medically reasonable and necessary.

ABNs for items listed in a DMEPOS competitive bidding program

The Social Security Act (Section 1862 (a)(17)(*http://www.ssa.gov/OP_Home/ssact/title18/1862.htm*) excludes Medicare payment for competitive bidding program (CBP) items/ services that are provided by a non-contract supplier in a competitive bidding area (CBA) except in special circumstances. A non-contracted supplier is permitted to provide a beneficiary with an item or service listed in the CBP when the supplier properly issues an ABN prior to delivery of the item or service per 42 CFR 414.408(e)(3)(ii) (*http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr414_main_02.tpl*). In order for the ABN to be considered valid when issued under these circumstances, the reason that Medicare may not pay must be clearly and fully explained on the ABN that is signed by the beneficiary.

Sample wording for the "Reason Medicare May Not Pay" blank of the ABN:

Since we are not a contracted supplier, Medicare will not pay for this item. If you get this item from a contracted supplier such as ABC Medical Supplies, Medicare will pay for it.

To be a valid ABN, the beneficiary must understand the meaning of the notice. Suppliers must explain to the beneficiary that Medicare will pay for the item if it is obtained from a different supplier in the area. While some suppliers may be reluctant to direct beneficiaries to a specific contracted supplier, the non-contracted supplier should at least direct the beneficiary to 1-800-MEDICARE to find a local contracted supplier at the beneficiary's request.

Emergencies or urgent situations/ambulance transport

In general, a notifier may not issue an ABN to a beneficiary who has a medical emergency or is under similar duress. Forcing delivery of an ABN during an emergency may be considered coercive. ABN usage in

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ABN *(continued)*

the emergency room (ER) may be appropriate in some cases where the beneficiary is medically stable with no emergent health issues.

Issuance of the ABN is mandatory if all of the following three criteria are met:

1. The service being provided is a Medicare covered ambulance benefit under Section 1861(s)(7) of the Social Security Act (*http://www.ssa.gov/OP_Home/ssact/title18/1861.htm*) and regulations under this section as stipulated in 42 CFR 410.40 -.41 (*http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr414_main_02.tpl*);
2. The provider believes that the service may be denied, in part or in full, as "not reasonable and necessary" under Section 1862(a)(1)(A) for the beneficiary on that particular occasion; and
3. The ambulance service is being provided in a non-emergency situation. (The patient is not under duress.)

Simplified, there are three questions to ask when determining if an ABN is required for an ambulance transport. If the answer to all of the following three questions is "yes", an ABN must be issued:

1. Is this service a covered ambulance benefit? AND
2. Will payment for part or all of this service be denied because it is not reasonable and necessary? AND
3. Is the patient stable and the transport non-emergent?

Example: A beneficiary requires ambulance transportation from her skilled nursing facility (SNF) to dialysis but insists on being transported to a new dialysis center 10 miles beyond the nearest dialysis facility. Medicare covers this type of transport; however, since this particular transport is not to the nearest facility, it is not considered a covered Medicare benefit. Therefore, NO ABN is required. As a courtesy to the beneficiary, an ABN could be issued as a voluntary notice alerting her to the financial responsibility.

Example: A beneficiary requires non-emergent ground transport from a local hospital to the nearest tertiary hospital facility; however, his family wants him taken by air ambulance. The ambulance service is a covered benefit, but the level of service (air transport) is not reasonable and necessary for this patient's condition. Therefore, an ABN MUST be issued prior to providing the service in order for the provider to shift liability to the beneficiary.

ABN issuance is mandatory only when a beneficiary's covered ambulance transport is modified to a level that is not medically reasonable and necessary and will incur additional costs. If an ambulance transport is statutorily excluded from coverage because it fails to meet Medicare's definition of the ambulance benefit, a voluntary ABN may be issued to notify the beneficiary of his/her financial liability as a courtesy.

Special issues associated with the ABN for hospice providers

General use – hospice

Mandatory use of the ABN is very limited for hospices. Hospice providers are responsible for providing the ABN when required as listed below for items and services billable to hospice. Hospices are not responsible for issuing an ABN when a hospice patient seeks care outside of the hospice's jurisdiction. The three situations that would require issuance of the ABN by a hospice are:

- Ineligibility because the beneficiary is not determined to be "terminally ill" as defined in Section 1879(g)(2) of the Act;
- Specific items or services that are billed separately from the hospice payment, such as physician services, are not reasonable and necessary as defined in either Section 1862(a)(1)(A) or 1862(a)(1)(C); or
- The level of hospice care is determined to be not reasonable or medically necessary as defined in Section 1862(a)(1)(A) or 1862(a)(1)(C), specifically for the management of the terminal illness and/or related conditions.

End of all Medicare covered hospice care

When it is determined that a beneficiary who has been receiving hospice care is no longer terminally ill and the patient is discharged from hospice, the hospice must issue the notice of Medicare noncoverage (NOMNC), CMS 10123 (see the "FFS ED Notices" link on the CMS website at *http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html* for details). If upon discharge the patient wants to continue receiving hospice care that will not be covered by Medicare, the hospice would issue an ABN to the beneficiary in order to transfer liability for the noncovered care to the beneficiary. If no further hospice services are provided after discharge, ABN issuance would not be required.

Hospice care delivered by non-hospice providers

It is the hospice's responsibility to issue an ABN when a beneficiary who has elected the hospice benefit chooses to receive inpatient hospice care in a hospital that is not under contract with the hospice.

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ABN *(continued)*

The hospice may delegate delivery of the ABN to the hospital in these cases.

The ABN must not be issued when the face to face requirement for hospice recertification is not met within the required timeframe. Failure to meet the face to face requirement for recertification should not be misrepresented as a determination that the beneficiary is no longer terminally ill. However, in this situation, the hospice would be required to issue a notice of Medicare noncoverage (NOMNC), CMS 10123, before the end of all covered care. (See the "FFS ED Notices" link on the CMS website at *http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html* for details.)

Since room and board are not part of the hospice benefit, an ABN would not be required when the patient elects hospice and continues to pay out of pocket for long term care room and board.

Special issues associated with the ABN for CORFs

Since comprehensive outpatient rehabilitation facility (CORF) services are billed under Part B, CORF providers must issue the ABN according to the instructions given in this section. The ABN is issued by CORFs before providing a service that is usually covered by Medicare but may not be paid for in a specific case because it is not medically reasonable and necessary.

When all Medicare covered CORF services end, CORF's are required to issue a notice regarding the beneficiary's right to an expedited determination called a notice of Medicare noncoverage (NOMNC), CMS 10123. Please see the "FFS ED Notices" link on the CMS website at *http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html* for these notification requirements. Upon termination of all CORF care, the ABN would be issued only if the beneficiary wants to continue receiving some or all services that will not be covered by Medicare because they are no longer considered medically reasonable and necessary. An ABN would not be issued if no further CORF services are provided.

Additional information

The official instruction, CR 7821, issued to your Medicare carrier, FI, RHHI, DME MAC, or A/B MAC regarding this change may be viewed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2480CP.pdf*.

If you have any questions, please contact your carrier, FI, RHHI, DME MAC, or A/B MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip* The ABN and instructions can be downloaded from *http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html*.

MLN Matters® Number: MM7821
Related Change Request (CR) #: CR 7821
Related CR Release Date: June 1, 2012
Effective Date: September 4, 2012
Related CR Transmittal #: R2480CP
Implementation Date: September 4, 2012

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ABN *(continued)*

ABN - Quick Glance Guide[1]

Notice Name:	Advance Beneficiary Notice of Noncoverage (ABN)
Notice Number:	Form CMS-R-131
Issued by:	Providers and suppliers of Medicare Part B items and services; Hospice and Religious Non-medical HealthCare Institute (RNHCI) providing Medicare Part A items and services
Recipient:	Original Medicare (fee for service) beneficiary
Additional Information:	The ABN, Form CMS-R-131 replaces the following notices: • ABN-G • ABN-L • Notice of Exclusion of Medicare Benefits (NEMB)

Type of notice:	Must be issued:	Timing of notice:	Optional/Voluntary
Financial liability notice	• Prior to providing an item or service that is usually paid for by Medicare under Part B (or under Part A for hospice and RNHCI providers only) but may not be paid for in this particular case because it is not considered medically reasonable and necessary • Prior to providing custodial care • For hospice providers, prior to caring for a patient who is not terminally ill • For DME suppliers, additional situations requiring issuance are outlined in Chapter 50.3.1 of the "Medicare Claims Processing Manual."	Prior to delivery of the item or service in question. Provide enough time for the beneficiary to make an informed decision on whether or not to receive the service or item in question and accept potential financial liability.	Yes. Prior to providing an item or service that is never covered by Medicare (not a Medicare benefit).

[1]*This is an abbreviated reference tool and is not meant to replace or supersede any of the directives contained in Section 50.*

Extracorporeal photopheresis (ICD-10)

Provider types affected

This *MLN Matters*® article is intended for physicians and other providers who bill Medicare carriers, fiscal intermediaries (FIs), or Medicare administrative contractors (A/B MACs) for providing extracorporeal photopheresis procedures for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation.

Provider action needed

Effective for claims with dates of service on and after April 30, 2012, Medicare will cover extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation, but only when provided under an approved clinical research study that meets specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. You should make sure that your billing staffs are aware of the expanded coverage provided in this national coverage determination (NCD).

Background

Extracorporeal photopheresis is a second-line treatment for a variety of oncological and autoimmune disorders that is performed in the hospital inpatient, hospital outpatient, and critical access hospital (CAH) settings. In the procedure, some of a patient's removed white blood cells are exposed first to the drug 8-methoxypsoralen (8-MOP) and then to ultraviolet A (UVA) light. After UVA light exposure, the treated white blood cells are re-infused into the patient, stimulating their immune system in a series of cascading reactions. This activation of the immune system then impacts the illness being treated.

Currently, Medicare covers extracorporeal photopheresis for the following indications:

- Palliative treatment of skin manifestations of CTCL that has not responded to other therapy;
- Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment; and
- Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment.

On August 4, 2011, the Centers for Medicare & Medicaid Services (CMS) accepted a formal request for a reconsideration to add coverage for extracorporeal photopheresis treatment for patients who have received lung allografts and then developed progressive BOS refractory to immunosuppressive drug treatment.

As a result of the reconsideration, effective for claims with dates of service on and after April 30, 2012, Medicare will begin to cover extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation; but only when provided under a clinical research study that meets specific requirements to assess its effect in the treatment of BOS following lung allograft transplantation.

NCD clinical research study requirements

This is a national coverage determination (NCD). In keeping with this NCD, any clinical research study that includes Medicare coverage of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation must be approved by meeting the requirements listed below. Additionally, consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet these standards and address the research questions.

An approved clinical research study:

1. Must address one or more aspects of the following question:

   Prospectively, do Medicare beneficiaries who have received lung allografts, developed BOS refractory to standard immunosuppressive therapy, and received extracorporeal photopheresis, experience improved patient-centered health outcomes as indicated by:

   a. Improved forced expiratory volume in one second (FEV1);

   b. Improved survival after transplant; and/or

   c. Improved quality of life?

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Photopheresis *(continued)*

2. Must adhere to the following standards of scientific integrity and relevance to the Medicare population:
   a. Its principal purpose is to test whether extracorporeal photopheresis potentially improves the participants' health outcomes;
   b. It is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
   c. It does not unjustifiably duplicate existing studies;
   d. Its design is appropriate to answer the research question being asked in the study;
   e. It is sponsored by an organization or individual capable of successfully executing the proposed study;
   f. It is in compliance with all applicable federal regulations concerning the protection of human subjects found at 45 *Code of Federal Regulations* CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must also be in compliance with 21 CFR parts 50 and 56;
   g. All of its aspects are conducted according to appropriate standards of scientific integrity (see *http://www.icmje.org*);
   h. It has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED) coverage;
   i. It is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR Section 312.81(a) and the patient has no other viable treatment options;
   j. It is registered on the ClinicalTrials.gov website (*http://clinicaltrials.gov*) by the principal sponsor/investigator prior to the enrollment of the first study subject;
   k. Its protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (*http://www.icmje.org*).
   l. It explicitly discusses subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary
   m. Its study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Billing requirements

Effective for claims with dates of service on and after April 30, 2012, your carrier, FI, or A/B MAC will accept and pay for hospital outpatient and physician claims containing Healthcare Common Procedure Coding System (HCPCS) procedure code *36522* along with one of the International Classification of Diseases (ICD-9-CM or ICD-10) diagnosis codes displayed in the following table.

ICD 9 CM	ICD 9 CM description	ICD-10	ICD-10 description
491.20	Obstructive chronic bronchitis without exacerbation	J44.9	Chronic obstructive pulmonary disease, unspecified
491.21	Obstructive chronic bronchitis with (acute) exacerbation	J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation

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Photopheresis *(continued)*

ICD 9 CM	ICD 9 CM description	ICD-10	ICD-10 description
491.9	Unspecified chronic bronchitis	J42	Unspecified chronic bronchitis
496	Chronic airway obstruction, not elsewhere classified	J44.9	Chronic obstructive pulmonary disease, unspecified
996.84	Complications of transplanted lung	T86.810	Lung transplant rejection
996.84	Complications of transplanted lung	T86.811	Lung transplant failure
996.84	Complications of transplanted lung	T86.812	Lung transplant infection (not recommended for ECP coverage)
996.84	Complications of transplanted lung	T86.818	Other complications of lung transplant
996.84	Complications of transplanted lung	T86.819	Unspecified complication of lung transplant
V70.7	Examination of participant in clinical trial	Z00.6	Encounter for examination for normal comparison and control in clinical research program (needed for CED)

Note: Any clinical study in which there is coverage of extracorporeal photopheresis for this indication under this NCD must be approved by April 30, 2014 (two years from the effective date of this NCD). If there are no approved clinical studies by this date, this NCD will expire and coverage of extracorporeal photopheresis for BOS will revert to the coverage policy in effect prior to the issuance of its final decision memorandum (DM) on April 30, 2012.

Please note that your claims will only be paid when they also contain all of the following:

- Diagnosis code V70.7 (as secondary diagnosis);
- Condition code 30 (institutional claims only);
- Clinical trial modifier Q0 (investigational clinical service provided in a clinical research study that is in an approved research study); and
- Value code D4 with an 8-digit clinical trial number (optional)(FIs only).

Additionally, should your Medicare contractor return your claims as unprocessable because they are missing: 1) Diagnosis code V70.7 (as secondary diagnosis), 2) Condition code 30 (institutional claims only), 3) Clinical trial modifier Q0 (institutional claims only), and 4) Value code D4 with an 8-digit clinical trial number (optional) (FIs only); they will use the following messages:

- CARC 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC MA 130 – Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.
- RARC M16 – Alert: Please see our website, mailings, or bulletins for more details concerning this policy/ procedure/decision.

Please keep in mind that your contractor will not retroactively adjust claims from April 30, 2012, processed prior to implementation of CR 7806. However, they may adjust claims that you bring to their attention.

Additional information

The official instruction, CR 7806, was issued in two transmittals. The first updates to the *Medicare National Coverage Determinations Manual* are available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R143NCD.pdf*. The second updates the *Medicare Claims Processing Manual* and it is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2473CP.pdf*.

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Photopheresis *(continued)*

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

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Screening for sexually transmitted infections (STIs) and high intensity behavioral counseling to prevent STIs

Note: This article was revised on May 29, 2012, to reflect a revised change request (CR) 7610 issued on May 23. In this article, the CR release date, transmittal number, and the Web address for accessing CR 7610 were revised. All other information is the same. This information was previously published in the February 2012 *Medicare A Connection*, Pages 25-28.

Provider types affected

This *MLN Matters*® article is intended for all physicians, providers, and suppliers submitting claims to Medicare contractors (fiscal intermediaries (FIs), carriers, and A/B Medicare administrative contractors (MACs)) for Medicare beneficiaries.

