

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1760	Date: JUNE 23, 2009
	Change Request 6492

NOTE: *Transmittal 1745, dated May 22, 2009, is being rescinded and replaced by Transmittal 1760. In the Recurring Update Notification attachment, Q4115 was incorrectly identified as a newly payable HCPCS in the hospital outpatient setting effective July 1, 2009 in Table 3. HCPCS Code Q4115 is not payable in the hospital outpatient setting. HCPCS Code Q4115 has been removed from Table 3 and the text identifying the number of new drug codes for July, immediately preceding Table 3 has been changed from three to two. All other information remains the same. The companion Pub. 100-02 instruction was unaffected and is therefore not being recommunicated.*

SUBJECT: July 2009 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 July 2009 OPSS update. It affects chapter 1, section 50.3; chapter 4, sections 10 and 290; and chapter 17, section 90.3. CMS is re-organizing information in these sections.

The July 2009 Integrated Outpatient Code Editor (I/OCE) and OPSS 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).

New / Revised Material

Effective Date: July 1, 2009

Implementation Date: July 6, 2009

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/50.3/When an Inpatient Admission May Be Changed to Outpatient Status
N	1/50.3.1/Background
N	1/50.3.2/Policy and Billing Instructions for Condition Code 44

R	4/Table of Contents
R	4/10.7.1/Outlier Adjustments
R	4/10.7.2.1/Identifying Hospitals and CMHCs Subject to Outlier Reconciliation
R	4/10.7.2.2/Reconciling Outlier Payments for Hospitals and CMHCs
R	4/10.7.2.3/Time Value of Money
R	4/10.7.2.4/Procedures for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
R	4/290.1/Observation Services Overview
R	4/290.2.1/Revenue Code Reporting
R	4/290.2.2/Reporting Hours of Observation
R	4/290.4.1/Billing and Payment for All Hospital Observation Services Furnished Between January 1, 2006 and December 31, 2007
R	4/290.4.2/Separate and Packaged Payment for Direct Referral for Observation Services Furnished Between January 1, 2006 and December 31, 2007
R	4/290.4.3/Separate and Packaged Payment for Observation Services Furnished Between January 1, 2006 and December 31, 2007
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	17/90.3/Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: 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.

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: 1760	Date: June 23, 2009	Change Request: 6492
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SUBJECT: July 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Effective Date: July 1, 2009

Implementation Date: July 6, 2009

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the July 2009 OPPS update. The July 2009 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).

July 2009 revisions to the I/OCE data files, instructions, and specifications are provided in CR 6480, “July 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.2.”

B. Policy:

1. Changes to Procedure and Device Edits for July 2009

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. 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. The updated lists of both types of edits can be found under “Device, Radiolabeled Product, and Procedure Edits” at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

2. Outlier Reconciliation

CMS updated Pub.100-04, Medicare Claims Processing Manual, chapter 4, §10.7.2 to more explicitly identify distinctions between the OPPS outlier reconciliation policy and those of other payment systems. CMS made changes to note that the OPPS outlier reconciliation criteria use OPPS specific-information, specifically 1) the CCR is the OPPS CCR used to make OPPS outlier payments and 2) total outlier payments are total OPPS outlier payments. These changes clarify the manual language to eliminate confusion that the OPPS reconciliation might consider IPPS or other payment system CCRs or total outlier payments across payment systems.

3. Updated Pricer Logic for Certain Blood Products

The January 2009 OPSS Pricer contained a programming error that may result in the underpayment or overpayment of certain blood products that are eligible for the blood deductible when billed together on the same claim. The whole blood and packed red cells described by the following HCPCS codes are eligible for the blood deductible:

P9010
P9016
P9021
P9022
P9038
P9039
P9040
P9051
P9054
P9056
P9057
P9058

The blood deductible is applied to these products only when the hospital incurs a charge for the blood product itself, in addition to a charge for processing and storage. The January 2009 OPSS Pricer programming error affects only those claims on which more than one of the blood product HCPCS codes listed above appears, when at least one of those codes is not subject to the blood deductible because the hospital did not incur a charge for the blood product itself.

Specifically, an underpayment or overpayment may occur when the following conditions are met:

- 1) More than one blood product that is eligible for the blood deductible (i.e., whole blood and packed red cells) appears on the claim;
- 2) At least one of the blood products appearing on the claim that is eligible for the blood deductible is not subject to the blood deductible due to the absence of payment adjustment flag (PAF) 5 and 6 indicating the hospital incurred a charge for the blood itself (the Integrated Outpatient Code Editor applies PAF 5 or 6 to blood lines eligible for the blood deductible when the hospital reports charges for the blood product itself using Revenue Code series 038X (excluding 0380) in addition to charges for processing and storage services using Revenue Code 0390, 0392, or 0399);
- 3) The dates of service fall on or after January 1, 2009, but prior to July 1, 2009; and
- 4) The claim was processed for payment prior to the installation of the July 2009 OPSS Pricer on July 6, 2009.

This programming error has been corrected in the July 2009 OPSS Pricer. Providers who think they may have received an incorrect payment as a result of this programming error may voluntarily submit claims to their contractors for repayment following the implementation of the July 2009 OPSS Pricer on July 6, 2009.

4. Category III CPT Codes

The AMA releases Category III CPT codes in January, for implementation beginning the following July, and in July, for implementation beginning the following January. Prior to CY 2006, CMS implemented new Category III CPT codes annually in January of the following year.

As discussed in the CY 2006 OPSS final rule with comment period (70 FR 68567), CMS modified its process for implementing the Category III codes that the AMA releases each January for implementation in July to ensure timely collection of data pertinent to the services described by the codes; to ensure patient access to the services the codes describe; and to eliminate potential redundancy between Category III CPT codes and some of the C-codes that are payable under the OPSS and were created by CMS in response to applications for new technology services. Therefore, on July 1, 2009, CMS implemented in the OPSS four Category III CPT codes that the AMA released in January 2009 for implementation in July 2009. The codes, along with their status indicators and APCs, are shown in Table 1 below. Payment rates for these services can be found in Addendum B of the July 2009 OPSS Update that is posted on the CMS Web site.

