

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1657</b>	<b>Date: December 31, 2008</b>
	<b>Change Request 6320</b>

**SUBJECT: January 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 January 2009 OPPS update. It affects Chapter 4, Sections 10, 20, 50, 61, 70, 160.1, 180.3, 200, 260, and 290; Chapter 17, Section 90.2; and Chapter 32, Sections 67, 68, and 69. CMS is re-organizing information in these sections.

The January 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.

**New / Revised Material**

**Effective Date: January 1, 2009**

**Implementation Date: January 5, 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-Only One Per Row.

R/N/D	Chapter / Section / Subsection / Title
R	4/Table of Contents
R	4/10.2.1/Composite APCs
R	4/10.4/Packaging
N	4/10.6.1/Payment Adjustment for Certain Rural Hospitals
N	4/10.6.2/Payment Adjustment for Failure to Meet the Hospital Outpatient Quality Reporting Requirements
N	4/10.6.2.1/ Hospitals to which the Payment Reduction Applies
N	4/10.6.2.2/Services to which the Payment Reduction Applies
N	4/10.6.2.3/Contractor Responsibilities
N	4/10.6.2.4/Application of the Payment Reduction Factor in Calculation of the Reduced Payment and Reduced Copayment
R	4/10.7/Outliers

N	4/10.7.1/Outlier Adjustments
N	4/10.7.2/Outlier Reconciliation
N	4/10.7.2.1/Identifying Hospitals and CMHCs Subject to Outlier Reconciliation
N	4/10.7.2.2/Reconciling Outlier Payments for Hospitals and CMHCs
N	4/10.7.2.3/Time Value of Money
N	4/10.7.2.4/Procedures for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
R	4/10.11.1/Requirement to Calculate CCRs for Hospitals Paid under OPPS and for CMHCs
R	4/10.11.2/Circumstances in Which CCRs are Used
R	4/10.11.3/Selection of the CCR to be Used
N	4/10.11.3.1/CMS Specification of Alternative CCR
N	4/10.11.3.2/Hospital or CMHC Request for Use of a Different CCR
N	4/10.11.3.3/Notification to Hospitals Paid Under the OPPS of a Change in the CCR
R	4/10.11.4/of CCRs in Mergers, Acquisitions, Other Ownership Changes, or Errors Related to CCRs
R	4/10.11.5/New Providers and Providers with Cost Report Periods Less Than a Full Year
R	4/10.11.6/Substitution of Statewide CCRs for Extreme OPPS Hospital Specific CCRs
R	4/10.11.7/Methodology for Calculation of Hospital Overall CCR for Hospitals That Do Not Have Nursing and Paramedical Education Programs
R	4/10.11.8/Methodology for Calculation of Hospital Overall CCR for Hospitals That Have Nursing and Paramedical Education Programs
R	4/10.11.9/Methodology for Calculation of CCR for CMHCs
R	4/10.11.10/Location of Statewide CCRs, Tolerances for Use of Statewide CCRs in Lieu of Calculated CCRs and Cost Centers to be Used in the Calculation of CCRs
R	4/10.11.11/Reporting of CCRs for Hospitals Paid Under OPPS and for CMHCs
R	4/20.1/General

R	4/20.6.9/Use of HCPCS Modifier FB
R	4/61/Billing for Devices Under the OPSS
R	4/20.6.10/Use of HCPCS Modifier FC
R	4/50.1/Outpatient Provider Specific File
R	4/61/Billing for Devices under the OPSS
R	4/61.3/Billing for Devices Furnished Without Cost to an OPSS Hospital or Beneficiary or for Which the Hospital Receives a Full or Partial Credit and Payment for OPSS Services Required to Furnish the Device
R	4/61.3.1/Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital
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
R	4/61.3.3/Reporting Requirements When the Hospital Receives Partial Credit for the Replacement Device
R	4/61.3.4/Medicare Payment Adjustment
R	4/70/Transitional Corridor Payments
R	4/70.1/Transitional Outpatient Payments (TOPs) for CY 2000 and CY 2001
R	4/70.2/Transitional Outpatient Payments (TOPs) for CY 2002
R	4/70.3/Transitional Outpatient Payments (TOPs) for CY 2003
R	4/70.4/Transitional Outpatient Payments (TOPs) for CY 2004 and CY 2005
R	4/70.5/Transitional Outpatient Payments (TOPs) for CY 2006-CY 2008
R	4/70.6/Transitional Outpatient Payments (TOPs) for CY 2009
N	4/70.7/TOPs Overpayments
R	4/160.1/Critical Care Services
R	4/180.3/Unlisted Service or Procedure
R	4/200.7.2/Cardiac Echocardiography With Contrast
R	4/200.8/Billing for Nuclear Medicine Procedures
R	4/260.1/Special Partial Hospitalization Billing Requirements for Hospitals, Community Mental Health Centers, and Critical Access Hospitals
R	4/260.1.1/- Bill Review for Partial Hospitalization Services Provided in Community Mental Health Centers (CMHC)

R	4/260.4/Reporting Service Units for Partial Hospitalization
R	4/260.5/Line Item Date of Service Reporting for Partial Hospitalization
R	4/290.5.1/Billing and Payment for Observation Services Beginning January 1, 2008
R	17/90.2/Drugs, Biologicals, and Radiopharmaceuticals
R	32/67.1/Practitioner Billing for No Cost Items
R	32/67.2/Institutional Billing for No Cost Items
R	32/67.2.1/Billing No Cost Items Due to Recall, Replacement, or Free Sample
R	32/68.1/General
R	32/68.2/Notifying Contractors of an IDE Device Trial
R	32/68.3/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE
R	32/68.4/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE
R	32/69.6/Requirements for Billing Routine Costs of Clinical Trials
R	32/69.5/Billing Requirements General
R	32/69.6/Requirements for Billing Routine Costs of Clinical Trials
R	32/69.6/Requirements for Billing Routine Costs of Clinical Trials
R	32/69.6/Requirements for Billing Routine Costs of Clinical Trials

### **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:**

**Manual Instruction**

**Recurring Update Notification**

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

# Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1657	Date: December 31, 2008	Change Request: 6320
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**SUBJECT: January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**Effective Date:** January 1, 2009

**Implementation Date:** January 5, 2009

## I. GENERAL INFORMATION

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

January 2009 revisions to I/OCE data files, instructions, and specifications are provided in Change Request (CR) 6315, “January 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.0.”

## B. Policy:

### 1. New Status Indicators for the Calendar Year (CY) 2009

For CY 2009, we are replacing current status indicator “Q” with three new separate status indicators: “Q1,” “Q2,” and “Q3.” Status indicator “Q1” is assigned to all “STVX-packaged codes;” status indicator “Q2” is assigned to all “T-packaged codes;” and status indicator “Q3” is assigned to all codes that may be paid through a composite APC-based on composite-specific criteria or separately through single code APCs when the criteria are not met. The change to establish new status indicators “Q1,” “Q2,” and “Q3” helps to make our policies more transparent to hospitals and facilitates the use of status indicator-driven logic in our ratesetting calculations, and in hospital billing and accounting systems.

For CY 2009, we are using new payment status indicator “R” for all blood and blood product APCs. This new status indicator was created in order to facilitate implementation of the reduced market basket conversion factor that applies to payments to hospitals that are required to report quality data but fail to meet the established quality reporting standards. This reduced conversion factor applies to CY 2009 payment for blood and blood products.

We created new status indicator “U” to designate brachytherapy source APCs for which separate payment is made in CY 2009. This definition does not specify the payment methodology. CY 2009 payment for brachytherapy sources, to which the reduced market basket conversion factor does not apply, is discussed in detail in section 20 below.

## **2. Reporting Unlisted Services or Procedures**

An unlisted HCPCS code represents an item, service, or procedure for which there is no specific CPT or Level II alphanumeric HCPCS code. The CPT code book lists a number of unlisted service or procedure codes, which can be found at the end of a section or subsection. Alternatively, a summary list of the unlisted CPT codes can be found in the Guidelines section for each chapter of the CPT code book. The long descriptors for these codes start with the term “Unlisted” and the last two digits of the codes often end in “99.”

Under the OPPTS, CMS generally assigns the unlisted service or procedure codes to the lowest level APC within the most appropriate clinically related series of APCs. Payment for items reported with unlisted codes is often packaged.

For non-OPPTS payment purposes, when an unlisted service or procedure code is reported, a report describing the service or procedure shall be submitted with the claim. Pertinent information includes a definition or description of the nature, extent, and need for the procedure or service, as well as the provider’s time, effort, and equipment necessary to provide the service.

When a Medicare contractor receives a claim with an unlisted HCPCS code for non-OPPTS payment, the contractor shall verify that no existing HCPCS code adequately describes the procedure or service. Unlisted codes should be reported only if no other specific HCPCS codes adequately describe the procedure or service. If an unlisted code is submitted on a claim and the contractor has verified that the code submitted is correct, the contractor pays the claim using the unlisted code, based on the applicable non-OPPTS payment methodology. However, if it is determined that an unlisted code was submitted in error because the procedure or service is described by a specific HCPCS code, the contractor shall advise the hospital or CAH of the appropriate code and process the claim with the correct code. If a procedure or service reported with an unlisted code is reported frequently, the contractor shall advise the provider that a request for a specific CPT code or alphanumeric HCPCS code should be made.

The latest list of “Unlisted” CPT codes for procedures and services can be found at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> under the category titled “Annual Policy Files.” Medicare contractors shall review this list once a year since it is updated annually on or about January 1 of the calendar year.

## **3. National Correct Coding Initiative (NCCI) Edits Update**

The NCCI edits are updated quarterly and the institutional version is one calendar quarter behind the physician version. In the past, the Outpatient Code Editor (OCE) had

not applied the NCCI edits for the following categories of services: anesthesiology, evaluation and management, and mental health services. Effective January 1, 2009, these categorical exclusions will no longer apply. As a result, a large number of new institutional NCCI edits will be applied to claims effective January 1, 2009 to take into account the edits that were previously excluded. Hospitals are encouraged to begin to educate their staff about the application of the additional categories of NCCI edits to their claims.

To review the types of NCCI edits that were previously excluded from the institutional version but are currently included in the physician version for these categories, refer to the NCCI files on the following site:

<http://www.cms.hhs.gov/NationalCorrectCodInitEd/NCCIEP/list.asp#TopOfPage>. One may use anesthesiology, evaluation and management, or mental health services CPT or Level II HCPCS codes to search these files. A subset of the corresponding edits in the physician version is being added to the institutional version. Consistent with longstanding practice, CMS makes specific decisions about NCCI edits that are appropriate for facilities, incorporating comments on potential edits from relevant professional associations and, therefore, the institutional NCCI edits may differ from the physician NCCI edits.

The institutional NCCI edit files for the quarter beginning January 1, 2009 will be available on or about January 1, 2009 on the following site:

<http://www.cms.hhs.gov/NationalCorrectCodInitEd/NCCIEHOPPS/list.asp#TopOfPage>.

#### **4. Payment Adjustment for Failure to Meet the Hospital Outpatient Quality Reporting Requirements**

Effective for services furnished on or after January 1, 2009, Section 1833(t)(17)(A) of the Act requires that “Subsection (d) hospitals” that have failed to meet the specified hospital outpatient quality reporting requirements for the relevant calendar year will receive payment under the OPSS that reflects a 2 percentage point reduction of the annual OPSS update factor. See [www.qualitynet.org](http://www.qualitynet.org) for information on complying with the reporting requirements and standards that must be met to receive the full update. Specific policy regarding the definition of Subpart (d) hospitals, the identification of the services for which payment will be reduced, and the process by which the reduced payment and reduced copayment will be calculated can be found in Transmittal 368, Change Request (CR) 6072, issued November 3, 2008, and in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 4, §10.6.2 “Payment Adjustment for Failure to Meet the Hospital Outpatient Quality Reporting Requirements” that is being issued as part of this transmittal.