Provider action needed

Effective for dates of service on or after November 8, 2011, the Centers for Medicare & Medicaid Services (CMS) will cover screening for sexually transmitted infections (STIs) – specifically chlamydia, gonorrhea, syphilis, and hepatitis B - with the appropriate Food and Drug Administration (FDA) approved/cleared laboratory tests when ordered by the primary care provider. The tests must be used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations and performed by an eligible Medicare provider for these services.

In addition, Medicare will cover high intensity behavioral counseling (HIBC) to prevent STIs. Ensure that your billing staffs are aware of these changes.

Background

Pursuant to Section 1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process. The preventive services must be:

1) Reasonable and necessary for the prevention or early detection of illness or disability;
2) Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and
3) Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS reviewed the USPSTF recommendations and supporting evidence for screening for STIs and HIBC to prevent STIs and determined that the criteria listed above were met, enabling CMS to cover these preventive services. Therefore, effective November 8, 2011, CMS will cover screening for the indicated STIs and HIBC to prevent STIs. The covered screening lab tests must be ordered by the primary care provider. The HIBC must be provided by primary care providers in primary care settings such as by the beneficiary's family practice physician, internal medicine physician, or nurse practitioner (NP) in the doctor's office.

A new Healthcare Common Procedure Coding System (HCPCS) code, G0445 (high-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes), has been created for use when reporting HIBC to prevent STIs, effective November 8, 2011. This code is included in the January 2012 Medicare physician fee schedule database (MPFSDB) and integrated outpatient code editor (IOCE) updates.

This code may be paid on the same date of service as an annual wellness visit (AWV), evaluation and management (E&M) code, or during the global billing period for obstetrical care, but only one G0445 may be

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STIs *(continued)*

paid on any one date of service. If billed on the same date of service with an E&M code, the E&M code should have a distinct diagnosis code other than the diagnosis code used to indicate high/increased risk for STIs for the G0445 service. **An E&M code should not be billed when the sole reason for the visit is HIBC to prevent STIs.**

The use of the correct diagnosis code(s) on the claims is imperative to identify these services as preventive services and to show that the services were provided within the guidelines for coverage as preventive services. The patient's medical record must clearly support the diagnosis of high/increased risk for STIs and clearly reflect the components of the HIBC service provided – education, skills training, and guidance on how to change sexual behavior – as required for coverage.

The appropriate screening diagnosis code (ICD-9-CM V74.5 (screening bacterial – sexually transmitted) or V73.89 (screening, disease or disorder, viral, specified type NEC)), when used with the screening lab tests identified by CR 7610, will indicate that the test is a screening test covered by Medicare.

Diagnosis code V69.8 (other problems related to life style) is used to indicate that the beneficiary is at high/increased risk for STIs. Providers should also use V69.8 for sexually active adolescents when billing G0445 counseling services.

Diagnosis codes V22.0 (supervision of normal first pregnancy), V22.1 (supervision of other normal pregnancy), or V23.9 (supervision of unspecified high-risk pregnancy) are also to be used when appropriate.

For services provided on an annual basis, this is defined as a 12-month period.

Further details

CMS will cover screening for chlamydia (*86631, 86632, 87110, 87270, 87320, 87490, 87491, 87810, 87800* (used for combined chlamydia and gonorrhea testing), gonorrhea (*87590, 87591, 87850, 87800* (used for combined chlamydia and gonorrhea testing), syphilis (*86592, 86593, 86780*), and hepatitis B (hepatitis B surface antigen) *87340, 87341*)) with the appropriate FDA approved/cleared laboratory tests, used consistent with FDA-approved labeling and in compliance with the CLIA regulations, when ordered by the primary care provider, and performed by an eligible Medicare provider for these services. As per the requirements, the presence of V74.5 or V73.89 and V69.8, denoting STI screening and high-risk behavior, respectively, and/or V22.0, V22.1, or V23.9, denoting pregnancy as appropriate, must also be present on the claim for STI services along with one of the procedure codes above.

Screening for chlamydia and gonorrhea:

- Pregnant women who are 24 years old or younger when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test;
- Pregnant women who are at increased risk for STIs when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test; and
- Women at increased risk for STIs annually.

Screening for syphilis:

- Pregnant women when the diagnosis of pregnancy is known and then repeat screening during the third trimester and at delivery if high-risk sexual behavior has occurred since the previous screening test; and
- Men and women at increased risk for STIs annually.

Screening for hepatitis B:

- Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known and then re-screening at the time of delivery for those with new or continuing risk factors.
- Coverage for HIBC
- CMS will also cover up to two, individual, 20- to 30-minute, face-to-face counseling sessions annually for Medicare beneficiaries for HIBC to prevent STIs (G0445) for all sexually active adolescents and for adults at increased risk for STIs (V69.8), if referred for this service by a primary care provider and provided by a Medicare eligible primary care provider in a primary care setting. HIBC is defined as a program intended to promote sexual risk reduction or risk avoidance which includes each of these broad topics, allowing flexibility for appropriate patient-focused elements:
- Education;

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STIs *(continued)*

- Skills training; and,
- Guidance on how to change sexual behavior.

The high/increased risk individual sexual behaviors, based on the USPSTF guidelines, include any of the following:

- Multiple sex partners;
- Using barrier protection inconsistently;
- Having sex under the influence of alcohol or drugs;
- Having sex in exchange for money or drugs;
- Age (24 years of age or younger and sexually active for women for chlamydia and gonorrhea);
- Having an STI within the past year;
- IV drug use (hepatitis B only); and,
- In addition, for men – men having sex with men (MSM) and engaged in high-risk sexual behavior, but no regard to age.

Community social factors such as high prevalence of STIs in the community populations should also be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis, and in recommending HIBC.

High/increased risk sexual behavior for STIs is determined by the primary care provider by assessing the patient's sexual history which is part of any complete medical history, typically part of an AWV or prenatal visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

For the purposes of this NCD, a primary care setting is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers (ASCs), independent diagnostic testing facilities, skilled nursing facilities (SNFs), inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

For the purposes of this NCD, a "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Social Security Act (Sections 1833(u)(6), 1833(x)(2)(A)(i)(I) and 1833(x)(2)(A)(i)(II)), as follows:

- 1833(u) (6) Physician defined. – For purposes of this paragraph, the term "physician" means a physician described in *Section 1861(r)(1)* and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.
- 1833(x)(2)(A)(i) (I) is a physician (as described in Section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or
- (II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in Section 1861(aa)(5)).

Billing reminders

- Institutional providers should note that coverage requires services be performed in a primary care setting. Consequently, if STI services are billed on types of bill (TOB) other than 13x, 14x and 85x (when the revenue code on the 85x is not 096x, 097x, or 098x), OR, if G0445 is submitted on a TOB other than 13x, 71x, 77x, or 85x, payment for the services will be denied using the following:
  - Claim adjustment reason code (CARC) 170 – "Payment is denied when performed/billed by this type of provider. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
  - Remittance advice remark code (RARC) N428 – "This service was denied because Medicare only covers this service in certain settings."
- When applying frequency limitations to HIBC services, contractors will allow both a claim for the professional service and a claim for the facility fee. Institutional claims may be identified as facility fee claims for screening services if they contain G0445, and TOB 13x or TOB 85x (when the revenue code is not 096x, 097x, or 098x). All other claims should be identified as professional service claims for HIBC services (professional claims, and institutional claims with TOB 71x or 77x, or 85x when the revenue code is 096x, 097x, or 098x.
- Contractors will allow institutional claims, TOBs 71x and 77x, to submit additional revenue lines on claims with G0445. Also, HCPCS G0445 will not pay separately with another encounter/visit on the same day for TOBs 71x and 77x with the exception of: initial preventive physical claims, claims containing modifier 59, and 77x claims containing diabetes self-management training and medical nutrition therapy services. If HCPCS G0445 is present on revenue lines along with an encounter/visit with the same line-item date of service, contractors will assign group code

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STIs *(continued)*

CO and reason code 97 – "The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Services Payment Information REF), if present."

- G0445 on institutional claims in hospital outpatient departments (TOB 13x) are paid based on OPPS, in critical access hospitals (TOB 85x, not equal to 096x, 097x, or 098x) based on reasonable cost. HCPCS G0445 with revenue codes 096x, 097x, or 098x, when billed on TOB 85x method II is paid based on 115 percent of the lesser of the MPFS amount or submitted charge.
- Medicare will enforce the frequency requirement for STI services, as mentioned above. Medicare will deny line items that exceed the coverage frequency requirements using the following:
  - CARC 119 – "Benefit maximum for this period or occurrence has been reached."
  - RARC N362 – "The number of days or units of service exceeds our acceptable maximum."
- Medicare will deny line items on claims submitted for screening for STIs if the claim lacks the appropriate ICD-9-CM code as mentioned earlier. Such services will be denied payment using:
  - CARC 50 – "These are non-covered services because this is not deemed a "medical necessity" by the payer. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
  - RARC N386 – "This decision was based on a national coverage determination (NCD), An NCD provides a coverage determination as to whether a specific item or service is covered. A copy of this policy is available at *http://www.cms.gov/mcd/search.asp*. If you do not have web access, you may contact the contractor to request a copy of the NCD."
- The presence of ICD-9 code V74.5 or V73.89 identifies STI laboratory tests as screening lab tests payable under CR 7610 rather than as diagnostic tests.
- Screening for STIs must be ordered by a primary care provider, and HIBC services, G0445, must be performed by a primary care provider in a primary care setting, with one of the following specialty codes:
  - 01 – General practice
  - 08 – Family practice
  - 11 – Internal medicine
  - 16 – Obstetrics/gynecology
  - 37 – Pediatric medicine
  - 38 – Geriatric medicine
  - 42 – Certified nurse midwife
  - 50 – Nurse practitioner
  - 89 – Certified clinical nurse specialist
  - 97 – Physician assistant
- STI screenings ordered by other than the above types of providers will be denied payment when submitted on professional claims using:
  - CARC 184 – "The prescribing/ordering provider is not eligible to prescribe/order the service billed. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
- Medicare will deny line items for G0445 if performed by other than the above types of providers when submitted on professional claims using:
  - CARC 185 – "The rendering provider is not eligible to perform the service billed. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
  - RARC N95 – "This provider type/provider specialty may not bill this service."
- Claims for G0445 must be for services performed in the following places of service (POS):
  - 11 – Physician office;
  - 22 – Outpatient hospital;
  - 49 – Independent clinic; or
  - 71 – State or local public health clinic.
- Medicare will deny line items for G0445 if the POS code is other than 11, 22, 49, or 71, using the following:
  - CARC 58 – "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
  - RARC N428 – "Not covered when performed in this place of service."

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STIs *(continued)*

- Upon full implementation in Medicare systems on July 2, 2012, providers may submit eligibility inquiries in order to identify the next eligible date that beneficiaries may receive these services.
- Until systems are implemented, contractors will hold institutional claims received before July 2, 2012, with TOBs 13x, 71x, 77x, and 85x reporting HCPCS G0445, or TOBs 13x, 14x, and 85x, when the revenue code is not 096x, 097x, or 098x, for STI services.
- Effective for dates of service on or after November 8, 2011, contractors will not apply deductible or coinsurance to claim lines containing HCPCS G0445, HIBC services.
- Contractors will load HCPCS G0445 to their HCPCS file with an effective date of November 8, 2011.

Additional information

The official instruction, CR 7610, was issued to your FI, carrier and A/B MAC regarding this change via two transmittals. The first updates the *Medicare Claims Processing Manual* and it is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2476CP.pdf*. The second transmittal conveys the NCD and it is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R141NCD.pdf*.

If you have any questions, please contact your FI, carrier or A/B MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

MLN Matters® Number: MM7610 Revised
Related Change Request (CR) #: 7610
Related CR Release Date: May 23, 2012
Effective Date: November 8, 2011
Related CR Transmittal #: R2476CP and R141NCD
Implementation Date: July 2, 2012 for full implementation

Additional instructions related to CR 7633 – screening and behavioral counseling interventions in primary care to reduce alcohol misuse

Note: This article was revised on June 22, 2012, to reflect a revised change request (CR) 7791 issued on June 21. The CR transmittal number, release date, and the Web address for accessing the CR have been changed. Also, a second sentence was added to the very last paragraph of the "Background" section. All other information is the same. This information was previously published in the May 2012 *Medicare A Connection*, Pages 5-6.

Provider types affected

This *MLN Matters*® article is intended for physicians, providers and suppliers submitting claims to fiscal intermediaries (FI), carriers and A/B Medicare administrative contractors (A/B MAC) for screening and behavioral counseling services provided to Medicare beneficiaries.

What you need to know

If a claim is submitted by a provider for G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes) when there are no claims for G0442 (Annual alcohol misuse screening, 15 minutes) in Medicare's claims history within a prior 12-month period, CR 7791 requires contractors to deny these claims. Be sure to inform your staff of these changes.

Background

Pursuant to Section 1861(ddd) of the Social Security Act, the Centers for Medicare & Medicaid Services (CMS) may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process if all of the following criteria are met. They must be: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and, (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program. CMS reviewed the USPSTF's "B" recommendation and supporting evidence for "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse" preventive services and determined that all three criteria were met.

According to the USPSTF (2004), alcohol misuse includes risky/hazardous and harmful drinking which place individuals at risk for future problems; and in the general adult population, risky or hazardous drinking is defined as >7 drinks per week or >3 drinks per occasion for women, and >14 drinks per week

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Alcohol *(continued)*

or >4 drinks per occasion for men. Harmful drinking describes those persons currently experiencing physical, social or psychological harm from alcohol use, but who do not meet criteria for dependence.

In the Medicare population, Saitz (2005) defined risky use as >7 standard drinks per week or >3 drinks per occasion for women and persons >65 years of age, and >14 standard drinks per week or >4 drinks per occasion for men ≤65 years of age. Importantly, Saitz included the caveat that such thresholds do not apply to pregnant women for whom the healthiest choice is generally abstinence. The 2005 "Clinician's Guide" from the National Institutes of Health National Institute on Alcohol Abuse and Alcoholism also stated that clinicians recommend lower limits or abstinence for patients taking medication that interacts with alcohol, or who engage in activities that require attention, skill, or coordination (e.g., driving), or who have a medical condition exacerbated by alcohol (e.g., gastritis).

CR 7791 adds further instructions for contractors if a claim is submitted by a provider for G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes) when there are no claims for G0442 (Annual alcohol misuse screening, 15 minutes) in claims history within a prior 12-month period. It requires contractors to deny such claims with the following specific messages:

- Claim adjustment reason code (CARC) B15 – This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- Remittance advice remark code (RARC) M16 – Alert: Please see our website, mailings, or bulletins for more details concerning this policy/procedure/decision.
- Group code PR (patient responsibility) assigning financial liability to the beneficiary, if a claim is received with a modifier indicating a signed Advanced Beneficiary Notice (ABN) is on file.
- Group code CO (contractual obligation) assigning financial liability to the provider, if a claim is received without a modifier indicating no signed ABN is on file.

Also, remember that Medicare will only pay for up to four G0443 services within a 12-month period. Claims for G0443 that exceed that four session limit in a 12-month period will be rejected. In addition, Medicare will continue to reject incoming claims when G0442 (PROF) and G0443 (PROF) are billed on the same day on types of bills 71x, 77x, and 85x with revenue codes 096x, 097x, and 098x.

Additional information

The official instruction, CR 7791, issued to your FI, carrier, and A/B MAC regarding this change, may be viewed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2488CP.pdf*.

The *MLN Matters*® Article MM7663, entitled, "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse," may be viewed at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7633.pdf*.

If you have any questions, please contact your FI, carrier, or A/B MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

MLN Matters® Number: MM7791 Revised
Related Change Request (CR) #: 7791
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Effective Date: October 1, 2012
Related CR Transmittal #: R2488CP
Implementation Date: October 1, 2012

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.

This section of *Medicare A Connection* features summaries of new and revised local coverage determinations (LCDs) developed as a result of either local medical review or comprehensive data analysis initiatives. These initiatives are designed to ensure the appropriateness of medical care and to make sure that the Medicare administrative contractor (MAC) jurisdiction 9 (J9) Part A LCDs and review guidelines are consistent with accepted standards of medical practice.