Table 1--Category III CPT Codes Implemented as of July 1, 2009

HCPCS	Long Descriptor	APC	SI
0199T	Physiologic recording of tremor using accelerometer(s) and gyroscope(s), (including frequency and amplitude) including interpretation and report	0215	S
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (if utilized), one or more needles	0049	T
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (if utilized), two or more needles	0050	T
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine		C

5. Billing for Drugs, Biologicals, and Radiopharmaceuticals

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

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

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

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective July 1, 2009

For CY 2009, payment for nonpass-through drugs and biologicals is made at a single rate of ASP+4 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. In CY 2009, a single payment of ASP+6 percent for pass-through drugs and biologicals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. CMS notes that for the third quarter of CY 2009, 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 reinstated sometime during CY 2009, CMS would again use the Part B drug CAP rate for pass-through drugs and biologicals if they are a part of the Part B drug CAP program, as required by the statute.

In the CY 2009 OPPS/ASC final rule with comment period, it was stated that payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary based on the most recent ASP submissions, CMS will incorporate changes to the payment rates in the July 2009 release of the OPPS Pricer. The updated payment rates, effective July 1 2009, will be included in the July 2009 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 July 1, 2009

Nine drugs and biologicals have been granted OPPS pass-through status effective July 1, 2009. 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 July 1, 2009

HCPCS Code	Long Descriptor	APC	Status Indicator Effective 7/1/09
C9250*	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	9250	G
C9251*	Injection, C1 esterase inhibitor (human), 10 units	9251	G
C9252*	Injection, plerixafor, 1 mg	9252	G
C9253*	Injection, temozolomide, 1 mg	9253	G
C9360*	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	9360	G
C9361*	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	9361	G
C9362*	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	9362	G
C9363*	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	9363	G
C9364*	Porcine implant, Permacol, per square centimeter	9364	G

NOTE: The HCPCS codes identified with an "*" indicate that these are new codes effective July 1, 2009.

c. New HCPCS Codes Effective for Certain Drugs and Biologicals

Two new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting for July 2009. These codes are listed in Table 3 below and are effective for services furnished on or after July 1, 2009.

Table 3- New HCPCS Codes Effective for Certain Drugs and Biologicals Effective July 1, 2009

HCPCS Code	Long Descriptor	APC	Status Indicator Effective 7/1/09
Q2023	Injection, factor viii (antihemophilic factor, recombinant) (Xyntha), per i.u.	1268	K
Q4116	Skin substitute, alloderm, per square centimeter	1270	K

d. Updated Payment Rates for Certain HCPCS Codes Effective January 1, 2009 through March 31, 2009

The payment rates for several HCPCS codes were incorrect in the January 2009 OPSS Pricer. The corrected payment rates are listed in Table 4 below and have been installed in the July 2009 OPSS Pricer, effective for services furnished on January 1, 2009, through implementation of the April 2009 update.

Table 4-Updated Payment Rates for Certain HCPCS Codes Effective January 1, 2009 Through March 31, 2009

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
J1441	K	7049	Filgrastim 480 mcg injection	\$304.27	\$60.85
J1740	K	9229	Ibandronate sodium injection	\$136.35	\$27.27
J2505	K	9119	Injection, pegfilgrastim 6mg	\$2,135.12	\$427.02
J7513	K	1612	Daclizumab, parenteral	\$341.09	\$68.22

e. Recognition of Multiple HCPCS Codes For Drugs

Prior to January 1, 2008, the OPSS generally recognized only the lowest available administrative dose of a drug if multiple HCPCS codes existed for the drug; for the remainder of the doses, the OPSS assigned a status indicator “B” indicating that another code existed for OPSS purposes. For example, if drug X has 2 HCPCS codes, one for a 1 ml dose and a second for a 5 ml dose, the OPSS would assign a payable status indicator to the 1 ml dose and status indicator “B” to the 5 ml dose. Hospitals then were required to bill the appropriate number of units for the 1 ml dose in order to receive payment under the OPSS. However, beginning January 1, 2008, the OPSS has recognized each HCPCS code for a Part B drug, regardless of the units identified in the drug descriptor. Hospitals may choose to report multiple HCPCS codes for a single drug, or to continue billing the HCPCS code with the lowest dosage descriptor available.

f. Correct Reporting of Drugs and 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. In circumstances where the

implanted biological has pass-through status, a separate payment for the biological 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 code, 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.

g. 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 code 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 code descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, bill 10 units, even though only 1 vial was administered. The HCPCS code 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.

h. Unit Correction – HCPCS code J9181, *Etoposide, 10 mg*

Table 5 ‘HCPCS Code Changes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals in CY 2008’ listed in Transmittal 1657, Change Request (CR) 6320, issued December 31, 2008, incorrectly listed the number of units in the long code descriptor for HCPCS code J9181, *Etoposide, 10 mg*. HCPCS code J9181 which is assigned status indicator ‘N’ in CY 2009 under the OPPS, is the code for 10 mg of etoposide, while HCPCS code J9182 was discontinued effective January 1, 2009. Providers may review the short and long HCPCS code descriptors in the HCPCS file that is available on the CMS Web site at <http://www.cms.hhs.gov/HCPCSReleaseCodeSets/>.

6. Clarification Related to the Appropriate Use of HCPCS Code C9399

CMS revised Pub. 100-04, Medicare Claims Processing Manual, chapter 17, §90.3 to clarify the appropriate use of HCPCS code C9399. Specifically, HCPCS code C9399 should be used by hospitals when billing a new drug or biological that has been approved by the FDA on or after January 1, 2004, and for which a product-specific HCPCS code has not been assigned. Beginning on or after the date of FDA approval, hospitals may bill for the drug or biological using C9399, Unclassified drug or biological. Hospitals will report in the ANSI ASC X-12 837 I in specific locations, or in the “Remarks” section of the CMS 1450:

1. The National Drug Code (NDC):

2. The quantity of the drug that was administered, expressed in the unit of measure applicable to the drug or biological, and
3. The date the drug was furnished to the beneficiary.

