CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2903	**Date: March 11, 2014**
	Change Request 8653

NOTE: Transmittal 2894, dated February 28, 2014, is being rescinded and replaced by Transmittal 2903, dated March 11, 2014, to replace the words Program Memorandum located in chapter 17 section 90.2.1 with Recurring Update Notification All other information remains the same.

SUBJECT: April 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES:
This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2014 OPPS update. The April 2014 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). The attached Recurring Update Notification applies to Pub. 100-04, Chapter 4, section 10.2.1.

The April 2014 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2014 I/OCE CR.

EFFECTIVE DATE: April 1, 2014
IMPLEMENTATION DATE: April 7, 2014

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/Table of Contents
R	4/10.2.1/Composite APCs
R	4/61.3.1/ Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital Prior to January 1, 2014
R	4/61.3.2/ Reporting and Charging Requirements When the Hospital Receives Full Credit for the Replaced Device against the Cost of a More Expensive Replacement Device Prior to January 1, 2014
R	4/61.3.3/ Reporting Requirements When the Hospital Receives Partial Credit for the Replacement Device Prior to January 1, 2014
R	4/61.3.4/ Medicare Payment Adjustment Prior to January 1, 2014
N	4/61.3.5/Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital or When the Hospital Receives a Full or Partial Credit for the Replacement Device Beginning January 1, 2014
N	4/61.3.6/Medicare Payment Adjustment Beginning January 1, 2014
R	4/290.5.1/Billing and Payment for Observation Services Beginning January 1, 2008
R	4/290.5.2/Billing and Payment for Direct Referral for Observation Care Furnished Beginning January 1, 2008
R	17/90.2/Drugs, Biologicals, and Radiopharmaceuticals
R	17/90.2.1/HCPCS Codes Replacements

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Recurring Update Notification
Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 2903	Date: March 11, 2014	Change Request: 8653

NOTE: Transmittal 2894, dated February 28, 2014, is being rescinded and replaced by Transmittal 2903, dated March 11, 2014, to replace the words Program Memorandum located in chapter 17 section 90.2.1 with Recurring Update Notification All other information remains the same.

SUBJECT: April 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: April 1, 2014
IMPLEMENTATION DATE: April 7, 2014

I. GENERAL INFORMATION

A. Background:

This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2014 OPPS update. The April 2014 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR).

The April 2014 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2014 I/OCE CR.

B. Policy:

1. Changes to Device Edits for Apri1 2014

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

2. No Cost/ Full Credit and Partial Credit Devices

Effective January 1, 2014, CMS will no longer recognize the FB or FC modifiers to identify a device that is furnished without cost or with a full or partial credit. Also effective January 1, 2014, for claims with APCs that require implantable devices and have significant device offsets (greater than 40%), the amount of the device credit will be specified in the amount portion for value code “FD” (Credit Received from the Manufacturer for a Replaced Medical Device) and will be deducted from the APC payment from the applicable procedure. The OPPS payment deduction for the applicable APCs referenced above will be limited to the total amount of the device offset when the FD value code appears on a claim. The offset amounts for the above referenced APCs are available on the CMS Web site.

CMS is updating Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, sections 61.3.1 through 61.3.4 and adding Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, sections 61.3.5 through 61.3.6 to reflect these changes to the reporting guidelines for no cost/ full credit and partial credit devices.

3. New Services

New services listed in table 1, Attachment A, are assigned for payment under the OPPS, effective April 1, 2014.

4. Extended Assessment and Management (EAM) Composite APC (8009)

Effective January 1, 2014 CMS will provide payment for all qualifying extended assessment and management encounters through newly created composite APC 8009 (Extended Assessment and

Management (EAM) Composite). Any clinic visit, Level 4 or Level 5 Type A ED visit, or Level 5 Type B ED visit furnished by a hospital in conjunction with observation services of eight or more hours will qualify for payment through APC 8009. Effective January 1, 2014 CMS will no longer provide payment for extended assessment and management encounters through APCs 8002 (Level I Extended Assessment and Management Composite) and 8003 (Level I Extended Assessment and Management Composite).

CMS is updating Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, sections 10.2.1 and 290.5, to reflect these changes to the EAM Composite APC reporting guidelines.