Refer to our LCDs/Medical Coverage Web page at *http://medicare.fcso.com/Landing/139800.asp* for full-text LCDs, including final LCDs, draft LCDs available for comment, LCD statuses, and LCD comment/response summaries.

Effective and notice dates

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

Contents

Advance beneficiary notice

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

Revisions to LCDs

AJ0881: Erythropoiesis stimulating agents – revision to the LCD

LCD ID number: L28836 (Florida)
LCD ID number: L28869 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for erythropoiesis stimulating agents was most recently revised August 23, 2011. Since that time, based on change requests 7831, 7844, and 7847, the LCD was revised to add HCPCS code Q2047 [Injection, peginesatide, 0.1 mg (for ESRD on dialysis)] to the "*CPT*/HCPCS Codes" section of the LCD. The "Indications and Limitations of Coverage and/or Medical Necessity", "ICD-9 codes that Support Medical Necessity" and "Utilization Guidelines" sections of the LCD were also updated per the Food and Drug Administration (FDA) label. In addition, the "Sources of Information and Basis for Decision" section of the LCD and the LCD "Coding Guidelines" attachment were updated.

Effective date

This LCD revision is effective for services rendered **on or after July 1, 2012.** First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

AJ9001: Doxorubicin, liposomal (Doxil®) – revision to the LCD

LCD ID number: L28827 (Florida)
LCD ID number: L28860 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for doxorubicin, liposomal (Doxil®) was most recently revised April 25, 2012. Since that time, the "Indications and Limitations of Coverage and/or Medical Necessity" and "*CPT*/HCPCS Codes" sections of the LCD were revised based on change requests 7831, 7844, and 7847. The LCD was revised to remove HCPCS code J9001 and replace it with new HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 MG). In addition, HCPCS code C9399 was removed and replaced with new HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox 10mg). Also, the "Contractor's Determination Number" AJ9001 was changed to AQ2048 and the "LCD Title" was changed to Doxorubicin, Liposomal (Doxil/Lipodox).

Effective date

This LCD revision is effective for services rendered **on or after July 1, 2012.** First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

AJ9310: Rituximab (Rituxan®) – revision to the LCD

LCD ID number: L28980 (Florida)
LCD ID number: L29013 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for rituximab (Rituxan®) was most recently revised April 19, 2011. Since that time, revisions were made under the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LCD. Under this section, the following indication was added to the off-labeled indications: "Second-line or salvage therapy with or without radiation therapy (RT) prior to autologous stem cell rescue for progressive disease or for relapsed disease in patients initially treated with chemotherapy with or without RT in combination with bendamustine". Also, a new "Limitations" subheading was added referencing individual consideration for Multiple Sclerosis (ICD-9-CM diagnosis code 340). Under this new "Limitations" section of the LCD, language was given indicating medical records may be requested for prepayment review when diagnosis code 340 is billed for rituximab (Rituxan®). In addition, the "ICD-9 Codes that Support Medical Necessity" section of the LCD was updated to add diagnosis code range 201.40-201.48 (Hodgkin disease, lymphocytic-histiocytic predominance), and the "Sources of Information and Basis for Decision" section of the LCD was also updated.

Effective date

This LCD revision is effective for services rendered **on or after June 8, 2012.** First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

ANCSVCS: Noncovered services – revision to the LCD

LCD ID number: L28991 (Florida)
LCD ID number: L29023 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for noncovered services was most recently revised June 12, 2012. In a previous publication (March 2012 Connection), First Coast Service Options Inc. published the following verbiage based on the Centers for Medicare & Medicaid Services (CMS) transmittal 2402, change request (CR) 7610, dated January 26, 2012.

"The "*CPT*/HCPCS Codes, Local Noncoverage Decisions – Laboratory Procedures" section of LCD was revised to add the following language (Not medically reasonable and necessary except when billed with diagnosis V74.5 or V73.89) for *CPT*® codes *87270* and *87320.*"

Since that time it has been determined that diagnosis V73.89 is not an applicable diagnosis for *CPT*® codes *87270* and *87320.*

Therefore, diagnosis V73.89 has been removed from the "*CPT*/HCPCS Codes, Local Noncoverage Decisions – Laboratory Procedures" section of LCD for *CPT*® codes *87270* and *87320*.

Effective date

This LCD revision is effective for claims processed **on or after July 2, 2012, for services rendered on or after November 8, 2011.** First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

ANCSVCS: Noncovered services – revision to delete HCPCS code C9732 and replace with *CPT*® code *0308T*

LCD ID number: L28991 (Florida)
LCD ID number: L29023 (Puerto Rico/U.S. Virgin Islands)
The local coverage determination (LCD) for noncovered services was most recently revised on June 12, 2012. Since that time, the LCD was revised to delete HCPCS code C9732 and replace it with *CPT*® code *0308T* under the "*CPT*/HCPCS Codes, Local Noncoverage Decisions-Procedures" section of the LCD based on the Centers for Medicare & Medicaid Services (CMS) transmittal 2481, change request (CR) 7844, dated June 1, 2012, (July Update to the CY 2012 Medicare Physician Fee Schedule Database [MPFSDB]) and CMS transmittal 157, CR 7847, dated June 8, 2012, (July 2012 Update of the Hospital Outpatient Prospective Payment System [OPPS]).

Effective date

This LCD revision is effective for claims processed **on or after July 2, 2012,** for services rendered **on or after July 1, 2012.** First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

ASKINSUB: Skin substitutes – revision to the LCD

LCD ID number: L28985 (Florida)
LCD ID number: L29327 (Puerto Rico/U.S. Virgin Islands
The local coverage determination (LCD) for skin substitutes was most recently revised January 1, 2012. Since that time, a revision was made to the LCD based on change request 7847, transmittal 2483, (July 2012 Update of the Hospital Outpatient Prospective Payment System [OPPS]), dated June 8, 2012, issued by the Centers for Medicare & Medicaid Services (CMS).

After further evaluation of HCPCS codes C9368 (Grafix core, per square centimeter) and C9369 (Grafix prime, per square centimeter) a decision was made to add HCPCS codes C9368 and C9369 to the "*CPT*/HCPCS Codes" section of the LCD under subsection "The following HCPCS codes are not separately payable and are considered not medically reasonable and necessary products."

Effective date

This LCD revision is effective for services rendered **on or after July 1, 2012**. First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

AVISCO: Viscosupplementation therapy for knee – revision to the LCD

LCD ID number: L29005 (Florida)
LCD ID number: L29037 (Puerto Rico/U.S. Virgin Islands)
The local coverage determination (LCD) for viscosupplementation therapy for knee was most recently revised January 1, 2010. Since that time, the LCD was revised to add HCPCS code J7326 (Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose) to the "*CPT*/HCPCS Codes" and the "Utilization Guidelines" sections of the LCD. In addition, the "Sources of Information and Basis for Decision" section of the LCD was updated.

Effective date

This LCD revision is effective for services rendered **on or after August 13, 2012.** First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/*. Coding guidelines for an LCD (when present) may be found by selecting "LCD Attachments" in the "Jump to Section…" drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs for jurisdiction 9 (J9), please *click here*.

Additional Information

Self-administered drug (SAD) list – Part A: C9399/J3490/J3590

The Centers for Medicare & Medicaid Services (CMS) provide instructions to contractors regarding Medicare payment for drugs and biologicals incident to a physician's service. The instructions also provides contractors with a process for determining if an injectable drug is usually self-administered and therefore, not covered by Medicare. Guidelines for the evaluation of drugs for the list of excluded self-administered injectable drugs incident to a physician's service are in the *Medicare Benefit Policy Manual*, Pub. 100-02, Chapter 15, Section 50.2.

Effective for services rendered **on or after August 6, 2012**, the following drug has been added to the MAC J-9 Part A SAD list.

- C9399 /J3490/ J3590 – Injection, Exenatide extended release for injectable suspension [Bydureon ™]

The evaluation of drugs for addition to the self-administered drug (SAD) list is an on-going process. Providers are responsible for monitoring the SAD list for the addition or deletion of drugs.

The First Coast Service Options Inc. (FCSO) SAD lists are available through the CMS Medicare Coverage Database at *http://www.cms.gov/medicare-coverage-database/.*

Reminders about HIPAA 5010 & D.0 implementation

Note: This article was revised on June 15, 2012, to include this statement that enforcement of the HIPAA 5010/D.0 standards began on July 1, 2012. Also, remember that when claims use nonspecific procedure codes, a corresponding description of the service is now required. All other information remains the same. This information was previously published in the March 2011 *Medicare A Bulletin*, Pages 21-24.

Provider types affected

This special edition *MLN Matters*® article is intended for all physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), Medicare administrative contractors (A/B MACs), and durable medical equipment MACs (DME MACs)) for services provided to Medicare beneficiaries.

Provider action needed

Stop – impact to you

The implementation of HIPAA 5010 and D.0 presents substantial changes in the content of the data that you submit with your claims as well as the data available to you in response to your electronic inquiries. The implementation requires changes to the software, systems, and perhaps procedures that you use for billing Medicare and other payers. It is important for new providers enrolling in Medicare to know that electronic data interchange (EDI) transactions are the normal mode of business for Medicare claims, claim status, and remittance advice.

Caution – what you need to know

Medicare requires the use of electronic claims (except for certain rare exceptions) in order for providers to receive Medicare payment. Effective January 1, 2012, you must be ready to submit your claims electronically using the Accredited Standards Committee (ASC) X12 version 5010 and National Council for Prescription Drug Programs (NCPDP) version D.0 standards. This also is a prerequisite for implementing the new ICD-10 codes. This special edition *MLN Matters*® article is being provided by the Centers for Medicare & Medicaid Services (CMS) to assist you and keep you apprised of progress on Medicare's implementation of the ASC X12 version 5010 and NCPDP version D.0 standards. Remember that the HIPAA standards, including the ASC X12 version 5010 and version D.0 standards are national standards and apply to your transactions with all payers, not just with fee-for-service (FFS) Medicare. Therefore, you must be prepared to implement these transactions with regard to your non-FFS Medicare business as well. Medicare began level II transitioning to the new formats on January 1, 2011, and will be ending the exchange of current formats on January 1, 2012. While the new claim format accommodates the ICD-10 codes, ICD-10 codes will not be accepted as part of the 5010 project. Separate *MLN Matters*® articles will address the ICD-10 implementation.

> Enforcement of the HIPAA 5010/D.0 standards began July 1, 2012.

Go – what you need to do

In preparing for the implementation of these new ASC X12 and NCPDP standards, providers should also consider the requirements for implementing the ICD-10 code set as well. You are encouraged to prepare for the implementation of these standards or speak with your billing vendor, software vendor, or clearinghouse to inquire about their readiness plans for these standards.

Background

The Health Insurance Portability and Accountability Act (HIPAA) requires the Secretary of the Department of Health and Human Services (HHS) to adopt standards that covered entities (health plans, health care clearinghouses, and certain health care providers) must use when they electronically conduct certain health care administrative transactions, such as claims, remittance, eligibility, claims status requests and responses, and others.

It is important that new providers enrolling in Medicare know that EDI transactions are the normal mode of business for Medicare claims, claim status, and remittance advice. More information about Medicare's EDI requirements can be found in the *Medicare Claims Processing Manual*, Chapter 24 – "General EDI and EDI Support Requirements, Electronic Claims and Coordination of Benefits Requirements, Mandatory Electronic Filing of Medicare Claims," at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c24.pdf*. Electronic billing and EDI transaction information can be found at *http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/index.html*. This section contains information on:

- EDI transaction and corresponding paper claims requirements;
- Links to those chapters of the *Medicare Claims Processing Manual* that contain further information on these types of transactions;

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- The Administrative Simplification Compliance Act (ASCA) requirement that claims be sent to Medicare electronically as a condition for payment;
- How you can obtain access to Medicare systems to submit or receive claim or beneficiary eligibility data electronically; and
- EDI support furnished by Medicare contractors.

Current versions of the transaction standards (ASC X12 version 4010/4010A1 for health care transactions, and the NCPDP version 5.1 for pharmacy transactions) are widely recognized as lacking certain functionality that the health care industry needs. Therefore, on January 16, 2009, HHS announced a final rule that replaced the current version 4010/4010A and NCPDP version 5.1 with version 5010 and version D.0, respectively. The final rule (CMS-0009-F) titled, "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards," can be found at *http://edocket.access.gpo.gov/2009/pdf/E9-740.pdf* on the US Government Printing Office (GSP) website.

Subsequently, CMS is performing activities to convert from processing the ASC X12 version 4010A1 to HIPAA ASC X12 version 5010, and the NCPDP version 5.1 to NCPDP version D.0.

HHS is permitting the dual use of existing standards (4010A1 and 5.1) and the new standards (5010 and D.0) from the March 17, 2009, effective date of the regulation until January 1, 2012, the fully compliant (level I and level II compliance) date to facilitate testing subject to trading partner agreement.

- **Level I compliance** means "that a covered entity can demonstrably create and receive compliant transactions, resulting from the compliance of all design/build activities and internal testing."
- **Level II compliance** means "that a covered entity has completed end-to-end testing with each of its trading partners, and is able to operate in production mode with the new versions of the standards."

The CMS Medicare fee-for-service implementation schedule is:

- Level I April 1, 2010, through December 31, 2010;
- Level II January 1, 2011, through December 31, 2011; and
- Fully compliant on January 1, 2012.

CMS has prepared a comparison of the current ASC X12 HIPAA EDI standards (version 4010/4010A1) with version 5010, and NCPDP EDI standards version 5.1 with version D.0. For more information see *http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/index.html*.

CMS has made the side-by-side comparison documents available to interested parties without guarantee and without cost. The documents are available for download in both Microsoft Excel and PDF formats.

The comparisons were performed for Medicare fee-for-service business use and while they may serve other uses, CMS does not offer to maintain for purposes other than Medicare fee-for-service. Maintenance will be performed without notification, as needed to support Medicare fee-for-service.

Readiness assessment 1– Have you done the following to be ready for 5010/D.0?

Are you ready for 5010/D.0? Testing with external trading partners began in January of 2011. Testing with version 5010A1 errata will begin in April 2011. Please don't wait until April to begin testing because compliance with the errata must be achieved by the original regulation compliance date of January 1, 2012.

Visit *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/readiness_1.pdf* to see a summary of information that is important for your readiness assessment.

Do not wait to begin testing with your MAC because the MACs may not be able to accommodate large volumes of trading partners seeking production status all at once.

Be sure to start testing version 5010 and D.0 as early as possible in 2011. Be prepared.

To download readiness checklists and a resource card with helpful Web links go to *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html*.

Readiness assessment 2 – What do you need to have in place to test with your MAC?

Providers/trading partners should make it a priority to test early during calendar year 2011 with their MACs for the implementation of versions 5010 and D.0 transactions so as not to impact future Medicare claim processing.

- Trading partner testing for the 5010 base version began with MACs on January 1, 2011.
- Testing with the 5010 errata version (5010A1) will be available for testing in April 2011.
- Successful testing with your MAC is required prior to being placed into production.

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Prior to testing, trading partners should ensure their billing service, clearinghouse, or software vendor:

- Has passed testing requirements for each transaction (testing with each Medicare contractor or a certification system that the Medicare contractor has accepted); and
- Is using the same program/software to generate the transaction for all of their clients.

Details about Medicare testing requirements and protocols and the 5010 national call presentation on provider outreach and education – transition year activities can be found at *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/OE_National_Presentation_12-8-10.pdf*.

Trading partners are encouraged to review the following:

- Version 5010 and D.0. transaction resources can be found at *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html?redirect=/Versions5010andD0/*;
- Educational resources (i.e., *Medicare Learning Network®* (*MLN*) articles, fact sheets, readiness checklists, brochures, quick reference charts and guides, frequently asked questions, and transcripts from previous national provider calls) can be found at *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html*; and
- The dedicated HIPAA 5010/D.0 Project Web page, which includes technical documents and communications at national conferences, can be found at *http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/index.html*.