When Transmittal 368 was issued, we discovered that we inadvertently omitted status indicator “R” in the specifications for the services to which the reduction is applicable and didn't list status indicator “R” in the Business Requirements. We are making a correction to include blood APCs with status indicator “R” under the application of the quality reporting ratio where appropriate. Specifically, we have revised the Business

Requirements previously issued in CR 6072 that specify the status indicator of the services to which the ratio applies by adding status indicator “R”.

For the CY 2009 OPSS, the reduced conversion factor that will apply to payments for applicable services to Subsection (d) hospitals that have failed to meet the specified hospital outpatient quality reporting requirements for CY 2009 is \$64.784. The full CY 2009 OPSS conversion factor that will apply to payments for applicable services to Subsection (d) hospitals that have satisfied the specified hospital outpatient quality reporting requirements for CY 2008 is \$66.059. The reporting ratio by which the payment and copayment for the applicable services will be adjusted for Subpart (d) hospitals that failed to meet the specified hospital outpatient quality reporting requirements for the CY 2009 update is 0.981.

The quality reporting support contractor to whom FIs/MACs should refer new hospitals is FMQAI which can be contacted at [hopqdrp@fmqai.com](mailto:hopqdrp@fmqai.com), by phone at 866-800-8756, or in writing at FQMAI, 5201 West Kennedy Blvd., Suite 900, Tampa, FL 33609.

## **5. CY 2009 Transitional Outpatient Payments (TOPs)**

Section 5105 of the Deficit Reduction Act of 2005 (DRA) extended hold harmless transitional outpatient payments (TOPs) through December 31, 2008 for rural hospitals having 100 or fewer beds that are not sole community hospitals (SCHs). Hospitals received 95 percent of the hold harmless amount for services furnished in CY 2006, 90 percent in CY 2007, and 85 percent in CY 2008. Section 147 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) extended the hold harmless provision for small rural hospitals with 100 or fewer beds through December 31, 2009, at 85 percent of the hold harmless amount. Section 147 also provided 85 percent of the hold harmless amount from January 1, 2009 through December 31, 2009 to sole community hospitals with 100 or fewer beds.

Eighty-five percent of hold harmless TOPs shall continue for services rendered through December 31, 2009, for rural hospitals with 100 or fewer beds. Eighty-five percent of hold harmless TOPs shall be paid for services rendered through December 31, 2009, for sole community hospitals with 100 or fewer beds. Essential Access Community Hospitals (EACHs) are considered to be sole community hospitals under Section 1886(d)(5)(D)(iii)(III) of the Act. Therefore, EACHs are also eligible for TOPs payments for CY 2009. Cancer and children's hospitals continue to receive hold harmless TOPs permanently.

The interim TOPs for these hospitals shall be calculated as 85 percent of the hold harmless amount (the amount by which the provider's charges multiplied by its cost-to-charge ratio (CCR) and then multiplied by its payment-to-cost ratio (PCR) exceeds the provider's OPSS payments).

For purposes of TOPs, a hospital is considered rural if it is either geographically rural or classified to rural for wage index purposes. For example, a hospital that is geographically rural is always considered rural for TOPs, even if it is reclassified to urban for wage index purposes. A hospital that is geographically urban, but reclassified to rural for the wage index, is considered rural for purposes of TOPs. Contractors shall use the Inpatient Provider Specific File (IPSF) to determine if a hospital is rural. We are also instructing contractors to ensure that all qualified hospitals have a PCR and CCR entered in their Outpatient Provider Specific File (OPSF) and that the Yes/No TOPs indicator is accurate in the OPSF.

The contractor shall make appropriate interim payments beginning January 1, 2009 through December 31, 2009.

## **6. Outlier Reconciliation**

Section 1833(t)(5) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for outpatient services furnished when they incur extraordinarily high costs. This additional payment, known as an “outlier,” is designed to mitigate the financial risk associated with extremely costly and complex services. In order to qualify for outlier payments, services must have estimated cost above a fixed-dollar threshold and a multiple threshold, which are published in the annual Outpatient Prospective Payment System final rule. The regulations governing payments for outlier cases are located at 42 CFR 419.43.

As provided in Section 1833(t) (5) (D) of the Act, CMS uses each hospital overall CCR, rather than a CCR for each department within the hospital, to estimate costs from charges for outlier payments. To ensure that an accurate CCR is used to estimate cost, CMS already requires substitution of a Statewide average CCR when the contractor is unable to identify an accurate CCR for a hospital, including hospitals that are new, hospitals experiencing a change of ownership that have not accepted assignment, and hospitals with CCRs greater than the upper limit. Under 42 CFR 419.43(d)(5)(i), CMS also may specify an alternative to the overall ancillary CCR from the hospital or community mental health center’s (CMHC) most recently settled or tentatively settled cost report. Further, a hospital or CMHC may request that its Medicare contractor use a different (higher or lower) CCR based on substantial evidence presented by the hospital. Such a request must be approved by CMS.

Under 42 CFR 419.43(d)(6)(i), for hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009, outlier payments may be reconciled upon cost report settlement to account for differences between the 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. Since OPPS outlier payments are no longer final payments, CMS will consider reprocessing claims for errors in CCRs or outlier payments on a case by case basis.

In addition, under 42 CFR 419.43(d)(6)(ii), for hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009, at the time of reconciliation under 42 CFR 419.43(d)(6)(i), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based on a widely available index to be established in advance by the Secretary, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

CMS is clarifying OPSS CCR and outlier reconciliation policies for Medicare contractors, specifically, when to specify an alternative CCR other than a Statewide average or one calculated from the hospital or CMHC's most recent cost report; how to use the outlier reconciliation thresholds to determine eligibility for reconciliation; how to execute OPSS outlier reconciliation; and how the time value of money will be applied to the amount of outlier under or overpayment. CMS has not finished the program that will recalculate outlier payments using the CCR determined at final settlement. Further instructions on performing outlier reconciliation will be forthcoming when this utility becomes available.

## **7. Partial Hospitalization APCs (APC 0172 and APC 0173)**

For CY 2009, we are creating two new APCs, 0172 (Level I Partial Hospitalization (3 services)) and 0173 (Level II Partial Hospitalization (4 or more services)), to replace APC 0033 (Partial Hospitalization), which we are deleting for CY 2009. When a community mental health center (CMHC) or hospital provides three units of partial hospitalization services and meets all other partial hospitalization payment criteria, the CMHC or hospital would be paid through APC 0172. When the CMHC or hospital provides four or more units of partial hospitalization services and meets all other partial hospitalization payment criteria, the hospital would be paid through APC 0173. We have updated the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §§260.1 and §260.1.1 to reflect these new APCs.

Effective January 1, 2009, we are updating the list of partial hospitalization program (PHP) billable codes. We provide this updated list in the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §260.1 and §260.1.1.

We are codifying existing policy regarding PHP patient eligibility as we believe it will strengthen the integrity of the PHP benefit by conforming our regulations at 42 CFR 410.43 to our longstanding policies and making these requirements available in one regulatory section (42 CFR 410.43). We have updated the Medicare Benefit Policy Manual, Pub 100-02, Chapter 6, §70.3 to reflect the patient eligibility criteria at 42 CFR 410.43.

## **8. Mental Health Services Composite APC (APC 0034)**

Since the beginning of the OPSS, we set the annual payment rate for the mental health composite APC at the same rate as APC 0033, the partial hospitalization APC. For CY

2009, we are creating two new APCs, 0172 (Level I Partial Hospitalization (3 services)) and 0173 (Level II Partial Hospitalization (4 or more services)), to replace APC 0033 (Partial Hospitalization), which we are deleting for CY 2009. When a community mental health center (CMHC) or hospital provides three units of partial hospitalization services and meets all other partial hospitalization payment criteria, the CMHC or hospital would be paid through APC 0172. When the CMHC or hospital provides four or more units of partial hospitalization services and meets all other partial hospitalization payment criteria, the hospital would be paid through APC 0173.

We set the CY 2009 payment rate for mental health composite APC 0034 at the same rate as APC 0173 (\$200.17), which is the maximum partial hospitalization per diem payment. The I/OCE will continue to determine whether to pay specified mental health services individually or to make a single payment at the same rate as the APC 0173 per diem rate for partial hospitalization for all of the specified mental health services furnished on that date of service. Through the I/OCE, when the payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services would exceed the maximum per diem partial hospitalization payment [listed as APC 0173], those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite), which has the same payment rate as APC 0173, and the hospital would be paid one unit of APC 0034.

## **9. Payment for Multiple Imaging Composite APCs**

Effective for services furnished on or after January 1, 2009, multiple imaging procedures performed during a single session using the same imaging modality will be paid by applying a composite APC payment methodology. The services will be paid with one composite APC payment each time a hospital bills for second and subsequent imaging procedures described by the HCPCS codes in one imaging family on a single date of service. The I/OCE logic will determine the assignment of the composite APCs for payment. Prior to January 1, 2009, hospitals receive a full APC payment for each imaging service on a claim, regardless of how many procedures are performed during a single session.

The composite APC payment methodology for multiple imaging services utilizes three imaging families (Ultrasound, CT and CTA, and MRI and MRA) and results in the creation of five new composite APCs: APC 8004 (Ultrasound Composite); APC 8005 (CT and CTA without Contrast Composite); APC 8006 (CT and CTA with Contrast Composite); APC 8007 (MRI and MRA without Contrast Composite); and APC 8008 (MRI and MRA with Contrast Composite). When a procedure is performed with contrast during the same session as a procedure without contrast, and the two procedures are within the same family, the “with contrast” composite APC (either APC 8006 or 8008) will be assigned. CMS is updating the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §10.2.1 to reflect the implementation of this new composite APC policy.

The specified HCPCS codes within the three imaging families and five composite APCs are provided below:

<b>Family 1 - Ultrasound</b>	
APC 8004 (Ultrasound Composite)	
76604	Us exam, chest
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited

<b>Family 2 - CT and CTA with and without Contrast</b>	
APC 8005 (CT and CTA without Contrast Composite)*	
0067T	Ct colonography;dx
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
APC 8006 (CT and CTA with Contrast Composite)	
70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye

70482	Ct orbit/ear/fossa w/o&w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o&w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o&w/dye
73206	Ct angio upr extrm w/o&w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
73706	Ct angio lwr extr w/o&w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
75635	Ct angio abdominal arteries
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, assign APC 8006 rather than 8005.	
<b>Family 3 - MRI and MRA with and without Contrast</b>	
APC 8007 (MRI and MRA without Contrast Composite)*	
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech

71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
C8901	MRA w/o cont, abd
C8904	MRI w/o cont, breast, uni
C8907	MRI w/o cont, breast, bi
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
APC 8008 (MRI and MRA with Contrast Composite)	
70549	Mr angiograph neck w/o&w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o&w/dye
70548	Mr angiography neck w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye

73220	Mri uppr extremity w/o&w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o&w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o&w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o&w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, assign APC 8008 rather than 8007.	