5. Billing for Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective April 1, 2014

In the CY 2014 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 April 2014 release of the OPPS Pricer. The updated payment rates, effective April 1, 2014 will be included in the April 2014 update of the OPPS Addendum A and Addendum B, which will be posted on the CMS Web site.

b. Drugs and Biologicals with OPPS Pass-Through Status Effective April 1, 2014

Two drugs and biologicals have been granted OPPS pass-through status effective April 1, 2014. These items, along with their descriptors and APC assignments, are identified in table 2, Attachment A.

c. Revised Status Indicator for HCPCS Codes A9545, J1446, and J7178, and Q0181

Effective April 1, 2014, the status indicator for HCPCS code A9545 (Iodine I-131 tositumomab, therapeutic, per treatment dose) will change from SI=K (Paid under OPPS; separate APC payment) to SI=E (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)).

Effective January 1, 2014, the status indicator for HCPCS code J1446 (Injection, TBO-Filgrastim, 5 micrograms) will change from SI=E (not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI=K (Paid under OPPS; separate APC payment).

Effective January 1, 2014, the status indicator for HCPCS code J7178 (Injection, human fibrinogen concentrate, 1 mg) will change from SI=N (Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.) to SI=K (Paid under OPPS; separate APC payment).

Effective January 1, 2014, the status indicator for HCPCS code Q0181 (Unspecified oral dosage form, FDA approved prescription anti-emetic, for use as) will change from SI=E (not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI=N (Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.).

These codes are listed in table 3, Attachment A, along with the effective date for the revised status indicator.

d. Updated Payment Rate for Q4127 Effective April 1, 2013 through June 30, 2013

The payment rate for Q4127 was incorrect in the April 2013 OPPS Pricer. The corrected payment rate is listed in table 4, Attachment A, and has been installed in the April 2014 OPPS Pricer, effective for services furnished on April 1, 2013 through June 30, 2013.

e. Updated Payment Rate for Q4127 Effective July 1, 2013 through September 30, 2013

The payment rate for Q4127 was incorrect in the July 2013 OPPS Pricer. The corrected payment rate is listed in table 5, Attachment A, and has been installed in the April 2014 OPPS Pricer, effective for services furnished on July 1, 2013 through September 30, 2013.

f. Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2013 through December 1, 2013

The payment rates for three HCPCS codes were incorrect in the October 2013 OPPS Pricer. The corrected payment rates are listed in table 6, Attachment A, and have been installed in the April 2014 OPPS Pricer, effective for services furnished on October 1, 2013 through December 31, 2013.

g. Reassignment of Skin Substitute Products that are New for CY 2014 from the Low Cost Group to the High Cost Group

In the CY 2014 OPPS/ASC final rule, CMS finalized a policy to package payment for skin substitute products into the associated skin substitute application procedure. For packaging purposes, CMS created two groups of application procedures: application procedures that use high cost skin substitute products (billed using CPT codes 15271-15278) and application procedures that use low cost skin substitute products (billed using HCPCS codes C5271-C5278). Assignment of skin substitute products to the high cost or low cost groups depended upon a comparison of the July 2013 payment rate for the skin substitute product to $32, which is the weighted average payment per unit for all skin substitute products using the skin substitute utilization from the CY 2012 claims data and the July 2013 payment rate for each product. Skin substitute products with a July 2013 payment rate that was above $32 per square centimeter are paid through the high cost group and those with a July 2013 payment rate that was at or below $32 per square centimeter are paid through the low cost group for CY 2014. As a reminder, for CY 2015, CMS will follow our usual policy with regard to the specific quarterly ASP data sets used for proposed and final rule-making in that CMS will use April 2014 ASP data to establish the proposed rule low/high cost threshold and CMS will use July 2014 ASP data to establish the final low/high cost threshold for CY 2015.

