

C Medicare A CONNECTION

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A Newsletter for MAC Jurisdiction N Providers

April 2015



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'Doc Fix' fixed – President signs the Medicare Access and CHIP Reauthorization Act of 2015 into law

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 was signed into law April 16, averting a potential negative 21 percent update in the Medicare physician fee schedule and adding a 0.5 percent update starting July 1, 2015.

The Act also restores exceptions to the therapy cap, add-on payments for ambulance services, payments for low volume hospitals, and payments for Medicare dependent hospitals that expired on April 1.

Section 202 of MACRA revises Medicare provisions affecting the outpatient therapy caps:

- The outpatient therapy cap exception process will remain in effect for claims with dates of service through December 31, 2017.
- Hospital outpatient claims for therapy services with dates of service through December 31, 2017, continue to apply to the therapy caps.
- Editing remains in effect to suspend claims for therapy

services that exceed the \$3,700 threshold for claims with dates of service through December 31, 2017.

MACRA extends through December 31, 2017, a three percent increase in the ambulance fee schedule for rural transports and a two percent increase for urban transports.

The Centers for Medicare & Medicaid Services will release a separate instruction to address mandated changes to the subsequent review of these claims.



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Publication staff:

Terri Drury
Kathleen Cruz Fuentes
Sofia Lennie
Martin Smith
Mark Willett
Robert Petty

Fax comments about this publication to:

Medicare Publications

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General Information

Medicare providers with overdue tax will see withholding increases from 15 to 30 percent

Provider types affected

This *MLN Matters*[®] article is intended for physicians, providers, and suppliers who submit claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

What you need to know

Change request (CR) 9154 instructs the Healthcare Integrated General Ledger Accounting System (HIGLAS) system maintainer to make necessary programming changes to increase the tax withhold percentage from 15 percent to 30 percent.

If you owe back taxes to the IRS and those taxes are eligible to be withheld from payments due you from Medicare, the withhold rate will increase from the current 15 percent to 30 percent on June 19, 2015.

Background

In July 2000, the IRS, in conjunction with the Department of the Treasury, Financial Management Service (FMS), started the FPLP which is authorized by the Internal Revenue Code Section 6331 (h) (see <http://www.gpo.gov/fdsys/pkg/USCODE-2011-title26/pdf/USCODE-2011-title26-subtitleF-chap64-subchapD-partIsec6331.pdf>), as prescribed by the Taxpayer Relief Act of 1997 Section 1024 (see <http://www.gpo.gov/fdsys/pkg/PLAW-105publ34/html/PLAW-105publ34.htm>).

Through the FPLP, authority is provided to the Centers for Medicare & Medicaid Services (CMS) to collect overdue taxes through a levy on certain federal payments. This includes federal payments made to Medicare providers.

Consistent with this authority, CMS introduced CR 6125 in October of 2008, which reduced federal payments subjected to the levy by the required 15 percent, or the exact amount of the tax owed if it is less than 15 percent of the payment.

You can review the *MLN Matters*[®] article (MM6125) corresponding to CR 6125 at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm6125.pdf>.

In December 2014, the Internal Revenue Code Section 6331 (h) was amended by the Tax Increase Prevention Act of 2014 Section 209 (a) (see <http://www.gpo.gov/fdsys/pkg/BILLS-113hr5771enr/html/BILLS-113hr5771enr.htm>), which mandated an increase of the tax levy to 30 percent.

Note: The tax levy is continuous until the overdue taxes are paid in full, or other arrangements are made to satisfy the debt.

Additional information

The official instruction CR 9154, issued to your MAC regarding this change is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1486OTN.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - *How Does It Work?*

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Updates to the 'Medicare Internet-Only Manual' for skilled nursing facility providers

Note: This article was revised April 8, 2015, to reflect the revised change request (CR) 8997 issued April 3. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same. This information was previously published in the [March 2015 Medicare A Connection](#), Pages 3-4.

Provider types affected

This *MLN Matters*[®] article is intended for physicians, providers, and suppliers submitting claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries who are in a skilled nursing facility (SNF).

Provider action needed

CR 8997 updates sections of the *Medicare Benefit Policy Manual* and the *Medicare Claims Processing Manual* in regards to SNF policy and billing. If you provide services to Medicare beneficiaries in a SNF stay, information in CR 8997 could impact your payments.

Background

CR 8997 updates two chapters of the *Medicare Claims Processing Manual* and one chapter of the *Medicare Benefit Policy Manual*. The following summarizes these manual updates:

'Medicare Benefit Policy Manual,' Chapter 8

Section 20.2.3: (Readmission to SNF)

- If an individual who is receiving covered post-hospital extended care, leaves a SNF and is readmitted to the same or any other participating SNF for further covered care within 30 days of the last covered skilled day, the 30-day transfer requirement is considered to be met; and
- **The same is true if the beneficiary remains in the SNF to receive custodial care following a covered stay, and subsequently develops a renewed need for covered care there within 30 consecutive days.** Thus, the period of extended care services may be interrupted briefly and then resumed, if necessary, without hospitalization preceding the **resumption** of SNF coverage.



'Medicare Claims Processing Manual,' Chapter 6

Section 20.1.1.2: Hospital's "facility charge" in connection with clinic services of a physician

- When a beneficiary receives clinic services from a hospital-based physician, the physician in this situation would bill his or her own professional services directly to the Part B **MAC** and would be reimbursed at the facility rate of the Medicare physician fee schedule – which does not include overhead expenses.
- The hospital historically has submitted a separate Part B "facility charge" for the associated overhead expenses to its Part A **MAC**. The hospital's facility charge does not involve a separate service (such as a diagnostic test) furnished in addition to the physician's professional service; rather, it represents solely the overhead expenses associated with furnishing the professional service itself.
 - Accordingly, hospitals bill for "facility charges" under the physician evaluation and management (E&M) codes in the range of 99201-99245 and **G0463 (for hospitals paid under the outpatient prospective payment system)**.
- E&M codes, representing the hospital's "facility charge" for the overhead expenses associated with furnishing the professional service itself, are excluded from SNF consolidated billing (CB). Effective for claims with dates of service on or after January 1, 2006, Medicare's common working file will bypass CB edits when billed with revenue code 0510 (clinic visit) with an E&M HCPCS code in the range of 99201-99245 and, **effective January 1, 2014, with HCPCS code G0463**.

Section 30.1: Health Insurance Prospective Payment System (HIPPS) Rate Code

- The HIPPS rate code consists of the three-character resource utilization group (RUG) code that is obtained from the "grouper" software program followed by a two digit assessment indicator (AI) that specifies the type of assessment associated with the RUG code obtained from the grouper. **Providers may access the Resident Assessment Instrument (RAI) manual located at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html>.**

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Section 30.2: Coding PPS bills for ancillary services

When coding PPS bills for ancillary services associated with a Part A inpatient stay, the traditional revenue codes will continue to be shown, for example, 0250 Pharmacy, 042x Physical Therapy, in conjunction with the appropriate entries in service units and total charges.

- SNFs are required to report the number of units based on the procedure or service.
- For therapy services, that is revenue codes 042x, 043x, and 044x, units represent the number of calendar days of therapy provided. For example, if the beneficiary received physical therapy, occupational therapy or speech-language pathology on May 1, that would be considered one calendar day and would be billed as one unit.
- SNFs are required to report the actual charge for each line item, in total charges.

Section 30.3: Adjustment requests

Adjustment requests based on corrected assessments must be submitted within 120 days of the service “through” date. The “through” date will be used to calculate the period during which adjustment requests may be submitted based on corrected RAI assessments. The “through” date indicates the last day of the billing period for which the HIPPS code is billed. Adjustment requests based on corrected assessments must be submitted within 120 days of the “through” date on the bill. For HIPPS changes resulting from an MDS correction, providers must append a condition code D2 on their adjustment claim. An edit is in place to limit the time for submitting this type of adjustment request to 120 days from the service “through” date.

CMS expects that most HIPPS code corrections will be made during the course of the beneficiary’s Medicare Part A stay. Therefore, providers that routinely submit corrections after the beneficiary’s Part A stay has ended may be subject to focused medical review.

Adjustment requests to change a HIPPS code may not be submitted for any claim that has already been medically reviewed. This applies whether or not the medical review was performed either pre- or post-payment. All adjustment requests submitted are subject to medical review. Information regarding medical review is located in the *Medicare Program Integrity Manual*.

Section 40.3.5.2: Leave of absence

- Leave of absence (LOA) days are shown on the bill with revenue code 018x and LOA days as units. However, charges for LOA days are shown as zero on the bill, and the SNF cannot bill the beneficiary for them except as specified in Chapter 1 of this manual

at section 30.1.1.1. Occurrence span code 74 is used to report the LOA from and through dates.

- Providers should review the RAI manual to clarify situations where an LOA is not appropriate, for example observation stays in a hospital lasting greater than 24 hours.