## 10. Payment for Extended Assessment and Management Composite APCs

Beginning January 1, 2009, HCPCS code G0384 (Level 5 Hospital Type B ED Visit) will be included in the criteria that determines eligibility for payment of composite APC 8003 (Level II Extended Assessment and Management). 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) Type A emergency department visit, a high level (Level 5) Type B emergency department visit, or critical care services in conjunction with observation services of substantial duration. There is no limitation on diagnosis for payment of these composite APCs; however, composite payment will not be made when observation services are reported in association with a surgical procedure (status indicator T) or the hours of observation care reported are less than 8. The I/OCE will evaluate 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 OPSS Pricer, will determine the appropriate status indicator, APC, and payment for every code on a claim.

## **11. Billing for Wound Care Services**

As provided under Section 1834(k)(5) of the Act, we created a therapy code list to identify and track therapy services paid under the Medicare Physician Fee Schedule (MPFS). We provide this list of therapy codes along with their respective designations in the Medicare Claims Processing Manual, Pub 100–04, Chapter 5, §20. Two of the designations that we use in that manual denote whether the listed therapy code is an "always therapy" service or a "sometimes therapy" service. We define an "always therapy" service as a service that must be performed by a qualified therapist under a certified therapy plan of care, and a "sometimes therapy" service as a service that may be performed by an individual outside of a certified therapy plan of care. We provide payment for several "sometimes therapy" wound care services under the OPSS if they are provided by the hospital outside of a certified therapy plan of care.

For CY 2009, CPT code 0183T, Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day, is newly designated as a "sometimes therapy" wound care service. In CY 2009, hospitals will receive separate payment under the OPSS when they bill for wound care services described by CPT code 0183T that are furnished to hospital outpatients by individuals independent of a therapy plan of care. In contrast, when such services are performed by a qualified therapist under a certified therapy plan of care, providers should attach an appropriate therapy modifier (that is, "GP" for physical therapy, "GO" for occupational therapy, and "GN" for speech language pathology) or report their charges under a therapy revenue code (that is, revenue codes in the 042x, 043x, or 044x series), or both, to receive payment under the MPFS.

## **12. Further Clarification Related to Billing for Medical and Surgical Supplies**

When medical and surgical supplies (other than prosthetic and orthotic devices as described in the Medicare Claims Processing Manual, Chapter 20, §10.1) described by HCPCS codes with status indicators other than "H" or "N," are provided incident to a physician's service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent supplies. Claims containing charges for medical and surgical supplies used in providing hospital outpatient services are submitted to the Medicare contractor providing OPSS payment for the services in which they are used. The hospital should include charges associated with these medical and surgical supplies on claims so their costs are incorporated in ratesetting, and payment for the supplies is packaged into payment for the associated procedures under the OPSS in accordance with 42 CFR 419.2(b)(4).

For example, if the hospital staff in the emergency department initiate the intravenous administration of a drug through an infusion pump described by HCPCS code E0781 (Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient), complete the drug infusion, and discontinue use of the infusion pump before the patient leaves the hospital outpatient

department, HCPCS code E0781 should not be reported because the infusion pump was used as a supply and would be paid through OPPS payment for the drug administration service. The hospital should include the charge associated with the infusion pump on the claim.

In another example, if hospital outpatient staff perform a surgical procedure on a patient in which temporary bladder catheterization is necessary and use a catheter described by HCPCS code A4338 (Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each), the hospital should not report A4338 because the catheter was used as a supply and would be paid through OPPS payment for the surgical procedure. The hospital should include the charge associated with the urinary catheter on the claim.

When hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting, adjustment, or other services necessary for the patient's use of the item, the hospital should not bill a visit or procedure HCPCS code to report the charges associated with the fitting, adjustment, or other related services. Instead, the HCPCS code for the device already includes the fitting, adjustment or other similar services. For example, if the hospital outpatient staff provides the orthotic device described by HCPCS code L1830 (KO, immobilizer, canvas longitudinal, prefabricated, includes fitting and adjustment), the hospital should only bill HCPCS code L1830 and should not bill a visit or procedure HCPCS code to describe the fitting and adjustment.

### **13. Reporting Hospital Critical Care Services under the OPPS**

Hospitals should separately report all HCPCS codes in accordance with correct coding principles, CPT code descriptions, and any additional CMS guidance, when available. Specifically with respect to CPT code 99291, Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes, hospitals must follow the CPT instructions related to reporting that CPT code. Any services that CPT indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by CPT) should not be billed separately by the hospital. Instead, hospitals should report charges for any services provided as part of the critical care services. In establishing payment rates for critical care services, and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services, and other services, according to the standard OPPS methodology for packaging costs.

Correct reporting by hospitals ensures the integrity of our CMS cost data. CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to prevent improper coding that could lead to inappropriate Part B payments. Medicare contractors implement NCCI edits in their systems for purposes of physician payment, and a subset of NCCI edits, commonly referred to as CCI edits, is incorporated into the I/OCE for claims processed through that system. While

CMS temporarily suspended the application of certain categories of CCI edits for a period of time to allow hospitals to incorporate coding for certain types of services in their systems, effective January 1, 2009, CMS applies all appropriate CCI edits for purposes of hospital reporting.

We refer readers to the July 2008 OPPS quarterly update, Transmittal 1536, CR 6094, issued on June 19, 2008, for further clarification about the reporting of CPT codes for hospital outpatient services paid under the OPSS.

#### **14. Changes to the Initial Preventive Physical Examination (IPPE)**

The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, extends the eligibility period for receiving an IPPE from 6 months to 12 months following the beneficiary's initial enrollment in Medicare Part B, effective January 1, 2009. Any beneficiary who has not yet had an IPPE and whose initial enrollment in Medicare began in CY 2008 will be able to have an IPPE in CY 2009, as long as it is done within 12 months of the beneficiary's initial enrollment. Medicare will pay for one IPPE for each beneficiary in a lifetime. The Medicare deductible does not apply to the IPPE if it is performed on or after January 1, 2009. OPSS providers will report IPPE visits occurring on or after January 1, 2009 using new HCPCS code G0402 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment). HCPCS code G0344 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 6 months of Medicare enrollment) will be active until December 31, 2008, for beneficiaries who have an IPPE prior to January 1, 2009.

The policy for reporting a medically necessary hospital visit during the same visit as the IPPE continues to apply for CY 2009. The CPT codes 99201 through 99215 for hospital clinic visits of new and established patients at all five levels of resource intensity may also be appropriately reported, depending on the circumstances, but they must be appended with the CPT -25 modifier, identifying the hospital visit as a separately identifiable service from the IPPE described by HCPCS code G0402.

The MIPPA also removes the screening electrocardiogram (EKG) as a mandatory requirement to be performed as part of the IPPE. The MIPPA requires that there be education, counseling, and referral for an EKG, as appropriate, for a once-in-a lifetime screening EKG performed as a result of a referral from an IPPE. The facility service for the screening EKG (tracing only) is payable under the OPSS when it is the result of a referral from an IPPE. Providers paid under the OPSS should report new HCPCS code G0404 (Electrocardiogram, routine ECG with 12 leads, tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination) for services furnished on or after January 1, 2009. HCPCS code G0367 (Tracing only, without interpretation and report, performed as a component of the initial preventive physical exam) will be active until December 31, 2008, for reporting the facility service for a screening EKG performed prior to January 1, 2009.

## **15. Changes to Device Edits for January 2009**

Claims for OPSS services must pass two types of device edits to be accepted for processing: procedure-to-device edits and device-to-procedure edits. Procedure-to-device edits, which have been in place for many procedures since 2005, continue to be in place. These edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code.

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

Both types of device edits can be found at [www.cms.hhs.gov/HospitalOutpatientPPS/](http://www.cms.hhs.gov/HospitalOutpatientPPS/). Failure to pass these edits will result in the claim being returned to the provider.

## **16. Manual Updates for the No Cost/Full Credit and Partial Credit Device Payment Adjustment Policy**

CMS is revising the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §§20.6.9, 20.6.10, and 61.3 to clarify correct coding and charging practices for devices furnished without cost or with a full or partial credit from the manufacturer. Effective January 1, 2009, payment is reduced only for procedure codes that map to the 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.

## **17. Manual Updates for Billing No Cost Items, Investigational Device Exemption (IDE), and Qualifying Clinical Trials**

CMS is revising the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §§67-69 to clarify correct billing practices for no cost items, IDE devices, and routine costs, and qualifying clinical trials. Typically, institutional providers should not report the usage of a no cost item. However, for some claims, providers may be required to bill a no cost item, including certain IDE devices and other items provided free of charge in a clinical trial, due to claims processing edits such as the OPSS procedure-to-device edits. Because these edits require a device to be billed along with an associated service, even if the item was received at no cost, OPSS providers must report a token charge of less than \$1.01 for the item in the covered charge field, along with HCPCS modifier –FB appended to the procedure code that reports the service that requires the device.

**18. Payment for Implanted Prosthetic Devices Furnished to Hospital Inpatients who Have Coverage Under Part B of Medicare but do not Have Coverage of Inpatient Hospital Services under Medicare Part A at the Time that the Device is Furnished**

Effective for services furnished on and after January 1, 2009 Medicare will make separate payment for implanted prosthetic devices furnished to hospital inpatients who have coverage under Part B of Medicare, but who do not have coverage of inpatient hospital services under Medicare Part A at the time the device is furnished. To receive payment for these services, hospitals must determine if the device furnished meets the definition of an implanted prosthetic device as defined in the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 6, §10. If so, hospitals should report the implanted prosthetic device using HCPCS code C9899, long descriptor: Implanted prosthetic device, payable only for inpatients who do not have inpatient coverage, and short descriptor: Inpt implant pros dev, no cov. The Medicare contractor will determine whether payment can be made and if so, will establish the payment to be made and the amount of copayment for which the beneficiary will be liable. See Transmittal 1628, CR 6050, issued November 3, 2008, and the Medicare Claims Processing Manual, Pub. 100-4, Chapter 4, §240, for the payment and claims processing instructions that apply to services reported by C9899.

**19. Stereotactic Radiosurgery (SRS) CPT Code 61793**

For CY 2009, CPT code 61793, Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator), one or more sessions, will be deleted on December 31, 2008, and replaced with several new CPT codes, specifically CPT codes 61796, 61797, 61798, 61799, 61800, 63620, and 63621, effective January 1, 2009. Similar to its predecessor code, all of the replacement codes have been assigned status indicator “B” under the OPPS because we are continuing to recognize the HCPCS G-codes for SRS treatment delivery services under the OPPS. Refer to §200.3 (Billing Codes for Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Radiosurgery (SRS)) of Chapter 4 of the Medicare Claims Processing Manual for information on the G-codes. The replacement codes for CPT code 61793 are displayed in Table 1 below.

**Table 1-Replacement Codes for CPT Code 61793 Effective January 1, 2009**

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>CY 2009 SI</b>
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion	B
61797	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional cranial lesion, simple	B
61798	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); 1 complex cranial lesion	B
61799	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional cranial lesion, complex	B
61800	Application of stereotactic headframe for stereotactic radiosurgery	B
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion	B

CPT Code	Long Descriptor	CY 2009 SI
63621	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional spinal lesion	B

## 20. Payment for Brachytherapy Sources

The MIPPA requires CMS to pay for brachytherapy sources for the period of July 1, 2008 through December 31, 2009, at hospitals' charges adjusted to the costs. We, therefore, have continued paying brachytherapy sources based on charges adjusted to cost for CY 2008. The status indicators of brachytherapy source HCPCS codes (except C2637) which were previously paid at charges adjusted to cost have remained "H" effective July 1, 2008 through December 31, 2008 for payment of brachytherapy sources at hospitals' charges adjusted to their costs.