CMS also finalized a policy that for any new skin substitute products approved for payment during CY 2014, CMS will use the $32 per square centimeter threshold to determine mapping to the high or low cost skin substitute group. Any new skin substitute products without pricing information were assigned to the low cost category until pricing information becomes available. There were 9 new skin substitute products that were effective January 1, 2014 and that were assigned to the low cost payment group because pricing information was not available for these products at the time of the January 2014 update. There is now pricing information available for 3 of these 9 products. Table 7, Attachment A, shows the 3 new products and their low/high cost status based on the comparison of the price per square centimeter for each product to the $32 square centimeter threshold for CY 2014.

h. Billing Guidance for the Topical Application of Mitomycin During or Following Ophthalmic Surgery

Hospital outpatient departments should only bill HCPCS code J7315 (Mitomycin, ophthalmic, 0.2 mg) or HCPCS code J3490 (unclassified drugs) for the topical application of mitomycin during or following ophthalmic surgery. J7315 may be reported only if the hospital uses mitomycin with the trade name Mitosol®. Any other topical mitomycin should be reported with J3490. Hospital outpatient departments are not permitted to bill HCPCS code J9280 (Injection, mitomycin, 5 mg) for the topical application of mitomycin.

6. New HCPCS Code Effective April 1, 2014

One new HCPCS code has been created for reporting services, supplies, and accessories used in the home under the Medicare intravenous immune globulin (IVIG) demonstration. This code is listed in table 8, Attachment A, and is effective for services furnished on or after April 1, 2014.

7. Changes to OPPS Pricer Logic

Effective January 1, 2014, for claims with APCs, which require implantable devices and have significant device offsets (greater than 40%), a device offset cap will be applied to the applicable procedure line based on the credit amount listed in the "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) value code. The credit amount in value code "FD", which reduces the post wage-adjusted APC line payment for the applicable procedure, will be capped by the device offset amount for that APC. The offset amounts for the above referenced APCs are available on the CMS website.

8. 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. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8653.1	Medicare contractors shall install the April 2014 OPPS Pricer.	X		X		X				COBC
8653.2	Medicare contactors shall manually add the following HCPCS codes to their systems: • HCPCS codes listed in table 1, effective April 1, 2014; and • HCPCS code C9021, effective April 1, 2014; and • HCPCS code Q2052, effective April 1, 2014; and • G9361 listed in the upcoming April I/OCE CR, effective January 1, 2014. **NOTE:** These HCPCS codes will be included with the April 2014 I/OCE update. Status and payment indicators for these HCPCS codes will be listed in the April 2014 update of the OPPS Addendum A and Addendum B on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-	X		X		X				COBC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Service Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html									
8653.3	Medicare contractors shall adjust, as appropriate, claims brought to their attention that: 1. Have dates of service that fall on or after April 1, 2013, but prior to July 1, 2013; and 2. Contain HCPCS code Q4127; and 3. Were originally processed prior to the installation of the April 2014 OPPS Pricer.	X		X						COBC
8653.4	Medicare contractors shall adjust, as appropriate, claims brought to their attention that: 1. Have dates of service that fall on or after July 1, 2013, but prior to October 1, 2013; and 2. Contain HCPCS code Q4127; and 3. Were originally processed prior to the installation of the April 2014 OPPS Pricer.	X		X						COBC
8653.5	Medicare contractors shall adjust, as appropriate, claims brought to their attention that: 1. Have dates of service that fall on or after October 1, 2013, but prior to January 1, 2014 ; and 2. Contain HCPCS codes listed in Table 6; and 3. Were originally processed prior to the installation of the April 2014 OPPS Pricer.	X		X						COBC
8653.6	Medicare contractors shall adjust any claims brought to their attention that were received in 2014 prior to the implementation of the April 2014 OPPS Pricer.	X		X						COBC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8653.7	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova, marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

(Attachment 1)

Attachment A – Tables for the Policy Section

Table 1 – New Services Payable under OPPS Effective April 1, 2014

HCPCS	Effective date	SI	APC	Short Descriptor	Long descriptor	Payment	Minimum Unadjusted Copayment
C9739	4/01/2014	T	0162	Cystoscopy prostatic imp 1-3	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	$2,007.32	$401.47
C9740	4/01/2014	T	1564	Cysto impl 4 or more	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	$4,750.00	$950.00

Table 2 – Drugs and Biologicals with OPPS Pass-Through Status Effective April 1, 2014

HCPCS Code	Short Descriptor	Long Descriptor	APC	Status Indicator
C9021*	Injection, obinutuzumab	Injection, obinutuzumab, 10 mg	1476	G
Q4121	Theraskin	Theraskin, per square centimeter	1479	G

NOTE: The HCPCS codes identified with an "*" indicate that these are new codes effective April 1, 2014.