‘Medicare Claims Processing Manual,’ Chapter 13

Section 90.5 (Transportation of Equipment Billed by a SNF to a MAC)

- When a SNF resident receives a portable X-ray service during the course of a Medicare-covered stay in the SNF, only the service’s professional component (representing the physician’s interpretation of the test results) is a separately billable physician service under Part B (see Section 20 of Chapter 6).
- By contrast, the technical component representing the procedure itself, including any associated transportation and setup costs, would be subject to consolidated billing (CB) (the SNF “bundling” requirement for services furnished to the SNF’s Part A residents), and must be included on the SNF’s Part A bill for the resident’s covered stay (bill type 21x) rather than being billed separately under Part B.

Additional information

The official instruction for CR 8997 was issued to your MAC via two transmittals. The first transmittal updates the *Medicare Claims Processing Manual* and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3230CP.pdf>. The second updates the *Medicare Benefit Policy Manual* and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R204BP.pdf>. If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - *How Does It Work?*

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General Coverage

Patient eligibility requirements for home health services

Provider types affected

This *MLN Matters*[®] article is intended for physicians, non-physician practitioners (NPPs), and home health agencies (HHAs) that submit claims to Medicare administrative contractors (MACs), including home health & hospice (HH&H) MACs for services provided to Medicare beneficiaries.

Provider action needed

Change request (CR) 9119 manualizes policies discussed in the calendar year 2015 home health prospective payment system (HH PPS) final rule published on November 6, 2014. CR 9119 instructs MACs to be aware of the revisions to the requirements for physician certification and recertification of patient eligibility for Medicare home health services. MACs are also instructed to be aware of the revised timeframe for therapy functional reassessments. Make sure that your billing staffs are aware of these changes.

Background

The Centers for Medicare & Medicaid Services (CMS) finalized clarifications and revisions to policies regarding physician certification and recertification of patient eligibility for Medicare home health services in the 2015 HH PPS final rule which was published on November 6, 2014 (see <http://www.gpo.gov/fdsys/pkg/FR-2014-11-06/pdf/2014-26057.pdf>). In the final rule, CMS also finalized revisions to the timeframe required for therapy functional reassessments.

Face-to-face encounter requirements

The Affordable Care Act requires that the certifying physician or allowed NPP must have a face-to-face encounter with the beneficiary before they certify the beneficiary's eligibility for the home health benefit.

CMS is implementing the following three changes to the face-to-face encounter requirements for episodes beginning on or after January 1, 2015. These changes will reduce administrative burden and provide HHAs with additional flexibilities in developing individual agency procedures for obtaining documentation supporting patient eligibility for Medicare home health care.

- CMS is eliminating the narrative requirement. The certifying physician is still required to certify (attest) that a face-to-face patient encounter occurred and document the date of the encounter as part of the certification of eligibility. For medical review purposes, Medicare requires documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to be used as the

basis for certification of patient eligibility.

- If a HHA claim is denied, the corresponding physician claim for certifying/re-certifying patient eligibility for Medicare-covered home health services is considered non-covered as well because there is no longer a corresponding claim for Medicare-covered home health services.
- CMS is clarifying that a face-to-face encounter is required for certifications, rather than initial episodes; and that a certification (versus a re-certification) is generally considered to be any time a new start of care assessment is completed to initiate care.

Therapy reassessments

CMS has eliminated the 13th and 19th visit therapy reassessment requirements. For episodes beginning on or after January 1, 2015; at least every 30 calendar days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient. This policy change will lessen HHAs' burden of counting visits. This change will reduce the risk of non-covered visits so that therapists can focus more on providing quality care for their patients, while still promoting therapist involvement and quality treatment for all beneficiaries regardless of the level of therapy provided.

Additional information

The official instruction, CR 9119, consists of two transmittals. The first updates the *Medicare General Information, Enrollment and Entitlement Manual* and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R91GI.pdf>. The second transmittal updates the *Medicare Benefit Policy Manual* at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R207BP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - *How Does It Work*.

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Preventive and screening services update

Note: This article was revised April 8, 2015, to reflect the revised change request (CR) 8874 issued April 3. In the article, the CR release date, transmittal number, and the Web address for accessing CR 8874 are revised. In addition, information regarding deductible and coinsurance applicability to HCPCS 00810 services in the “Anesthesia furnished in conjunction with colonoscopy” section of the article is updated. All other information remains the same. This information was previously published in the [January 2015 Medicare A Connection](#), Pages 11-13.

Provider types affected

This *MLN Matters*[®] article is intended for Medicare practitioners providing preventive and screening services to Medicare beneficiaries and billing Medicare administrative contractors (MACs) for those services.

Provider action needed

CR 8874 is an update from the Centers for Medicare & Medicaid Services (CMS) to ensure accurate program payment for three screening services. The coinsurance and deductible for these services are currently waived, but due to coding changes and additions, the payments for 2015 would not be accurate without updated CR 8874 for intensive behavioral group therapy for obesity, digital breast tomosynthesis, and anesthesia associated with screening colonoscopy. Make sure billing staffs are aware of these updates.

Background

The following outlines the CMS updates:

Intensive behavioral therapy for obesity

Intensive behavioral therapy for obesity became a covered preventive service under Medicare, effective November 29, 2011. It is reported with HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes). Coverage requirements are in the *Medicare National Coverage Determinations (NCDs) Manual*, Chapter 1, Section 210.

To improve payment accuracy, in 2015 physician fee schedule (PFS) proposed rule, CMS created a new HCPCS code for the reporting and payment of behavioral group counseling for obesity – HCPCS codes G0473 face-to-face behavioral counseling for obesity, group (2-10), 30 minutes).

For coverage requirements of intensive behavioral therapy for obesity, see the NCD for intensive behavioral therapy for obesity.

The same claims editing that applies to G0447 applies to G0473. Therefore, effective for claims with dates of service on or after January 1, 2015, MACs will recognize HCPCS code G0473, but only when billed with one of



the ICD-9 codes for body mass index (BMI) 30.0 and over (V85.30,-V85.39, V85.41-V85.45). (Once ICD-10 is effective, the related ICD-10 codes are Z68.30-Z68.39 and Z68.41-Z68.45.) When claims for G0473 are submitted without a required diagnosis code, they will be denied using the following remittance codes:

- **Claim adjustment reason code (CARC) 167:** This (these) diagnosis(es) is (are) not covered. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **Remittance advice remarks code (RARC) N386:** This decision was based on a NCD. An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.mcd.search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Effective for claims with dates of service on or after January 1, 2015, beneficiary coinsurance and deductible do not apply to claim lines with HCPCS code G0473.

Note that Medicare pays claims with code G0473 only when submitted by the following provider specialty types as found on the provider’s Medicare enrollment record:

- 01 – General practice
- 08 – Family practice
- 11 – Internal medicine
- 16 – Obstetrics/gynecology
- 37 – Pediatric medicine
- 38 – Geriatric medicine
- 50 – Nurse practitioner
- 89 – Certified clinical nurse specialist
- 97 – Physician assistant

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Claim lines submitted with G0473, but without an appropriate provider specialty will be denied with the following remittance codes:

- **CARC 8:** The procedure code is inconsistent with the provider type/specialty (taxonomy). **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.
- **Group Code CO** (if GZ modifier present) or PR (if modifier GA is present).

Further, effective for dates of service on or after January 1, 2015, claim lines with G0473 are only payable for the following places of service (POS) codes:

- 11 – Physician's office
- 22 – Outpatient hospital
- 49 – Independent clinic
- 71 – State or local public health clinic

Claim lines for G0473 will be denied without an appropriate POS code using the following remittance codes:

- **CARC 5:** The procedure code/bill type is inconsistent with the place of service. **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **RARC M77:** Missing/incomplete/invalid place of service.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

Remember that Medicare will deny claim lines billed for HCPCS codes G0447 and G0473 if billed more than 22 times in a 12-month period using the following codes:

- **CARC 119:** Benefit maximum for this time period or occurrence has been reached.
- **RARC N362:** The number of days or units of service exceeds our acceptable maximum.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

Note: MACs will display the next eligible date for obesity counseling on all MAC provider inquiry screens.

MACs will allow both a claim for the professional service and a claim for a facility fee for G0473 when that code is billed on type of bill (TOB) 13x or on TOB 85x when revenue code 096x, 097x, or 098x is on the TOB 85x. Payment on such claims is based on the following:

- TOB 13x paid based on the OPPS:
- TOB 85x in critical access hospitals based on reasonable cost; except
- TOB 85x Method II hospitals based on 115 percent of the lesser of the fee schedule amount or the submitted charge.

Institutional claims submitted on other than TOB 13x or 85x will be denied using:

- **CARC 171:** Payment is denied when performed by this type of provider on this type of facility. **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.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

Digital breast tomosynthesis

In the 2015 PFS final rule with comment period, CMS established a payment rate for the newly created CPT® code 77063 for screening digital breast tomosynthesis mammography. The same policies that are applicable to other screening mammography codes are applicable to CPT® code 77063. In addition, since this is an add-on code it should only be paid when furnished in conjunction with a 2D digital mammography.