Errata requirements and testing schedule

HIPAA version 5010 has new errata, which can be found at *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/Errata_Req_and_Testing.pdf*. According to the published regulation (*Federal Register*, Vol. 74, No. 11, 3296-3328, January 16, 2009; RIN 0938-AM50 of 45 CFR Part 162), testing with external trading partners must begin in January of 2011. **Compliance with the errata must be achieved by the original regulation compliance date of January 1, 2012.**

Medicare FFS will implement the errata versions of the affected 5010 transactions to meet HIPAA compliance requirements, and Medicare FFS contractors will be ready to test the 5010 errata versions in April 2011.

Transactions not impacted by the errata can be tested starting January 2011 without regard to the published errata schedule. Trading partners should contact their local Medicare FFS contractor for specific testing schedules. To find a Medicare FFS contractor in your state, please refer to the "Downloads" section at *http://www.cms.gov/ElectronicBillingEDITrans/*.

CMS 5010 provider outreach and education materials

CMS has developed extensive information and educational resources pertaining to the topics listed below. This information is available on the CMS website:

- Version 5010 – the new version of the X12 standards for HIPAA transactions;
- Version D.0 – the new version of the National Council for Prescription Drug Program (NCPDP) standards for pharmacy and supplier transactions;
- Version 3.0 – a new NCPDP standard for Medicaid pharmacy subrogation.

The information posted at *http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/index.html* may be applicable to the health care industry at large, or may be specifically Medicare-related information. The "Overview" Web page is designed to distinguish the Medicare-related information from the industry related.

Please note there are separate resource pages for D.0 and 3.0 for tools and information specific to these pharmacy-related standards. The highlights and overview of these pages are as follows:

- Federal Regulation & Notices (*http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html*)

  This Web page contains general information related to federal regulations and notices and contains the following link to the final rule for X12 5010, D.0 and 3.0 document. See *http://edocket.access.gpo.gov/2009/pdf/E9-740.pdf*.
- CMS Communications (*http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html*)

  This CMS Communications Web page includes versions 5010 & D.0 implementation information and the following downloads:

  - 5010 implementation calendar [PDF, 325KB]; see *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/5010ImplementationCalendar.pdf*.

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- Readiness assessment – What do you need to have in place to test with your MAC? [PDF, 241KB]; see *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/Readiness_2.pdf*.

- Educational Resources (*http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html*)

  The Educational Resources Web page includes information designed to increase national awareness and assist in the implementation of versions 5010, D.0 and 3.0. Products that target a specific population, such as Medicare FFS, are clearly identified. Otherwise, products and information may be appropriate for the healthcare industry at large. This Web page includes the following downloads:

  - Version 5010 resource card [PDF, 243KB] (see *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/5010EDI_RefCard_ICN904284.pdf*);
  - *Preparing for Electronic Data Interchange (EDI) Standards: The Transition to Versions 5010 and D.0* fact sheet [PDF, 1208KB] (see *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/w5010TransitionFctSht.pdf*);
  - *Checklist for Level I Testing Activities* [PDF, 324 KB] (see *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads//w5010PrepChklst.pdf*);
  - *Provider Action Checklist for a Smooth Transition* [PDF, 333KB] (see *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/w5010PvdrActionChklst.pdf*); and
  - Versions 5010 and D.0 *MLN Matters*® articles [PDF, 31KB] (see *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/Versions_5010_and_D0_MLN_Matters_Articles.pdf*).

- 5010 national calls

  Throughout the implementation of version 5010, CMS has been hosting a variety of national education calls that inform the provider community of the steps that they need to take in order to be ready for implementation. These calls also give participants an opportunity to ask questions of CMS subject matter experts. The 5010 Web page contains the list of past calls with links to Web pages where you can download the past call presentations, transcripts, and audio files.

Additional information

A special edition *MLN Matters*® article on the ICD-10 code set can be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0832.pdf*.

You may want to review *MLN Matters*® article SE1131 (*http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1131.pdf*) that references the approaching deadline of January 1, 2012, for 5010 implementation. SE1131 urges providers to contact their MACS for the free version 5010 software and begin testing to avoid delays in payment for fee-for-service claims.

CMS is also using the open door forums and Listservs to keep providers informed of its implementation progress and will also use these vehicles to assist providers in preparing for the new standards. Information on the open door forums can be found at *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

If you have any questions, please contact your carrier, FI, A/B MAC or DME MAC at their toll-free number, which may be found at *http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/index.html?redirect=/ElectronicBillingEDITrans/*.

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Implementation Date: N/A

Important update regarding 5010/D.0 implementation – action needed now

Note: This article was revised June 15, 2012, to include this statement that enforcement of the HIPAA 5010/D.0 standards began July 1, 2012. Also, remember that when claims use nonspecific procedure codes, a corresponding description of the service is now required. All other information remains the same. This information was previously published in the October 2011 *Medicare A Connection*, Pages 18-19.

Provider types affected

This *MLN Matters*® special edition article is intended for all physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), Medicare administrative contractors (A/B MACs), home health and hospice MACs (HH+H MACs), and durable medical equipment MACs (DME MACs)) for services provided to Medicare beneficiaries.

> Electronic transactions that do not use version 5010 are not compliant with HIPAA and will be rejected.

Provider action needed

Stop – impact to you

You and your billing and software vendors must be ready to begin processing the Health Insurance Portability and Accountability Act (HIPAA), versions 5010 & D.0 production transactions by December 31, 2011. Beginning January 1, 2012, all electronic claims, eligibility and claim status inquiries, must use versions 5010 or D.0 version 4010/5.1 claims and related transactions will no longer be accepted. The electronic remittance advice will only be available in the 5010 version.

Caution – what you need to know

You must comply with this important deadline to avoid delays in payments for Medicare fee-for-service (FFS) claims after December 31, 2011. The implementation requires changes to the software, systems, and perhaps procedures that you use for billing Medicare and other payers.

Go – what you need to do.

Contact your MACs to receive the free version 5010 software (PC-Ace Pro32) and begin testing now. Consider contracting with a version 5010 compliant clearinghouse who can translate the non-compliant transactions into compliant 5010 transactions. For Part B and DME providers, download the free Medicare Remit Easy Print (MREP) software to view and print compliant HIPAA 5010 835 remittance advices, which are available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/AccesstoDataApplication/index.html*. Part A providers may download the free PC-Print software to view and print compliance HIPAA 5010 835 remittance advices, which is available on your A/B MACs website. Contact your respective professional associations and other payers for guidance and resources in order to meet their deadlines.

Background

HIPAA requires the Secretary of the Department of Health and Human Services (HHS) to adopt standards that covered entities (health plans, health care clearinghouses, and certain health care providers) must use when they electronically conduct certain health care administrative transactions, such as claims, remittance, eligibility, claims status requests and responses, and others.

The implementation of HIPAA 5010 and the National Council for Prescription Drug Programs (NCPDP) version D.0 presents substantial changes in the content of the data that you submit with your claims, as well as the data available to you in response to your electronic inquiries. The implementation requires changes to the software, systems, and perhaps procedures that you use for billing Medicare and other payers.

Version 5010 refers to the revised set of HIPAA transaction standards adopted to replace the current version 4010/4010A standards. Every standard has been updated, from claims to eligibility to referral authorizations.

All HIPAA covered entities must transition to version 5010 by January 1, 2012. Any electronic transaction for which a standard has been adopted must be submitted using version 5010 on or after January 1, 2012. Electronic transactions that do not use version 5010 are not compliant with HIPAA and **will be rejected**.

To allow time for testing, CMS began accepting electronic transactions using either version 4010/4010A or version 5010 standards on January 1, 2011, and will continue to do so through December 31, 2011. This process allows a provider and its vendors to complete end-to-end testing with Medicare contractors and demonstrate that they are able to operate in production mode with versions 5010 and D.0.

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Note: HIPAA standards, including the ASC X12 version 5010 and version D.0 standards are national standards and apply to your transactions with all payers, not just with FFS Medicare. Therefore, you must be prepared to implement these transactions for your non-FFS Medicare business as well.

Are you at risk of missing the deadline?

If you can answer NO to any of the following questions, you are at risk of not being able to meet the January 1, 2012, deadline and not being able to submit claims:

1. Have you contacted your software vendor (if applicable) to ensure that they are on track to meet the deadline or contacted your MAC to get the free version 5010 software (PC-Ace Pro32)?
2. Alternatively, have you contacted clearinghouses or billing services to have them translate your version 4010 transactions to version 5010 (if not converting your older software)?
3. Have you identified changes to data reporting requirements?
4. Have you started to test with your trading partners, which began on January 1, 2011?
5. Have you started testing with your MAC, which is required before being able to submit bills with the version 5010?
6. Have you updated MREP software to view and print compliant HIPAA 5010 835 remittance advices?

Additional information

MLN Matters® article MM7466, "Medicare Remit Easy Print (MREP) and PC Print User Guide Update for Implementation of Version 5010A1," is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7466.pdf*.

The *Medicare Learning Network*® (*MLN*) fact sheet, "Preparing for Electronic Data Interchange (EDI) Standards: The Transition to Versions 5010 and D.0," is available at *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/w5010TransitionFctSht.pdf*.

MLN Matters® special edition article SE1106 titled "Important Reminders about HIPAA 5010 & D.0 Implementation," is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1106.pdf*. *MLN Matters*® special edition article SE1138 is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1138.pdf*.

Additional educational resources about HIPAA 5010 & D.0 are available at *http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html*.

If you have any questions, please contact your Medicare contractor (carrier, FI, A/B MAC, HH+H MAC, and DME MACs) at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

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Get motivated by Medicare …

Find out about provider incentive programs

- e-Prescribing (eRx)
- Electronic Health Records (EHR)
- Health Professional Shortage Area (HPSA)
- Primary Care Incentive Program (PCIP)

Modifying the timely filing exceptions on retroactive Medicare entitlement

Provider types affected

This *MLN Matters*® article is intended for physicians, providers, and suppliers submitting claims to fiscal intermediaries (FIs), regional home health intermediaries (RHHIs), carriers, A/B Medicare administrative contractors (MACs), and durable medical equipment MACs for services provided to Medicare beneficiaries.

What you need to know

This article is based on change request (CR) 7834, which advises you that the Centers for Medicare & Medicaid Services (CMS) is revising the *Medicare Claims Processing Manual* to specify that, if a provider, supplier, or beneficiary is unable to provide the Medicare contractor with an official Social Security Administration (SSA) letter, the contractor must check the common working file (CWF) database in order to verify a beneficiary's retroactive Medicare entitlement date. Be sure that your staffs are aware of this change.

Background

The Medicare regulations at 42 *Code of Federal Regulations* (CFR), Section 424.44, specify the time limits for filing Part A and Part B fee-for-service claims. Section 424.44 also identifies certain exceptions to the claims filing time limit. If the requirements for satisfying a timely filing exception are met, an extension to file the claims may be granted.

Section 6404 of the Affordable Care Act reduced the maximum period for the submission of all Medicare fee-for-service claims to no more than 12 months, or one calendar year, after the date a service is furnished. Section 6404 also gave the Secretary of Health and Human Services the authority to create exceptions to the 12-month timely filing limit. As a result of this legislation, revisions were made to the timely filing regulations at 42 CFR, Section 424.44, and the relevant Internet-only manual sections. (See Transmittal 2140/CR 7270, published on January 21, 2011, available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads//R2140CP.pdf*.

The *Medicare Claims Processing Manual* currently requires that, in order to be granted a timely filing extension, the provider, supplier, or beneficiary must furnish an official letter from the SSA to the beneficiary in order to meet one of the conditions that the beneficiary was retroactively entitled to Medicare on or before the date of the furnished service. The purpose of CR 7834 is to revise Sections 70.7, 70.7.2, and 70.7.3 of the manual to specify that, if an official SSA letter to the beneficiary is not submitted, Medicare contractors must check the CWF database and may interpret the CWF data in order to verify that the beneficiary was retroactively entitled to Medicare on or before the date of the furnished service. Consequently, CR 7834 requires the Medicare contractors to accept the SSA letter or, in the absence of such letter, to check the CWF database for a beneficiary's date of Medicare entitlement. Contractors may interpret the CWF data in order to verify retroactive Medicare entitlement that may permit a claim to be processed after the 12-month timely filing limit.

Additional information

The official instruction, CR 7834, issued to your FI, RHHI, carrier, A/B MAC, and DME MAC regarding this change, may be viewed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2477CP.pdf*.

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

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Implementation Date: August 27, 2012

Questionable billing by suppliers of lower limb prostheses

Note: This article was revised on June 7, 2012, to include the full Office of Inspector General (OIG) recommendations, to make several minor clarifications, and to delete a reference to recent legislation requiring face-to-face encounters for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). All other information is the same. This information was previously published in the April 2012 *Medicare A Connection*, Pages 31-38.

Provider types affected

This *MLN Matters*® special edition article is intended for providers who bill Medicare for lower limb prostheses. No new policies are contained in this article.

What you need to know

This article highlights the August 2011 report from the Department of Health and Human Services (DHHS), OIG study titled "Questionable Billing by Suppliers of Lower Limb Prostheses." It also discusses Medicare policy regarding the coverage of lower limb prostheses under its Part B DMEPOS benefit.

The study was designed to meet the following objectives:

1. Identify payments for lower limb prostheses in 2009 that did not meet certain Medicare requirements;
2. Identify Medicare payments for lower limb prostheses in 2009 for beneficiaries with no claims from their referring physicians;
3. Identify suppliers of lower limb prostheses that had questionable billing in 2009; and
4. Describe the program safeguards in place in 2009 and the first half of 2010 to prevent inappropriate payments for lower limb prostheses.

Background

Between 2005 and 2009, Medicare spending for lower prostheses increased 27 percent, from $517 million to $655 million. The number of Medicare beneficiaries receiving lower limb prostheses decreased by 2.5 percent, from almost 76,000 to about 74,000.

Medicare policy requires that a supplier have an order from the referring physician before providing prostheses to the beneficiary. Upon receipt of the referring physician's order, the supplier can move forward with the prostheses fitting for the beneficiary with the applicable prostheses. Medicare policy also requires that suppliers follow local coverage determination policies. These policies provide guidelines for determining the beneficiary's potential functional level and specify how suppliers must submit claims for certain types and combinations of prostheses.

The study completed by the OIG was based on an analysis of Medicare Part B claims for lower limb prostheses from 2009 and Part A and Part B claims from 2004 to 2009 for beneficiaries who received lower limb prostheses in 2009. OIG staff also completed interviews with the four DME Medicare administrative contractors (MACs), three zone program integrity contractors (ZPICs), and two DME program safeguard contractors (PSCs). The OIG considered a paid claim did not meet the requirements if the supplier:

- Did not indicate whether the prosthesis was for the right or left limb;
- Billed for a prosthesis for both limbs on the same date using two claims;
- Did not meet potential functional level requirements;
- Billed for a higher number of units of a prosthesis than allowed on a claim;
- Billed for combinations of prostheses that were not allowed; or
- Billed for prostheses that were not covered.

Claims data was an additional component of the OIG's analysis to determine the number of claims for beneficiaries with no claims from their referring physicians during the last five years and the Medicare payments for these claims. The following elements were analyzed to identify suppliers that had questionable billing:

- Suppliers that had at least 10 beneficiaries, and
- Suppliers that were paid at least $100,000 for lower limb prostheses in 2009.

This sample included 1,632 of the 4,575 Medicare suppliers who had a paid claim for lower limb prostheses in 2009, which accounted for 92 percent of the $655 million who billed for lower limb prostheses.

Findings:

In 2009, the study found that:

1. In 2009, Medicare inappropriately paid $43 million for lower limb prostheses that did not meet certain requirements. These payments could have been prevented by using claims processing edits.
2. Medicare paid an additional $61 million for beneficiaries with no claims from their referring physicians.