Table 3 – Drugs and Biologicals with Revised Status Indicators

HCPCS Code	Long Descriptor	APC	Status Indicator	Effective Date
A9545	Iodine I-131 tositumomab, therapeutic, per treatment dose		E	4/1/2014
J1446	Injection, TBO-Filgrastim, 5 micrograms	1477	K	1/1/2014
J7178	Injection, human fibrinogen concentrate, 1 mg	1478	K	1/1/2014
Q0181	Unspecified oral dosage form, FDA approved prescription anti-emetic, for use as		N	1/1/2014

Table 4 – Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2013 through June 30, 2013

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
Q4127	G	1449	Talymed	$13.78	$2.76

Table 5 – Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2013 through September 30, 2013

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
Q4127	G	1449	Talymed	$13.78	$2.76

Table 6 – Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2013 through December 31, 2013

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
A9600	K	0701	Sr89 strontium	$1,196.47	$239.29
J2323	K	9126	Natalizumab injection	$12.99	$2.60
Q4127	G	1449	Talymed	$13.78	$2.76

Table 7– Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2014

HCPCS Code	Long Descriptor	Status Indicator	Low/High Cost Status
Q4143	Repriza, Per Square Centimeter	N	Low
Q4147	Architect Extracellular Matrix, Per Square Centimeter	N	High
Q4148	Neox 1k, Per Square Centimeter	N	High

Table 8 – New HCPCS Code Effective April 1, 2014

HCPCS Code	Long Descriptor	Short Descriptor	Status Indicator Effective 4/1/14
Q2052	Services, supplies and accessories used in the home under the Medicare intravenous immune globulin (ivig) demonstration	Ivig demo, services/supplies	N

Medicare Claims Processing Manual

Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS)

Table of Contents

(Rev.2903, Issued: 03-11-14)

Transmittals for Chapter 4

10.2.1 - Composite APCs

(Rev.2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Composite APCs provide a single payment for a comprehensive diagnostic and/or treatment service that is defined, for purposes of the APC, as a service typically reported with multiple HCPCS codes. When HCPCS codes that meet the criteria for payment of the composite APC are billed on the same date of service, CMS makes a single payment for all of the codes as a whole, rather than paying individually for each code.

The table below identifies the composite APCs that are *currently* effective for services furnished on or after January 1, 2008. See Addendum A at www.cms.hhs.gov/HospitalOutpatientPPS/ for the national unadjusted payment rates for these composite APCs.

Composite APC	Composite APC Title	Criteria for Composite Payment
8000	Cardiac Electrophysiologic Evaluation and Ablation Composite	At least one unit of CPT code 93619 or 93620 and at least one unit of CPT code 93650 on the same date of service; or, at least one unit of CPT codes 93653, 93654, or 93656 (no additional concurrent service codes required).
8001	Low Dose Rate Prostate Brachytherapy Composite	One or more units of CPT codes 55875 and 77778 on the same date of service.
0034	Mental Health Services Composite	Payment for any combination of mental health services with the same date of service exceeds the payment for APC 0173 in years prior to 2011 or APC 0176 after January 1, 2011. For the list of mental health services to which this composite applies, see the I/OCE supporting files for the pertinent period.
8004	Ultrasound Composite	Payment for any combination of designated imaging procedures within the Ultrasound imaging family on the same date of service. For the list of imaging services included in the Ultrasound imaging family, see the I/OCE specifications document for the pertinent period.
8005	Computed Tomography (CT) and Computed Tomographic Angiography (CTA) without Contrast Composite	Payment for any combination of designated imaging procedures within the CT and CTA imaging family on the same date of service. If a “without contrast” CT or CTA procedure is performed on the same date of service as a “with contrast” CT or CTA procedure, the IOCE will assign APC 8006 rather than APC 8005. For the list of imaging services included in the CT and CTA imaging family, see the I/OCE specifications document for the pertinent period.
8006	CT and CTA with Contrast Composite	