Effective January 1, 2015, HCPCS code 77063 (*Screening digital breast tomosynthesis, bilateral (list separately in addition to code for primary procedure)*), must be billed in conjunction with the screening mammography HCPCS code G0202 (*Screening mammography, producing direct digital image, bilateral, all views, 2D imaging only*). Effective January 1, 2015, beneficiary coinsurance and deductible does not apply to claim lines with 77063 (*Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)*).

Payment for 77063 is made only when billed with an ICD-9 code of V76.11 or V76.12 (and when ICD-10 is effective with ICD-10 code Z12.31). When denying claim lines for 77063 that are submitted without the appropriate diagnosis code, the claim lines are denied using the following messages:

- **CARC 167:** This (these) diagnosis(es) is (are) not covered. **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

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coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.mcd.search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

On institutional claims:

- MACs will pay for tomosynthesis, HCPCS code 77063, on TOBs 12x, 13x, 22x, 23x based on MPFS, and TOB 85x with revenue code other than 096x, 097x, or 098x based on reasonable cost. TOB 85x claims with revenue code 096x, 097x, or 098x are paid based on MPFS (115 percent of the lesser of the fee schedule amount and submitted charge).
- MACs will pay for tomosynthesis, HCPCS code 77063 with revenue codes 096x, 097x, or 098x when billed on TOB 85x Method II based on 115 percent of the lesser of the fee schedule amount or submitted charge.
- MACs will return to the provider any claim submitted with tomosynthesis, HCPCS code 77063 when the TOB is not 12x, 13x, 22x, 23x, or 85x.
- MACs will pay for tomosynthesis, HCPCS code 77063, on institutional claims TOBs 12x, 13x, 22x, 23x, and 85x when submitted with revenue code 0403 and on professional claims TOB 85x when submitted with revenue code 096x, 097x, or 098x.
- Effective for claims with dates of service on or after January 1, 2015, MACs will RTP claims for HCPCS code 77063 that are not submitted with revenue code 0403, 096x, 097x, or 098x.

Anesthesia furnished in conjunction with colonoscopy

Section 4104 of the Affordable Care Act defined the term “preventive services” to include “colorectal cancer screening tests” and as a result it waives any coinsurance that would otherwise apply under Section 1833(a)(1) of the Act for screening colonoscopies. In addition, the Affordable Care Act amended Section 1833(b)(1) of the Act to waive the Part B deductible for screening colonoscopies. These provisions are effective for services furnished on or after January 1, 2011.

In the 2015 PFS proposed rule, CMS proposed to revise the definition of “colorectal cancer screening tests” to include anesthesia separately furnished in conjunction with screening colonoscopies; and in the 2015 PFS final rule with comment period, CMS finalized this proposal. The definition of “colorectal cancer screening tests” includes anesthesia separately furnished in conjunction with screening colonoscopies in the Medicare regulations

at Section 410.37(a)(1)(iii). As a result, beneficiary coinsurance and deductible does not apply to anesthesia services associated with screening colonoscopies.

As a result, effective for claims with dates of service on or after January 1, 2015, anesthesia professionals who furnish a separately payable anesthesia service in conjunction with a screening colonoscopy (HCPCS code 00810 performed in conjunction with G0105 and G0121) shall include the following on the claim for the services that qualify for the waiver of coinsurance and deductible:

- **Modifier 33: Preventive services** – when the primary purpose of the service is the delivery of an evidence based service in accordance with a USPSTF A or B rating in effect and other preventive services identified in preventive services mandates (legislative or regulatory), the service may be identified by adding 33 to the procedure. For separately reported services specifically identified as preventive, the modifier should not be used.

In addition, deductible is not applied to claim lines with HCPCS 00810 services that are billed with the PT modifier for services on or after January 1, 2015. The deductible is also not applied when the PT modifier is appended to at least either one of the CPT® codes within the surgical range of CPT® codes (10000-69999) or HCPCS codes G6018-G6028 on the claim for services that were furnished on the same date of service as the procedure. But, MACs will apply deductible and coinsurance to claim lines for HCPCS 00810 services billed without modifier 33 or modifier PT.

Additional information

The official instruction, CR 8874, issued to your MAC regarding this change is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3232CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - *How Does It Work*.

MLN Matters® Number: MM8874 *Revised*
Related Change Request (CR) #: CR 8874
Related CR Release Date: April 3, 2015
Effective Date: January 1, 2015
Related CR Transmittal #: R3232CP
Implementation Date: January 5, 2015

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.

Removal of multiple national coverage determinations using an expedited process

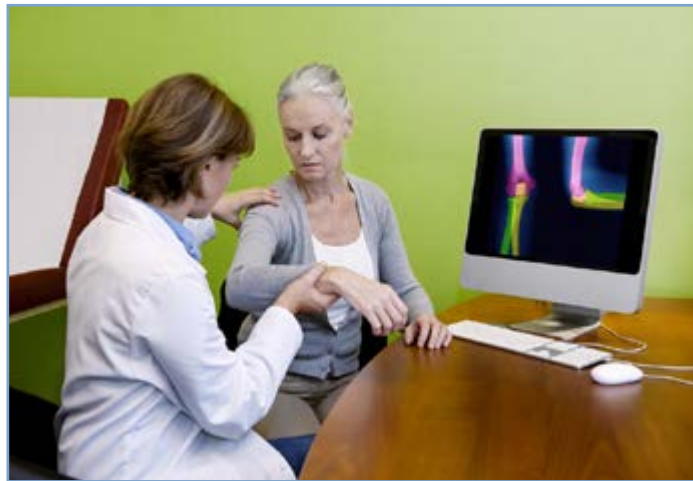
Note: This article was revised on March 28, 2015, to reflect the revised CR 9095 issued on March 27. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same. This article was previously published in the *March 2015 edition of Medicare A Connection, Page 14.*

Provider types affected

This *MLN Matters*[®] article is intended for physicians, providers, and suppliers who submit claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

Provider action needed

Effective December 18, 2014, change request (CR) 9095 removes Sections 50.6 – Tinnitus masking, 160.4 – Stereotactic Cingulotomy as a Means of Psychosurgery, 160.6 – Carotid Sinus Nerve Stimulator, 160.9 – Electroencephalographic (EEG) Monitoring During Open – Heart Surgery, 190.4 – Electron Microscope, 220.7 – Xenon Scan, and 220.8 – Nuclear Radiology Procedure from the Medicare *National Coverage Determinations Manual* or the *NCD Manual*. Providers and their staffs should be aware that removing an NCD results in coverage determinations being at the discretion of local MACs within their respective jurisdictions.



Background

CR 9095 removes seven NCDs from Publication 100-03, *NCD Manual*, pursuant to the expedited process that was established in an August 7, 2013, *Federal Register* (FR) notice (78 FR 48164).

The FR notice is available at <http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf>.

A CMS decision memorandum dated December 18, 2014, contains a summary of the expedited removal process and explicitly removes seven NCDs from the *NCD Manual* sections as follows:

- 50.6 – Tinnitus masking;
- 160.4 – Stereotactic Cingulotomy as a Means of Psychosurgery;

- 160.6 – Carotid Sinus Nerve Stimulator;
- 160.9 – Electroencephalographic (EEG) Monitoring During Open-Heart Surgery;
- 190.4 – Electron Microscope;
- 220.7 – Xenon Scan; and
- 220.8 – Nuclear Radiology Procedure.

You can review the CMS decision memorandum at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=29&mcDtypeName=National+Coverage+Determinations+Proposed+for+Removal&MCDIndexType=7&bc=AgAEAAAAAAAAAAA%3d%3d&>.

In the absence of an NCD, MACs should revert to historical standing policy and consider whether any Medicare claims for these services are reasonable and necessary under the Social Security Act (Section 1862(a)(1)(A)); see http://www.ssa.gov/OP_Home/ssact/title18/1862.htm) consistent with the existing guidance for making such decisions when there is no NCD.

Additional information

The official instruction, CR 9095, issued to your MAC

regarding this change is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R181NCD.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - *How Does It Work*.

MLN Matters[®] Number: MM9095
 Related Change Request (CR) #: CR 9095
 Related CR Release Date: March 27, 2015
 Effective Date: December 18, 2014
 Related CR Transmittal #: R181NCD
 Implementation Date: April 6, 2015

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Changes to the laboratory national coverage determination software for July 2015

Provider types affected

This *MLN Matters*[®] article is intended for physicians, other providers, and suppliers submitting claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

What you need to know

Change request (CR) 9124 informs MACs about the changes that will be included in the July 2015 quarterly release of the edit module for clinical diagnostic laboratory services. Make sure that your billing staffs are aware of these changes.