Contractors shall manually price the drug or biological at 95 percent of AWP. They shall pay hospitals 80 percent of the calculated price and shall bill beneficiaries 20 percent of the calculated price, after the deductible is met. Drugs and biological that are manually priced at 95 percent of AWP are not eligible for outlier payment. HCPCS code C9399 is to be reported only for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which there is no HCPCS code that describes the drug.

7. Changes to Nuclear Medicine Procedure-to-Radiolabeled Product Edits for July 2009

Nuclear medicine procedure-to-radiolabeled product edits require that when a nuclear medicine procedure HCPCS code is billed, the claim must also contain an appropriate radiolabeled product. Failure to pass these edits will result in the claim being returned to the provider. Nuclear medicine procedure-to-radiolabeled product edits require that a claim that contains one of a specified set of nuclear medicine codes be returned to the provider if it fails to contain an appropriate radiolabeled product code. The updated lists of both types of edits can be found under “Device, Radiolabeled Product, and Procedure Edits” at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

8. Clarification Related to Observation Services

CMS updated Pub.100-04, Medicare Claims Processing Manual, chapter 4, §290, and Pub.100-02, Medicare Benefit Policy Manual, chapter 6, §20.6, to clarify that a hospital begins billing for observation services, reported with HCPCS code G0378, 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. Editorial changes to the manuals remove references to “admission” and “observation status” in relation to outpatient observation services and direct referrals for observation services. These terms may have been confusing to hospitals. The term “admission” is typically used to denote an inpatient admission and inpatient hospital services. For payment purposes, there is no payment status called “observation”, observation care is an outpatient service, ordered by a physician and reported with a HCPCS code.

9. Clarification Related to Condition Code 44

The changes to Pub.100-04, Medicare Claims Processing Manual, Chapter 1, §50.3, incorporate information and guidance published in MLN Matters article SE0622, published March, 2006. MLN Matters article SE0622 provided clarification to Transmittal 299, CR 3444, issued September 10, 2004.

10. Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPSS 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.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I M A C	C A R I E R	R H I E	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6492.1	Medicare contractors shall install the July 2009 OPPS Pricer.	X		X		X	X				COBC
6492.2	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <ol style="list-style-type: none"> 1) Have dates of services that fall on or after January 1, 2009, but prior to July 1, 2009; 2) Were originally processed prior to the installation of the July 2009 OPPS Pricer; 3) Contain more than one blood product eligible for the blood deductible (see list of eligible codes below); and 4) Do not contain payment adjustment flag 5 or 6 on at least one of the blood products eligible for the blood deductible. <p>List of blood products eligible for blood deductible: P9010, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9057, P9058.</p>	X		X		X				COBC	
6492.3	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <ol style="list-style-type: none"> 1) Have dates of service that fall on or after January 1, 2009, but prior to April 1, 2009; 2) Contain HCPCS code listed in Table 4; and 3) Were originally processed prior to the installation of the July 2009 OPPS Pricer. 	X		X		X				COBC	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	R H I I S S	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6492.4	<p>A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your 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.</p>	X		X		X					COBC

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
CR 6480	"July 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.2"

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

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

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

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.

Medicare Claims Processing Manual

Chapter 1 - General Billing Requirements

Table of Contents

(Rev. 1760, 06-23-09)

50.3.1 - Background

50.3.2 - Policy and Billing Instructions for Condition Code 44

50.3 - When an Inpatient Admission May Be Changed to Outpatient Status

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

50.3.1 - Background

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Payment is made under the *h*ospital Outpatient Prospective Payment System (OPPS) for Medicare Part B services furnished by hospitals subject to the OPPS, and under *the applicable other* payment methodologies for hospitals not subject to *the* OPPS. “Outpatient” means a person who has not been admitted as an inpatient but who is registered on the hospital or critical access hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.

Patients are admitted to the hospital as inpatients only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital. For more detail, see the hospital Conditions of Participation (CoP) at 42 C.F.R. §482.12(c). In some instances, a physician may order a beneficiary to be admitted *as an* inpatient, but upon reviewing the case, the hospital’s utilization review (*UR*) committee determines that an inpatient level of care does not meet the hospital’s admission criteria.

The hospital CoP require all hospitals to have a UR plan. The hospital is responsible to ensure that all the UR activities, including the review of medical necessity of hospital admissions and continued stays are fulfilled as described in 42 CFR §482.30. The CoP standards in 42 C.F.R. §482.30 of the regulations are comprehensive and broadly applicable with regard to the medical necessity of admissions to the hospital and continued inpatient stays.

Review of admissions may be performed before, at, or after hospital admission. More information about the hospital CoP may be found in Pub.100-07, State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.

Taking into consideration these requirements, CMS obtained a condition code from the National Uniform Billing Committee (NUBC), effective April 1, 2004, that specifies:

Condition Code 44--Inpatient admission changed to outpatient – For use on outpatient claims only, when the physician ordered inpatient services, but upon internal utilization review performed before the claim was originally submitted, the hospital determined that the services did not meet its inpatient criteria.

CMS set the policy for the use of Condition Code 44 to address those relatively infrequent occasions, such as a late-night weekend admission when no case manager is on duty to offer guidance, when internal review subsequently determines that an inpatient

admission does not meet hospital criteria and that the patient would have been registered as an outpatient under ordinary circumstances. The State Operations Manual states that in no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate (see Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals). However, CMS encourages and expects hospitals to employ case management staff to facilitate the application of hospital admission protocols and criteria, to facilitate communication between practitioners and the UR committee or Quality Improvement Organization (QIO), and to assist the UR committee in the decision-making process. Use of Condition Code 44 is not intended to serve as a substitute for adequate staffing of utilization management personnel or for continued education of physicians and hospital staff about each hospital's existing policies and admission protocols. As education and staffing efforts continue to progress, the need for hospitals to correct inappropriate admissions and to report condition code 44 should become increasingly rare.