Composite APC	Composite APC Title	Criteria for Composite Payment
8007	Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA) without Contrast Composite	Payment for any combination of designated imaging procedures within the MRI and MRA imaging family on the same date of service. If a "without contrast" MRI or MRA procedure is performed on the same date of service as a "with contrast" MRI or MRA procedure, the I/OCE will assign APC 8008 rather than APC 8007. For the list of imaging services included in the MRI and MRA imaging family, see the I/OCE specifications document for the pertinent period.
8008	MRI and MRA with Contrast Composite	
8009	*Extended Assessment and Management Composite*	*1) Eight or more units of HCPCS code G0378** are billed--* • *On the same day as HCPCS code G0379*; or* • *On the same day or the day after HCPCS code G0463 or CPT codes 99284, 99285, G0384, or 99291; and* *2) There is no service with SI=T on the claim on the same date of service or 1 day earlier than HCPCS code G0378.*

*Payment for direct admission to observation care (HCPCS code G0379) is made either under *APC 0633 (Level 3 Examinations & Related Services) or APC 8009 (Extended Assessment and Management Composite)* or is packaged into payment for other separately payable services. See §290.5.2 for additional information and the criteria for payment of HCPCS code G0379.

** For additional reporting requirements for observation services reported with HCPCS code G0378, see §290.5.1 of this chapter.

Future updates will be issued in a Recurring Update Notification.

61.3.1 - Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital *Prior to January 1, 2014*

Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Effective January 1, 2007, the definition of modifier –FB is "**Item Provided Without Cost to Provider, Supplier or Practitioner, or Credit Received for Replacement Device (Examples, but not Limited to: Covered Under Warranty, Replaced Due to Defect, Free Samples).**"

When a hospital furnishes a device received without cost or with full credit from a manufacturer, the hospital must append modifier –FB to the procedure code (not the device code) that reports the service provided to furnish the device. The hospital must report a token charge for the device (less than $1.01) in the covered charge field.

This includes circumstances in which the cost of a replacement device is less than the cost of the device being replaced, such that the hospital incurs no net cost for the device being inserted. For example, if a device that originally cost $20,000 fails and is replaced by a device that costs $16,000 and for which the manufacturer gives a credit of $16,000, there is no cost to the hospital for the device being inserted and the hospital would append modifier –FB to the procedure code and report a token charge for the device.

61.3.2 - Reporting and Charging Requirements When the Hospital Receives Full Credit for the Replaced Device against the Cost of a More Expensive Replacement Device *Prior to January 1, 2014*

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

When a hospital replaces a device with a more expensive device and receives a credit in the amount that the device being replaced would otherwise cost, the hospital must append modifier –FB to the procedure code (not on the device code) that reports the service provided to replace the device. The hospital must charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received credit. This charge should be billed in the covered charge field.

Hospitals should not report modifier –FB when the hospital receives a partial credit for a replacement device when the amount of the credit is less than the amount that the device would otherwise cost the hospital. For example, a device fails in the 6th month of a 1 year warranty and under the terms of the warranty, the hospital receives a credit of 50 percent of the cost of a replacement device. The hospital should not append modifier –FB to the procedure code in which the device is implanted. See the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §61.3.3 for billing instructions pertaining to partial credit situations.

61.3.3 - Reporting Requirements When the Hospital Receives Partial Credit for the Replacement Device *Prior to January 1, 2014*

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

When a hospital receives a partial credit of 50 percent or more of the cost of a new replacement device due to warranty, recall, or field action, the hospital must append modifier –FC to the procedure code (not on the device code) that reports the service provided to replace the device.

61.3.4 - Medicare Payment Adjustment *Prior to January 1, 2014*

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Effective January 1, 2007, Medicare payment is reduced by the full offset amount for specified procedure codes reported with modifier –FB. Effective January 1, 2008, Medicare payment is reduced by the partial offset amount for specified procedure codes reported with modifier –FC. Effective January 1, 2009, payment is only reduced for procedure codes that map to the Ambulatory Payment Classification groups (APCs) on the list of APCs subject to the adjustment that are reported with modifier –FB or –FC and that are present on claims with specified device HCPCS codes.

The Integrated Code Editor (I/OCE) assigns a payment adjustment flag when a procedure code in an APC subject to an offset adjustment is billed with modifier –FB or –FC and a specified device HCPCS code. The payment adjustment flag communicates to the OPPS PRICER that the payment for the procedure code line is to be reduced by the established full or partial offset amount for the APC to which the procedure code is assigned. The I/OCE uses the offset APC payment rate (APC payment amount minus the established offset amount) as the rate used in the I/OCE's determination of which multiple procedure line(s) will be discounted.