Background

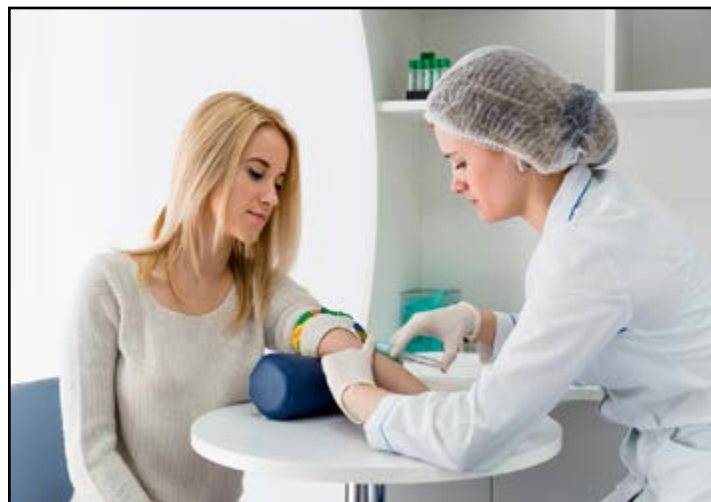
CR 9124 announces the changes that will be included in the July 2015 quarterly release of the edit module for clinical diagnostic laboratory services.

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

These changes are effective for services furnished on or after October 1, 2015, for International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10). (There are no ICD-9 updates in the July update.)

CR 9124 conveys four changes to the edit module, which are:

- Delete ICD-10-CM code I513 from the list of ICD-10-CM codes that are covered by Medicare for the Partial Prothrombin Time (PTT) (190.16) NCD;
- Add ICD-10-CM code S069X3A to the list of ICD-10-CM codes that are covered by Medicare for the Partial Prothrombin Time (PTT) (190.16) NCD;
- Delete ICD-10-CM codes I513 and T560X4A from the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD; and



- Add ICD-10-CM code S069X3A to the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.

Additional information

The official instruction, CR 9124 issued to your MAC regarding this change is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3228CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - *How Does It Work?*

MLN Matters[®] Number: MM9124
 Related Change Request (CR) #: CR 9124
 Related CR Release Date: April 3, 2015
 Effective Date: October 1, 2015
 Related CR Transmittal #: R3228CP
 Implementation Date: July 6, 2015

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Local Coverage Determinations

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 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.

More information

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

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



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**.

First Coast Service Options Inc provides current and draft local coverage determinations (LCDs), when they exist, for Medicare-covered procedure codes.

Not every procedure code is covered by an LCD. *Click here to look up current LCDs*



Noncovered services – revision to the LCD (HPV lab tests)

LCD ID number: L28991 (Florida)

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

The local coverage determination (LCD) for noncovered services has been revised to remove Current Procedural Terminology (CPT®) codes 87623-87625 (HPV testing) from the “Local Noncoverage Decisions/Laboratory Procedures” section of the LCD.

Claims submitted for CPT® codes 87623-87625 may have been denied in error with the following denial message: “These are non-covered services because this is not deemed a ‘medical necessity’ by the payer.”

This error was corrected **on April 8, 2015**. Claims processed on or after this date were adjudicated correctly. No action is required by providers.

Providers whose claims were incorrectly denied due to this error do not need to take any action.

First Coast Service Options Inc. will perform adjustments to correct the error on all the affected claims. We apologize for any inconvenience this may have caused.

Effective date

The LCD revision is effective for **claims processed on or after April 8, 2015**, for services rendered **on or after January 1, 2015**.

First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

Coding guidelines for an LCD (when present) may be found by selecting “Attachments” in the “Section Navigation” drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs, please [click here](#).

Hemophilia clotting factors – revision to the Part A LCD

LCD ID number: L28851 (Florida)

LCD ID number: L28884 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for hemophilia clotting factors was revised based on the Food and Drug Administration’s (FDA’s) approval of Obizur (antihemophilic factor (recombinant), porcine sequence) for the treatment of bleeding episodes in adults with acquired hemophilia A (acquired factor VIII deficiency), HCPCS codes C9399 and J7199 were added under the “CPT®/HCPCS Codes” section of the LCD, and diagnosis code 286.52 was added to the “ICD-9 Codes that Support Medical Necessity” section of the LCD for Obizur.

Additionally, language was added to the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD to include background on acquired hemophilia. The “Sources of Information and Basis for Decision” section of the LCD was also updated. In addition, based on change request (CR) 9097 and CR 9107 (April 2015 Quarterly Updates), HCPCS code C9136 was deleted and

replaced with HCPCS code Q9975.

Effective date

The LCD revision related to the addition of Obizur is effective for **claims processed on or after April 23, 2015**, for **services rendered on or after October 23, 2014**.

The LCD revision for the deletion of HCPCS codes C9136 and the addition of HCPCS code Q9975 is effective for **claims processed on or after April 6, 2015**, for **services rendered on or after April 1, 2015**.

First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

Coding guidelines for an LCD (when present) may be found by selecting “Attachments” in the “Section Navigation” drop-down menu at the top of the LCD page.

Note: To review active, future, and retired LCDs, please [click here](#).



Puzzled about your enrollment status?

Put the pieces together using the enrollment status lookup. View all active applications, specific applications, and confirm if you have been sent a revalidation request at <http://medicare.fcso.com/Enrollment/PEStatus.asp>

Changes to the investigational device exemption approval process

The Centers for Medicare & Medicaid Services (CMS) change request (CR) 8921, announced changes effective on or after January 1, 2015, to Medicare coverage requirements and review procedures related to the Food and Drug Administration (FDA) approved Category A (Experimental) and Category B (Nonexperimental/ investigational) IDE studies.

Effective for Category A and B IDE studies approved by the FDA on or after January 1, 2015, study sponsors that wish to seek Medicare coverage must submit a request for review and approval to CMS. CMS approval for a Category A IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. A CMS approval for a Category B (Nonexperimental/ investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial. Refer to the *Medicare Benefit Policy Manual*, Chapter 14 for detailed instructions on seeking CMS approval.

To ensure proper claims payment, First Coast Service Options, Inc. (First Coast), the Part A and Part B claims administrator for jurisdiction N (JN) will continue to require investigational study sites to submit for the contractor's review, all documentation that is currently required. Please refer to the following article titled "Investigational device exemption (IDE) approval requirements" and request form for a complete list of items the contractor requires for each investigational site. Study sites may submit all of the documentation electronically to clinicaltrials@fcsso.com.

Of note, the contractor no longer requires study sites to send a list of Medicare beneficiaries participating in any

approved study for Category B IDE Extension Requests.

For IDE studies approved by CMS, the JN MAC will require a copy of the complete FDA approval letter(s) provided to the principal investigator and/or the sponsor or manufacturer of the device, AND a copy of the CMS approval as posted on the CMS website.

Useful links related to devices and clinical trials:

[Devices and clinical trials -- clinical trials background information](#)

[Clinical trial coding and cost information form](#)

[Post-approval and 510K for carotid artery stenting \(CAS\) study continuation request](#)

[Post-approval and 510K extension studies for CAS approval requirements and request form](#)

[Humanitarian use device exemption \(HUD/HDE\)](#)

[Investigational device exemption \(IDE\) approval requirements and request form](#)

[IDE extension requirements and request form](#)

[Medicare Benefit Policy Manual \(Pub. 100-02, Ch. 14\), medical devices](#)

[Food and Drug Administration \(FDA\) clinical trial and investigational device exemption Web page](#)

[Frequently asked questions \(FAQs\) about clinical trials and device coverage](#)

Contact [MAC JN First Coast Service Options' Medical Policy & Procedures Dept. via email](#)



Learn the secrets to billing Medicare correctly

Who has the power to improve your billing accuracy and efficiency?

You do – visit the *Tools to 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 First Coast's most popular self-audit resources, including the E/M interactive worksheet, provider data summary (PDS) report, and the comparative billing report (CBR).

Devices and clinical trials

Medicare covers the use of devices that are “reasonable and necessary for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member”.

Certain Health & Human Services (HHS) agencies have addressed agreements to facilitate the categorization and approval of devices for marketing related to safety issues under The Food and Drug Administration (FDA) jurisdiction and to facilitate consideration of Medicare coverage related to the reasonable and necessary threshold under the Centers for Medicare & Medicaid Services (CMS) jurisdiction. (See definitions at the end of this article.)

The CMS delegates responsibilities to its Medicare administrative contractors (MACs) for Medicare claims administration that encompass proper billing and coding by the provider and coverage and payment by the contractor via its systems – FISS (for Part A providers including hospitals) and MCS (Part B providers including physicians). For dates prior to January 1, 2015, Part A and B MAC administers pre-approval of clinical trials limited to certain DEVICE categories in clinical studies as outlined below.

Claims for devices described by these categories cannot be considered for coverage until the pre-approval requirements are met and acknowledged in writing by the medical policy and procedures department at First Coast Service Options Inc.

Principle investigators (PIs) and Medicare providers conducting research studies with traditional Medicare patients should be familiar with several regulations and guidance documents:

1. Medicare consideration of coverage of category B devices under the investigational device exemption (IDE) provision. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

There are devices which are refinements of existing technologies or replications of existing technologies made by other manufacturers. Many of these devices are under an FDA-approved IDE as a means of gathering the scientific information (via a clinical study) needed for FDA to establish the safety and effectiveness of that particular device, even though there is evidence that the device type can be safe and effective.

