DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters®

Information for Medicare Fee-for-Service Health Care Professionals

News Flash – The "Rehabilitation Therapy Information Resource for Medicare" fact sheet has been revised and is now available in downloadable format from the Medicare Learning Network® at http://www.CMS.gov/MLNProducts/downloads/Rehab_Therapy_Fact_Sheet.pdf on the Centers for Medicare & Medicaid Services (CMS) website. This fact sheet is designed to provide education on rehabilitation therapy services and includes information on coverage requirements, billing and payment information, and a list of contacts and resources.

MLN Matters® Number: MM7545

Related Change Request (CR) #: CR 7545

Related CR Release Date: September 2, 2011

Effective Date: October 1, 2011

Related CR Transmittal #: R2296CP

Implementation Date: October 3, 2011

October 2011 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Provider Types Affected

Providers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for outpatient services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

Provider Action Needed

This article is based on Change Request (CR) 7545 which describes changes to the OPPS to be implemented in the October 2011 update. Be sure your billing staffs are aware of these changes.

Background

CR7545 describes changes to and billing instructions for various payment policies implemented in the October 2011 OPPS update. The October 2011 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer will reflect the Healthcare Common

Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, Status Indicator (SI), and Revenue Code additions, changes, and deletions identified in this notification.

Note that the October 2011 revisions to I/OCE data files, instructions, and specifications are provided in CR7541, "October 2011 Integrated Outpatient Code Editor (I/OCE) Specifications Version 12.3." An MLN Matters article is available for that CR at http://www.cms.gov/MLNMattersArticles/downloads/MM7541.pdf on the Centers for Medicare & Medicaid Services (CMS) website. The key changes in the October update to the hospital OPPS are as follows:

Changes to Device Edits for October 2011

Device-to-procedure edits require that a claim that contains one of a specified set of device codes be returned to the provider if it fails to contain an appropriate procedure code. CMS is adding procedure code 64569 (Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator) as an appropriate procedure for device code C1778 (Lead, neurostimulator) because the procedure may be appropriately reported on the same claim with the device code. CMS is adding it to the file with an effective date of January 1, 2011, because the procedure code is effective for services furnished on and after January 1, 2011. Any claims with dates of service after January 1, 2011, that were submitted prior to this update and returned to providers may be resubmitted.

Procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code. Failure to pass these edits will result in the claim being returned to the provider. Procedures for which both a Device A and a Device B are specified require that at least one each of Device A and Device B be present on the claim (i.e., there must be some combination of a Device A with a Device B in order to pass the edit). Device B can be reported with any Device A for the same procedural HCPCS code. CMS is not adding C1778 as a required device for procedure code 64569 because the device is not essential to the procedure described by the code 64569.

The updated lists of both types of edits can be found under "Device, Radiolabeled Product, and Procedure Edits" at http://www.cms.gov/HospitalOutpatientPPS/ on the CMS website.

New Device Pass-Through Categories

The Social Security Act (Section 1833(t)(6)(B); see http://www.ssa.gov/OP_Home/ssact/title18/1833.htm on the Internet) requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. The Social Security Act (Section 1833(t)(6)(B)(ii)(IV) requires that CMS creates additional categories for transitional

pass-through payment of new medical devices not described by existing or previously existing categories of devices.

CMS is establishing two new categories as of October 1, 2011. The following table provides a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

Table 1 – New Device Pass-Through Codes

HCPCS	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Device Offset from Payment
C1830	10-01-11	H	1830	Power bone marrow bx needle	Powered bone marrow biopsy needle	$0
C1840	10-01-11	H	1840	Telescopic intraocular lens	Lens, intraocular (telescopic)	$221.71

Billing Instructions for C1840: C1840 is to be billed and paid for, when provided, with Current Procedural Terminology (CPT) codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage), or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification)). These codes are assigned to APC 0246.

Device Offset from Payment: The Social Security Act (Section 1833(t)(6)(D)(ii); see http://www.ssa.gov/OP_Home/ssact/title18/1833.htm on the Internet) requires that CMS deducts from pass-through payments for devices an amount that reflects the portion of the APC payment amount that CMS determines is associated with the cost of the device (70 FR 68627-8).