The OPPS PRICER then applies the multiple procedure discounting and terminated procedure discounting factors after offsetting the unadjusted APC payment rate. The offset reduction also is made to the unadjusted payment rate before wage adjustment, which ensures that the beneficiary's coinsurance is based on the reduced amount.

NOTE: The tables of APCs and devices to which the offset reductions apply, and the full and partial offset amounts, are available on the CMS Web site at: www.cms.hhs.gov/HospitalOutpatientPPS/.

61.3.5 - Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital or When the Hospital Receives a Full or Partial Credit for the Replacement Device Beginning January 1, 2014

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Effective January 1, 2014, when a hospital furnishes a new replacement device received without cost or with a credit of 50 percent or more of the cost of a new replacement from a manufacturer, due to warranty, recall, or field action, the hospital must report the amount of the device credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Medical Device). Also effective January 1, 2014 hospitals must report one of the following condition codes when the value code "FD" is present on the claim:

*• **49 Product Replacement within Product Lifecycle**—Replacement of a product earlier than the anticipated lifecycle due to an indication that the product is not functioning properly.*

*• **50 Product Replacement for Known Recall of a Product**—Manufacturer or FDA has identified the product for recall and therefore replacement.*

61.3.6 - Medicare Payment Adjustment Beginning January 1, 2014

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Effective January 1, 2014, Medicare payment is reduced by the amount of the device credit for specified procedure codes reported with value code "FD." The payment deduction is limited to the full device offset when the FD value code appears on a claim. Payment is only reduced for procedure codes that map to the Ambulatory Payment Classification groups (APCs) on the list of APCs subject to the adjustment that are reported with value code "FD" and that are present on claims with specified device HCPCS codes.

The OPPS Pricer deducts the lesser of the device credit or the full unadjusted device offset amount from the Medicare payment for a procedure code in an APC subject to the adjustment when billed with value code "FD" on the claim. This deduction is made from the Medicare payment after the multiple procedure discounting and terminated procedure discounting factors are applied, units of service are accounted for, and after the APC payment has been wage adjusted.

When two or more procedures assigned to APCs subject to the adjustment are reported with value code "FD" the OPPS Pricer will apportion the device credit to the applicable line on the claim for each procedure assigned to an APC subject to the adjustment. When value code "FD" is reported on a claim where multiple APCs would be subject to the adjustment, the OPPS Pricer apportions the device credit to each of those lines. The percentage of the device credit apportioned to each applicable line is based on the percentage that the unadjusted payment of each applicable line represents, relative to the total unadjusted payment for all applicable lines.

***NOTE**: The tables of APCs and devices to which the offset reductions apply, and the full and partial offset amounts, are available on the CMS Web site at: www.cms.hhs.gov/HospitalOutpatientPPS/.*

290.5.1 - Billing and Payment for Observation Services Beginning January 1, 2008

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). Beginning January 1, 2008, HCPCS code G0378 for hourly observation services is assigned status indicator N, signifying that its payment is always packaged. No separate payment is made for observation services reported with HCPCS code G0378, and APC 0339 is deleted as of January 1, 2008. In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. *Beginning January 1, 2014, in* certain circumstances when observation care is billed in conjunction with a clinic visit, high level Type A emergency department visit (Level 4 or 5), high level Type B emergency department visit (Level 5), critical care services, or a direct referral as an integral part of a patient's extended encounter of care, payment may be made for the entire extended care encounter through *APC 8009 (Extended Assessment and Management Composite*) when certain criteria are met. *Prior to January 1, 2014, in certain circumstances when observation care was billed in conjunction with a high level clinic visit (Level 5), high level Type A emergency department visit (Level 4 or 5), high level Type B emergency department visit (Level 5), critical care services, or a direct referral as an integral part of a patient's extended encounter of care, payment could be made for the entire extended care encounter through one of two composite APCs (APCs 8002 and 8003) when certain criteria were met. APCs 8002 and 8003 are deleted as of January 1, 2014.* For information about payment for extended assessment and management composite APC, see §10.2.1 (Composite APCs) of this chapter.