Brachytherapy sources will continue to be paid at charges adjusted to cost from January 1, 2009 through December 31, 2009, as required by MIPPA. However, beginning January 1, 2009, brachytherapy sources will have their own unique status indicator, "U." This change, proposed and finalized in the CY 2009 OPSS/ASC final rule with comment period (provide cite), is reflected in the table below for all sources (with the exception of C2637, which is non-payable.) In addition, because of their cost-based payment methodology through CY 2009, brachytherapy sources will continue to not be eligible for outlier payments or for the rural sole community hospital (SCH) adjustment during that time period. The HCPCS codes for separately paid brachytherapy sources, long descriptors, status indicators, and APCs for CY 2009 are listed in Table 2, the comprehensive brachytherapy source table below.

**NOTE:** When billing for stranded sources, providers should bill the number of units of the appropriate source HCPCS C-code according to the number of brachytherapy sources in the strand, and should not bill as one unit per strand. See Transmittal 1259, CR 5623, issued on June 1, 2007, for further information on billing for brachytherapy sources and the OPSS coding changes made for brachytherapy sources effective July 1, 2007.

**Table 2- Comprehensive List of Brachytherapy Sources Payable as of January 1, 2009**

HCPCS Code	Long Descriptor	SI	APC
A9527	Iodine I-125, sodium iodide solution, therapeutic, per millicurie	U	2632
C1716	Brachytherapy source, non-stranded, Gold-198, per source	U	1716
C1717	Brachytherapy source, non-stranded, High Dose Rate Iridium-192, per source	U	1717
C1719	Brachytherapy source, non-stranded, Non-High Dose Rate Iridium-192, per source	U	1719
C2616	Brachytherapy source, non-stranded, Yttrium-90, per source	U	2616
C2634	Brachytherapy source, non-stranded, High Activity, Iodine-125,	U	2634

<b>HCPCS Code</b>	<b>Long Descriptor</b>	<b>SI</b>	<b>APC</b>
	greater than 1.01 mCi (NIST), per source		
C2635	Brachytherapy source, non-stranded, High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source	U	2635
C2636	Brachytherapy linear source, non-stranded, Palladium-103, per 1MM	U	2636
C2637	Brachytherapy source, non-stranded, Ytterbium-169, per source	B	
C2638	Brachytherapy source, stranded, Iodine-125, per source	U	2638
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	U	2639
C2640	Brachytherapy source, stranded, Palladium-103, per source	U	2640
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	U	2641
C2642	Brachytherapy source, stranded, Cesium-131, per source	U	2642
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	U	2643
C2698	Brachytherapy source, stranded, not otherwise specified, per source	U	2698
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source	U	2699

## **21. Billing for Drugs, Biologicals, and Radiopharmaceuticals**

### **a. Newly Recognized HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals for CY 2009**

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.

We remind hospitals that under the OPPI, 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 descriptions 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.

For CY 2009, several new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available. These codes are listed in Table 3 below.

**Table 3- New HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals in CY 2009**

<b>CY2009 HCPCS Code</b>	<b>CY 2009 Short Descriptor</b>	<b>CY 2009 SI</b>	<b>CY 2009 APC</b>
A9580	Sodium fluoride F-18	N	
C9245	Injection, romiplostim	G	9245
C9246	Inj, gadoxetate disodium	G	9246
C9247	Inj, iobenguane, I-123, dx	N	
C9248	Inj, clevidipine butyrate	G	9248
J0641	Levoleucovorin injection	K	1236
J3300	Triamcinolone A inj PRS-free	N	
Q4100	Skin substitute, NOS	N	
Q4111	Gammagraft skin sub	K	1252
J8705	Topotecan oral	K	1238

In addition, similar to our policy for CY 2008 where we began recognizing multiple HCPCS codes for the same drugs with different dosage descriptors, for CY 2009 we are newly recognizing the six HCPCS codes shown in Table 4 below. Payment for these newly recognized HCPCS drug codes for different doses of the same drugs is made on the same basis as payment for the previously recognized HCPCS codes for those drugs. Hospitals that may be burdened by reporting multiple HCPCS codes for the same drugs need not change their current billing practices for purposes of the OPDS, but hospitals that would like additional flexibility when billing for drugs with multiple HCPCS code dosages may report these codes.

**Table 4 – HCPCS Codes Unrecognized in CY 2007 and CY 2008, Associated Recognized HCPCS Codes, and Status Indicators for CY 2009**

<b>CY 2009 HCPCS Codes Previously Unrecognized</b>	<b>CY 2007 SI</b>	<b>CY 2009 Short Descriptor</b>	<b>Associated HCPCS Recognized in CY 2007</b>	<b>Final CY 2009 SI for Newly Recognized HCPCS Code</b>
Q0165	B	Prochlorperazine maleate 10 mg	Q0164	N
Q0168	B	Dronabinol 5 mg oral	Q0167	N
Q0170	B	Promethazine HCl 25 mg oral	Q0169	N
Q0172	B	Chlorpromazine HCl 25 mg oral	Q0171	N
Q0176	B	Perphenazine 8 mg oral	Q0175	N
Q0178	B	Hydroxyzine pamoate 50 mg	Q0177	N

Many HCPCS codes for drugs, biologicals, and radiopharmaceuticals have undergone changes in their HCPCS code descriptors that will be effective in CY 2009. In addition, several temporary C-codes have been deleted effective December 31, 2008 and replaced with permanent HCPCS codes in CY 2009. Hospitals should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the active CY 2009 HCPCS codes.

**Table 5-HCPCS Code Changes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals in CY 2008**

<b>CY 2008 HCPCS Code</b>	<b>CY 2008 Long Descriptor</b>	<b>CY 2009 HCPCS Code</b>	<b>CY 2009 Long Descriptor</b>
C9003	Palivizumab-RSV-IgM, per 50 mg	90378	Respiratory syncytial virus immune globulin (rsv-igim), for intramuscular use, 50 mg, each
J0348	Injection, anadulafungin, 1 mg	J0348	Injection, anidulafungin, 1 mg
C9241	Injection, doripenem, 10 mg	J1267	Injection, doripenem, 10 mg
C9242	Injection, fosaprepitant, 1 mg	J1453	Injection, fosaprepitant, 1 mg
Q4097	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg	J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1751	Injection, iron dextran, 165, 50 mg	J1750	Injection, iron dextran, 50 mg
J1752	Injection, iron dextran 267, 50 mg		
Q4098	Injection, iron dextran, 50 mg		
C9237	Injection, lanreotide acetate, 1mg	J1930	Injection, lanreotide, 1 mg
C9238	Injection, levetiracetam, 10 mg	J1953	Injection, levetiracetam, 10 mg
C9244	Injection, regadenoson, 0.4 mg	J2785	Injection, regadenoson, 0.1 mg
J3100	Injection, tenecteplase, 50 mg	J3101	Injection, tenecteplase, 1 mg
Q4096	Injection, von willebrand factor complex, human, ristocetin cofactor (not otherwise specified), per i.u. vwf:rc0	J7186	Injection, antihemophilic factor viii/von willebrand factor complex (human), per factor viii i.u.
C9243	Injection, bendamustine hcl, 1 mg	J9033	Injection, bendamustine hcl, 1 mg
J9182	Etoposide, 100 mg	J9181	Etoposide 100 MG inj
C9240	Injection, ixabepilone, 1 mg	J9207	Injection, ixabepilone, 1 mg
C9239	Injection, temsirolimus, 1 mg	J9330	Injection, temsirolimus, 1 mg
J7340	Dermal and epidermal, (substitute) tissue of human origin, with or without bioengineered or processed elements, with metabolically active elements, per square centimeter	Q4101	Skin substitute, Apligraf, per square centimeter
J7341	Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter	Q4102	Skin substitute, Oasis Wound Matrix, per square centimeter
		Q4103	Skin substitute, Oasis Burn Matrix, per square centimeter
J7343	Dermal and epidermal, (substitute) tissue of nonhuman origin, with or	Q4104	Skin substitute, Integra Bilayer Matrix Wound Dressing (BMWD), per square

<b>CY 2008 HCPCS Code</b>	<b>CY 2008 Long Descriptor</b>	<b>CY 2009 HCPCS Code</b>	<b>CY 2009 Long Descriptor</b>
	without other bioengineered or processed elements, without metabolically active elements, per square centimeter		centimeter
		Q4105	Skin substitute, Integra Dermal Regeneration Template (DRT), per square centimeter
J7342	Dermal (substitute) tissue of human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter	Q4106	Skin substitute, Dermagraft, per square centimeter
J7344	Dermal (substitute) tissue of human origin, with or without other bioengineered or processed elements, without metabolically active elements, per square centimeter	Q4107	Skin substitute, Graft Jacket, per square centimeter
J7347	Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Integra Matrix), per sq. cm.	Q4108	Skin substitute, Integra Matrix, per square centimeter
J7348	Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (TissueMend), per sq. cm.	Q4109	Skin substitute, Tissuemend, per square centimeter
J7349	Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (PriMatrix), per sq. cm.	Q4110	Skin substitute, Primatrix, per square centimeter
J7346	Dermal (substitute) tissue of human origin, injectable, with or without other bioengineered or processed elements, but without metabolically active elements, 1 cc	Q4112	Allograft, Cymetra, Injectable, 1cc
		Q4113	Allograft, Graft Jacket Express, injectable, 1cc
C9357	Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc	Q4114	Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc

**b. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)  
Effective January 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. We note that for the first 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 is suspended beginning January 1, 2009. Should the Part B Drug CAP program be reinstated sometime during CY 2009, we 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 OPSS/ASC final rule with comment period, it was stated that payments for drugs and biologicals based on average sale prices (ASPs) will be updated on a quarterly basis as later quarter ASP submissions become available. Effective January 1, 2009, payment rates for many drugs and biologicals have changed from the values published in the CY 2009 OPSS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2008. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2009 release of the OPSS Pricer. CMS is not publishing the updated payment rates in this Change Request implementing the January 2009 update of the OPSS. However, the updated payment rates effective January 1, 2009 can be found in the January 2009 update of the OPSS Addendum A and Addendum B on the CMS Web site.

**c. Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2008 through June 30, 2008**

The payment rates for several HCPCS codes were incorrect in the April 2008 OPSS Pricer. The corrected payment rates are listed below and have been installed in the January 2009 OPSS Pricer, effective for services furnished on April 1, 2008 through implementation of the July 2008 update.

**Table 6-Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2008 through June 30, 2008**

<b>HCPCS Code</b>	<b>CY 2008 SI</b>	<b>CY 2008 APC</b>	<b>Short Descriptor</b>	<b>Corrected Payment Rate</b>	<b>Corrected Minimum Unadjusted Copayment</b>
J0150	K	0379	Injection adenosine 6 MG	\$12.71	\$2.54
J1626	K	0764	Granisetron HCl injection	\$5.99	\$1.20
J2405	K	0768	Ondansetron hcl injection	\$0.23	\$0.05
J2730	K	1023	Pralidoxime chloride inj	\$83.17	\$16.63
J9208	K	0831	Ifosfomide injection	\$36.77	\$7.35
J9209	K	0732	Mesna injection	\$7.81	\$1.56

**d. Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2008 through September 30, 2008**

The payment rates for several HCPCS codes were incorrect in the July 2008 OPSS Pricer. The corrected payment rates are listed below and have been installed in the January 2009 OPSS Pricer, effective for services furnished on July 1, 2008 through implementation of the October 2008 update.