On September 8, 1995, the FDA entered into an agreement with the administrator of the Medicare program, the Health Care Finance Administration (HCFA- now CMS), to provide information about devices under an IDE to aid in its reimbursement decisions. Under this agreement certain devices could be viewed as “reasonable



and necessary” by Medicare and treatments could be covered if all other applicable Medicare coverage requirements are met. This was a compromise to address the coverage of devices given that Medicare does not usually cover investigational services/procedures.

Specifically, FDA will place all IDEs it approves in one of two categories:

Category A – experimental (not covered by Medicare)

The IDE involves innovative devices in which “absolute risk” has not been established (i.e., initial questions of safety and effectiveness have not been resolved and thus FDA is unsure whether the device type can be safe and effective)

Category B – investigational; non-experimental (can be covered by Medicare)

The clinical investigations involve device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved).

This category includes device types that can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Non-significant risk studies may also be included in this category.

FDA provides the category determination on the IDE approval letter to the sponsor and also forwards this information to CMS. An approved IDE is identified by a six-digit IDE number preceded by a “G” (Gxxxxxx). Investigators/Providers must submit all the required information on the device and clinical study for contractor review and approval prior to submitting Medicare claims. The Part A and Part B MAC required IDE pre approval process is outlined on the website.

2. Medicare clinical trials policies. <http://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html>

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On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health & Human Services to “explicitly authorize [Medicare] payment for routine patient care costs... and costs due to medical complications associated with participation in clinical trials.”

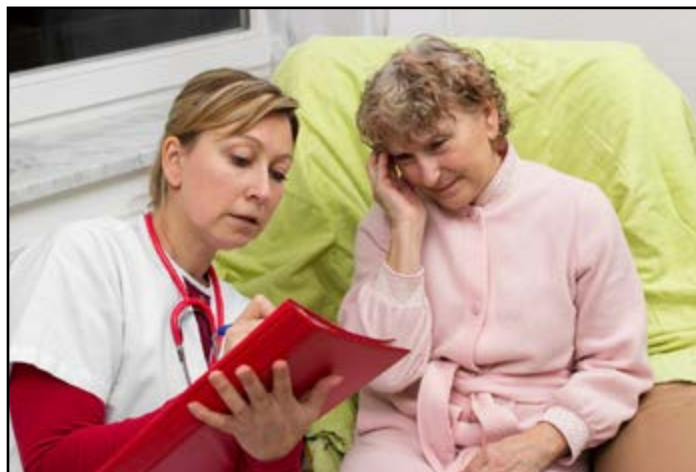
Medicare covers the routine costs of qualifying clinical trials, as such costs are defined in national coverage determination (NCD) 310.1 (routine cost in clinical trials, version 2 effective July 9, 2007), as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply. The definition of a routine cost excludes the investigational item or service, itself, unless otherwise covered outside of the clinical trial. Though submitting a Medicare claim for routine cost in a qualifying clinical trial has specific billing requirements, Contractors do not pre review clinical trials except for certain device categories as noted in this article.

Therefore, physicians and allied providers must be compliant with applicable billing, coding, and coverage requirements via the two claim systems (physician and facility claims) in regard to patients in clinical trials. Claims for traditional Medicare beneficiaries in clinical trials should meet the requirements of NCD 310.1 in that the services billed as routine cost must meet the definition of routine cost, and the clinical trial must be a qualifying trial.

Effective January 1, 2005 (change request [CR] 3548, Transmittal 131) Medicare covers the routine cost of clinical trials involving IDE category A devices (the device itself remains non covered) assuming all aspects of the contractor’s pre approval IDE process are met and only when the device is used in the trial for the diagnosis, monitoring, or treatment on an immediately life-threatening disease or condition (defined as “a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment”).

3. CMS has asked its contractors to assist in the administration of certain national coverage determinations (NCDs)

NCDs such as percutaneous transluminal angioplasty (PTA) (20.7) located at the following website: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201&ncdver=8&bc=BAABAAAAAgAA&> (specific indication - Carotid Artery Stenting [CAS]) with pre-approval of certain IDE studies and certain post approval studies. Also, a CMS NCD can incorporate broader authority such as coverage with evidence development (CED) that may require the contractor to administer information such as approved



facility, registry verification, or other data. Located at the following website: <http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Medicare-Coverage-Guidance-Documents-.html>. Such requirements are published to the provider community.

Post-approval studies & post-approval extension studies related to CAS procedures

Effective October 12, 2004 (CR 3489, Transmittal 314), Medicare covers Percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. As the post-approval studies began to end, CMS extended coverage to post-approval extension studies that receive FDA review of each study protocol (effective February 28, 2006, CR 5088).

The process for claims for post-approval studies and post-approval extension studies is similar to the Category B IDE pre approval process, except that under post-approval coverage, providers must use the pre-market approval (PMA) number assigned to the stent system by the FDA given that the FDA cannot issue post marketing numbers. The FDA will issue a letter acknowledging a valid study, and CMS will issue a letter to the sponsor (and both letters should be submitted to the contractor along with the other materials). An approved PMA number is a six-digit number preceded by a “P” (Pxxxxxx).

510K Post-approval extension studies related to embolic protection devices during CAS procedures

Effective October 22, 2010 (CR 7249, Transmittal 2113), CMS has determined that all 510K post-approval extension studies must be reviewed by the FDA. The FDA will issue an acknowledgment letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data.

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Upon receipt of this letter and review of the 510k post-approval extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. The process for claims for 510k post-approval studies is similar to the Category B IDE pre approval process except that the FDA evaluates these studies via the pre-IDE process and each 510k post-approval extension study is identified by a six-digit study identification number preceded by an "I" (Ixxxxx).

In December 2013, CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local Medicare administrative contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies.

An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services (NCD 310.1-Routine Costs in Clinical Trials) furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial.

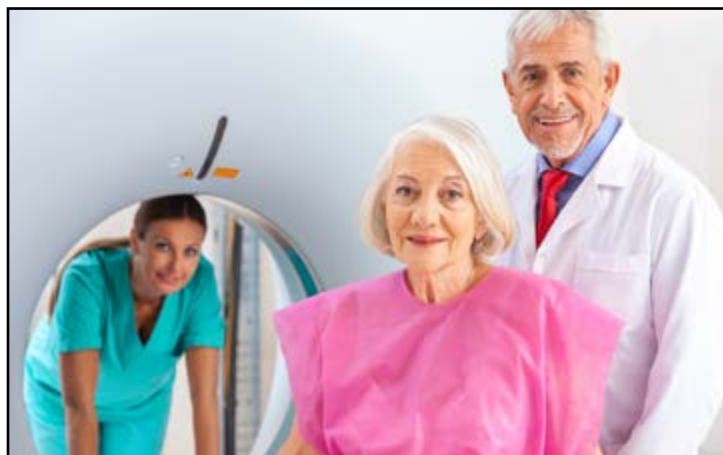
Based on CR 8921, CMS announced changes effective on and after January 1, 2015, to Medicare coverage requirements and review procedures related to Category A and B IDE studies. Please refer to the following Medicare manuals:

- *Medicare Benefit Policy Manual*, Chapter 14;
- *Medicare Benefit Policy Manual*, Chapter 16, Section 10; and
- *Medicare Claims Processing Manual*, Chapter 32, Section 68.

IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by the MAC. Study sponsors do not have to submit the protocol to CMS if the participating study investigator sites have already received approval from their MAC. Study sponsors should continue to follow the process established by the MAC for any site additions or protocol changes.

In summary, Medicare limits pre-approval of clinical trials to DEVICES, specifically to Category A and B IDEs and certain post approval studies related to CAS procedures. The Part A and the Part B MAC required IDE pre approval process outlined on the website includes the following topics:

- Background on devices and clinical trials (this document)
- Medicare routine cost in clinical trials NCD (#310.10)



Located at the following website: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&SearchType=Advanced&CoverageSelection=National&NCSelection=NCD&Keyword=clinical+trials&KeywordLookUp=Doc&KeywordSearchType=Exact&kq=true&bc=IAAABAAAAAA&>.

- IDE coverage background and approval requirements done prior to any claim submission (Also addresses related requirements for post approval studies. Link to clinical trials on the First Coast website Coding & Cost form & IDE extension request requirements: http://medicare.fcso.com/Clinical_trials/138007.pdf)
- IDE, post – approval, and 510 K billing guidelines (submission of claims post approval)
- HUD background – see paragraph below. Clinical trials are not reviewed.
- Frequently asked questions on devices and clinical trials (available on the First Coast provider website: http://medicare.fcso.com/Clinical_trials/195745.asp)
- Of note, a humanitarian use device (HUD), as defined by the Food and Drug Administration (FDA), is a device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals per year in the United States. Part A and Part B MAC does not review clinical trials for HDE (humanitarian device exemption) given trials are not a requirement of the FDA and Medicare coverage of such devices would be rare and very patient specific. Such devices may only be used in institutions where a local institutional review board (IRB) has approved the use of the device to treat or diagnose the specific rare disease. Medicare Part A and Part B MAC administer claims under HDE on a case by case basis. See article on website for information that must be made available if practitioner and/or institutional records are requested (pre or post payment) related to claim submission.