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Prostheses (*continued*)

3. In 2009, 267 suppliers of lower limb prostheses had questionable billing. Approximately 136 suppliers frequently submitted claims that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians. An additional 131 suppliers had other questionable billing. This included billing for a high percentage of beneficiaries with no history of an amputation or missing limb or a high percentage of beneficiaries with unusual combinations of prostheses.
4. Medicare contractors conducted varying degrees of program safeguard activities related to lower limb prostheses.
    - The four DME MACs had varying claims processing edits in place, but none had edits for all requirements.
    - None of the DME MACs conducted medical reviews, and not all had conducted data analyses or provided education related to lower limb prostheses.
    - All ZPICs and DME PSCs conducted data analyses and opened investigations related to lower limb prostheses.

Recommendations

The OIG made six recommendations based upon their findings. The Centers for Medicare & Medicaid Services (CMS) concurred with five of the six recommendations made by the OIG. The recommendations and CMS actions are as follows:

1. **OIG recommendation: Implement additional claims processing edits to prevent inappropriate payments.** CMS should instruct the four DME MACs to implement claims processing edits based on all of the local coverage determination requirements.

   CMS response: CMS concurred and stated it would instruct the DME MACs to implement consistent claims processing edits based on local coverage determination requirements.

2. **OIG recommendation: Strengthen monitoring of billing for lower limb prostheses.** CMS should instruct the DME MACs, ZPICs, and DME PSCs to monitor billing for lower limb prostheses using the measures discussed in this report. CMS should develop thresholds for these measures and instruct its contractors to conduct additional reviews of suppliers that exceed the thresholds.

   CMS response: CMS concurred and stated it would issue guidance to the DME MACs and instruct them to consider the measures used in the OIG report as supplemental criteria for detecting high-risk suppliers.

3. **OIG recommendation: Implement requirements for a face-to-face encounter to establish the beneficiary's need for prostheses.** We recommend that CMS implement requirements that the referring physician document that a face-to-face encounter occurred. This would help ensure that lower limb prostheses provided to beneficiaries are medically necessary.

   CMS response: CMS concurred and stated it is exploring its current authorities to implement such requirements. CMS also stated that it would issue an educational article to further explain policy requirements for lower limb prostheses and to providers and suppliers.

4. **OIG recommendation: Revise the requirements in the local coverage determination.** CMS should work with the DME MACs to clarify several aspects of the local coverage determination. First, CMS should clarify the definitions of beneficiaries' functional levels. Second, CMS should revise the local coverage determination or take other steps to require that licensed/certified medical professionals, such as physical therapists, evaluate beneficiaries to determine their potential functional levels. Finally, CMS should consider denying as medically unnecessary certain combinations of prostheses.

   CMS response: CMS concurred and stated it would review the definitions for the functional levels and develop refinements as appropriate. CMS also stated it would consider adapting an algorithm to guide determination of the functional status of the beneficiary.

5. **OIG recommendation: Enhance screening for currently enrolled suppliers of lower limb prostheses.** Federal regulations place new DMEPOS suppliers at the high-risk level and currently enrolled DMEPOS suppliers at the moderate-risk level. CMS should consider placing current suppliers of lower limb prostheses at the high-risk level, thus subjecting them to the more rigorous screening procedures.

   CMS response: CMS did not concur and stated that it has in place sufficient tools that allow for increased scrutiny of existing DMEPOS suppliers. CMS noted that if an existing supplier meets one of several triggering events, that supplier automatically is elevated to the high-risk level.

(*continued on next page*)

Prostheses (*continued*)

6. **OIG recommendation: Take appropriate action on suppliers with questionable billing.** In a separate memorandum, we will refer the suppliers that we identified to CMS for appropriate action.

   CMS response: CMS concurred and stated it would share the information with the DME MACs and the recovery audit contractors. Recovery audit contractors review Medicare claims on a post payment basis to identify inappropriate payments.

The following section reviews Medicare policy for coverage of lower limb prostheses.

Key points

Medicare requirements for lower limb prostheses

Provisions of the Social Security Act (the Act) govern Medicare payment for all items or services, including lower limb prostheses. The act states that Medicare will cover only services and items considered reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part.

In addition, Medicare requires that a supplier have an order from a physician before providing prostheses to the beneficiary. This physician is known as the referring physician. Upon receiving the order, the supplier consults with the referring physician, as needed, to confirm the order and recommend any necessary changes and evaluates the beneficiary. The supplier fits the beneficiary with the most appropriate prostheses. The supplier then determines the group of codes that best describes the prostheses provided, choosing from 178 Healthcare Common Procedure Coding System (HCPCS) codes that are specific to lower limb prostheses.

Note: If a supplier is replacing an old prosthesis and there is no upgrade in the model, the supplier does not need a physician order. Also, the "ordering" physician need not be a surgeon and may be the beneficiary's primary care physician.

Further, local coverage determination policies provide additional Medicare requirements for lower limb prostheses. These policies, consistent with policies for other DMEPOS, are identical across the country. The local coverage determination specifies how suppliers must submit claims for certain types and combinations of prostheses. In particular, it states that each claim must include a modifier to indicate whether the prosthesis is for the right or left limb. When a supplier provides prosthesis for each limb on the same date, the supplier must submit only one claim and include both the right and left modifiers on the claim.

The local coverage determination also has guidelines for determining the beneficiary's potential functional level. Specifically, it states that a beneficiary is placed at one of five potential functional levels based on the reasonable expectations of the supplier and the referring physician. When determining the potential functional level, suppliers and the referring physicians must take into account the beneficiary's history, current overall medical condition, and desire to walk. The supplier then uses a modifier on the claim to indicate the beneficiary's potential functional level (K0 to K4). Prostheses are not considered medically necessary if the beneficiary has the lowest potential functional level (K0), which indicates that he or she does not have the ability or the potential to walk. In addition, for some prostheses, the local coverage determination specifies the minimum potential functional level that the beneficiary must have for the prosthesis to be considered medically necessary.

Further, the local coverage determination limits the number of certain items that can be billed on a claim. If the number of units of these prostheses exceeds the limit, the additional items will be denied as not medically necessary. The local coverage determination also considers certain combinations of prostheses to be medically unnecessary. For example, certain sockets are not allowed for use with temporary base prostheses. Finally, the local coverage determination states that HCPCS L5990, a specific type of foot addition, will be denied as not medically necessary.

In addition, CMS recently established new screening procedures for provider enrollment. For example, screening may include licensure and criminal background checks. CMS created three levels of screening – limited, moderate, and high – based on the risk of fraud, waste, and abuse. New DMEPOS suppliers were placed at the high risk level, while currently-enrolled DMEPOS suppliers were placed at the moderate risk level.

Note: You should ensure that any items or services submitted on Medicare claims are referred or ordered by Medicare-enrolled providers of a specialty type authorized to order or refer the same. You must also place the ordering or referring provider or supplier's NPI on the claim you submit to Medicare for the service or item you provide. You may want to review *MLN Matters*® article SE1201 at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1201.pdf* for important reminders on the requirements for ordering and referring physicians.

Additional information

If you are unsure of, or have questions about, documentation requirements, contact your Medicare contractor at their toll-free number which may be

(*continued on next page*)

Prostheses (*continued*)

found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

The entire OIG report titled "Questionable Billing By Suppliers of Lower Limb Prostheses" is available at *http://oig.hhs.gov/oei/reports/oei-02-10-00170.pdf*.

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Related CR Transmittal #: N/A
Implementation Date: N/A

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ICD-9-CM (*continued*)

October 1. You can view the new updated codes at this site in June. You can also visit the National Center for Health Statistics (NCHS) website at *http://www.cdc.gov/nchs/icd.htm*. The NCHS will post the new ICD-9-CM addendum on their website in June. You are encouraged to purchase a new ICD-9-CM book or CD-ROM annually.

Medicare fee-for-service contractors will apply the annual ICD-9-CM coding update effective for dates of service on or after October 1, 2012, (effective for discharges on or after October 1, 2012, for institutional providers).

Partial code freeze for ICD-9-CM and ICD-10

The ICD-9-CM Coordination and Maintenance Committee implemented a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10. More information on the freeze is available at *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/Downloads/Partial_Code_Freeze.pdf*. For information pertaining to ICD-10, please refer to *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

Additional information

The official instruction, CR 7863, issued to your FI and A/B MAC regarding this change, may be viewed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2485CP.pdf*. If you have any questions, please contact your FI or A/B MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

MLN Matters® Number: MM7863
Related Change Request (CR) #: 7863
Related CR Release Date: June 8, 2012
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Related CR Transmittal #: R2485CP
Implementation Date: October 1, 2012

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Learn the secrets to billing Medicare correctly

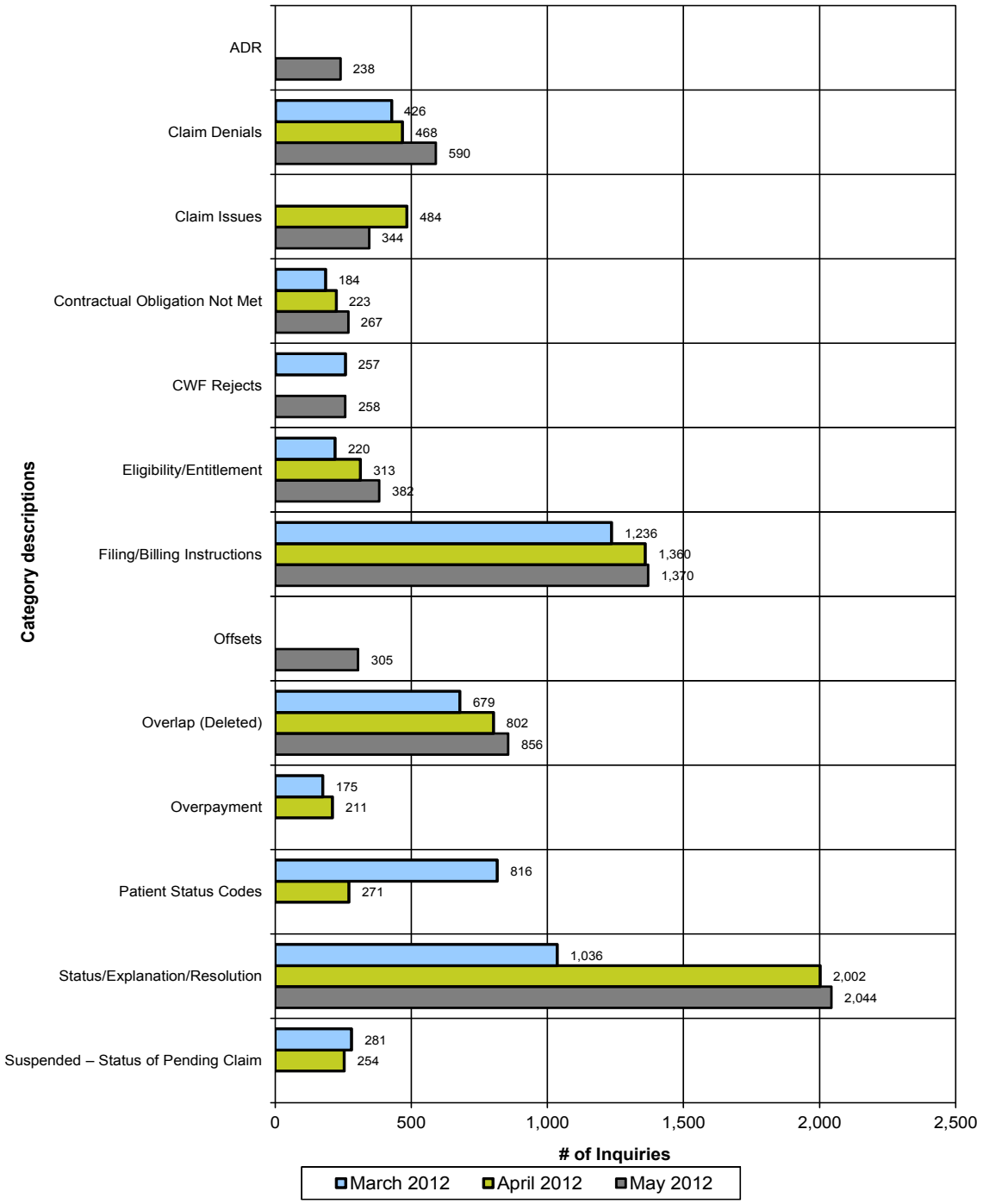
Who has the power to improve your billing accuracy and efficiency? You do – visit the *Improve Your Billing* section where you'll discover the tools you need to learn how to consistently bill Medicare correctly – the first time. You'll find FCSO's most popular self-audit resources, including the E/M interactive worksheet, provider data summary (PDS) report, and the comparative billing report (CBR).

Top inquiries, rejects, and return to provider claims – March-May 2012

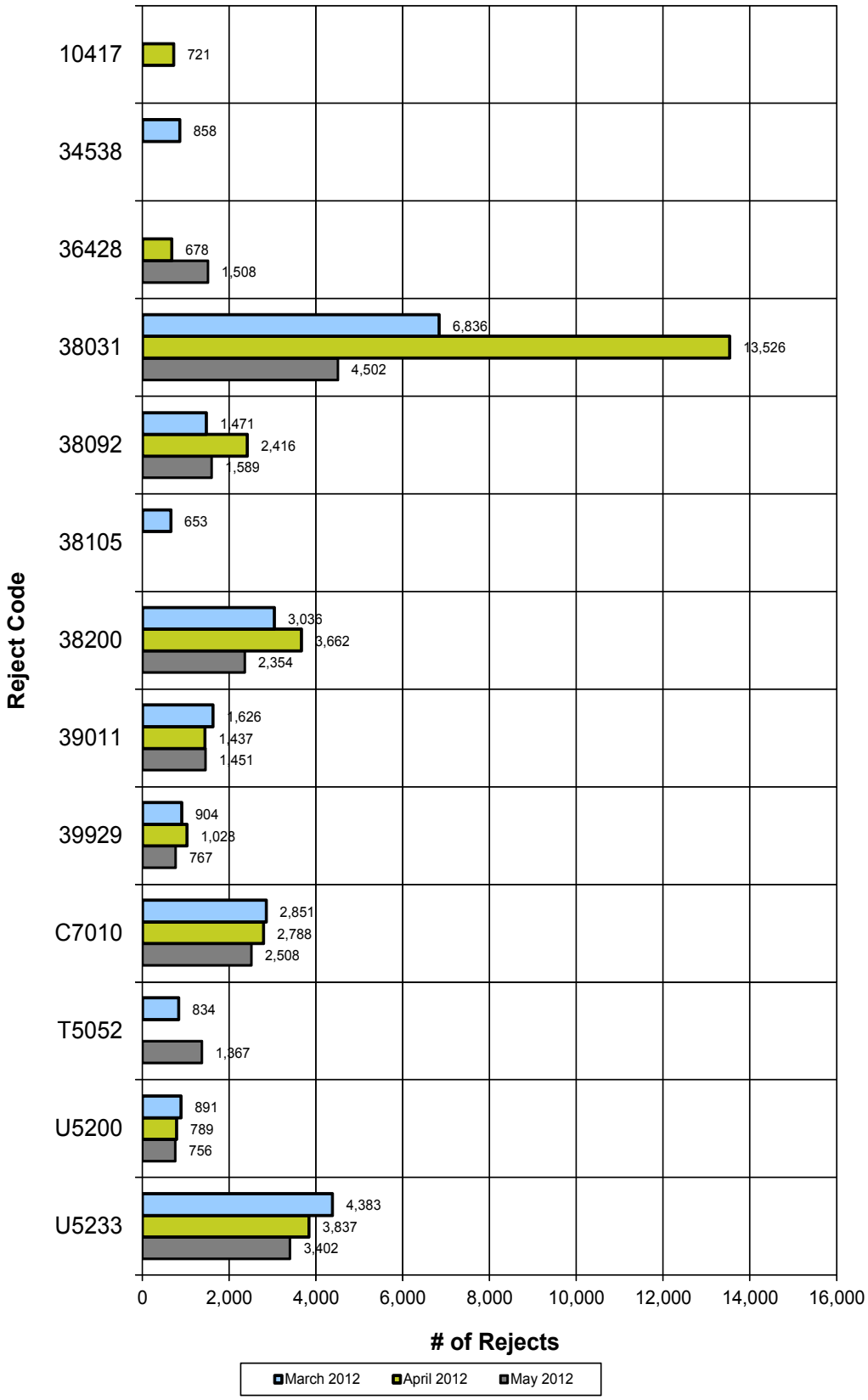
The following charts provide the most frequent inquiries and reason codes for rejected and returned to provider (RTP) claims submitted to First Coast Service Options Inc. (FCSO), by providers in Florida, Puerto Rico, and the U.S. Virgin Islands during March through May 2012.