**Table 7-Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2008 through September 30, 2008**

<b>CY 2008 HCPCS Code</b>	<b>CY 2008 SI</b>	<b>CY 2008 APC</b>	<b>Short Descriptor</b>	<b>Corrected Payment Rate</b>	<b>Corrected Minimum Unadjusted Copayment</b>
J0150	K	0379	Injection adenosine 6 MG	\$11.57	\$2.31
J1566	K	2731	Immune globulin, powder	\$28.37	\$5.67
J1569	K	0944	Gammagard liquid injection	\$34.66	\$6.93
J2730	K	1023	Pralidoxime chloride inj	\$84.90	\$16.98
J7190	K	0925	Factor viii	\$0.85	\$0.17
J7192	K	0927	Factor viii recombinant	\$1.12	\$0.22
J7198	K	0929	Anti-inhibitor	\$1.47	\$0.29
J8510	K	7015	Oral busulfan	\$2.55	\$0.51
J9208	K	0831	Ifosfomide injection	\$34.04	\$6.81

**e. Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2008 through December 31, 2008**

The payment rates for certain HCPCS codes were incorrect in the October 2008 OPSS Pricer. The corrected payment rates are listed below and have been installed in the January 2009 OPSS Pricer, effective for services furnished on October 1, 2008 through implementation of the January 2009 update.

**Table 8-Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2008 through December 31, 2008**

<b>CY 2008 HCPCS Code</b>	<b>CY 2008 SI</b>	<b>CY 2008 APC</b>	<b>Short Descriptor</b>	<b>Corrected Payment Rate</b>	<b>Corrected Minimum Unadjusted Copayment</b>
J1568	K	0943	Octagam injection	\$35.58	\$7.12
J2323	G	9126	Natalizumab injection	\$7.51	\$1.49

**f. Correct Reporting of Biologicals When Used As Implantable Devices**

When billing for biologicals where the HCPCS code describes a product that is solely surgically implanted or inserted, whether the HCPCS code is identified as having pass-through status or not, hospitals are to report the appropriate HCPCS code for the

product. 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 OPSS payment for the biological is packaged into the payment for the associated procedure.

When billing for biologicals where the HCPCS code describes a product that may either be surgically implanted or inserted or otherwise applied in the care of a patient, hospitals should not separately report the biological HCPCS codes, with the exception of biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPSS, 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 descriptor. For example, if the description for the drug code is 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. As another example, if the description for the drug code is 50 mg, but 200 mg of the drug was administered to the patient, the units billed should be 4. Providers and hospitals should not bill the units based on the way the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, bill 10 units, even though only 1 vial was administered. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

#### **h. Vaccines approved by FDA**

In July 2007, the CPT Editorial Panel released two vaccine codes on the American Medical Association Web site, specifically CPT codes 90681 and 90696 that were implemented in January 2008. Although the vaccines associated with these codes were not approved by the Food and Drug Administration (FDA) until April 2008 (for CPT code 90681) and June 2008 (for CPT code 90696), and we did not assign the codes to separate APCs under the OPSS until the January 2009 update, their payments are retroactive to the FDA approval dates. Below in Table 9 are the long

descriptors for CPT codes 90681 and 90696 and their APC assignments. Also, note that the “Effective Date of Payment Rate” listed in Table 9 reflects the specific date the vaccine received its FDA approval. Items that are reported using these HCPCS codes with dates of service prior to the date of the FDA approval, will be rejected.

**Table 9 – New Vaccine Codes**

<b>HCPCS Code</b>	<b>CY 2008 SI</b>	<b>CY 2008 APC</b>	<b>Long Descriptor</b>	<b>Payment Rate</b>	<b>Effective Date of Payment Rate</b>
90681	K	1239	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use	\$106.60	4/3/2008
90696	K	1219	Diphtheria, tetanus toxoids, acellular pertussis vaccine and poliovirus vaccine, inactivated (DTaP-IPV), when administered to children 4 through 6 years of age, for intramuscular use	\$49.92	6/24/2008

**i. Payment for Therapeutic Radiopharmaceuticals**

The Medicare Improvement for Patients and Providers Act of 2008 requires CMS to pay for therapeutic radiopharmaceuticals for the period of July 1, 2008 through December 31, 2009 at hospitals’ charges adjusted to the costs. Therefore, the status indicators of therapeutic radiopharmaceutical HCPCS codes will remain “H” effective July 1, 2008 through December 31, 2009, to indicate payment will be made for therapeutic radiopharmaceuticals at hospitals’ charges adjusted to their costs.

**Table 10 – Therapeutic Radiopharmaceuticals Paid At Charges Adjusted to Cost From July 1, 2008 through December 31, 2009**

<b>CY 2009 HCPCS Code</b>	<b>CY 2009 Long Descriptor</b>	<b>CY 2009 SI</b>
A9517	Iodine I-131 sodium iodide capsule(s), therapeutic, per millicurie	H
A9530	Iodine I-131 sodium iodide solution, therapeutic, per millicurie	H
A9543	Yttrium Y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 millicuries	H
A9545	Iodine I-131 tositumomab, therapeutic, per treatment dose	H
A9563	Sodium phosphate P-32, therapeutic, per millicurie	H
A9564	Chromic phosphate P-32 suspension, therapeutic, per millicurie	H
A9600	Strontium Sr-89 chloride, therapeutic, per millicurie	H

A9605	Samarium Sm-153 lexidronamm, therapeutic, per 50 millicuries	H
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**j. Reporting of Outpatient Diagnostic Nuclear Medicine Procedures**

Effective January 1, 2008 under the OPSS, payment for all nonpass-through diagnostic radiopharmaceuticals is packaged into payment for their associated nuclear medicine procedures and this payment methodology is continuing for CY 2009. In order to ensure that we capture appropriate diagnostic radiopharmaceutical costs for future ratesetting purposes, we implemented nuclear medicine procedure-to-radiolabeled product edits in the I/OCE effective January 2008 that required a radiolabeled product to be present on the same claim as a nuclear medicine procedure for payment under the OPSS to be made. These edits have been revised quarterly, based on information provided to us by members of the public with regard to certain clinical scenarios.

Most recently, for the October 2008 update we created HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) to be reported by hospitals on outpatient claims for nuclear medicine procedures to indicate that a radiolabeled product that provides the radioactivity necessary for the reported diagnostic nuclear medicine procedure was provided during a hospital inpatient stay. This HCPCS code is assigned status indicator “N” because no separate payment is made for the code under the OPSS. The effective date of the code is January 1, 2008, the date the nuclear medicine procedure-to-radiolabeled product edits were initially implemented. Because the Medicare claims processing system requires that there be a charge for each HCPCS code reported on the claim, hospitals should always report a token charge of less than \$1.01 for HCPCS code C9898. The date of service reported on the claim for HCPCS code C9898 should be the same as the date of service for the nuclear medicine procedure HCPCS code, which should always accompany the reporting of HCPCS code C9898. HCPCS code C9898 should never be reported on a claim without a diagnostic nuclear medicine procedure that is subject to the nuclear medicine procedure-to-radiolabeled product edits.

With the specific exception described above for HCPCS code C9898, hospitals should only report HCPCS codes for products they provide in the hospital outpatient department and should not report a HCPCS code and charge for a radiolabeled product on the nuclear medicine procedure-to-radiolabeled product edit list solely for the purpose of bypassing those edits present in the I/OCE.

We expect that the majority of hospital outpatient claims for diagnostic nuclear medicine procedures will include reporting of a diagnostic radiopharmaceutical because both the radiopharmaceutical and the nuclear medicine procedure are provided in the hospital outpatient department, and that it will be only in uncommon circumstances that hospitals will provide a radiolabeled product during a hospital inpatient stay, followed by a diagnostic nuclear medicine procedure after the patient has been discharged. We will be monitoring claims to ensure that this is the case.

The complete list of updated nuclear medicine procedure-to-radiolabeled product edits can be found at

[http://www.cms.hhs.gov/HospitalOutpatientPPS/02\\_device\\_procedure.asp](http://www.cms.hhs.gov/HospitalOutpatientPPS/02_device_procedure.asp).

## 22. Drug Administration Services

Several of the CY 2008 CPT codes for drug administration services have been renumbered or edited for CY 2009. Both the CY 2008 CPT codes and the CY 2009 CPT codes, along with the CY 2009 long code descriptors, are shown in Table 11 below.

**Table 11–Drug Administration CPT and HCPCS Codes Effective CY 2009**

<b>2008 HCPCS Code</b>	<b>2009 HCPCS Code</b>	<b>2009 Long Descriptor</b>
90760	96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
90761	96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
90765	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
90766	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
90767	96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure)
90769	96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to one hour, including pump set-up and establishment of subcutaneous infusion site(s)
90770	96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
90771	96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
90772	96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
90773	96373	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial
90774	96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
90775	96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
90779	96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

## 23. Billing for Cardiac Echocardiography Services

### a. Cardiac Echocardiography Without Contrast

Hospitals are instructed to bill for echocardiograms without contrast in accordance with the CPT code descriptors and guidelines associated with the applicable Level I CPT code(s) (93303-93350). We note that for CY 2009, the AMA revised several CPT codes in the 93000 series to more specifically describe particular services provided during echocardiography procedures. These new and revised codes are listed in Table 12 below.

**Table 12 – New and Revised CY 2009 Electrocardiography CPT Codes**

<b>CY 2009 HCPCS</b>	<b>Long Descriptor</b>	<b>New or Revised for CY 2009</b>
93306	Echocardiography, transthoracic real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography	New
93307	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography	Revised
93308	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study	Revised
93350	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report	Revised
93351	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision	New
93352	Use of echocardiographic contrast agent during stress echocardiography (List separately in addition to codes for stress echocardiography) (Use 93352 in conjunction with 93350 or 93351)	New

### b. Cardiac Echocardiography With Contrast

Hospitals are instructed to bill for echocardiograms with contrast using the applicable HCPCS code(s) included in Table 13 below. Hospitals should also report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms. CPT codes should be used for without contrast studies only. In the without contrast followed by with contrast case, hospitals should not bill the CPT code for a without contrast study in addition to the C-code when they provide a without contrast followed by with contrast study.