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(As with any claim, payment of claim does not mean coverage hurdle met since not all claims are reviewed prepayment.)

Definitions

HHS

Department of Health and Human Services – refers to cabinet department of the United States government with the goal of protecting the health of all Americans and providing essential human services

FDA

Food and Drug Administration – agency of HHS responsible for protecting and promoting public health through the regulation and supervision of medical device safety (as well as drugs and other products with medical applications).

FDA definitions: <http://www.fda.gov/MedicalDevices/default.htm>.

CMS

Centers for Medicare & Medicaid Services (CMS) – previously known as the Health Care Financing Administration (HCFA), agency of HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and Health Insurance Portability and Accountability Act (HIPAA) standards.

MACs

Medicare administrative contractors – entities contracted with CMS to administer various aspects of the Medicare program and specifically claims payment for medically reasonable and necessary services.

A/B MAC

First Coast Service Options Inc. is the Medicare Part A and B MAC for (Florida, Puerto Rico, and the U.S. Virgin Islands).

FISS

Fiscal intermediary standard system – used to process Medicare claims related to medical care provided by hospitals (Part A and certain Part B benefits) and by certain other providers that submit claims via the UB04 format.

MCS

Multi-carrier system – used to process Medicare claims related to non-hospital based physician care and to certain other Part B services that submit via the CMS-1500 format.

Medical devices – classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. (Some Class III pre-amendment devices may require a Class III 510(k).)

Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Examples of Class I devices include examination gloves hand & held surgical instruments; Class II devices include powered wheelchairs & infusion pumps; and Class III devices include replacement heart valves (PMA needed) & implantable pacemaker pulse generator (PMA generally needed).

Premarket approval (PMA) – 21 CFR (Code of Federal Regulations) Part 814 -- product requiring PMAs are Class III devices that are high risk devices that pose a significant risk of illness or injury,

or devices found not substantially equivalent to Class I and II predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device. A premarket approval means any premarket approval application for a Class III medical device, including all information submitted with or incorporated by reference therein.

Premarket notification (PMN or 510(k)) – a 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. This type of submission is used for most Class II devices and some Class I devices (and some Class III devices).

See **TRIALS**, next page



TRIALS

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The majority of these submissions do not involve clinical data.

Investigational device exemption (IDE) – allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification [510(k)] submission to FDA. clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application.

Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. IDE refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.

Significant risk device (SR device) – an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject.

Investigator – an individual who actually conducts a clinical investigation, i.e., under whose immediate direction



the investigational device is administered, dispensed to, or used involving a subject. In the event of an investigation being conducted by a team of individuals, "investigator" refers to the responsible leader of that team.

Sponsor – a person or other entity that initiates but does not actually conduct the investigation. An entity other than an individual (e.g., a corporation or an agency) which uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor, not a sponsor-investigator, and the employees are considered to be investigators. The sponsor of an IDE must be located in the United States (see 21 CFR 812.18).

Sponsor-investigator – an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed, or used. The term does not, for example, include a corporation or agency. The obligations of a sponsor-investigator include those of an investigator and those of a sponsor.

Comment period extended for skin substitute grafts

Application of skin substitute grafts for treatment of DFU and VLU of lower extremities-published for an additional 45-day comment period

Draft LCD, application of skin substitute grafts for treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) of lower extremities was initially published for a 45-day comment period in June 2014. The draft is being reposted for an additional 45-day comment period given input from practicing physicians suggested revised language and indication changes that could be considered more restrictive coverage criteria. The current comment period will extend from April 10 through May 25, 2015.

Any comments previously submitted to the contractor during the 45-day comment period in June 2014 will be addressed along with any new comments submitted during the current 45-day comment period.

Comments should be submitted to the medical policy department at medical.policy@fcsso.com. After review of all comments, this revised draft policy will be finalized and posted for a 45-day notice period, followed by implementation.

The draft LCD can be viewed by selecting the following link: http://www.cms.gov/medicare-coverage-database/reports/draft-lcd-status-report.aspx?name=370*1&bc=AQAAGAAAAAAAA%3d%3d&#ResultAnchor

Reimbursement

Partial hospitalization coding and per diem payments

Provider types affected

This *MLN Matters*[®] special edition is intended for hospitals and community mental health centers (CMHCs) that submit claims to Medicare administrative contractors (MACs) for partial hospitalization program (PHP) services provided to Medicare beneficiaries.

What you need to know

This article alerts providers that the Centers for Medicare & Medicaid Services (CMS) issued the 2015 final corrected per diem payment rates for PHP services. See the *Additional information* section of this article for specifics.

Background

CMS reminds hospitals and CMHCs that provide PHP services to follow existing claims coding requirements given in the *Medicare Claims Processing Manual*, Chapter 4, Section 260. This manual section is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>.

Those requirements include using acceptable revenue codes and appropriate Healthcare Common Procedure Coding System (HCPCS) codes for reporting PHP services. Acceptable revenue codes for hospitals and CMHCs providing PHP services are as shown in the following table:

Table 1: Acceptable revenue codes for hospitals and CMHCs providing PHP services

Revenue code	Description
0250	Drugs and biologicals
043X	Occupational therapy
0900	Behavioral health treatment/services
0904	Activity therapy
0914	Individual therapy
0915	Group therapy

Revenue code	Description
0916	Family therapy
0918	Testing
0942	Education training

PHP providers (other than critical access hospitals) are required to report appropriate HCPCS codes on their claims. As described in the *Medicare Claims Processing Manual*, the appropriate HCPCS codes for services paid in the PHP per diem rate are as presented in the following table:

Table 2: HCPCS codes for services paid in the PHP per diem rate

Revenue code	HCPCS code
043X	G0129
0900	90791 or 90792
0904	G0176
0914	90785, 90832, 90833, 90834, 90836, 90837, 90838, 90845, 90865, or 90880
0915	G0410 or G0411
0916	90846 or 90847
0918	96101, 96102, 96103, 96116, 96118, 96119, or 96120
0942	G0177

Note: Remember that revenue code 0250 does not require HCPCS coding. Medicare does not cover drugs that can be self-administered. Your MAC will edit to ensure that HCPCS codes are present when the above revenue codes are billed and that they are valid HCPCS codes.

2015 PHP final corrected per diem payment rates

The 2015 final corrected per diem payment rates for PHP services are as follows below in Table 3:

Table 3: 2015 PHP Final Corrected Per Diem Payment Rates

Amb. pmt. class. (APC)	Group title	Status ind. (SI)	Relative wt.	Pmt. rate	Ntl. unadj. co-pmt	Min. unadj co-pmt
0172	Level I Partial Hospitalization (3 services) for CMHCs	P	1.3016	\$96.54		\$19.31
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	P	1.5406	\$114.27		\$22.86
0175	Level I Partial Hospitalization (3 services) for Hospital-based PHPs	P	2.4157	\$179.18		\$35.84
0176	Level II Partial Hospitalization (4 or more services) for Hospital-based PHPs	P	2.6384	\$195.70		\$39.14

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PARTIAL

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The 2015 PHP final rule per diem payment rates were published in Addendum A to the Hospital Outpatient Prospective Payment Final Rule with comment period and 2015 payment rates, which is available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-FC.html>.

The per diem rates were corrected, and the final rates are now posted at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>.

The correction notice is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-CN.html>.

Additional information

If you have any questions, please contact your DME MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under *How Does It Work*.

MLN Matters® Number: SE1512
Related Change Request (CR) #: NA
Related CR Release Date: NA
Effective Date: NA
Related CR Transmittal #: NA
Implementation Date: NA

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. CPT only copyright 2014 American Medical Association.

New RARC alerts providers about transition to ICD-10

By mid-April, providers will begin seeing a new remittance advice remark code (RARC) N742 on their remittance advices (RAs), "Alert: This claim was processed based on one or more ICD-9 codes. The transition to ICD-10 is required by October 1, 2015, for health care providers, health plans, and clearinghouses.

More information can be found at <http://www.cms.gov/Medicare/Coding/ICD10/ProviderResources.html>." Medicare administrative contractors will start using the new RARC in April.

Since RARCs are an industry standard, the new RARC

has been available for other health plans to use since March 1, 2015.

This is another example of the unprecedented level of outreach by CMS to prepare the health care community for ICD-10.

CMS has a very mature and rigorous testing program for its Medicare fee-for-service claim processing systems and has completed extensive testing in preparation for ICD-10.

CMS is ready for ICD-10 and encourages medical practices and hospitals that bill Medicare to complete their preparations for the October 1, 2015, implementation date.