CMS has determined that it is not able to identify a portion of the APC payment amount associated with the cost of C1830 in APC 0003, Bone Marrow Biopsy/Aspiration. The device offset from payment represents this deduction from pass-through payments for category C1830, when it is billed with a service included in APC 0003. Therefore, CMS is establishing an offset amount for C1830 of $0 and will not make any deductions from pass-through payment for category C1830.

CMS has also determined that it is able to identify a portion of the APC payment amount associated with the cost of C1840 in APC 0246, Cataract Procedures with IOL Insert. The device offset for APC 0246 is $221.71. The device offset from payment represents this deduction from pass-through payments for category C1840, when it is billed with a service included in APC 0246. Therefore, CMS is establishing an offset amount for C1830 of $221.71.

Billing for Drugs, Biologicals, and Radiopharmaceuticals

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

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

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

Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2011

For Calendar Year (CY) 2011, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP + 5 percent, which provides payment for both the acquisition cost and pharmacy overhead cost associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2011, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead cost of these pass-through items. CMS notes that for the fourth quarter of CY 2011, payment for drugs and biologicals with pass-through status is not made at the Part B Drug Competitive Acquisition Program (CAP) rate, as the CAP program was suspended beginning January 1, 2009. Should the Part B Drug CAP program be reinstituted, CMS would again use the Part B drug CAP rate for pass-

through drugs and biologicals that are a part of the Part B drug CAP program, as required by the statute.

In the CY 2011 OPPS/ASC final rule with comment period, CMS stated that payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary based on the most recent ASP submissions, CMS will incorporate changes to the payment rates in the October 2011 release of the OPPS PRICER. The updated payment rates, effective October 1, 2011, will be included in the October 2011 update of the OPPS Addendum A and Addendum B, which will be posted at http://www.cms.gov/HospitalOutpatientPPS/AU/list.asp on the CMS website.

Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2011

Two drugs and biologicals have been granted OPPS pass-through status effective October 1, 2011. These items, along with their descriptors and APC assignments, are identified in Table 2 below.

Table 2 – Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2011

HCPCS Code	Long Descriptor	APC	Status Indicator Effective 10/1/11
C9286*	Injection, belatacept, 1 mg	9286	G
J0638	Injection, canakinumab, 1 mg	1311	G

Note: The HCPCS codes identified with an "*" indicate that these are new codes effective October 1, 2011.

Updated Payment Rate for HCPCS Code J9185 Effective July 1, 2011, through September 30, 2011

The payment rate for HCPCS code J9185 was incorrect in the July 2011 OPPS Pricer. The corrected payment rate is listed in Table 3 below and has been installed in the October 2011 OPPS Pricer, effective for services furnished on July 1, 2011, through implementation of the October 2011 update. Any claims already processed with the incorrect amount will be adjusted, but only if you bring such claims to the attention of your Medicare contractor.

Table 3 – Updated Payment Rates for HCPCS Code J9185
Effective July 1, 2011,through September 30, 2011

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
J9185	K	0842	Fludarabine phosphate inj	$104.52	$20.90

Correct Reporting of Biologicals When Used As Implantable Devices

When billing for biologicals where the HCPCS code describes a product that is solely surgically implanted or inserted, whether the HCPCS code is identified as having pass-through status or not, hospitals are to report the appropriate HCPCS code for the product. Units should be reported in multiples of the units included in the HCPCS descriptor. Providers and hospitals should not bill the units based on the way the implantable biological is packaged, stored, or stocked. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the implantable biological. Therefore, before submitting Medicare claims for biologicals that are used as implantable devices, it is extremely important to review the complete long descriptors for the applicable HCPCS codes. In circumstances where the implanted biological has pass-through status as a device, a separate payment for the device is made. In circumstances where the implanted biological does not have pass-through status, the OPPS payment for the biological is packaged into the payment for the associated procedure.

When billing for biologicals where the HCPCS code describes a product that may either be surgically implanted or inserted or otherwise applied in the care of a patient, hospitals should not separately report the biological HCPCS codes, with the exception of biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPPS, hospitals are provided a packaged APC payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using biologicals during surgical procedures as implantable devices, hospitals may include the charges for these items in their charge for the procedure, report the charge on an uncoded revenue center line, or report the charge under a device HCPCS code (if one exists) so these costs would appropriately contribute to the future median setting for the associated surgical procedure.