**Table 13 – HCPCS Codes For Echocardiograms With Contrast**

HCPCS	Long Descriptor	New or Revised for CY 2009
C8921	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete	No change
C8922	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study	No change
C8923	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography	Revised
C8924	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study	Revised
C8925	Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, real time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report	No change
C8926	Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	No change
C8927	Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis	No change
C8928	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report	Revised
C8929	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography	New
C8930	Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision	New

## 24. Changes to OPSS Pricer Logic

- a. Rural sole community hospitals and essential access community hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2009. The rural SCH and EACH payment adjustment excludes drugs, biologicals, items and services paid at charges reduced to cost, and services paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of Pub. L. 108-173.
- b. New OPSS payment rates and coinsurance amounts will be effective January 1, 2009. All coinsurance rates will be limited to a maximum of 40 percent of the APC payment rate. Coinsurance rates cannot exceed the inpatient deductible of \$1,068.
- c. For hospital outlier payments under OPSS, there will be no change in the multiple threshold of 1.75 for 2009. This threshold of 1.75 is multiplied by the total line item APC payment to determine eligibility for outlier payments. This factor also is used to determine the outlier payment, which is 50 percent of estimated cost less 1.75 times the APC payment amount. The payment formula is  $(\text{cost} - (\text{APC payment} \times 1.75)) / 2$ .
- d. However, there will be a change in the fixed-dollar threshold in CY 2009. The estimated cost of service must be greater than the APC payment amount plus \$1,800 in order to qualify for outlier payments. The previous fixed-dollar threshold was \$1,575.
- e. The charges for services included in a composite payment will be aggregated to one line using Composite Adjustment Flags (CAF) 01-ZZ for each composite on a claim, including partial hospitalization composite APCs 0172 (Level I Partial Hospitalization (3 services)) and 0173 (Level II Partial Hospitalization (4 or more services)), and mental health services composite APC 0034 (Mental Health Services Composite), and will be considered the total charge for each composite service when determining eligibility for outlier payments. (Note: Effective January 1, 2009, the Payment Adjustment Flag values of 91-99 are no longer valid; thus, they are no longer used by Pricer to identify composites. See CR 6056 for more information.)
- f. Payment will be made through APC 0034 if the total payment amount for mental health services provided on one day would otherwise exceed payment for APC 0173.
- g. For outliers for Community Mental Health Centers (bill type 76x), there will be no change in the multiple threshold of 3.4 for 2009. This threshold of 3.4 is multiplied by the total line item APC payment to determine eligibility for outlier payments. This multiple amount is also used to determine the outlier payment,

which is 50 percent of estimated costs less 3.4 times the APC payment amount. The payment formula is  $(\text{cost} - (\text{APC payment} \times 3.4)) / 2$ .

- h. The OPSS Pricer will continue to respond to claim lines that have an I/OCE Payment Adjustment Flag (PAF) #7 (Item provided without cost to provider) applied to the line. The OPSS I/OCE will apply the PAF #7 whenever a claim line has a HCPCS C code and procedure code on the lists of codes subject to this adjustment and an FB modifier. When OPSS Pricer finds a PAF #7 for a line item, it will apply the offset reduction to offset the device portion from the APC payment, which includes payment for packaged devices. The procedure payment amount remaining after the offset reduction is subject to normal procedure discounting rules. OPSS Pricer will apply the offset to line item payment before applying coinsurance logic so that coinsurance is based on the payment amount remaining after the offset reduction.
- i. The OPSS Pricer will continue to respond to lines that have an I/OCE Payment Adjustment Flag (PAF) #8 (i.e., Item provided with partial credit to provider) applied to the line. The OPSS I/OCE will apply the PAF #8 whenever a claim line has a HCPCS C-code and procedure code on the lists of codes subject to this adjustment and an FC modifier. When OPSS Pricer finds a PAF #8 for a line item, it will apply 50 percent of the dollar offset reduction to offset the device portion from the APC payment, which includes payment for packaged devices. The procedure payment amount remaining after the offset reduction is subject to normal procedure discounting rules. OPSS Pricer will apply the offset to line item payment before applying coinsurance logic so that coinsurance is based on the payment amount remaining after the offset reduction.
- j. Effective January 1, 2009, brachytherapy sources will be paid at charges adjusted to cost, as required by the MIPPA. Additionally, status indicator "U" will be used to denote brachytherapy sources for payment purposes.
- k. Effective January 1, 2009, status indicator "R" will be used to denote blood and blood products for payment purposes.
- l. Effective January 1, 2009, no items are eligible for pass through payment in the OPSS Pricer logic. There are no associated APC offset amounts or specific logic assigning device payment to associated APC payment for determining outlier eligibility and payment.
- m. Effective January 1, 2009, the OPSS Pricer will apply a reduced update ratio of 0.981 to the payment and copayment for hospitals that fail to meet their reporting requirements or that fail to meet CMS validation edits. The reduced payment amount will be used to calculate outlier payments.

## **25. Updating the Outpatient Provider Specific File**

For January 1, 2009, contractors shall maintain the accuracy of the provider records in the Outpatient Provider Specific File (OPSF) as changes occur in data element values.

### **a. Updating the OPSF for New CBSA and Wage Indices for Non-IPPS Hospitals Eligible for the Section 505 Out-Commuting Adjustment.**

This includes updating the Core-Based Statistical Area (CBSA) in the provider records, as well as updating the “special wage index” value for those providers who qualify for the 505 adjustment as annotated in Table 14.<sup>1</sup> As always, the IPPS fiscal year 2009 wage index is applied to all hospitals participating in the OPSS for the 2009 calendar year, with the exception of section 508 wage index reclassifications, which expires on September 30, 2009.

Hospitals reclassified for IPPS effective October 1, 2008, will be reclassified for OPSS effective January 1, 2009. OPSF treatment of section 508 wage indexes is discussed under B below.

Section 401 designations and floor CBSA designations effective October 1, 2008, will be effective for OPSS January 1, 2009.

Contractors shall do the following to update the OPSF (effective January 1, 2009):

1. Update the CBSA value for each provider (as given in Table 14);
2. For providers who qualify for the 505 adjustment in CY 2009;
  - a) Enter a value of “1” in the Special Payment Indicator field on the OPSF; and
  - b) Enter the final wage index value (given for the provider in Table 14) in the Special Wage Index field in the OPSF.
3. For providers who received a special wage index in CY 2008, but no longer receive it in CY 2009;
  - a) Create a new provider record, effective January 1, 2009; and
  - b) Enter a blank in the Special Payment Indicator field; and
  - c) Enter zeroes in the special wage index field.

**NOTE:** Although the 505 adjustment is static for each qualifying county for 3 years, the special wage index will need to be updated (using the final

wage index in Table 14) because the post- reclassification CBSA wage index has changed.

**NOTE:** Payment for Distinct Part Units (DPUs) located in an acute care hospital is based on the wage index for the labor market area where the hospital is located, even if the hospital has a reclassified wage index. If the DPU falls in a CBSA eligible to receive the 505 out-migration adjustment, the DPU's final wage index should consist of the geographic wage index plus the appropriate out-migration adjustment.

**Table 14- Wage Index by CBSA for NON-IPPS Hospitals that are Eligible for the Section 505 Out-Commuting Adjustment**<sup>1</sup>

<b>Provider</b>	<b>CBSA</b>	<b>Section 505 Out-commuting Adjustment</b>	<b>Final Wage Index for Calendar Year 2009</b>
012011	11500	YES	0.8025
013027	01	YES	0.7752
013032	23460	YES	0.8022
014006	23460	YES	0.8022
042007	38220	YES	0.8392
043034	04	YES	0.7681
052034	36084	YES	1.5640
052035	42044	YES	1.1985
052037	40140	YES	1.1983
052039	42044	YES	1.1985
052040	40140	YES	1.1983
053034	42044	YES	1.1985
053037	40140	YES	1.1983
053301	36084	YES	1.5640
053304	42044	YES	1.1985
053306	42044	YES	1.1985
053308	42044	YES	1.1985
054003	41884	YES	1.5211
054074	46700	YES	1.4245
054093	40140	YES	1.1983
054110	36084	YES	1.5640
054111	40140	YES	1.1983
054122	34900	YES	1.4125
054123	44700	YES	1.2104
054135	42044	YES	1.1985
054141	46700	YES	1.4245
063033	24540	YES	1.0058
064007	14500	YES	1.0050
064016	22660	YES	0.9722
074000	14860	YES	1.2869
074012	14860	YES	1.2869

<b>Provider</b>	<b>CBSA</b>	<b>Section 505 Out- commuting Adjustment</b>	<b>Final Wage Index for Calendar Year 2009</b>
074014	14860	YES	1.2869
082000	48864	YES	1.0649
083300	48864	YES	1.0649
084001	48864	YES	1.0649
084002	48864	YES	1.0649
084003	48864	YES	1.0649
092002	47894	YES	1.0684
092003	47894	YES	1.0684
093025	47894	YES	1.0684
093300	47894	YES	1.0684
094001	47894	YES	1.0684
094004	47894	YES	1.0684
114018	11	YES	0.8041
132001	17660	YES	0.9470
134010	13	YES	0.8293
153040	15	YES	0.8680
154014	15	YES	0.8658
154035	15	YES	0.8570
154047	15	YES	0.8680
183028	21060	YES	0.8515
184012	21060	YES	0.8515
192022	19	YES	0.7717
192026	19	YES	0.8043
192034	19	YES	0.7843
192036	19	YES	0.7899
192040	19	YES	0.7899
192050	19	YES	0.7917
193036	19	YES	0.7843
193044	19	YES	0.7899
193047	19	YES	0.7845
193049	19	YES	0.7845
193055	19	YES	0.7731
193058	19	YES	0.7741
193063	19	YES	0.7899
193067	19	YES	0.7757
193068	19	YES	0.7899
193069	19	YES	0.7741
193073	19	YES	0.7843
193079	19	YES	0.7899
193081	19	YES	0.7917
193088	19	YES	0.7917
193091	19	YES	0.7741
194047	19	YES	0.8043
194065	19	YES	0.7717
194075	19	YES	0.7757

<b>Provider</b>	<b>CBSA</b>	<b>Section 505 Out- commuting Adjustment</b>	<b>Final Wage Index for Calendar Year 2009</b>
194077	19	YES	0.7717
194081	19	YES	0.7700
194082	19	YES	0.7757
194083	19	YES	0.7741
194085	19	YES	0.7917
194087	19	YES	0.7717
194091	19	YES	0.7899
194092	19	YES	0.7691
212002	25180	YES	0.9455
214001	12580	YES	1.0061
214003	25180	YES	0.9455
214015	21	YES	0.8978
222000	15764	YES	1.1359
222003	15764	YES	1.1359
222024	15764	YES	1.1359
222026	37764	YES	1.1059
222044	37764	YES	1.1059
222047	37764	YES	1.1059
222048	49340	YES	1.0977
223026	15764	YES	1.1359
223028	37764	YES	1.1059
223029	49340	YES	1.0977
223033	49340	YES	1.0977
224007	15764	YES	1.1359
224026	49340	YES	1.0977
224032	49340	YES	1.0977
224033	37764	YES	1.1059
224038	15764	YES	1.1359
232023	47644	YES	0.9960
232025	35660	YES	0.9162
232028	12980	YES	1.0048
232030	47644	YES	0.9964
232034	23	YES	0.9298
232036	27100	YES	0.9665
233025	12980	YES	1.0048
233028	47644	YES	0.9964
233031	47644	YES	0.9960
234011	47644	YES	0.9964
234021	47644	YES	0.9960
234023	47644	YES	0.9964
234024	47644	YES	0.9960
234025	23	YES	0.9139
234037	12980	YES	1.0048
234039	47644	YES	0.9960
252011	25	YES	0.8071