CMS updates IRIS software for reporting on resident training

The IRIS software programs (IRISV3 and IRISEDV3) each have three updated files (medical school codes, residency type codes, and IRISV3 Operating Instructions) for collecting and reporting information on resident training in hospital and non-hospital settings. They are categorized as follows:

- August 2014 IRISV3 operating instructions and excerpts from IRISV3 operating instructions to use with IRISEDV3:
- The Centers for Medicare & Medicaid Services (CMS)

added nine new IRIS residency type codes to the IRIS residency type code table.

- CMS also added seven new IRIS medical school codes to the IRIS medical school code table.

Providers may begin using the new medical school and residency type codes in the IRIS programs for cost reporting periods ending on or after June 30, 2014.

The IRIS programs are available for downloading via the IRIS website (<http://go.usa.gov/Grw3>)

Correcting the display issue for OPPS claims where value code 'FD' is present

Note: CMS updated this article April 17, 2015, to add type of bill 12x to the notice. This article was previously printed in the [March 2015 Medicare A Connection, Page 40](#).

CMS is correcting a display issue for outpatient prospective payment system (OPPS) claims with value code "FD," which was caused by the implementation of payer-only value code "QD."

The following claims are affected:

- Type of Bill 12x, 13x

- Processed on or after January 1, 2014 and prior to the July 2015 OPSS Pricer quarterly release
- Value code "FD" is present

Medicare administrative contractors will be mass adjusting any processed claims not reflecting a difference that met the above criteria within 60 days after successful implementation of the payer-only value code "QD" into production on or about July 6, 2015.

No action is required by providers.

Claim hold for the April 2015 OPSS pricer for code A9586

Medicare administrative contractors (MACs) have been notified by the Centers for Medicare & Medicaid Services (CMS) of an error in the third release of the April 2015 outpatient prospective payment system (OPSS) pricer. The coinsurance amount was erroneously set to \$551.20 instead of \$0.00 for HCPCS code A9586.

For dates of service on and after April 1, 2015, A/B MACs shall hold all OPSS claims on type of bill 12x and 13x for HCPCS code A9586. Upon installation of the July 2015 OPSS pricer into production on or around July 6, 2015, A/B MACs shall release any suspended claims for OPSS providers and, if applicable, append condition code 15.

Attention health professionals: information regarding the Medicare Access and CHIP Reauthorization Act of 2015

On April 14, 2015, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015; the President is expected to sign it shortly. This law eliminates the negative update of 21 percent scheduled to take effect as of April 1, 2015, for the Medicare physician fee schedule.

In addition, provisions allowing for exceptions to the therapy cap, add-on payments for ambulance services, payments for low volume hospitals, and payments for Medicare dependent hospitals that expired on April 1 have been extended. CMS will immediately begin work to implement these provisions.

In an effort to minimize financial effects on providers, CMS previously instituted a 10-business day processing hold for all impacted claims with dates of service April 1, 2015, and later. While the Medicare administrative contractors (MACs) have been instructed to implement the rates in the legislation, a small volume of claims will be processed at the reduced rate based on the negative update amount. The MACs will automatically reprocess claims paid at the reduced rate with the new payment rate.

No action is necessary from providers who have already submitted claims for the impacted dates of service.

Mass adjustment of OPSS claims with APC 1448

For outpatient prospective payment system (OPSS) claims with ambulatory payment classification (APC) 1448 (ophthalmic mitomycin), the national unadjusted copayment was erroneously set to 20 percent instead of \$0 for claims with dates of service of January 1, 2014, through claims received prior to the installation of the April 2015 OPSS pricer.

The error has been corrected in the April 2015 OPSS addendums A and B, as well as in the release of the April 2015 OPSS pricer.

Medicare administrative contractors will mass adjust affected claims to issue corrected payments. Providers must reimburse beneficiaries for any overpayment of copayment caused by this error.

Educational Events

Provider outreach and educational events – May 2015

Chiropractic services and documentation webcast

When: Thursday, May 14
Time: 11:30 a.m. - 1:30 p.m. ET – Delivery language: English
Type of Event: Webcast
Location: Jacksonville, FL
http://medicare.fcso.com/Events/0240294.asp

Medicare Speaks: Fort Lauderdale

When: May 19-20
Time: 7:30 a.m. -4:30 p.m. ET – Delivery language: English
Type of Event: Conference/Seminar
http://medicare.fcso.com/Medicare_Speaks/278353.pdf

Two easy ways to register

- 1. Online – Visit www.fcouniversity.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 with no 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 First Coast 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 www.fcouniversity.com.



CMS MLN Connects® Provider eNews

The Centers for Medicare & Medicaid Services (CMS) MLN Connects® Provider eNews is an official *Medicare Learning Network*® (MLN) – branded product that contains a week’s worth of news for Medicare fee-for-service (FFS) providers. CMS sends these messages weekly to national health industry provider associations, who then disseminates the e-News to their membership as appropriate.

MLN Connects® Provider eNews for March 26, 2015

MLN Connects® Provider eNews for March 26, 2015

[View this edition as a PDF](#)

In this edition:

MLN Connects® National Provider Calls

- Medicare Shared Savings Program ACO: Preparing to Apply for 2016 — Register Now
- Open Payments (Sunshine Act) 2015: Prepare to Review Reported Data — Registration Now Open
- How to Register for the PQRS Group Practice Reporting Option in 2015 — Registration Now Open
- Medicare Shared Savings Program ACO: Application Process — Register Now
- New MLN Connects® National Provider Call Audio Recording and Transcript

CMS Events

- Volunteer for ICD-10 End-to-End Testing in July — Forms Due April 17
- Medicare Basics for New Providers Webinar — Register Now

Announcements

- DOJ and HHS Announce over \$27.8 Billion in Returns from Joint Efforts to Combat Health Care Fraud
- HHS Announces Proposed Rules to Support the Path to Nationwide Interoperability
- Star Ratings for Home Health Compare: Provider Preview Reports Available in Late March
- Medicare EHR Incentive Program Hospitals: Apply for Hardship Exception by April 1

Claims, Pricers, and Codes

- New RARC Alerts Providers about Upcoming Transition to ICD-10
- Updates to IRIS Software
- FY 2015 Inpatient PPS PC Pricer Update Available

Medicare Learning Network® Educational Products

- “Safeguard Your Identity and Privacy Using PECOS” Fact Sheet — Reminder
- “Internet-based PECOS FAQs” Fact Sheet — Reminder
- Medicare Learning Network® Product Available In Electronic Publication Format

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MLN Connects® Provider eNews – Special Edition

Update on the status of provisions expired April 1

The negative 21 percent payment rate adjustment under current law for the Medicare Physician Fee Schedule is scheduled to take effect on April 1, 2015. CMS is taking steps to limit the impact on Medicare providers and beneficiaries by holding claims for a short period of time beginning today (April 1, 2015).

Holding claims for a short period of time allows CMS to implement any subsequent Congressional action while minimizing claims reprocessing and disruption of physician cash flow in the event of legislation addressing the 21 percent payment reduction. Under current law, electronic claims are not paid sooner than 14 calendar days (29 days for paper claims) after the date of receipt. As we stated [in our recent email](#) to physicians, CMS will provide more information about next steps by April 11, 2015.

In addition to the Medicare physician fee schedule adjustment, other provisions affecting providers will also expire by April 1, including exceptions to the outpatient therapy caps, add-on payments for ambulance services, payments for low volume hospitals, and payments for Medicare dependent hospitals. These provisions include:

Exceptions process for Medicare Part B outpatient therapy caps—These caps are the annual per beneficiary cap amounts for occupational therapy and for physical therapy and speech-language pathology services combined, determined for each calendar year.

Based on current law, exceptions to the therapy caps, which are allowed for reasonable and necessary therapy services above the caps, will be considered only for dates of service through March 31, 2015.

Add-on Payments for Ambulance Services—Currently Medicare provides for an increase in the ambulance

fee schedule amounts (both base rate and mileage) for covered ground ambulance transports that originate in rural areas by three percent and covered ground ambulance transports that originate in urban areas by two percent.

In addition, currently Medicare provides for an increase of 22.6 percent in the base rate of the ambulance fee schedule amount for covered ground ambulance transports that originate in rural areas designated as super rural. These provisions expire today (April 1, 2015).

Payments for Low-Volume Hospitals and Medicare Dependent Hospitals—The Affordable Care Act and subsequent legislation made temporary changes to the low-volume hospital payment adjustment for hospitals that meet certain discharge and mileage criteria.

The Medicare Dependent Hospital program also provides enhanced payment to support small rural hospitals for which Medicare patients make up a significant percentage of inpatient days or discharges. These temporary changes to the low-volume hospital adjustment and the Medicare Dependent Hospital provision expire today (April 1, 2015).

Recovery Auditor Inpatient Hospital Status Reviews—CMS will continue to prohibit Recovery Auditor inpatient hospital patient status reviews for dates of admission occurring between October 1, 2013 and April 30, 2015. In addition, CMS will continue the Inpatient Probe and Educate process through April 30, 2015.