50.3.2. - Policy and Billing Instructions for Condition Code 44

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

In cases where a hospital utilization review committee determines that an inpatient admission does not meet the hospital's inpatient criteria, the hospital may change the beneficiary's status from inpatient to outpatient and submit an outpatient claim (*bill type* 13x *or* 85x) for medically necessary Medicare Part B services that were furnished to the beneficiary, provided all of the following conditions are met:

1. The change in patient status from inpatient to outpatient is made prior to discharge or release, while the beneficiary is still a patient of the hospital;
2. The hospital has not submitted a claim to Medicare for the inpatient admission;
3. A physician concurs with the utilization review committee's decision; and
4. The physician's concurrence with the utilization review committee's decision is documented in the patient's medical record.

When the hospital has determined that it may submit an outpatient claim according to the conditions described above, the entire episode of care should be billed as an outpatient episode of care.

Refer to Pub. 100-04, Medicare Claims Processing Manual; Chapter 30, Financial Liability Protections; Section 20, Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Disallowed, for information regarding financial liability protections.

When the hospital submits a 13x or 85x bill for services furnished to a beneficiary whose status was changed from inpatient to outpatient, the hospital is required to report

Condition Code 44 on the outpatient claim *in one of Form Locators 24-30, or in the ANSI X12N 837 I in Loop 2300, HI segment, with qualifier BG, on the outpatient claim. Additional information may be found in Chapter 25 of this manual, (Completing and Processing the Form CMS-1450 Data Set). Condition Code 44 is used by CMS and QIOs to track and monitor these occurrences. The reporting of Condition Code 44 on a claim does not affect the amount of hospital outpatient payment that would otherwise be made for a hospital outpatient claim that did not require the reporting Condition Code 44.*

One of the requirements for the use of Condition Code 44 is physician concurrence with the determination that an inpatient admission does not meet the hospital's admission criteria and that the patient should have been registered as an outpatient. This prerequisite for use of Condition Code 44 is consistent with the requirements in the CoP in 42 C.F.R. §482.30 (d) of the regulations. This paragraph provides that the practitioner or practitioners responsible for the care of the patient must be consulted and allowed to present their views before the UR committee or QIO makes its determination that an admission is not medically necessary. It may also be appropriate to include the practitioner who admitted the patient if this is a different person than the practitioner responsible for the care of the patient.

If the conditions for use of Condition Code 44 are not met, the hospital may submit a 12x bill type for covered "Part B Only" services that were furnished to the inpatient. Medicare may still make payment for certain Part B services furnished to an inpatient of a hospital when payment cannot be made under Part A because an inpatient admission is determined not to be medically necessary. Information about "Part B Only" services is located in Pub. 100-02, Medicare Benefit Policy Manual, chapter 6, section 10. Examples of such services include, but are not limited to, diagnostic x-ray tests, diagnostic laboratory tests, surgical dressings and splints, prosthetic devices, and certain other services. The Medicare Benefit Policy Manual includes a complete list of the payable "Part B Only" services.

Entries in the medical record cannot be expunged or deleted and must be retained in their original form. Therefore, all orders and all entries related to the inpatient admission must be retained in the record in their original form. If a patient's status changes in accordance with the requirements for use of Condition Code 44, the change must be fully documented in the medical record, complete with orders and notes that indicate why the change was made, the care that was furnished to the beneficiary, and the participants in making the decision to change the patient's status.

Medicare Claims Processing Manual

Chapter 4 - Part B Hospital

(Including Inpatient Hospital Part B and OPPS)

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10.7.1 - Outlier Adjustments

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

The OPSS incorporates an outlier adjustment to ensure that outpatient services with variable and potentially significant costs do not pose excessive financial risk to providers. Section 419.43(f) of the Code of Federal Regulations excludes drugs, biologicals and items and services paid at charges adjusted to cost from outlier payments. The OPSS determines eligibility for outliers using either a “multiple” threshold, which is the product of a multiplier and the APC payment rate, or a combination of a multiple and fixed-dollar threshold. A service or group of services becomes eligible for outlier payments when the cost of the service or group of services estimated using the hospital’s most recent overall cost-to-charge ratio (CCR) separately exceeds each relevant threshold. For community mental health centers (CMHCs), CMS determines whether billed partial hospitalization services are eligible for outlier payments using a multiple threshold specific to CMHCs. The outlier payment is a percentage of the difference between the cost estimate and the multiple threshold. The CMS OPSS Web site at www.cms.hhs.gov/HospitalOutpatientPPS/ under “Annual Policy Files” includes a table depicting the specific hospital and CMHC outlier thresholds and the payment percentages in place for each year of the OPSS.

Beginning in CY 2000, CMS determined outlier payments on a claim basis. CMS determined a claim’s eligibility to receive outlier payments using a multiple threshold. A claim was eligible for outlier payments when the total estimate of charges reduced to cost for the entire claim exceeded a multiple of the total claim APC payment amount. As provided in Section 1833(t)(5)(D), CMS used each hospital’s overall CCR rather than a CCR for each department within the hospital. CMS continues to use an overall hospital CCR specific to ancillary cost centers to estimate costs from charges for outlier payments.

In CY 2002, CMS adopted a policy of calculating outlier payments based on each individual OPSS (line-item) service. CMS continued using a multiple threshold, modified to be a multiple of each service’s APC payment rather than the total claim APC payment amount, and an overall hospital CCR to estimate costs from charges. For CY 2004, CMS established separate multiple outlier thresholds for hospitals and CMHCs.

Beginning in CY 2005, for hospitals only, CMS implemented the use of a fixed-dollar threshold to better target outlier payments to complex and costly services that pose hospitals with significant financial risk. The current hospital outlier policy is calculated on a service basis using both fixed-dollar and multiple thresholds to determine outlier eligibility.

The current outlier payment is determined by:

- Calculating the cost related to an OPSS line-item service, including a pro rata portion of the total cost of packaged services on the claim and adding payment for any device with pass-through status to payment for the associated procedure, by

multiplying the total charges for OPSS services by each hospital's overall CCR (see §10.11.8 of this chapter); and

- Determining whether the total cost for a service exceeds 1.75 times the OPSS payment and separately exceeds the fixed-dollar threshold determined each year; and
- If total cost for the service exceeds both thresholds, the outlier payment is 50 percent of the amount by which the cost exceeds 1.75 times the OPSS payment.