<b>Provider</b>	<b>CBSA</b>	<b>Section 505 Out- commuting Adjustment</b>	<b>Final Wage Index for Calendar Year 2009</b>
264005	26	YES	0.8502
264027	26	YES	0.8502
303026	40484	YES	1.1040
304001	40484	YES	1.1040
312018	20764	YES	1.1503
312020	35084	YES	1.1717
313025	35084	YES	1.1786
313300	20764	YES	1.1503
314010	35084	YES	1.1786
314011	20764	YES	1.1503
314016	35084	YES	1.1717
314020	35084	YES	1.1786
322001	32	YES	0.9314
323025	32	YES	0.9314
323032	29740	YES	0.8858
324007	29740	YES	0.8858
324009	29740	YES	0.8858
324010	29740	YES	0.8858
324011	32	YES	0.9171
324012	29740	YES	0.8858
334017	39100	YES	1.1564
334061	39100	YES	1.1564
344011	39580	YES	0.9660
344014	39580	YES	0.9660
362007	36	YES	0.8689
362016	15940	YES	0.8824
362032	15940	YES	0.8824
364031	15940	YES	0.8824
364040	44220	YES	0.8903
372017	37	YES	0.8040
372019	37	YES	0.8242
373032	37	YES	0.8040
384011	38	YES	1.0969
392030	39	YES	0.8865
392031	27780	YES	0.8336
392034	10900	YES	0.9859
393026	39740	YES	0.9492
393050	10900	YES	0.9859
394014	39740	YES	0.9492
394016	39	YES	0.8355
394020	30140	YES	0.9338
422004	43900	YES	0.9020
423028	16740	YES	0.9535
423029	11340	YES	0.9805
424011	11340	YES	0.9805

<b>Provider</b>	<b>CBSA</b>	<b>Section 505 Out- commuting Adjustment</b>	<b>Final Wage Index for Calendar Year 2009</b>
442016	28700	YES	0.7952
443027	28700	YES	0.7952
444008	44	YES	0.8308
452018	23104	YES	0.9674
452019	23104	YES	0.9674
452028	23104	YES	0.9674
452041	43300	YES	0.9390
452088	23104	YES	0.9674
452099	23104	YES	0.9674
453040	23104	YES	0.9674
453041	23104	YES	0.9674
453042	23104	YES	0.9674
453089	45	YES	0.8250
453094	23104	YES	0.9674
453300	23104	YES	0.9674
453303	23104	YES	0.9674
454009	45	YES	0.8337
454012	23104	YES	0.9674
454019	23104	YES	0.9674
454051	23104	YES	0.9674
454052	23104	YES	0.9674
454061	23104	YES	0.9674
454072	23104	YES	0.9674
454086	23104	YES	0.9674
454101	45	YES	0.8191
522005	39540	YES	0.9596
523026	39540	YES	0.9596
524020	52	YES	0.9594
524021	52	YES	0.9643
524022	52	YES	0.9547
673026	41700	YES	0.8992

<sup>1</sup>Table 14 includes the list of hospitals paid under the OPSS but not the IPPS that were included either in the August 2008 OSCAR file or the October 2008 OPSF that are eligible to receive the 505 out-commuting wage adjustment in CY 2009. The CBSA and final wage index are given for each hospital on this list. All other Non-IPPS hospitals not eligible to receive the 505 out-commuting adjustment should be paid using the IPPS post-reclassification wage index for their CBSA location.

**b. Updating the OPSF for New CBSA and Wage Indices for Hospitals Receiving Section 508 Reclassification**

In accordance with section 124 of Pub. L. 110-275, for CY 2009, we are adopting all section 508 geographic reclassifications extended through September 30, 2009. Similar to our treatment of section 508 reclassifications as previously extended under the MMSEA, hospitals with section 508 reclassifications will revert to their home area wage index, with out-migration adjustment if applicable, from October 1, 2009 to December 31, 2009. As we did for CY 2008, we also are extending the special exception wage indices for certain hospitals through December 31, 2009.

For January 1, 2009, contractors shall maintain the accuracy of the provider records in the OPSF. This includes updating the CBSA in the provider records, as well as updating the “special wage index” value for those providers who qualify for section 508 reclassifications using the wage index values that are shown in Table 15<sup>2</sup> below.

Contractors shall do the following to update the OPSF (effective January 1, 2009):

1. Update the CBSA value for each provider (as given in Table 15);
2. For providers for which reclassifications under section 508 have been extended through September 30, 2009 that are no longer reclassified under section 508 for the last quarter of CY 2009 (10/1-12/31);

Create a new provider record, effective October 1, 2009; and

1. If the provider is not eligible for the out commuting adjustment,
  - i. Enter a blank in the Special Payment Indicator field; and
  - ii. Enter zeroes in the special wage index field.
2. If the provider is eligible for the out commuting adjustment,
  - i. Enter a value of “1” in the Special Payment Indicator field; and
  - ii. Enter the final wage index value (given for the provider in column 4 of Table 15) in the Special Wage Index field in the OPSF.

**Table 15 – October 1, 2009 to December 31, 2009 Wage Index for Section 508 Hospitals that Receive Payment Under the OPFS**

<b>Provider</b>	<b>CBSA</b>	<b>Final Wage Index for last quarter of CY 2009 (10/1-12/31) includes out-commuting adjustment, if applicable</b>	<b>Section 505 Out-Commuting Adjustment</b>	<b>Section 508 Provider</b>
010150	01	0.7745	YES	YES
020008	02	1.1852		YES
050549	37100	1.1972		YES
060075	06	0.9311		YES
070001	35300	1.2214		YES
070005	35300	1.2214		YES
070016	35300	1.2214		YES
070017	35300	1.2214		YES
070019	35300	1.2214		YES
070022	35300	1.2214		YES
070031	35300	1.2214		YES
070039	35300	1.2214		YES
150034	23844	0.9267		YES
160040	47940	0.8954		YES
160064	16	0.8954		YES
160067	47940	0.8954		YES
160110	47940	0.8954		YES
190218	19	0.7656		YES
220046	38340	1.0406		YES
230003	26100	0.9287	YES	YES
230004	34740	1.019		YES
230013	47644	0.9964	YES	YES
230019	47644	0.9964	YES	YES
230020	19804	1.002		YES
230024	19804	1.002		YES
230029	47644	0.9964	YES	YES
230036	23	0.8863		YES
230038	24340	0.9245		YES
230053	19804	1.002		YES
230059	24340	0.9245		YES
230066	34740	1.019		YES
230071	47644	0.9964	YES	YES
230072	26100	0.9287	YES	YES
230089	19804	1.002		YES
230097	23	0.8863		YES
230104	19804	1.002		YES
230106	24340	0.9245		YES
230119	19804	1.002		YES
230130	47644	0.9964	YES	YES
230135	19804	1.002		YES
230146	19804	1.002		YES
230151	47644	0.9964	YES	YES
230165	19804	1.002		YES

<b>Provider</b>	<b>CBSA</b>	<b>Final Wage Index for last quarter of CY 2009 (10/1-12/31) includes out-commuting adjustment, if applicable</b>	<b>Section 505 Out-Commuting Adjustment</b>	<b>Section 508 Provider</b>
230174	26100	0.9287	YES	YES
230176	19804	1.002		YES
230207	47644	0.9964	YES	YES
230223	47644	0.9964	YES	YES
230236	24340	0.9245		YES
230254	47644	0.9939		YES
230269	47644	0.9964	YES	YES
230270	19804	1.002		YES
230273	19804	1.002		YES
230277	47644	0.9964	YES	YES
250002	25	0.7625		YES
250122	25	0.7625		YES
270023	33540	0.8876		YES
270032	27	0.8607		YES
270057	27	0.8607		YES
310021	45940	1.1294		YES
310028	35084	1.1518		YES
310050	35084	1.1717	YES	YES
310051	35084	1.1518		YES
310060	10900	1.1294		YES
310115	10900	1.1294		YES
310120	35084	1.1518		YES
330049	39100	1.0922		YES
330106	35004	1.2809	YES	YES
330126	39100	1.1564	YES	YES
330135	39100	1.1564	YES	YES
330205	39100	1.1564	YES	YES
330264	39100	1.1564	YES	YES
340002	11700	0.9159		YES
350002	13900	0.7336		YES
350003	35	0.7336		YES
350006	35	0.7336		YES
350015	13900	0.7336		YES
350017	35	0.7336		YES
350030	35	0.7336		YES
380090	38	1.0862		YES
390001	42540	0.8333		YES
390003	39	0.8333		YES
390072	39	0.8333		YES
390095	42540	0.8333		YES
390119	42540	0.8333		YES
390137	42540	0.8333		YES
390169	42540	0.8333		YES

Provider	CBSA	Final Wage Index for last quarter of CY 2009 (10/1-12/31) includes out-commuting adjustment, if applicable	Section 505 Out-Commuting Adjustment	Section 508 Provider
390185	42540	0.8333		YES
390192	42540	0.8333		YES
390237	42540	0.8333		YES
390270	42540	0.8333		YES
430005	43	0.8396		YES
430015	43	0.8396		YES
430048	43	0.8525	YES	YES
430060	43	0.8396		YES
430064	43	0.8396		YES
450072	26420	0.989		YES
450591	26420	0.989		YES
470003	15540	1.0255		YES
490001	49	0.8032		YES
530015	53	0.9189		YES

<sup>2</sup>Table 15 shows the final wage indices, including the out-commuting adjustment if applicable, that would be in effect under the OPSS for providers that would no longer be reclassified under section 508 for the last quarter of CY 2009 (10/1/09-12/31/09).

**c. Updating the OPSF for the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) Requirements**

Effective for OPSS services furnished on or after January 1, 2009, Subsection (d) hospitals that have failed to submit timely hospital outpatient quality data as required in Section 1833(t)(17)(A) of the Act will receive payment under the OPSS that reflects a 2 percentage point deduction from the annual OPSS update for failure to meet the HOP QDRP requirements. This reduction will not apply to hospitals not required to submit quality data or hospitals that are not paid under the OPSS.

For January 1, 2009, contractors shall maintain the accuracy of the provider records in the OPSF by updating the Hospital Quality Indicator Field. CMS will release a Joint Signature Memorandum/Technical Direction Letter that lists Subsection (d) hospitals that are subject to and fail to meet the HOP QDRP requirements. Once this list is released, FIs/MACs shall update the OPSF by removing the '1' in the Hospital Quality Indicator field. We note that if these hospitals are later determined to have met the HOP QDRP requirements, FIs/MACs shall update the OPSF accordingly by entering a '1' in the Hospital Quality Indicator field. For greater detail regarding updating the OPSF for the

HOP QDRP requirements, please see Transmittal 368, CR 6072, issued on August 15, 2008.

In this transmittal, we are updating section 50.1 “Outpatient Provider Specific File” of Chapter 4 of the Medicare Claims Processing Manual to incorporate the addition of the Hospital Quality Indicator into our description of the record layout for the Outpatient Provider Specific File.

**d. Updating the Outpatient Termination Date Field in the OPSF for Terminated Providers**

In maintaining the accuracy of the OPSF we expect contractors to maintain the provider records in the OPSF by ensuring that a termination date is entered appropriately for all providers that have already received a “tie-out” notice from CMS.