For tips and resources to help providers to avoid or reduce the amount of time spent on many of these issues, refer to the Inquiries and Denials section of our website at *http://medicare.fcso.com/Inquiries_and_denials/index.asp*.

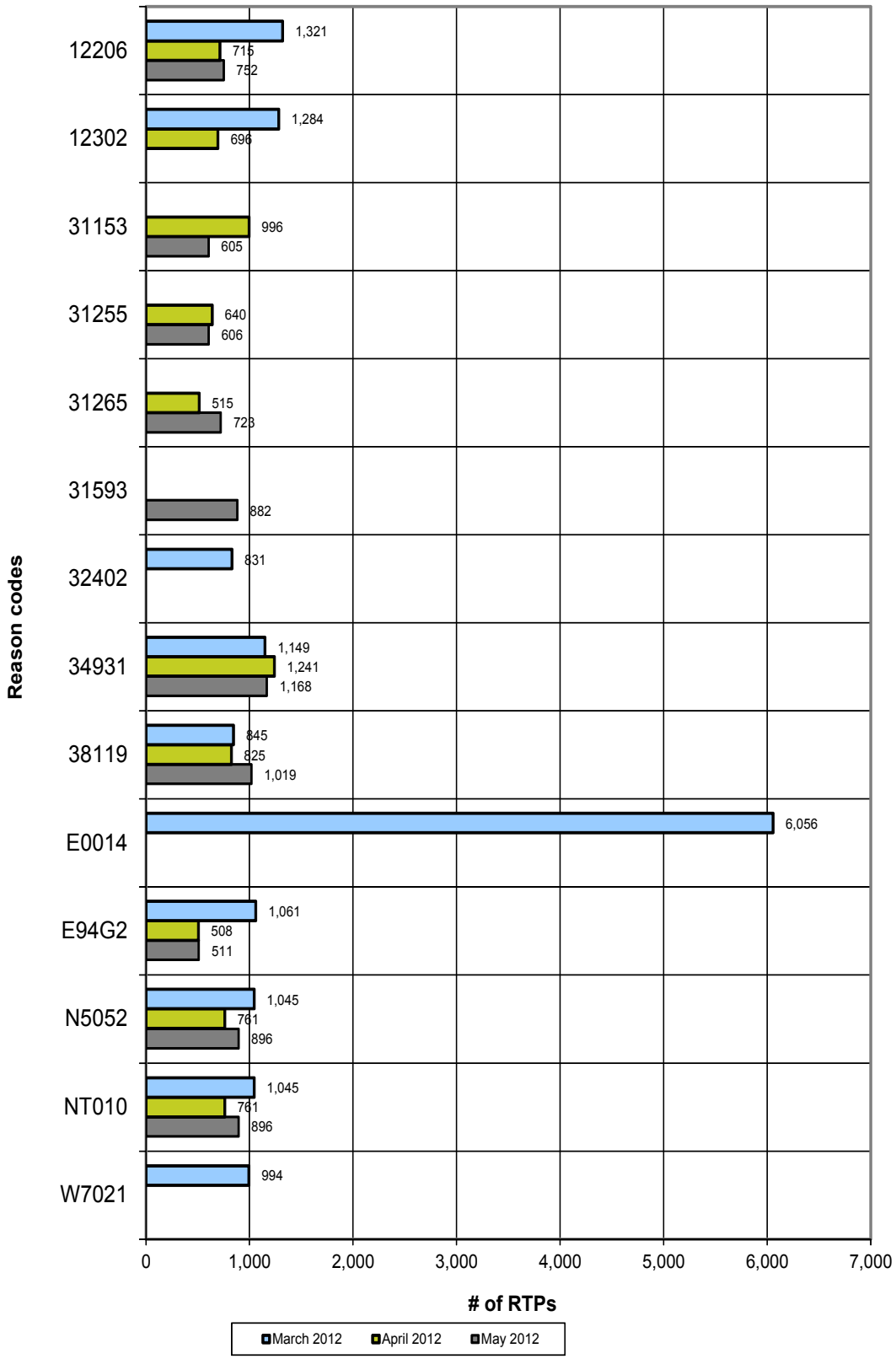
Part A top inquiries for March-May 2012



Part A top rejects for March-May 2012



Part A top return to providers (RTPs) for March-May 2012



July 2012 update of the hospital outpatient prospective payment system

Provider types affected

This *MLN Matters*® article is intended for providers and suppliers who submit claims to Medicare contractors (fiscal intermediaries (FIs), A/B Medicare administrative contractors (A/B MACs), and/or regional home health intermediaries (RHHIs)) for services provided to Medicare beneficiaries and paid under the outpatient prospective payment system (OPPS).

Provider action needed

This article is based on change request (CR) 7847 which describes changes to and billing instructions for various payment policies implemented in the July 2012 OPPS update. Be sure your billing staffs are aware of these changes.

Background

CR 7847 describes changes to and billing instructions for various payment policies implemented in the July 2012 OPPS update. The July 2012 integrated outpatient code editor (I/OCE) and OPPS Pricer will reflect the Healthcare Common Procedure Coding System (HCPCS), ambulatory payment classification (APC), HCPCS modifier, and revenue code additions, changes, and deletions identified in this CR.

The July 2012 revisions to I/OCE data files, instructions, and specifications are provided in CR 7841, "July 2012 Integrated Outpatient Code Editor (I/OCE) Specifications Version 13.2." A related article is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7841.pdf*. The key changes in the July 2012 update are as follows:

Changes to device edits for July 2012

Claims for OPPS services must pass two types of device edits to be accepted for processing: procedure-to-device edits and device-to-procedure edits. Procedure-to-device edits, which have been in place for many procedures since 2005, continue to be in place. These edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code. Procedures for which both a Device A and Device B are specified require that at least one each of a Device A and Device B be present on the claim (i.e., there must be some combination of a Device A with a Device B in order to pass the edit). Device B can be reported with any Device A for the same procedural HCPCS code.

Since January 1, 2007, the Centers for Medicare & Medicaid Services (CMS) also has required that a claim that contains one of a specified set of device codes be returned to the provider if it fails to contain an appropriate procedure code. CMS has determined that the devices contained in this list cannot be correctly reported without one of the specified procedure codes also being reported on the same claim. Where these devices were billed without an appropriate procedure code prior to January 1, 2007, the cost of the device was being packaged into the median cost for an incorrect procedure code and therefore inflated the payment for the incorrect procedure code. In addition, hospitals billing devices without the appropriate procedure code were being incorrectly paid. The device-to-procedure edits are designed to ensure that the costs of these devices are assigned to the appropriate APC in OPPS rate setting.

The most current edits for both types of device edits can be found under "Device, Radiolabeled Product, and Procedure Edits" at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/*. Failure to pass these edits will result in the claim being returned to the provider.

On April 1, 2012, HCPCS code C1882 (Cardioverter defibrillator, other than single or dual chamber (implantable)) was removed from the list of those devices required to be billed with *CPT* code *33249* (*Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber*) on the procedure-to-device edit list, retroactive to January 1, 2012. Based on clinical input from hospitals and other interested stakeholders, HCPCS code C1882 is being reinstated as a device code that can satisfy the edit for *CPT* code *33249*, retroactive to January 1, 2012.

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Outpatient *(continued)*

Category III *CPT* codes

The American Medical Association (AMA) releases category III *CPT* codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January. As discussed in the CY 2006 OPPS final rule with comment period (70 FR 68567), CMS modified its process for implementing the category III codes that the AMA releases each January for implementation in July to ensure timely collection of data pertinent to the services described by the codes; to ensure patient access to the services the codes describe; and to eliminate potential redundancy between category III *CPT* codes and some of the C-codes that are payable under the OPPS and were created by CMS in response to applications for new technology services.

For the July 2012 update, CMS is implementing in the OPPS seven (7) category III *CPT* codes that the AMA released in January 2012 for implementation on July 1, 2012. All seven category III *CPT* codes are separately payable under the hospital OPPS. The category III *CPT* codes, status indicators, and APCs are shown in Table 1 below. Payment rates for these services can be found in Addendum B of the July 2012 OPPS update that is posted at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*.

Table 1 – Category III *CPT* codes implemented as of July 1, 2012

CPT code	Long descriptor	SI	APC
0302T	*Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)*	T	0089
0303T	*Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only*	T	0106
0304T	*Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only*	T	0090
0305T	*Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report*	S	0690
0306T	*Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report*	S	0690
0307T	*Removal of intracardiac ischemia monitoring device*	T	0105
*0308T**	*Insertion of ocular telescope prosthesis including removal of crystalline lens*	T	0234

*HCPCS code C9732 (Insertion of ocular telescope prosthesis including removal of crystalline lens) was deleted June 30, 2012, and replaced with *CPT* code *0308T* effective July 1, 2012.

New instructions for device pass-through category C1840

Effective July 1, 2012, device pass-through category C1840 must be billed with *CPT* code *0308T* (*Insertion of ocular telescope prosthesis including removal of crystalline lens*) to receive pass-through payment, because C9732 is deleted effective June 30, 2012. *CPT* code *0308T* is assigned to APC 0234 (Level IV anterior segment eye procedures), as was C9732, so no change in the device offset for C1840 is necessary. See the OPPS Web page at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/* for the CY 2012 device offset for APC 0234.

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Outpatient *(continued)*

Billing for drugs, biologicals, and radiopharmaceuticals

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

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

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

a. Drugs and biologicals with payments based on average sales price (ASP) effective July 1, 2012

For CY 2012, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP + 4 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2012, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Note that for the third quarter of CY 2012, payment for drugs and biologicals with pass-through status is not made at the Part B drug competitive acquisition program (CAP) rate, as the CAP program was suspended beginning January 1, 2009. Should the Part B Drug CAP program be reinstituted sometime during CY 2012, CMS would again use the Part B drug CAP rate for pass-through drugs and biologicals if they are a part of the Part B drug CAP program, as required by the statute.

In the CY 2012 OPPS/ASC final rule with comment period, CMS stated that payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary based on the most recent ASP submissions, CMS will incorporate changes to the payment rates in the July 2012 release of the OPPS PRICER. The updated payment rates, effective July 1, 2012, will be included in the July 2012 update of the OPPS Addendum A and Addendum B, which will be posted at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*.

b. Drugs and biologicals with OPPS pass-through status effective July 1, 2012

Two drugs and biologicals have been granted OPPS pass-through status effective July 1, 2012. These items, along with their descriptors and APC assignments, are identified in Table 2.

Table 2 – Drugs and biologicals with OPPS pass-through status effective July 1, 2012

HCPCS code	Long descriptor	APC	Status indicator effective 7/1/12
C9368*	Grafix core, per square centimeter	9368	G
C9369*	Grafix prime, per square centimeter	9369	G

Note: The HCPCS codes identified with an "*" indicate that these are new codes effective July 1, 2012.

c. New HCPCS codes effective July 1, 2012 for certain drugs and biologicals

Six new HCPCS codes have been created for reporting certain drugs and biologicals (other than new pass-through drugs and biologicals listed in Table 2) in the hospital outpatient setting for July 1, 2012. These codes are listed in Table 3 and are effective for services furnished on or after July 1, 2012.

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Outpatient *(continued)*

Table 3 – New HCPCS codes effective for certain drugs and biologicals effective July 1, 2012

HCPCS code	Long descriptor	APC	Status indicator effective 7/1/12
Q2045*	Injection, human fibrinogen concentrate, 1 mg	1414	K
Q2046**	Injection, aflibercept, 1 mg	1420	G
Q2047	Injection, Peginesatide, 0.1 MG (for ESRD on Dialysis)	N/A	A
Q2048***	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	7046	K
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	1421	K
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	N/A	L

*Level II HCPCS code J1680 (Injection, human fibrinogen concentrate, 100 mg) will be replaced with HCPCS code Q2045 effective July 1, 2012. The status indicator for HCPCS code J1680 will change to E, "Not Payable by Medicare", effective July 1, 2012.

**Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) will be deleted June 30, 2012, and replaced with HCPCS code Q2046 effective July 1, 2012.

***Level II HCPCS code J9001 (Injection, doxorubicin hydrochloride, all lipid formulations, 10 mg) will be replaced with HCPCS code Q2048 effective July 1, 2012. The status indicator for HCPCS code J9001 will change to E, "Not Payable by Medicare", effective July 1, 2012.

d. Adjustment to the status indicator for certain HCPCS codes effective April 1, 2012

Effective April 1, 2012, the status indicators for several HCPCS codes listed in Table 4 will change from SI=E (not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI=K (paid under OPPS; separate APC payment). For the remainder of CY 2012, these HCPCS codes will be separately paid and the price will be updated on a quarterly basis.

The payment rates for these HCPCS codes are listed in Table 4 and have been installed in the July 2012 OPPS Pricer effective for services furnished on April 1, 2012, through the implementation of the July 2012 update.

Table 4 – Adjustment to status indicators for certain drugs and biologicals effective April 1, 2012

HCPCS code	Long descriptor	APC	Status indicator effective 4/1/12	Payment rate	Minimum unadjusted copayment rate
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1422	K	$112.86	$22.57
J2265	Injection, minocycline hydrochloride, 1 mg	1423	K	$0.57	$0.11
J8650	Nabilone, oral, 1 mg	1424	K	$22.99	$4.60
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen	1425	K	$0.80	$0.16

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Outpatient *(continued)*

HCPCS code	Long descriptor	APC	Status indicator effective 4/1/12	Payment rate	Minimum unadjusted copayment rate
Q4123	Alloskin rt, per square centimeter	1427	K	$13.77	$2.75
Q4125	Arthroflex, per square centimeter	1428	K	$123.61	$24.72
Q4128	Flexhd or allopatch hd, per square centimeter	1429	K	$39.93	$7.99
Q4129	Unite biomatrix, per sqaure centimeter	1430	K	$35.49	$7.10

e. Correct reporting of biologicals when used as implantable devices

When billing for products that are used as either a surgically implanted or inserted biological or as a skin substitute, hospitals should report the appropriate HCPCS code for the product. Implantable biologicals with pass-through status receive separate payment, but for those that do not have pass-through status, the OPPS payment for the implanted biological is packaged into the payment for the associated procedure. Products that can be used as either a skin substitute or as an implantable biological will only be separately paid when billed with a skin substitute application procedure. Units should be reported in multiples of the units included in the HCPCS descriptor. Providers and hospitals should not bill the units based on the way the implantable biological is packaged, stored, or stocked, if different from the HCPCS descriptor. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the implantable biological. Therefore, before submitting Medicare claims for biologicals that are used as implantable devices, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

Inpatient only list

Section 1833(t)(1)(B)(i) of the Social Security Act allows CMS to define the services for which payment under the OPPS is appropriate and the Secretary has determined that the services designated to be “inpatient only” services are not appropriate to be furnished in a hospital outpatient department. Medicare billing instructions in the *Medicare Claims Processing Manual*, Chapter 4, Sections 10.12 and 180.7, for inpatient only reporting guidelines are being clarified to state that procedures removed from the “inpatient only” list may be appropriately furnished in both the inpatient and outpatient settings and such procedures continue to be payable when furnished in the inpatient setting.

Drugs treated as hospital outpatient supplies

Language has also been added to Chapter 15, Section 50.2 of the *Medicare Benefit Policy Manual* to discuss drugs treated as hospital outpatient supplies. The revised chapter is attached to CR 7847. That language is as follows:

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.

- Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.
- Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient’s eye drops that the patient uses pre-and postoperatively.

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Outpatient *(continued)*

- Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.
- Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.
- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.

The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.

- Drugs given to a patient for his or her continued use at home after leaving the hospital.
- Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.
- Daily routine insulin or hypertension medication given preoperatively to a patient.
- A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.
- A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.

These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.

Corrected OPPS payment rates for July 2012

CMS made corrections to the CY 2012 OPPS payment rates issued in the CY 2012 OPPS/ASC final rule with comment period (CMS-1525-FC), in a correction notice published in the *Federal Register* on January 4, 2012 (CMS-1525-CN). CMS made additional corrections to CMS-1525-FC, in a correction notice published in the *Federal Register* on April 24, 2012. The July 2012 addenda A and B are impacted by these corrections and reflect the corrected rates. These payment rates are retroactive to dates of service beginning with January 1, 2012. To view the revised OPPS payment rates, see the July 2012 addenda posted at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*. Providers who think they may have received an incorrect payment between January 1, 2012, and June 30, 2012, may request contractor adjustment of the previously processed claims.

Hospital outpatient therapy services

Medicare pays for physical therapy, occupational therapy, and speech language pathology services that are furnished to hospital outpatients at the applicable amount under the physician fee schedule. The manual language has been revised to clarify that the site of service and other requirements in Chapter 6, Section 20 of the *Medicare Benefit Policy Manual* do not apply to these services when they are furnished "as therapy," meaning under a therapy plan of care. The paragraph on end-stage renal disease (ESRD) services has been edited to clarify that the requirements in Section 20 do not apply to services that are covered and paid under the ESRD prospective payment system. The revised manual section is attached to CR 7847.

Supervision levels for hospital outpatient therapeutic services

In the calendar year (CY) 2012 OPPS/ASC final rule, CMS established a process to obtain independent advice from the hospital outpatient payment panel regarding the appropriate supervision levels for individual hospital outpatient therapeutic services. Based on the panel's recommendations to CMS at its meeting on February 27-28, 2012, CMS is issuing changes to the required supervision levels for 28 HCPCS codes effective July 1, 2012. These changes are an attachment to one of the transmittals of CR 7847, which is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R157BP.pdf.*

Coverage determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or

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Outpatient *(continued)*

service may be paid if covered by the program. Fiscal intermediaries (FIs)/Medicare administrative contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, FIs/MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

Additional information

The official instruction, CR 7847, was issued to your Medicare contractor regarding this change in two transmittals. The first updates the *Medicare Benefit Policy Manual* and it may be viewed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R157BP.pdf*. The second provides claim processing requirements and it is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2483CP.pdf*.

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

MLN Matters®Number: MM7847
Related Change Request (CR) #: CR 7847
Related CR Release Date: June 8, 2012
Effective Date: July 1, 2012
Related CR Transmittal #: R2483CP and R157BP
Implementation Date: July 2, 2012

July update to the CY 2012 Medicare physician fee schedule database

Provider types affected

This *MLN Matters®* article is intended for physicians, non-physician practitioners, and other providers submitting claims to Medicare contractors (fiscal intermediaries (FIs), carriers, and A/B Medicare administrative contractors (MACs)) for professional services provided to Medicare beneficiaries that are paid under the Medicare physician fee schedule (MPFS).

Provider action needed

This article is based on change request (CR) 7844 and instructs Medicare contractors to download and implement a new Medicare physician fee schedule database (MPFSDB) as of July 2, 2012. Affected providers should be aware that Medicare contractors will only adjust claims processed before July 2, but impacted by changes effective prior to July 2, if you bring such claims to their attention. Please make sure your billing staff is aware of these changes.

Background

Payment files were issued to contractors based upon the CY 2012 MPFS final rule, published in the *Federal Register* on November 28, 2011, as modified by the final rule correction notice, published in the *Federal Register* on January 4, 2012, and relevant statutory changes applicable January 1, 2012. On December 23, 2011, the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) became law and suspended the automatic negative update that would have taken effect with current law. TPTCCA temporarily allowed for a zero percent update to the Medicare physician fee schedule from January 1, 2012, until February 29, 2012. On February 22, 2012, The Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) was signed into law and extended the zero percent update to the end of the calendar year, to December 31, 2012. CR 7844 is the July amendment to those payment files.

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Physician *(continued)*

Key changes are as follows:

HCPCS codes with revised Medicare physician fee schedule payment indicators effective July 1, 2012

Code	Short descriptor
J1680	Human fibrinogen conc inj
J9001	Doxorubicin hcl liposome inj
15777	Acellular derm matrix implt
*38205**	Harvest allogeneic stem cells
*57155**	Insert uteri tandem/ovoids
*94729**	CO diffuse capacity

* Only a short descriptor correction – AMA errata

New HCPCS codes to be added with the effective date of April 1, 2012

HCPCS code	G8907	G8908	G8909	G8910	G8911	G8912
Procedure status	X	X	X	X	X	X
Short descriptor	Pt doc no events on discharge	Pt doc w burn prior to D/C	Pt doc no burn prior to D/C	Pt doc to have fall in ASC	Pt doc no fall in ASC	Pt doc with wrong event

HCPCS code	G8913	G8914	G8915	G8916	G8917	G8918
Procedure status	X	X	X	X	X	X
Short descriptor	Pt doc no wrong event	Pt trans to hosp post D/C	Pt not trans to hosp at D/C	Pt w IV AB given on time	Pt w IV AB not given on time	Pt w/o preop order IV AB prop

Note that the various indicators, relative value unit (RVU) values, long descriptors, and payment amounts are included in a table in CR 7844.

New HCPCS codes to be added to the MPFSDB with the effective date of July 1, 2012

HCPCS code	Q2034	Q2045	Q2046	Q2047	Q2048	Q2049
Procedure status	X	E	E	E	E	E
Short descriptor	Agriflu vaccine	Human fibrinogen conc inj	Aflibercept injection	Peginesatide injection	Doxil injection	Imported Lipodox inj

HCPCS code	*0302T*	*0303T*	*0304T*	*0305T*	*0306T*	*0307T*	*0308T*
Procedure status	C	C	C	C	C	C	C
Short descriptor	Icar ischm mntrng sys compl	Icar ischm mntrng sys eltrd	Icar ischm mntrng sys device	Icar ischm mntrng prgrm eval	Icar ischm mntrng interr eval	Rmvl icar ischm mntrng dvce	Insj ocular telescope prosth

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Physician *(continued)*

Note that the various indicators, relative value unit (RVU) values, long descriptors, and payment amounts are included in a table in CR 7844.

Additional information

The official instruction, CR 7844 issued to your carrier, FI, RHHI, and A/B MAC regarding this change may be viewed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2481CP.pdf*.

If you have any questions, please contact your carrier, FI, RHHI and A/B MAC at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

MLN Matters® Number: MM7844
Related Change Request (CR) #: CR 7844
Related CR Release Date: June 1, 2012
Effective Date: July 1, 2012; except April 1, 2012 for ASC Measurement G-codes
Related CR Transmittal #: R2841
Implementation Date: July 2, 2012

Changes to the hospice aggregate cap calculation method

Provider types affected

This *MLN Matters*® article is intended for hospice providers submitting claims to Medicare contractors (fiscal intermediaries (FIs), regional home health intermediaries (RHHIs), carriers, A/B Medicare administrative contractors (MACs), and durable medical equipment MACs or DME MACs) for services to Medicare beneficiaries.

Provider action needed

This article is based on change request (CR) 7838 which informs Medicare contractors about a new addition to the *Medicare Benefit Policy Manual*, Chapter 9, Section 90. The new addition is titled, "Caps and Limitations on Hospice Payment." Some of the information in this new section was originally found in the *Medicare Claims Processing Manual*, Chapter 11, Section 80. Be sure your staffs are aware of the updates in the policy as a result of CR 7838.

Background

Medicare pays hospice care providers on a per diem basis. The total payment to a hospice in an accounting year (November 1, to October 31, also known as the cap year) is limited, however, by a statutory cap. Payments made in excess of the statutory cap are considered overpayments and must be refunded by the hospice care provider. The statutory cap is calculated for each hospice care provider by multiplying the applicable "cap amount," which is updated annually, by the "number of Medicare beneficiaries in the hospice program in that year." The statute provides that the number of Medicare beneficiaries in a hospice program in an accounting year "is equal to the number of individuals who have made an election [to receive hospice care] and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan of care established by another hospice program."

In 1983, the Department of Health and Human Services (HHS) adopted a rule that allocates hospice care on an aggregate basis by allocating each beneficiary entirely to the cap year in which he or she would be likely to receive the preponderance of his or her care. The original 1983 regulation calculates the number of hospice beneficiaries as follows:

Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24, from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

Since 1983, the vast majority of hospice providers have not objected to how Medicare beneficiaries are counted in the calculation of the aggregate cap. However, the original method of counting beneficiaries set forth in 42 CFR 418.309(b)(1) has been the subject of recent litigation. A small percentage of hospice providers have filed appeals challenging this methodology, seeking to have hospice overpayment determinations using this methodology invalidated.

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Hospice *(continued)*

In April 2011, the Centers for Medicare & Medicaid Services (CMS) issued Ruling CMS 1355-R, which addresses cap years prior to the cap year ending October 31, 2012; CMS has also issued a proposed and final rule revising the previous regulation set forth at § 418.309(b)(1) to provide for application of a patient-by-patient proportional methodology for cap years 2012 and beyond, or, for qualifying providers, application of the streamlined methodology at the provider's election. CMS is also allowing certain hospice providers to elect to have that determination calculated pursuant to a patient-by-patient proportional methodology.

The key provisions of the new Chapter 9, Section 90 of the *Medicare Benefit Policy Manual* are summarized as follows:

Caps and limitations on hospice payments

The statute requires that hospice payments be limited by an inpatient cap and by an aggregate cap. Medicare contractors make the cap calculations annually, after the end of the aggregate cap year, which runs from November 1 to October 31. Contractors send each provider a cap determination letter, which serves as a notice of program reimbursement under 42 CFR §405.1803(a)(3), showing the results of those calculations. Any amounts in excess of either cap are considered to be overpayments, and must be repaid to Medicare. Contractors compute the inpatient cap and the aggregate cap in order to determine whether a provider has exceeded the allowable hospice cap amount. The contractor shall issue a demand for the overpayment from hospices that exceeded the allowable hospice cap amount.

Limitation on payments for inpatient care

There were no policy changes to this section of the manual. Please see the *Medicare Benefit Policy Manual* (Chapter 9, Section 90.1) for details on the limitation on payments for inpatient care.

Aggregate cap on overall reimbursement to Medicare-certified hospices

Overall aggregate Medicare payments made to a Medicare-certified hospice are subject to an aggregate cap, calculated by the contractor at the end of the hospice cap period. The cap year is from November 1 of each year to October 31 of the next year. The aggregate cap is calculated by multiplying a Medicare beneficiary count during the period by a statutory "cap amount." The hospice cap amount for the cap year ending October 31, 2011, is $24,527.69. This amount is adjusted annually to reflect the percentage increase or decrease in the medical care expenditure category of the consumer price index (CPI) for all urban consumers. All Medicare-certified hospices are subject to the aggregate cap calculation. When a beneficiary receives hospice care from more than one hospice, only the care provided by the Medicare-certified hospice(s) is considered when computing the aggregate cap.

Actual Medicare payments counted

"Total actual Medicare payments made for services furnished to Medicare beneficiaries during the cap year" refers to Medicare payments for services rendered beginning November 1 and ending October 31, regardless of when payment is actually made. All payments made to hospices on behalf of all Medicare hospice beneficiaries receiving services during the cap year are counted, regardless of which year(s) the beneficiary is counted in determining the cap, using the best data available at the time of the calculation. For example payments made to a hospice for an individual initially electing hospice care on October 5, 2011, and dying on October 25, 2011, pertain to services rendered in the cap year beginning November 1, 2010, and ending October 31, 2011, and are counted as payments made during the 2011 cap year (November 1, 2010 - October 31, 2011), even though the beneficiary would be counted in the 2012 cap year if that hospice used the streamlined method (the period for counting beneficiaries using the streamlined method is September 28, 2011, to September 27, 2012).

New hospices

The hospice aggregate cap is calculated in a different manner for new hospices entering the Medicare program if the hospice has not participated in the program for an entire cap year. In this situation, the initial cap calculations for newly certified hospices must cover a period of at least 12 months but less than 24 months. For example, the first cap period for a hospice entering the program on October 1, 2010, is from October 1, 2010, through October 31, 2011. Similarly, the first cap period for hospice providers entering the program after November 1, 2009, but before November 1, 2010, ends October 31, 2011.

Counting beneficiaries for calculation

From the inception of the hospice benefit in 1983 until April 14, 2011, the original method for counting beneficiaries for use in the aggregate cap calculation remained unchanged. That method is described below, and is now also known as the streamlined method:

Each hospice's cap amount is calculated by the contractor multiplying the adjusted cap amount by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of

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Hospice *(continued)*

Medicare beneficiaries includes—

1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care from the hospice during the period beginning on September 28 (34 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice.

Two methods for counting beneficiaries

The procedures for counting beneficiaries used in the hospice cap calculation were described in CMS Ruling 1355-R (published in the *Federal Register* as CMS-1355-NR (76 FR 26731, May 9, 2011, found at *http://www.gpo.gov/fdsys/pkg/FR-2011-05-09/pdf/2011-10694.pdf#page=1*) and in the fiscal year (FY) 2012 hospice wage index final rule. The two methods for counting beneficiaries are the streamlined method and the proportional method.

Proportional method:

Under the proportional method, for each hospice, the contractor shall include in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total days of care in all hospices and all years that was spent in that hospice in that cap year (November 1 to October 31), using the best data available at the time of the calculation (subject to revision at a later time based on updated data). The whole and fractional shares of Medicare beneficiaries' time in a given cap year are then summed to compute the total number of Medicare beneficiaries served by that hospice in that cap year.

When a hospice's cap is calculated using the proportional method, and a beneficiary included in that calculation survives into another cap year, the contractor may need to make adjustments to prior cap determinations. Reopening is allowed for up to three years from the date of the cap determination notice, except in the case of fraud, where reopening is unlimited. A revised cap determination letter issued as a result of a reopening may itself be reopened, subject to the three year limitation on reopening.

Streamlined method:

When a beneficiary receives care from only one hospice: The hospice includes in its number of Medicare beneficiaries those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap, and who have filed an election to receive hospice care during the period beginning on September 28 (34 days before the beginning of the cap year) and ending on September 27 (35 days before the end of the cap year), using the best data available at the time of the calculation.

Once a beneficiary has been included in the calculation of a hospice cap, he or she may not be included in the cap for that hospice again, even if the number of covered days in a subsequent cap year exceeds that of the period where the beneficiary was included (this could occur when the beneficiary has breaks between periods of election).

When a beneficiary receives care from more than one Medicare-certified hospice during a cap year or years: Each Medicare-certified hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total days of care in all Medicare-certified hospices and all years that was spent in that hospice in that cap year (November 1 to October 31), using the best data available at the time of the calculation. Cap determinations are subject to reopening/adjustment to account for updated data. The streamlined method cap calculation for a Medicare beneficiary who has been in more than one Medicare-certified hospice is identical to the proportional method.

Which method applies, and when:

1. **Hospice appeals for review of an overpayment determination (Ruling CMS-1355-R):**

   Effective April 14, 2011, a CMS Ruling entitled "Medicare Program; Hospice Appeals for Review of an Overpayment Determination" (CMS-1355-R), and also published in the *Federal Register* as CMS-1355-NR (76 FR 26731, May 9, 2011, found at *http://www.gpo.gov/fdsys/pkg/FR-2011-05-09/pdf/2011-10694.pdf#page=1*), was issued related

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Hospice *(continued)*

to the aggregate cap calculation for hospices. The ruling provides that, for any hospice which has a timely-filed administrative appeal of the method used to determine the number of Medicare beneficiaries used in the aggregate cap calculation for a cap year ending on or before October 31, 2011, the Medicare contractors shall recalculate that year's cap determination using the proportional method.