The total cost of all packaged items and services, including the cost of uncoded revenue code lines *with a revenue code status indicator of "N"*, that appear on a claim is allocated across all separately paid OPSS services that appear on the same claim. The proportional amount of total packaged cost allocated to each separately paid OPSS service is based on the percent of the APC payment rate for that service out of the total APC payment for all separately paid OPSS services on the claim.

To illustrate, assume the total cost of all packaged services and revenue codes on the claim is \$100, and the three APC payment amounts paid for OPSS services on the claim are \$200, \$300, and \$500 (total APC payments of \$1000). The first OPSS service or line-item is allocated \$20 or 20 percent of the total cost of packaged services, because the APC payment for that service/line-item represents 20 percent (\$200/\$1000) of total APC payments on the claim. The second OPSS service is allocated \$30 or 30 percent of the total cost of packaged services, and the third OPSS service is allocated \$50 or 50 percent of the total cost of packaged services.

If a claim has more than one service with a status indicator (SI) of S or T and any lines with an SI of S or T have less than \$1.01 as charges, charges for all S and/or T lines are summed and the charges are then divided across the two lines in proportion to their APC payment rate. The new charge amount is used in place of the submitted charge amount in the line-item outlier calculation.

If a claim includes a composite payment that pays for more than one otherwise separately paid service, the charges for all services included in the composite are summed up to one line. To determine outlier payments, CMS estimates a single cost for the composite APC from the summarized charges. Total packaged cost is allocated to the composite line-item in proportion to other separately paid services on the claim.

In accordance with Section 1833(t)(5)(A)(i) of the Act, if a claim includes a device receiving pass-through payment, the payment for the pass-through device is added to the payment for the associated procedure, less any offset, in determining the associated procedure's eligibility for outlier payment, and the outlier payment amount. The estimated cost of the device, which is equal to payment, also is added to the estimated cost of the procedure to ensure that cost and payment both contain the procedure and device costs when determining the procedure's eligibility for an outlier payment.

10.7.2.1 - Identifying Hospitals and CMHCs Subject to Outlier Reconciliation

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Under Section 419.43(d)(6)(i), for hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009, OPSS high cost outlier payments may be reconciled upon cost report settlement to account for differences between the overall ancillary CCR used to pay the claim at its original submission by the provider, and the CCR determined at final settlement of the cost reporting period during which the service was furnished. Hospitals and CMHCs that Medicare contractors identify using the criteria listed below are subject to the *OPSS* outlier reconciliation policies described in this section. *OPSS* outlier payments are reconciled if the CMS central office and regional office confirm that reconciliation is appropriate. Services with an APC payment paid at charges adjusted to cost are not subject to reconciliation policies.

Subject to the approval of the CMS central office and regional office, a hospital's *outpatient* outlier claims are reconciled at the time of cost report final settlement if they meet the following criteria:

1. The actual overall ancillary CCR is found to be plus or minus 10 percentage points or more from the CCR used during that time period to make *OPSS* outlier payments, and
2. Total *OPSS* outlier payments in that cost reporting period exceed \$500,000.

Subject to the approval of the CMS central office and regional office, a CMHC's outlier claims are reconciled at the time of cost report final settlement if they meet the following criteria:

1. The actual overall CCR is found to be plus or minus 10 percentage points or more from the CCR used during that time period to make *OPSS* outlier payments, and
2. Any CMHC *OPSS* outlier payments are made in that cost reporting period.

To determine if a hospital or CMHC meets the criteria above, the Medicare contractor shall incorporate all the adjustments from the cost report, run the cost report, calculate the revised CCR, and compute the actual overall ancillary CCR prior to issuing a Notice of Program Reimbursement (NPR). If the criteria for *OPSS outlier* reconciliation are not met, the cost report shall be finalized. If the criteria for reconciliation are met, Medicare contractors shall follow the instructions below in section 10.7.2.4 of this chapter. The NPR cannot be issued nor can the cost report be finalized until *OPSS* outlier reconciliation is complete. These hospital and CMHC cost reports will remain open until their claims have been processed for *OPSS* outlier reconciliation.

As stated above, if a cost report is reopened after final settlement and as a result of this reopening there is a change to the CCR (which could trigger or affect *OPPS* outlier reconciliation and outlier payments), Medicare contractors shall notify the CMS central and regional offices for further instructions. Notification to the CMS Central Office shall be sent to the address and email address provided in §10.11.3.1.

Any cost report that has been final settled that meets the qualifications for *OPPS outlier* reconciliation shall be reopened. Medicare contractors shall notify the CMS Central Office and regional office that the *OPPS* outlier payments need to be reconciled, using the procedures included in §10.7.2.4. After CMS' approval of the reconciliation, the Medicare contractor shall issue a reporting notice to the provider.

10.7.2.2 - Reconciling Outlier Payments for Hospitals and CMHCs *(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)*

For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009, all hospitals and CMHCs are subject to the *OPPS outlier* reconciliation policies set forth in this section. If a hospital or CMHC meets the criteria in §10.7.2.1, the Medicare contractors shall notify the central office and regional office at the address and email address provided in §10.11.3.1. Further instructions for Medicare contractors on reconciliation and the time value of money are provided below in §§10.7.2.3 and 10.7.2.4 of this chapter. The following examples demonstrate how to apply the criteria for reconciliation:

EXAMPLE A:

Cost reporting period: 01/01/2009-12/31/2009

Overall ancillary CCR used to pay original claims submitted during cost reporting period: 0.40

(In this example, this CCR is from the tentatively settled 2007 cost report.)

Final settled overall ancillary CCR from 01/01/2009 – 12/31/2009 cost report: 0.50

Total *OPPS* outlier payout in 01/01/2009-12/31/2009 cost reporting period: \$600,000

Because the CCR of 0.40 used at the time the claim was originally paid changed to 0.50 at the time of final settlement, and the provider received greater than \$500,000 in *OPPS* outlier payments during that cost reporting period, the criteria are met for reconciliation, and therefore, the Medicare contractor notifies the central office and the regional office. The provider's *OPPS* outlier payments for this cost reporting period are reconciled using the correct CCR of 0.50.