There is no limitation on diagnosis for payment of *APC 8009*; however, composite APC payment will not be made when observation services are reported in association with a surgical procedure (T status procedure) or the hours of observation care reported are less than 8. The I/OCE evaluates every claim received to determine if payment through a composite APC is appropriate. If payment through a composite APC is inappropriate, the I/OCE, in conjunction with the Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim.

All of the following requirements must be met in order for a hospital to receive an APC payment for an extended assessment and management composite APC:

1. Observation Time

   a. Observation time must be documented in the medical record.

   b. Hospital billing for observation services begins at the clock time documented in the patient's medical record, which coincides with the time that observation services are initiated in accordance with a physician's order for observation services.

   c. A beneficiary's time receiving observation services (and hospital billing) ends when all clinical or medical interventions have been completed, including follow-up care furnished by hospital staff and physicians that may take place after a physician has ordered the patient be released or admitted as an inpatient.

   d. The number of units reported with HCPCS code G0378 must equal or exceed 8 hours.

2. Additional Hospital Services

   a. The claim for observation services must include one of the following services in addition to the reported observation services. The additional services listed below must have a line item date of service on the same day or the day before the date reported for observation:

      - A Type A or B emergency department visit (CPT codes 99284 or 99285 or HCPCS code G0384); or
      - A clinic visit (*HCPCS code G0463 beginning January 1, 2014;* CPT code 99205 or 99215 *prior to January 1, 2014*); or
      - Critical care (CPT code 99291); or

- Direct referral for observation care reported with HCPCS code G0379 (APC *0633*) must be reported on the same date of service as the date reported for observation services.

b. No procedure with a T status indicator can be reported on the same day or day before observation care is provided.

3. Physician Evaluation

a. The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by outpatient registration, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.

b. The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.

Criteria 1 and 3 related to observation care beginning and ending time and physician evaluation apply regardless of whether the hospital believes that the criteria will be met for payment of the extended encounter through extended assessment and management composite payment.

Only visits, critical care and observation services that are billed on a 13X bill type may be considered for a composite APC payment.

Non-repetitive services provided on the same day as either direct referral for observation care or observation services must be reported on the same claim because the OCE claim-by-claim logic cannot function properly unless all services related to the episode of observation care, including hospital clinic visits, emergency department visits, critical care services, and T status procedures, are reported on the same claim. Additional guidance can be found in chapter 1, section 50.2.2 of this manual.

If a claim for services provided during an extended assessment and management encounter including observation care does not meet all of the requirements listed above, then the usual APC logic will apply to separately payable items and services on the claim; the special logic for direct admission will apply, and payment for the observation care will be packaged into payments for other separately payable services provided to the beneficiary in the same encounter.

290.5.2 - Billing and Payment for Direct Referral for Observation Care Furnished Beginning January 1, 2008

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

Direct referral for observation is reported using HCPCS code G0379 (Direct referral for hospital observation care). : Prior to January 1, 2010, the code descriptor for HCPCS code G0379 was (Direct admission of patient for hospital observation care). Hospitals should report G0379 when observation services are the result of a direct referral for observation care without an associated emergency room visit, hospital outpatient clinic visit, or critical care service on the day of initiation of observation services. Hospitals should only report HCPCS code G0379 when a patient is referred directly to observation care after being seen by a physician in the community.

Payment for direct referral for observation care will be made either separately as a low level hospital clinic visit under APC 0633 *(Level 3 Examinations & Related Services)* or packaged into payment for composite APC *8009 (Extended Assessment and Management Composite)* or packaged into the payment for other separately payable services provided in the same encounter. For information about payment for extended assessment and management composite APCs, see, §10.2.1 (Composite APCs) of this chapter.

The criteria for payment of HCPCS code G0379 under either APC *0633* or APC *8009* include:

1. Both HCPCS codes G0378 (Hospital observation services, per hr.) and G0379 (Direct referral for hospital observation care) are reported with the same date of service.

2. No service with a status indicator of T or V or Critical Care (APC 0617) is provided on the same day of service as HCPCS code G0379.

If either of the above criteria is not met, HCPCS code G0379 will be assigned status indicator N and will be packaged into payment for other separately payable services provided in the same encounter.