2. **Cap year ending October 31, 2011, (the 2011 cap year) and all prior cap years:**

   Ruling CMS-1355-R applies only to the 2011 cap year and any prior cap year(s) for which a hospice received an overpayment determination and filed a timely qualifying appeal. For any hospice that received relief through ruling CMS-1355-R in the form of a recalculation of one or more of its cap determinations, or for any hospice that receives relief from a court after challenging the validity of the cap regulation, the hospice's cap determination for any subsequent cap year is also calculated using a proportional method.

   Additionally, there are hospices that have not filed an appeal of an overpayment determination challenging the validity of the original method for counting beneficiaries and which are waiting for CMS to make a cap determination for cap years ending on or before October 31, 2011. Any such hospice provider, as of October 1, 2011, may elect to have its final cap determination for such cap year(s), and all subsequent cap years, calculated using the proportional method.

   Finally, those hospices which would like to continue to have the original method (hereafter called the streamlined method) used to determine the number of beneficiaries in a given cap year would not need to take any action, and would have their cap calculated using the streamlined method for cap years ending on or before October 31, 2011.

3. **Cap year ending October 31, 2012, (the 2012 cap year) and subsequent cap years:**

   For cap years ending on or after October 31, 2012, and all subsequent cap years, the hospice aggregate cap is calculated using the proportional method, except that eligible hospices can make a one-time election up to 60 days after receiving their 2012 cap determination to have their aggregate cap calculated using the streamlined method. The option to elect the continued use of the streamlined method for cap years 2012 and beyond is available only to hospices that have had their cap determinations calculated using the streamlined method for all cap years prior to cap year 2012. Contractors shall provide hospices with details on how to make that one-time election.

Transitioning from the streamlined method to the proportional method: There are advantages and disadvantages for hospices transitioning from the streamlined method to the proportional method. When a transition to the proportional method occurs for the 2012 cap year, contractors shall not re-open the cap determination for prior cap years to pro-rate beneficiaries calculated under the streamlined method, who are included in beneficiary count for the 2012 cap year, unless those beneficiaries were in more than one hospice. Contractors shall consider all days of hospice care for these beneficiaries, including those in the previous cap year(s), when computing the proportional share of a beneficiary headcount using the proportional method. Therefore, some beneficiaries that were previously counted as one may be counted as more than 1 as a result of the transition.

When a hospice that elects to continue to have the streamlined method used for its cap calculation in 2012, later elects to change to the proportional method for the 2013 cap year or a later cap year, contractors can reopen cap determinations for the 2012 and later cap years. Reopening is allowed for up to three years from the date of the applicable cap determination, except in the case of fraud, where reopening is unlimited.

Additionally, when a transition to the proportional method is made, the timeframe for counting beneficiaries changes from September 28 – September 27 to November 1 – October 31. As a result, there is a 34 day period from September 28 – October 31, 2011 in the transition year where beneficiaries who elect hospice and die within that period are not counted in the total number of beneficiaries for either the 2011 or the 2012 cap year. However, the payments associated with those beneficiaries are counted in the 2011 cap year.

When a hospice transitions from the streamlined method to the proportional method, the beneficiaries' days of care from September 28 – October 31, 2011 (34 days) would not be included in the numerator for the beneficiary count calculation. However, that 34-day period would be included in the denominator because the proportional method includes in the denominator all days of hospice care provided to a beneficiary in order to prorate the beneficiary correctly. As such, any beneficiary that elected hospice care during the 34-day period would be counted as less than one, since the numerator only includes days of service in the new cap

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Hospice *(continued)*

year, but the denominator includes all days of care, including the days in the 34-day transition period. The counting of these beneficiaries as less than one could be offset (in whole or in part) by other beneficiaries that will be carried over from years prior to the 2012 cap year that would be counted as more than one beneficiary.

These methods and procedures are explained in more detail in Chapter 9, Section 90.2.3 of the *Medicare Benefit Policy Manual*; that entire chapter is attached to one of the transmittals of CR 7838, which you will find at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R156BP.pdf*. There are a number of illustrative examples of counting beneficiaries and on transitioning from the streamlined method to the proportional method of counting beneficiaries in the same section of that attachment to CR 7838.

Changing aggregate cap calculation methods

Hospices are not allowed to switch back and forth between cap calculation methods, as doing so would greatly complicate the cap determination calculation, would be difficult to administer, and could lead to inappropriate switching by hospices seeking merely to maximize Medicare payments. Additionally, in the year of a change in the calculation method or when a previous cap determination cannot be re-opened, there is a potential for over-counting some beneficiaries. Allowing hospices to switch back and forth between methods would perpetuate the risk of over-counting beneficiaries. Therefore:

1) Those hospices that have their cap determination calculated using the proportional method for any cap year prior to the 2012 cap year will continue to have their cap calculated using the proportional method for the 2012 cap year and all subsequent cap years; and,

2) All other hospices would have their cap determinations for the 2012 cap year and all subsequent cap years calculated using the proportional method unless they make a one-time election to have their cap determinations for cap year 2012 and beyond calculated using the streamlined method. Contractors do not reopen cap determinations for the 2011 cap year and prior cap years as a result of a hospice transition from the streamlined to the proportional method for the 2012 cap year. **Note:** This does not apply to hospices that appealed their cap determination.

3) A hospice would be able to elect the streamlined method no later than 60 days following the receipt of its 2012 cap determination.

4) Hospices which elected to have their cap determination calculated using the streamlined method may later elect to have their cap determinations calculated using the proportional method by either:

   a) electing to change to the proportional method (if the election is made prior to receipt of the cap determination associated with the cap year where the change is desired); or

   b) appealing a cap determination calculated using the streamlined method to determine the number of Medicare beneficiaries.

5) If a hospice elected the streamlined method, and changed to the proportional method for a subsequent cap year, the hospice's aggregate cap determination for that cap year (i.e., the cap year of the change) and all subsequent cap years would be calculated using the proportional method. Past cap year determinations for the 2012 cap year and later cap years are subject to reopening; existing re-opening rules allow reopening for up to 3 years from the date of the cap determination, except in cases of fraud, where reopening is unlimited. A revised cap determination letter issued as a result of reopening may itself be reopened, subject to the three year limitation on reopening.

Other issues

The computation and application of the aggregate cap is made by the contractor after the cap year ends. The updated Provider Statistical & Reimbursement (PS&R) system enables each hospice's contractor to correctly determine proportional allocations. For all cap years through the 2011 cap year, hospices are responsible for reporting the number of Medicare beneficiaries electing hospice care during the period to the contractor. This must be done within 30 days after the end of the cap period. For the 2012 cap year and beyond, hospices no longer need to report the number of Medicare beneficiaries to be counted in the aggregate cap calculation due to the updated PS&R system.

Hospices can obtain instructions regarding the cap determination method election process from their contractors. Regardless of which method is used, the contractor shall continue to demand any additional overpayment amounts due to CMS at the time of the hospice cap determination. Cap determinations are subject to the existing CMS reopening regulations, which allow reopening for up to three years from the date of the cap determination letter, except in cases of fraud, where reopening is not limited.

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Hospice *(continued)*

There were no policy changes related to updating to the cap amount or to administrative appeals. Information about these two topics is included in Chapter 9, of the *Medicare Benefit Policy Manual* in Section 90.2.6 ("Updates to the Cap Amount") and Section 90.3 ("Administrative Appeals"). Chapter 9 is attached to one of the transmittals of CR 7838, which you will find at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R156BP.pdf*.

Additional information

The official instruction, CR 7838 was issued to your contractor via two transmittals. The first removes the hospice policy discussion from the *Medicare Claims Processing Manual* and it is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2482CP.pdf*. The second adds the Chapter 9, Section 90 to the *Medicare Benefit Policy Manual* at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R156BP.pdf*.

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip*.

MLN Matters® Number: MM7838
Related Change Request (CR) #: CR 7838
Related CR Release Date: June 1, 2012
Effective Date: April 14, 2011 for the 2011 cap year and prior CYs; October 1, 2011 for the 2012 and subsequent cap years
Related CR Transmittal #: R156BP and R2482CP
Implementation Date: July 2, 2012

Prompt payment interest rate revision

Medicare must pay interest on clean claims if payment is not made within the applicable number of calendar days (i.e., 30 days) after the date of receipt. The applicable number of days is also known as the payment ceiling. For example, a clean claim received on March 1, 2012, must be paid before the end of business on March 31, 2012.

The interest rate is determined by the applicable rate on the day of payment. This rate is determined by the Treasury Department on a six-month basis, effective every January and July 1. Providers may access the Treasury Department Web page *http://fms.treas.gov/prompt/rates.html* for the correct rate. The interest period begins on the day after payment is due and ends on the day of payment.

The new rate of 1.75 percent is in effect through December 31, 2012.

Interest is not paid on:

- Claims requiring external investigation or development by the Medicare contractor
- Claims on which no payment is due
- Claims denied in full
- Claims for which the provider is receiving periodic interim payment
- Claims requesting anticipated payments under the home health prospective payment system.

Note: The Medicare contractor reports the amount of interest on each claim on the remittance advice to the provider when interest payments are applicable.

Source: Publication 100-04, Chapter 1, Section 80.2.2

Medicare administrative contractor-initiated mass adjustments

First Coast Service Options Inc. is mandated to perform Medicare administrative contractor (MAC) initiated mass adjustments for various reasons. Effective immediately, when a mass adjustment is initiated by the MAC, a unique remark/message will added to the remark section of the claim.

The remark section of the claim will be populated with one the following remarks "FI Adjustment TDL XXXXX (number)" or "FI Adjustment CR XXXXX (number)" or "FI Adjustment procedure/reason code XXXXX (number)." The addition of this unique remark/message will inform you as to why your claim has been adjusted.

Educational Events

Upcoming provider outreach and educational events – July 2012

Internet-based PECOS class (A/B)

When: Tuesday, July 17
Time: 8 a.m. – noon ET **Delivery language:** English
Type of Event: Face-to-face **Focus:** Florida, Puerto Rico, and U.S. Virgin Islands

Prepayment medical review of inpatient hospital claims

When: Wednesday, July 18
Time: 11:30 a.m. – 1 p.m. ET **Delivery language:** English
Type of Event: Webcast **Focus:** Florida, Puerto Rico, and U.S. Virgin Islands

Medifest 2012 Panama City (A/B)

When: July 25-26
Time: 8 a.m. – 5 p.m. ET **Delivery language:** English
Type of Event: Face-to-face **Focus:** Florida, Puerto Rico, and U.S. Virgin Islands

Two easy ways to register

1. **Online** – Visit our provider training website at *fcsouniversity.com*, logon to your account and select the course you wish to register. Class materials are available under "My Courses" no later than one day before the event.

   First-time user? Set up an account by completing "Request a New Account" online. Providers who do not have a national provider identifier may enter "99999" in the NPI field. You will receive logon information within 72 hours of your request.

2. **Fax** – Providers without Internet access may request a fax registration form through our Registration Hotline at 904-791-8103. Class materials will be faxed to you the day of the event.

Please note:

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

Registrant's Name: _____

Registrant's Title: _____

Provider's Name: _____

Telephone Number: _____ Fax Number: _____

Email Address: _____

Provider Address: _____

City, State, ZIP Code: _____

Keep checking the *Education* section of our website, *medicare.fcso.com*, for details and newly scheduled educational events (teleconferences, webcasts, etc.) or call the FCSO Provider Education Registration Hotline at 904-791-8103 to learn more about the about our newest training opportunities for providers.

Never miss a training opportunity

If you were unable to attend one of our past Medicare educational webcasts, you still have the opportunity to learn about the topics covered during the training session. Visit *medicare.fcso.com*, download the recording of the event, and listen to the webcast when you have the time.

Take advantage of 24-hour access to free online training

In addition to our live training events, we also offer you the advantage of self-paced, free online courses that will allow you and your staff to train when and where it is most convenient for you. Our comprehensive course catalog allows you to find the Medicare training that fits your specific needs, and several of our online courses offer CEUs. Explore our catalog of online courses and learn more at *fcsouniversity.com*.

Addresses

First Coast Service Options

American Diabetes Association certificates
Medicare Provider Enrollment – ADA
P. O. Box 2078
Jacksonville, FL 32231-0048

Claims/correspondence
Florida:
Medicare Part A Customer Service
P. O. Box 2711
Jacksonville, FL 32231-0021

U.S. Virgin Islands:
First Coast Service Options Inc.
P. O. Box 45071
Jacksonville, FL 32232-5071

Electronic claim filing
Direct Data Entry
P. O. Box 44071
Jacksonville, FL 32231-4071

Fraud and abuse
Complaint Processing Unit
P. O. Box 45087
Jacksonville, FL 32232-5087

Freedom of Information Act requests
(relative to cost reports and audits)

Provider Audit and Reimbursement (PARD)
Attn: FOIA PARD – 16T
P. O. Box 45268
Jacksonville, FL 32232-5268

Local coverage determinations
Medical Policy and Procedures – 19T
P.O. Box 2078
Jacksonville, FL 32231-0048

Medicare secondary payer (MSP)
General information, conditional payment
Medicare Secondary Payer
P. O. Box 2711
Jacksonville, FL 32231-0021

Hospital protocols, admission questionnaires, audits
MSP – Hospital Review
P. O. Box 45267
Jacksonville, FL 32232-5267

MSPRC DPP debt recovery, automobile accident cases, settlements/lawsuits, liabilities
Auto/Liability – 17T
P. O. Box 44179
Jacksonville, FL 32231-4179

Overpayment collections
Repayment plans, cost reports, receipts and acceptances, tentative settlement determinations, provider statistical and reimbursement reports, cost report settlement, interim rate determinations, TEFRA target limit and SNF routine cost limit exceptions

Provider Audit and Reimbursement
P. O. Box 45268
Jacksonville, FL 32232-5268

Post-pay medical review
First Coast Service Options Inc.
P. O. Box 44159
Jacksonville, FL 32231-4159

Provider enrollment
CMS-855 Applications
P. O. Box 44021
Jacksonville, FL 32231-4021

Redetermination
Florida:
Medicare Part A Redetermination and Appeals
P. O. Box 45053
Jacksonville, FL 32232-5053

U.S. Virgin Islands:
First Coast Service Options Inc
P. O. Box 45097
Jacksonville, FL 32232-5097

Special delivery mail and courier services
First Coast Service Options Inc.
532 Riverside Avenue
Jacksonville, FL 32202-4914

Other Medicare carriers and intermediaries

Durable medical equipment regional carrier (DMERC)
DME, orthotic and prosthetic device, take-home supply, and oral anti-cancer drug claims

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

Railroad Medicare
Palmetto Government Benefit Administrators
P. O. Box 10066
Augusta, GA 30999-0001

Regional home health and hospice intermediary
Palmetto Government Benefit Administrators
Medicare Part A
P.O. Box 100238
Columbia, SC 29202-3238

Phone numbers

Customer service/IVR
Providers:
888-664-4112
Speech and hearing impaired
877-660-1759

Beneficiaries:
800-MEDICARE (800-633-4227)
Speech and hearing impaired
800-754-7820

Credit balance report
Debt recovery
904-791-6281
Fax
904-361-0359

Electronic data interchange
888-670-0940

Option 1 – Transaction support

Option 2 – PC-ACE support

Option 3 – Direct data entry (DDE)

Option 4 – Enrollment support

Option 5 – 5010 testing

Option 6 – Automated response line

Provider audit and reimbursement
904-791-8430

Provider education and outreach
Seminar registration hotline
904-791-8103
Seminar registration fax
904-361-0407

Provider enrollment
877-602-8816

Websites

First Coast Service Options Inc. (Florida and U.S. Virgin Islands Medicare contractor)
medicare.fcso.com

Centers for Medicare & Medicaid Services
Providers:
www.cms.gov

Beneficiaries:
www.medicare.gov

Medicare A *Connection*

First Coast Service Options, Inc.
P.O. Box 2078 Jacksonville, FL 32231-0048