In the event that multiple *overall ancillary* CCRs are used in a given cost reporting period to calculate outlier payments, Medicare contractors should calculate a weighted average of the CCRs in that cost reporting period. Example B below shows how to weight the CCRs. The Medicare contractor shall then compare the weighted CCR to the CCR determined at the time of final settlement of the cost reporting period to determine if *OPPS outlier* reconciliation is required. Total *OPPS* outlier payments for the entire cost reporting period must exceed \$500,000 in order to trigger reconciliation.

EXAMPLE B:

Cost reporting period: 01/01/2009-12/31/2009

Overall ancillary CCR used to pay original claims submitted during cost reporting period:

- 0.40 from 01/01/2009 to 03/31/2009 (This CCR could be from the tentatively settled 2006 cost report.)
- 0.50 from 04/01/2009 to 12/31/2009 (This CCR could be from the tentatively settled 2007 cost report.)

Final settled operating CCR from 01/01/2009 – 12/31/2009 cost report: 0.35

Total *OPPS* outlier payout in 01/01/2009 -12/31/2009 cost reporting period: \$600,000

Weighted average CCR: 0.476

CCR	Days	Weight	Weighted CCR
0.40	90	0.247 (90 Days / 365 Days)	(a) 0.099 = (0.40 * 0.247)
0.50	275	0.753 (275 Days / 365 Days)	(b) 0.377 = (0.50 * 0.753)
TOTAL	365		(a)+(b) = 0.476

The hospital meets the criteria for *OPPS outlier* reconciliation in this cost reporting period because the weighted average CCR at the time the claim was originally paid changes from 0.476 to 0.35 (which is greater than 10 percentage points) at the time of final settlement, and the provider received an *OPPS* outlier payment greater than \$500,000 for the entire cost reporting period.

Even if a hospital or CMHC does not meet the criteria for reconciliation in §10.7.2.1, subject to approval of the central and regional offices, the Medicare contractor has the

discretion to request that a hospital or CMHC's *OPPS* outlier payments in a cost reporting period be reconciled if the hospital's most recent cost and charge data indicate that the *OPPS* outlier payments to the hospital were significantly inaccurate. The Medicare contractor sends notification to the regional office and central office via the address and email address provided in §10.11.3.1. Upon approval of the central and regional office that a hospital or CMHC's *outpatient* outlier claims need to be reconciled, Medicare contractors should follow the instructions in §10.7.2.4.

10.7.2.3 - Time Value of Money

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Effective for hospital outpatient services furnished in the first cost reporting period on or after January 1, 2009, at the time of any reconciliation under §10.7.2.2, *OPPS* outlier payment may be adjusted to account for the time value of money of any adjustments to *OPPS* outlier payments as a result of reconciliation. As described in *42 CFR* 419.43(d)(6)(ii), the time value of money is applied from the midpoint of the hospital or CMHC's cost reporting period being settled to the date on which the CMS central office receives notification from the Medicare contractor that reconciliation should be performed.

If a hospital or CMHC's *OPPS* outlier payments have met the criteria for reconciliation, CMS will calculate the aggregate adjustment using the instructions below concerning reprocessing claims and determine the additional amount attributable to the time value of money of that adjustment. The index that is used to calculate the time value of money is the monthly rate of return that the Medicare trust fund earns. This index can be found at <http://www.ssa.gov/OACT/ProgData/newIssueRates.html>.

The following formula is used to calculate the rate of the time value of money:

$$\left(\frac{\text{Rate from Web site as of the midpoint of the cost report being settled}}{\text{\# of days from that midpoint until date of reconciliation}} \right) \times 365 \text{ or } 366$$

For purposes of calculating the time value of money, the "date of reconciliation" is the day on which the CMS central office receives notification. This "date of reconciliation" is based solely on the date CMS central office receives notification and not on the date that reconciliation is approved by the CMS central and regional offices. This date is either the postmark from the written notification sent to the CMS central office via mail by the Medicare contractor, or the date an email was received from the Medicare contractor by the CMS central office, whichever is first.

The following is an example of the procedures for reconciliation and computation of the adjustment to account for the time value of money:

EXAMPLE C:

Cost reporting period: 01/01/2009 – 12/31/2009

Midpoint of cost reporting period: 07/01/2009

Date of reconciliation: 12/31/2010

Number of days from midpoint until date of reconciliation: 548

Rate from Social Security Web site: 4.625%

Overall ancillary CCR used to pay actual original claims in cost reporting period:
0.40 (This CCR could be from the tentatively settled 2006 or 2007 cost report.)

Final settled operating CCR from 01/01/2009 – 12/31/2009 cost report: 0.50
Total **OPPS** outlier payout in 01/01/2009 – 12/31/2009 cost reporting period:
\$600,000

Because the CCR fluctuated from 0.40 at the time the claims were originally paid to 0.50 at the time of final settlement and the provider has an **OPPS** outlier payout greater than \$500,000, the criteria have been met to trigger reconciliation. The Medicare contractor notifies the central and regional offices.

CMS reprocesses the claims. The reprocessing indicates the revised **OPPS** outlier payments are \$700,000.

Using the values above, the rate that is used for the time value of money is determined:

$$(4.625 / 365) * 548 = 6.9438\%$$

Based on the claims reconciled, the provider is owed \$100,000 (\$700,000 - \$600,000) for the reconciled amount and \$6,943.80 for the time value of money.

10.7.2.4 - Procedures for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

CMS has not finished the offline utility that will recalculate OPPS outlier payment using the CCR determined at final settlement. Additional instructions on performing outlier reconciliation will be forthcoming when this process has been finalized.