Correct Reporting of Units for Drugs

Hospitals and providers are reminded to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in

the HCPCS descriptor. For example, if the description for the drug code is 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. As another example, if the description for the drug code is 50 mg, but 200 mg of the drug was administered to the patient, the units billed should be 4. Providers and hospitals should not bill the units based on the way the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient; hospitals should bill 10 units, even though only 1 vial was administered. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

As discussed in the "Medicare Claims Processing Manual," Chapter 17, Section 40; see http://www.cms.gov/manuals/downloads/clm104c17.pdf on the CMS website), CMS encourages hospitals to use drugs efficiently and in a clinically appropriate manner. However, CMS also recognizes that hospitals may discard some drug and biological product when administering from a single use vial or package. In that circumstance, Medicare pays for the amount of drug or biological discarded *as well as* the *dose* administered, up to the amount of the drug or biological as indicated on the vial or package label. Multi-use vials are not subject to payment for discarded amounts of drug or biological.

Reporting of Outpatient Diagnostic Nuclear Medicine Procedures

With the specific exception of HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) to be reported by hospitals on outpatient claims for nuclear medicine procedures to indicate that a radiolabeled product that provides the radioactivity necessary for the reported diagnostic nuclear medicine procedure was provided during a hospital inpatient stay, hospitals should only report HCPCS codes for products they provide in the hospital outpatient department and should not report a HCPCS code and charge for a radiolabeled product on the nuclear medicine procedure-to-radiolabeled product edit list solely for the purpose of bypassing those edits present in the I/OCE.

Use of HCPCS Code C9399

As stated in the "Medicare Claims Processing Manual" (Pub. 100-04, Chapter 17, Section 90.3; see http://www.cms.gov/manuals/downloads/clm104c17.pdf on the CMS website), hospitals are to report HCPCS code C9399, Unclassified drug or biological, solely for new outpatient drugs or biologicals that are approved by the FDA on or after January 1, 2004, and that are furnished as part of covered outpatient department services for which a product-specific HCPCS code has not been assigned. It is not appropriate to report HCPCS code C9399 for drugs and biologicals that are defined as usually self-administered drugs by the patient as defined in the

"Medicare Benefit Policy Manual," Pub. 100-02, Chapter 15, Section 50.2. See http://www.cms.gov/manuals/Downloads/bp102c15.pdf on the CMS website.

Calculation of Overall Cost to Charge Ratios (CCRs) for Cost Reporting Periods On or After May 1, 2010 based on Form CMS-2552-10

CR7545 updates the "Medicare Claims Processing Manual" (Chapter 4, Section 10.11 (Calculation of Overall Cost to Charge Ratios (CCRs) for Hospitals Paid Under the Outpatient Prospective Payment System (OPPS) and Community Mental Health Centers (CMHCs) Paid Under the Hospital OPPS)). Specifically, Sections 10.11.7.1 and 10.11.8.1 are added which contain Worksheet/Column/line edits and reflect the new Hospital and Hospital Health Care Complex Cost Report, Form CMS-2552-10. This does not replace Sections 10.11.7 and 10.11.8 as these existing instructions are relevant for cost report Form CMS-2552-96.

The revised sections of the "Medicare Claims Process Manual" (Chapter 4, Sections 10.11.7.1 and 10.11.8.1) are included as an attachment to CR7545.

Clarifications to Condition Code 44 Policy (When a Patient's Status may be Changed from Inpatient to Outpatient)

CR7545 updates the "Medicare Claims Processing Manual" (Chapter 50, Section 3.1 (Background) and Section 3.2 (Policy and Billing Instructions for Condition Code 44)) to clarify several CMS manual requirements for changing a patient's status from inpatient to outpatient (using Condition Code 44). CMS is clarifying that the practitioner who is responsible for the care of the patient must concur with any decision by the hospital's Utilization Review committee to change a patient's status from inpatient to outpatient. Also CMS is clarifying that the Condition Code 44 policies apply to critical access hospitals as well as other types of hospitals.

These revised sections of the "Medicare Claims Process Manual" are included as an attachment to CR7545.

Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, FIs/MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

Additional Information

The official instruction, CR7545, issued to your FIs, A/B MACs, and RHHIs regarding this change may be viewed at http://www.cms.gov/Transmittals/downloads/R2296CP.pdf on the CMS website.

If you have any questions, please contact your FIs, A/B MACs, or RHHIs at their toll-free number, which may be found at http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS website.