CMS must take steps to implement the negative update and the expiration of the other provisions noted above. Providers should remember that claims for services furnished on or before March 31, 2015 are not affected by the payment cut and will be processed and paid under normal time frames. We are working to limit any impact to Medicare providers and beneficiaries as much as possible.

Expand your knowledge of Medicare

Visit the *Medicare Learning Network*® (MLN) Educational Web Guides Overview page, for educational and informational resources to improve your knowledge of Medicare billing and policies.

The *MLN Educational Web Guides* provides information on evaluation and management (E/M) services; guided pathways to resources and topics of interest; lists of health care management products; as well as easy-to-understand billing and coding products.

[Click here](#) to explore educational Web guides.



MLN Connects® Provider eNews for April 2, 2015

MLN Connects® Provider eNews for April 2, 2015

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MLN Connects® National Provider Calls

- Medicare Shared Savings Program ACO: Preparing to Apply for 2016 — Last Chance to Register
- Open Payments (Sunshine Act) 2015: Prepare to Review Reported Data — Register Now
- How to Register for the PQRS Group Practice Reporting Option in 2015 — Register Now
- Medicare Shared Savings Program ACO: Application Process — Register Now
- New MLN Connects® National Provider Call Audio Recording and Transcript

CMS Events

- Volunteer for ICD-10 End-to-End Testing in July — Forms Due April 17

Announcements

- Screening and Counseling to Reduce Alcohol Misuse
- Newly Approved Drugs and Biologicals
- Notices of Intent to Apply for Medicare Shared Savings Program January 1, 2016, Start Date Due by May 29

MLN Connects® Provider eNews for April 9, 2015

MLN Connects® Provider eNews for April 9, 2015

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MLN Connects® National Provider Calls

- Open Payments (Sunshine Act) 2015: Prepare to Review Reported Data — Last Chance to Register
- How to Register for the PQRS Group Practice Reporting Option in 2015 — Last Chance to Register
- Medicare Shared Savings Program ACO: Application Process — Register Now

CMS Events

- Volunteer for ICD-10 End-to-End Testing in July — Forms Due April 17
- Webinar for Comparative Billing Report on Ophthalmology

Announcements

- Results From March 2015 ICD-10 Acknowledgement Testing Week

- Register for the Health Care Payment Learning and Action Network
- Quarterly Provider Update for April 2015
- CMS is Accepting Suggestions for Potential PQRS Measures

Claims, Pricers, and Codes

- Modifications to HCPCS Code Set
- Partial Hospitalization Program Claims Coding and Payment Rates for CY 2015
- New RARC Alerts Providers about Upcoming Transition to ICD-10

Medicare Learning Network® Educational Products

- “Preventive Services” Educational Tool — Revised
- “Long Term Care Hospital Prospective Payment System” Fact Sheet — Revised
- “Clinical Laboratory Fee Schedule” Fact Sheet — Revised
- “Medicare Appeals Process” Fact Sheet — Reminder
- “Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians” Fact Sheet — Reminder
- Medicare Learning Network® Product Available In Electronic Publication Format

- Prepare for a Successful Transition to ICD-10 with Medicare Testing Resources
- 2015 PV-PQRS GPRO Registration is Now Open
- Open Payments Physician and Teaching Hospital Review and Dispute Period Began April 6
- EHR Stage 3 Proposed Rule: Comment Period Closes May 29
- Medscape Article for CME Credit: Public Reporting on Quality and Payments

Claims, Pricers, and Codes

- Mass Adjustment of OPSS Claims with APC 1448
- April 2015 Outpatient Prospective Payment System Pricer File Update
- January 2015 PPS Provider Data Available — Revised

Medicare Learning Network® Educational Products

- “Food and Drug Administration Approval of First Biosimilar Product” MLN Matters® Article — Released
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MLN Connects® Provider eNews for April 16, 2015

MLN Connects® Provider eNews for April 16, 2015

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In this edition:

MLN Connects® National Provider Calls

Medicare Shared Savings Program ACO: Application Process — Last Chance to Register

CMS Events

Volunteer for ICD-10 End-to-End Testing in July — Forms Due April 17

Announcements

- April is Sexually Transmitted Infections Month
- Is Your National Association an MLN Connects® Partner?

- LTCH Quality Reporting Program Data Submission Deadline: May 15
- IRF Quality Reporting Program Data Submission Deadline: May 15
- Notices of Intent to Apply for Medicare Shared Savings Program January 1, 2016, Start Date Due by May 29
- Proposed Rule Outlines EHR Requirements for Providers for 2015 through 2017

Medicare Learning Network® Educational Products

- “Medicare Quarterly Provider Compliance Newsletter [Volume 5, Issue 3]” Educational Tool — Released
- Medicare Learning Network® Product Available In Electronic Publication Format

APRIL 9

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- “Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014” MLN Matters® Article — Released
- “Partial Hospitalization Program (PHP) Claims Coding & CY2015 per Diem Payment Rates” MLN Matters® Article — Released
- “Medicare Information for Advanced Practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants” Booklet — Revised
- “The ABCs of the Initial Preventive Physical Examination (IPPE)” Educational Tool — Revised
- “The ABCs of the Annual Wellness Visit (AWV)” Educational Tool — Revised “Medicare Learning Network® Suite of Products & Resources for Billers and Coders” Educational Tool – Reminder
- “Medicare Learning Network® Suite of Products & Resources for Inpatient Hospitals” Educational Tool – Reminder
- “Medicare Learning Network® Suite of Products & Resources for Compliance Officers” Educational Tool – Reminder
- Medicare Learning Network® Products Available In Electronic Publication Format

**First Coast Service Options
Phone Numbers**

(Note: Specific geographic contact information is noted when phone numbers and addresses are different for providers in Florida, U.S. Virgin Islands or Puerto Rico.)

Customer service

Monday to Friday
8:00 a.m. to 4:00 p.m.
888-664-4112 (FL/USVI)
877-908-8433 (Puerto Rico)
877-660-1759 (TDD-FL/USVI)
888-216-8261 (TDD-Puerto Rico)

Electronic data interchange

888-670-0940 (FL/USVI)
888-875-9779 (Puerto Rico)

Interactive Voice Response

877-602-8816

Provider education/outreach

Event registration hotline
904-791-8103

Overpayments

904-791-6281

SPOT Help Desk

FCSOSPOTHelp@fcso.com
855-416-4199

Websites

medicare.fcso.com
medicareespanol.fcso.com

**First Coast Service Options
Addresses**

**Claims/correspondence
Florida/ U.S. Virgin Islands**

Medicare Part A Customer Service
P. O. Box 2711
Jacksonville, FL 32231-0021

Puerto Rico

First Coast Service Options Inc.
P.O. Box 45003
Jacksonville, FL 32232-5003

**Medicare EDI
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

**FOIA requests
Provider audit/reimbursement**

(relative to cost reports and audits)
Attn: FOIA PARD – 16T
P. O. Box 45268
Jacksonville, FL 32232-5268

General Inquiries

Online Form (Click here)

Email: AskFloridaA@fcso.com

Local coverage determinations

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

Medicare secondary payer (MSP)

Medicare Secondary Payer
P. O. Box 2711
Jacksonville, FL 32231-0021

Hospital audits

MSP – Hospital Review
P. O. Box 45267
Jacksonville, FL 32232-5267

**MSPRC DPP debt recovery, auto
accident settlements/lawsuits, liabilities**

Auto/Liability – 17T
P. O. Box 44179
Jacksonville, FL 32231-4179

**Overpayment collections and
debt recovery**

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

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

Credit balance reports

First Coast Service Options Inc.
P.O. Box 45011
Jacksonville, FL 32232-5011

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/Appeals
P. O. Box 45053
Jacksonville, FL 32232-5053

Redetermination (cont'd)

U.S. Virgin Islands:

First Coast Service Options Inc
P. O. Box 45097
Jacksonville, FL 32232-5097

Puerto Rico

First Coast Service Options Inc.
P.O. Box 45028
Jacksonville, FL 32232-5028

Special delivery/courier services

First Coast Service Options Inc.
532 Riverside Avenue
Jacksonville, FL 32202-4914

**Other Medicare carriers and
intermediaries**

DME regional carrier (DMERC)

DME, orthotic, prosthetic device, take-home supply, oral anti-cancer drug claims

CGS Administrators, LLC
P. O. Box 20010
Nashville, Tennessee 37202

Railroad Medicare

Palmetto GBA
P. O. Box 10066
Augusta, GA 30999-0001

**Regional home health/hospice
intermediary**

Palmetto GBA
Medicare Part A
34650 US HWY 19N
Palm Harbor, FL 34684

Contact CMS

**Centers for Medicare & Medicaid
Services (CMS) (www.cms.gov)**

Centers for Medicare & Medicaid Services,
Division of Financial Management and Fee
for Service Operations

ROATLFM@CMS.HHS.GOV

Office of Inspector General (OIG)

Medicare fraud hotline
800-HHS-TIPS (800-447-8477)

**Medicare beneficiary
customer service**

1-800-MEDICARE
1-800-633-4227

Hearing and speech impaired (TDD)

1-800-754-7820