The following is a step-by-step explanation of how Medicare contractors are to notify CMS and hospitals (or CMHCs) that **OPPS outlier** reconciliation should be performed and to record reconciled **OPPS** outlier claims for hospitals and CMHCs that meet the criteria for reconciliation:

- 1) The Medicare contractor sends notification to the CMS central office (not the hospital or CMHC), via the street address and email address provided in section 10.11.3.1 and to the regional office that a hospital or CMHC has met the criteria for *OPPS outlier* reconciliation.
- 2) If the Medicare contractor receives approval from the CMS central office and regional office that *OPPS outlier* reconciliation is appropriate, the Medicare contractor follows steps 3-8 below.
- 3) Hospital and CMHC cost reports will remain open until their claims have been processed for *OPPS* outlier reconciliation.
- 4) The Medicare contractor shall notify the hospital or CMHC and copy the CMS regional office and central office in writing and via email (through the address provided in §10.11.3.1) that the hospital or CMHC's *OPPS* outlier claims are to be reconciled.
- 5) CMS will reprocess claims in an offline Pricer/FISS utility program to determine the correct *OPPS* outlier payment amounts. Items paid at charges adjusted to cost using the prospective overall CCR are not subject to reconciliation.
- 6) CMS will calculate the time value of money attributable to the adjustment.
- 7) The Medicare contractor shall record the reconciled amount, the original *OPPS* outlier amount, the time value of money, and the rate used to calculate the time value of money in the cost report. (TOPS payments will be calculated including the reconciled *OPPS* outlier payments and time value of money.)
- 8) The Medicare contractor shall finalize the cost report, issue an NPR, and make the necessary adjustment from or to the provider.

The central office works as quickly as possible to reconcile these claims in order to allow Medicare contractors to finalize the cost report and issue an NPR within the normal CMS time frames. If a Medicare contractor has any questions regarding this process, it should contact the central and regional offices, using the address and e-mail address provided in §10.11.3.1 of this chapter.

290.1 - Observation Services Overview

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation *services are* commonly *ordered for* patients who present to the emergency department

and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient services.

Observation services must also be reasonable and necessary to be covered by Medicare. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours.

290.2.1 - Revenue Code Reporting

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Hospitals are required to report observation charges under the following revenue codes:

Revenue Code	Subcategory
0760	General Classification category
0762	Observation Room

Other ancillary services performed while the patient receives observation services are reported using appropriate revenue codes and HCPCS codes as applicable.

290.2.2 - Reporting Hours of Observation

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Observation time begins at the clock time documented in the patient's medical record, which coincides with the time *that observation care is initiated* in accordance with a physician's order. Hospitals should round to the nearest hour. For example, a patient who *began receiving observation services* at 3:03 p.m. according to the nurses' notes and *was discharged to home at 9:45 p.m. when observation care and other outpatient services were completed*, should have a "7" placed in the units field of the reported observation HCPCS code.

General standing orders for observation services following all outpatient surgery are not recognized. Hospitals should not report as observation care, services that are part of another Part B service, such as postoperative monitoring during a standard recovery period (e.g., 4-6 hours), which should be billed as recovery room services. Similarly, in the case of patients who undergo diagnostic testing in a hospital outpatient department, routine preparation services furnished prior to the testing and recovery afterwards are

included in the payments for those diagnostic services. Observation services should not be billed concurrently with diagnostic or therapeutic services for which active monitoring is a part of the procedure (e.g., colonoscopy, chemotherapy). In situations where such a procedure interrupts observation services, hospitals would record for each period of observation services the beginning and ending times during the hospital outpatient encounter and add the length of time for the periods of observation services together to reach the total number of units reported on the claim for the hourly observation services HCPCS code G0378 (Hospital observation service, per hour). Observation time ends when all medically necessary services related to observation care are completed. For example, this could be before discharge when the need for observation has ended, but other medically necessary services not meeting the definition of observation care are provided (in which case, the additional medically necessary services would be billed separately or included as part of the emergency department or clinic visit). Alternatively, the end time of observation services may coincide with the time the patient is actually discharged from the hospital or admitted as an inpatient. Observation time may include medically necessary services and follow-up care provided after the time that the physician writes the discharge order, but before the patient is discharged. However, reported observation time would not include the time patients remain in the *hospital* after treatment is finished for reasons such as waiting for transportation home.

If a period of observation spans more than 1 calendar day, all of the hours for the entire period of observation must be included on a single line and the date of service for that line is the date that observation care begins.

290.4.1 - Billing and Payment for All Hospital Observation Services Furnished Between January 1, 2006 and December 31, 2007

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Since January 1, 2006, two G-codes have been used to report observation services and direct *referral* for observation care. For claims for dates of service January 1, 2006 through December 31, 2007, the Integrated Outpatient Code Editor (I/OCE) determines whether the observation care or direct *referral* services are packaged or separately payable. Thus, hospitals provide consistent coding and billing under all circumstances in which they deliver observation care.

Beginning January 1, 2006, hospitals should not report CPT codes 99217-99220 or 99234-99236 for observation services. In addition, the following HCPCS codes were discontinued as of January 1, 2006: G0244 (Observation care by facility to patient), G0263 (Direct Admission with congestive heart failure, chest pain or asthma), and G0264 (Assessment other than congestive heart failure, chest pain, or asthma).

The three discontinued G-codes and the CPT codes that were no longer recognized were replaced by two new G-codes to be used by hospitals to report all observation services, whether separately payable or packaged, and direct *referral* for observation care, whether separately payable or packaged:

- G0378- Hospital observation service, per hour; and
- G0379- Direct admission of patient for hospital observation care.

The I/OCE determines whether observation services billed as units of G0378 are separately payable under APC 0339 (Observation) or whether payment for observation services will be packaged into the payment for other services provided by the hospital in the same encounter. Therefore, hospitals should bill HCPCS code G0378 when observation services are *ordered and* provided to any patient regardless of the patient's condition. The units of service should equal the number of hours the patient *receives observation services*.