Only a direct referral for observation services billed on a 13X bill type may be considered for a composite APC payment.

Medicare Claims Processing Manual
Chapter 17 - Drugs and Biologicals

90.2 - Drugs, Biologicals, and Radiopharmaceuticals
(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

A. General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and Radiopharmaceuticals

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

Payment for drugs, biologicals and radiopharmaceuticals under the OPPS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.

Under the OPPS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug code (J9999 or J3490). In these situations, it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Recurring Update Notifications. The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively, that can be found under the CMS quarterly provider updates on the CMS Web site at:
http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp

Future updates will be issued in a Recurring Update Notification.

***B*. Pass-Through Drugs, Biologicals, and Radiopharmaceuticals**

Payment for drugs, biologicals, and radiopharmaceuticals may be made under the pass-through provision which provides additional payments for drugs, biologicals, and radiopharmaceuticals that meet certain requirements relating to newness and relative costs. According to section 1833(t) of the Social Security Act, transitional pass-through payments can be made for at least 2 years, but no more than 3 years. For the process and information required to apply for transitional pass-through payment status for drugs, biologicals, and radiopharmaceuticals, go to the main OPPS Web page, currently at http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage to see the latest

instructions. (**NOTE:** Due to the continuing development of the new cms.hhs.gov Web site, this link may change.) Payment rates for pass-through drugs, biologicals, and radiopharmaceuticals are updated quarterly. The all-inclusive list of billable drugs, biologicals, and radiopharmaceuticals for pass-through payment is included in the current quarterly Addendum B. The most current Addendum B can be found under the CMS quarterly provider updates on the CMS

***C*. Non Pass-Through Drugs and Biologicals**

Under the OPPS, drugs and biologicals that are not granted pass-through status receive either packaged payment or separate payment. Payment for drugs and biologicals with estimated per day costs equal to or below the applicable drug packaging threshold is packaged into the payment for the associated procedure, commonly a drug administration procedure. Drugs and biologicals with per day costs above the applicable drug packaging threshold are paid separately through their own APCs.

***D*. Radiopharmaceuticals**

1. General

Beginning in CY 2008, the OPPS divides radiopharmaceuticals into two groups for payment purposes: diagnostic and therapeutic. Diagnostic radiopharmaceuticals function effectively as products that enable the provision of an independent service, specifically, a diagnostic nuclear medicine scan. Therapeutic radiopharmaceuticals are themselves the primary therapeutic modality.

Beginning January 1, 2008, the I/OCE requires claims with separately payable nuclear medicine procedures to include a radiolabeled product (i.e., diagnostic radiopharmaceutical, therapeutic radiopharmaceutical, or brachytherapy source). Hospitals are required to submit the HCPCS code for the radiolabeled product on the same claim as the HCPCS code for the nuclear medicine procedure. Hospitals are also instructed to submit the claim so that the services on the claim each reflect the date the particular service was provided. Therefore, if the nuclear medicine procedure is provided on a different date of service from the radiolabeled product, the claim will contain more than one date of service. More information regarding these edits is available on the OPPS Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/.

There are rare situations where a hospital provides a radiolabeled product to an inpatient, and then the patient is discharged and later returns to the outpatient department for a nuclear medicine imaging procedure but does not require additional radiolabeled product. In these situations, hospitals are to include HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) with a token charge (of less than $1.01) on the same claim as the nuclear medicine procedure in order to receive payment for the nuclear medicine procedure. HCPCS code C9898 should only be reported under the circumstances described above, and the date of service for C9898 should be the same as the date of service for the diagnostic nuclear medicine procedure.

2. Diagnostic Radiopharmaceuticals

Beginning in CY 2008, payment for nonpass-through diagnostic radiopharmaceuticals is packaged into the payment for the associated nuclear medicine procedure.

3. Therapeutic Radiopharmaceuticals

The OPPS will continue to pay for therapeutic radiopharmaceuticals at charges adjusted to cost from January 1, 2008 through December 31, 2009.

90.2.1 - HCPCS Codes Replacements

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Recurring Update Notification. The latest payment rates associated with each APC number may be found in the OPPS PRICER file available on the CMS Web site, as well as in Addendum A and B of OPPS, *which is available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html