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, critical care service, or hospital outpatient surgical procedure (status indicator T procedure) on the day of initiation of observation services. Hospitals should only report HCPCS code G0379 when a patient is *referred directly for* observation care after being seen by a physician in the community (see §290.4.2 below)

Some non-repetitive OPPS services provided on the same day by a hospital may be billed on different claims, provided that all charges associated with each procedure or service being reported are billed on the same claim with the HCPCS code which describes that service. *See chapter 1, section 50.2.2 of this manual.* It is vitally important that all of the charges that pertain to a non-repetitive, separately paid procedure or service be reported on the same claim with that procedure or service. It should also be emphasized that this relaxation of same day billing requirements for some non-repetitive services does not apply to non-repetitive services provided on the same day as either direct *referral* to observation care or observation services because the OCE claim-by-claim logic cannot function properly unless all services related to the episode of observation care, including diagnostic tests, lab services, hospital clinic visits, emergency department visits, critical care services, and status indicator T procedures, are reported on the same claim. Additional guidance can be found in *chapter 1, section 50.2.2 of this manual.*

290.4.2 - Separate and Packaged Payment for Direct *Referral for* Observation *Services Furnished* Between January 1, 2006 and December 31, 2007

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

In order to receive separate payment for a direct *referral for* observation *care* (APC 0604), the claim must show:

1. Both HCPCS codes G0378 (Hourly Observation) and G0379 (Direct Admit to Observation) with the same date of service;

2. That no services with a status indicator T or V or Critical care (APC 0617) were provided on the same day of service as HCPCS code G0379; and
3. The observation care does not qualify for separate payment under APC 0339.

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

Separate payment is not allowed for HCPCS code G0379, direct admission to observation care, when billed with the same date of service as a hospital clinic visit, emergency room visit, critical care service, or “T” status procedure.

If a bill for *the* direct *referral for* observation *services* does not meet the three requirements listed above, then payment for the direct *referral* service will be packaged into payments for other separately payable services provided to the beneficiary in the same encounter.

290.4.3 - Separate and Packaged Payment for Observation Services Furnished Between January 1, 2006 and December 31, 2007

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Separate payment may be made for observation services provided to a patient with congestive heart failure, chest pain, or asthma. The list of ICD-9-CM diagnosis codes eligible for separate payment is reviewed annually. Any changes in applicable ICD-9-CM diagnosis codes are included in the October quarterly update of the OPSS and also published in the annual OPSS Final Rule. The list of qualifying ICD-9-CM diagnosis codes is also published on the OPSS Web page.

All of the following requirements must be met in order for a hospital to receive a separate APC payment for observation services through APC 0339:

1. Diagnosis Requirements
 - a. The beneficiary must have one of three medical conditions: congestive heart failure, chest pain, or asthma.
 - b. Qualifying ICD-9-CM diagnosis codes must be reported in Form Locator (FL) 76, Patient Reason for Visit, or FL 67, principal diagnosis, or both in order for the hospital to receive separate payment for APC 0339. If a qualifying ICD-9-CM diagnosis code(s) is reported in the secondary diagnosis field, but is not reported in either the Patient Reason for Visit field (FL 76) or in the principal diagnosis field (FL 67), separate payment for APC 0339 is not allowed.
2. 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.

3. 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:
 - An emergency department visit (APC 0609, 0613, 0614, 0615, 0616) or
 - A clinic visit (APC 0604, 0605, 0606, 0607, 0608); or
 - Critical care (APC 0617); or
 - Direct *referral for* observation *care* reported with HCPCS code G0379 (APC 0604); 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.

4. 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.

Only observation services that are billed on a 13X bill type may be considered for a separate APC payment.

Hospitals should bill all of the other services associated with the observation care, including direct *referral for* observation, hospital clinic visits, emergency room visits, critical care services, and T status procedures, on the same claim so that the claims processing logic may appropriately determine the payment status (either packaged or separately payable) of HCPCS codes G0378 and G0379.

If a bill for observation care does not meet all of the requirements listed above, then payment for the observation care will be packaged into payments for other separately payable services provided to the beneficiary in the same encounter.

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

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

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. In certain circumstances when observation care is 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 may be made for the entire extended care encounter through one of two composite APCs when certain criteria are met. For information about payment for extended assessment and management composite APCs, see §10.2.1 (Composite APCs) of this chapter.

APC 8002 (Level I Extended Assessment and Management Composite) describes an encounter for care provided to a patient that includes a high level (Level 5) clinic visit or direct *referral for* observation in conjunction with observation services of substantial duration (8 or more hours). APC 8003 (Level II Extended Assessment and Management Composite) describes an encounter for care provided to a patient that includes a high level (Level 4 or 5) emergency department visit or critical care services in conjunction with observation services of substantial duration. Beginning January 1, 2009, APC 8003 also includes high level (Level 5) Type B emergency department visits. There is no limitation on diagnosis for payment of these composite APCs; 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 (CPT code 99205 or 99215); or
 - Critical care (CPT code 99291); or
 - Direct *referral for* observation *care* reported with HCPCS code G0379 (APC 0604) 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. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Direct *referral for* observation care continues to be reported using HCPCS code G0379 (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 0604 or packaged into payment for composite APC 8002 (Level I Prolonged 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 0604 or APC 8002 include:

1. Both HCPCS codes G0378 (Hospital observation services, per hr) and G0379 (Direct admission of patient 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

90.3 – Hospital Outpatient Payment Under OPSS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Section 621(a) of the MMA amends Section 1833(t) of the Social Security Act by adding paragraph (15), Payment for New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services for which a product-specific HCPCS code has not been assigned shall be paid an amount equal to 95 percent of average wholesale price (AWP). This provision applies only to payments under the hospital outpatient prospective payment system (OPSS).

Beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which *a product-specific HCPCS code has not been assigned. Beginning on or after the date of FDA approval, hospitals may bill for the drug or biological using HCPCS code C9399, Unclassified drug or biological.*

Hospitals report in the ANSI ASC X-12 837 I in specific locations, or in the “Remarks” section of the CMS 1450):

- 1. the National Drug Code (NDC),*
- 2. the quantity of the drug that was administered, expressed in the unit of measure applicable to the drug or biological, and*
- 3. the date the drug was furnished to the beneficiary.*

Contractors shall manually price the drug or biological at 95 percent of AWP. They shall pay hospitals 80 percent of the calculated price and shall bill beneficiaries 20 percent of the calculated price, after the deductible is met. Drugs and biologicals that are manually priced at 95 percent of AWP are not eligible for outlier payment.

HCPCS code C9399 is only to be reported for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which there is no HCPCS code that describes the drug.