**26. Coverage Determinations**

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

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6320.1	Medicare contractors shall install the January 2009 OPPS Pricer.	X		X		X	X				COBC
6320.2	When a Medicare contractor receives a claim with an unlisted HCPCS code for non-OPPS payment, the contractor shall verify that no existing HCPCS code adequately describes the procedure or service.	X		X		X					COBC
6320.2.1	If an unlisted code is submitted on a claim and the contractor has verified that the code submitted is correct, the contractor pays the claim using the unlisted code, based on the applicable non-OPPS payment methodology.	X		X		X					COBC
6320.2.2	If it is determined that an unlisted code was submitted in error because the procedure or service is described by a specific HCPCS code, the contractor shall advise the hospital or CAH of the appropriate code and process the claim with the correct code.	X		X		X					COBC
6320.2.3	If a procedure or service reported with an unlisted code is reported frequently, the contractor shall advise the provider that a request for a specific CPT code or alphanumeric HCPCS code should be made.	X		X		X					COBC
6320.2.4	The latest list of "Unlisted" CPT codes for procedures and services can be found at <a href="http://www.cms.hhs.gov/HospitalOutpatientPPS/">http://www.cms.hhs.gov/HospitalOutpatientPPS/</a> . Medicare contractors shall review this list once a year since it is updated annually on or about January 1 of the calendar year.	X		X		X					COBC
6320.3	OPPS Pricer shall reduce the APC payment by applying the reduced update ratio applicable to the date of service if the quality reporting field in the OPSF is blank and the payment APC on the line has a status indicator equal to any of the following: P, R, S if APC is not 1491-1537, T if APC is not 1539-1574, V, X. (Refer to section 4 of this transmittal.)										OPPS Pricer, COBC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I S S I O N	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6320.3.1	OPPS Pricer shall assign new return code 11, "Reduced for absent quality reporting", if the quality reporting field in the OPSF is blank and the payment APC on the line has a status indicator equal to any of the following: P, R, S if APC is not 1491-1537, T if APC is not 1539-1574, V, X. (Refer to section 4 of this transmittal.)						X				OPPS Pricer, COBC
6320.3.2	OPPS Pricer shall apply the reduced update ratio to the full update coinsurance if the quality reporting field in the OPSF is blank and the payment APC on the line has a status indicator equal to any of the following: P, R, S if APC is not 1491-1537, T if APC is not 1539-1574, V, X. (Refer to section 4 of this transmittal.)										OPPS Pricer, COBC
6320.3.3	OPPS Pricer shall use the reduced payment when applicable (following application of the reduced update ratio) in the calculation of outlier payments in cases in which the quality reporting field in the OPSF is blank and the payment APC on the line has a status indicator equal to any of the following: P, R, S if APC is not 1491-1537, T if APC is not 1539-1574, V, X. (Refer to section 4 of this transmittal.)										OPPS Pricer, COBC
6320.4	Using the IPSF for reference, Medicare contractors shall verify that there is a PCR and CCR in the OPSF for all small rural hospitals, all small sole community hospitals (SCHs) including EACHs, all cancer hospitals, and all children's hospitals. <b>NOTE:</b> Hospitals are considered designated as rural if either the Geographic/Actual CBSA IPSF field or the Wage Index CBSA IPSF field indicates a rural value. Hospital bed size is also listed in the IPSF.	X		X		X					COBC
6320.4.1	Medicare contractors shall indicate a "Y" in the TOPs indicator field in the OPSF for all hospitals eligible for TOPs payments for CY 2009.	X		X		X					COBC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R I E R	R H I S S	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6320.4.2	Medicare contractors shall calculate interim TOPs for services furnished on or after January 1, 2009 through December 31, 2009 for small rural hospitals and small SCHs, including EACHs. <b>NOTE:</b> The interim TOPs for these hospitals shall continue to be calculated as 85% of the hold harmless amount (the amount by which the provider's charges x CCR x PCR exceeds the provider's OPSS payments).					X	X				COBC
6320.4.3	Medicare contractors shall continue to calculate interim TOPs indefinitely for services furnished by cancer hospitals and children's hospitals.					X	X				COBC
6320.5	Medicare contractors may apply the Statewide average CCR for non-IPPS hospitals (e.g., long-term care, psychiatric, rehabilitation hospitals, etc.) that convert to IPPS status, or IPPS hospitals that maintain their IPPS status but receive a new provider number.	X		X		X					COBC
6320.5.1	The Medicare contractor shall notify CMS central and regional offices to seek approval to use a CCR based on alternative data if a Medicare contractor finds evidence that indicates that using data from the latest settled or tentatively settled cost report would not result in the most accurate CCR. Use of the alternative CCR is subject to the approval of CMS central and regional offices.	X		X		X					COBC
6320.5.2	If a hospital or CMHC requests that a different CCR be applied in the event it believes the CCR being applied is inaccurate, the hospital or CMHC is required to present substantial evidence supporting its request to identify a CCR for payment purposes. The Medicare contractor shall evaluate the evidence presented by the hospital or CMHC and, finding it relevant, notify the CMS central and regional offices to seek approval to use a CCR based on alternative data. Use of the alternative CCR is subject to the approval of the CMS central and regional offices.	X		X		X					COBC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R I E R	R H I S S	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6320.5.3	If it is determined by the Medicare contractor that a hospital or CMHC meets the criteria for reconciliation, the Medicare contractor shall send notification that the hospital or CMHC has met the criteria for reconciliation to the CMS central (not the hospital) and regional offices.	X		X		X					COBC
6320.5.4	If the Medicare contractor receives approval from the CMS central and regional offices that reconciliation is appropriate, the Medicare contractor shall follow steps 3-8 in section 10.7.2.4 of Chapter 4 of the Medicare Claims Processing Manual.	X		X		X					COBC
6320.5.5	Medicare contractors shall contact the CMS central office to seek further guidance in instances where errors related to CCRs and/or outlier payments are discovered.	X		X		X					COBC
6320.5.6	Medicare contractors shall contact and notify the CMS central and regional offices for further instructions, if a cost report is reopened after final settlement, and the reopening affects the hospital or CMHC's CCR or outlier payments.	X		X		X					COBC
6320.5.7	The Medicare contractor shall notify a hospital or CMHC under the OPPTS whenever it makes a change to its CCR, as noted in section 10.11.3.3 of Chapter 4 of the Medicare Claims Processing Manual.	X		X		X					COBC
6320.5.7.1	Medicare contractors shall include the change in the notice that is issued to each provider after a tentative or final settlement is completed, when a CCR is changed as a result of a tentative settlement or a final settlement. <b>NOTE:</b> Medicare contractors can also send notification of a change to a hospital or CMHC's CCR in a separate notice outside of the notice that is issued to each provider after a tentative or final settlement is completed.	X		X		X					COBC
6320.6	Medicare contractor shall determine whether payment	X		X		X					COBC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I  M A C	C A R R I E R	R H I  S S	Shared-System Maintainers				OTHER
						F I S	M C S	V M S	C W F		
	can be made for services reported by C9899 and if so, will establish the payment to be made and the amount of copayment for which the beneficiary will be liable in accordance with Transmittal 1597, CR 6050, issued on September 12, 2008, and the Medicare Claims Processing Manual, Pub. 100-4, Chapter 4, section 240.										
6320.7	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service that fall on or after April 1, 2008, but prior to July 1, 2008; 2) Contain HCPCS code listed in Table 6; and 3) Were originally processed prior to the installation of the January 2009 OPSS Pricer.	X		X		X				COBC	
6320.7.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service that fall on or after July 1, 2008, but prior to October 1, 2008; 2) Contain HCPCS code listed in Table 7; and 3) Were originally processed prior to the installation of the January 2009 OPSS Pricer.	X		X		X				COBC	
6320.7.2	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service that fall on or after October 1, 2008, but prior to January 1, 2009; 2) Contain HCPCS code listed in Table 8; and 3) Were originally processed prior to the installation of the January 2009 OPSS Pricer.	X		X		X				COBC	
6320.8	As specified in Change Request 5689, the Medicare contractors shall maintain the accuracy of the data and update the OPSF file as changes occur in data element values. For CY 2009, this includes all changes to the OPSF identified in section 25 of this transmittal.	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  M A C	C A R I E R	R H I  S S	Shared-System Maintainers				OTHER
						F I S	M C S	V M S	C W F		
6320.9	<p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin.</p> <p>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:

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

Please refer to CR6315 "January 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.0" for supporting information.

## V. CONTACTS

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**Post-Implementation Contact(s):** Regional Office

## VI. FUNDING

### **Section A: For *Fiscal Intermediaries (FIs) and Regional Home Health Intermediaries (RHHIs)*:**

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.

# Medicare Claims Processing Manual

## Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPTS)

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*(Rev.1657, 12-31-08)*

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## 10.2.1 - Composite APCs

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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 effective for services furnished on or after January 1, 2008. See Addendum A at [www.cms.hhs.gov/HospitalOutpatientPPS/](http://www.cms.hhs.gov/HospitalOutpatientPPS/) for the national unadjusted payment rates for these composite APCs.

<b>Composite APC</b>	<b>Composite APC Title</b>	<b>Criteria for Composite Payment</b>
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, 93651 or 93652 on the same date of service.
8001	Low Dose Rate Prostate Brachytherapy Composite	One or more units of CPT codes 55875 and 77778 on the same date of service.
8002	Level I Extended Assessment and Management Composite	<p>1) Eight or more units of HCPCS code G0378 are billed--</p> <ul style="list-style-type: none"> <li>● On the same day as HCPCS code G0379*; or</li> <li>● On the same day or the day after CPT codes 99205 or 99215; and</li> </ul> <p>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.</p>
8003	Level II Extended Assessment and Management Composite	1) Eight or more units of HCPCS code G0378** are billed on the same date of service or the date of service after CPT codes 99284, 99285, G0384, or 99291; and

Composite APC	Composite APC Title	Criteria for Composite Payment
		2) There is no service with SI=T on the claim on the same date of service or 1 day earlier.
0034	Mental Health Services Composite	Payment for any combination of mental health services with the same date of service exceeds the payment for APC <i>0173</i> . For the list of mental health services to which this composite applies, see the I/OCE supporting files for the pertinent period.
<i>8004</i>	<i>Ultrasound Composite</i>	<i>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.</i>
<i>8005</i>	<i>Computed Tomography (CT) and Computed Tomographic Angiography (CTA) without Contrast Composite</i>	<i>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.</i>
<i>8006</i>	<i>CT and CTA with Contrast Composite</i>	
<i>8007</i>	<i>Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA) without Contrast Composite</i>	<i>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</i>

Composite APC	Composite APC Title	Criteria for Composite Payment
8008	<i>MRI and MRA with Contrast Composite</i>	<i>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.</i>

\*Payment for direct admission to observation care (HCPCS code G0379) is made either under APC 604 (Level 1 Hospital Clinic Visits) or APC 8002 (Level I Extended Management and Assessment 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.*

## 10.4 - Packaging

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Under the OPPS, packaged services are items and services that are considered to be an integral part of another service that is paid under the OPPS. No separate payment is made for packaged services, because the cost of these items and services is included in the APC payment for the service of which they are an integral part. For example, routine supplies, anesthesia, recovery room use, and most drugs are considered to be an integral part of a surgical procedure so payment for these items is packaged into the APC payment for the surgical procedure.

### A. Packaging for Claims Resulting in APC Payments

If a claim contains services that result in an APC payment but also contains packaged services, separate payment for the packaged services is not made since payment is included in the APC. However, charges related to the packaged services are used for outlier and Transitional Corridor Payments (TOPs) as well as for future rate setting.

Therefore, it is extremely important that hospitals report all HCPCS codes *consistent with their descriptors; CPT and/or CMS instructions and correct coding principles*, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged.

## **B. Packaging for Claims Resulting in No APC Payments**

If the claim contains only services payable under cost reimbursement, such as corneal tissue, and services that would be packaged services if an APC were payable, then the packaged services are not separately payable. In addition, these charges for the packaged services are not used to calculate TOPs.

If the claim contains only services payable under a fee schedule, such as clinical diagnostic laboratory tests, and also contains services that would be packaged services if an APC were payable, the packaged services are not separately payable. In addition, the charges are not used to calculate TOPs.

If a claim contains services payable under cost reimbursement, services payable under a fee schedule, and services that would be packaged services if an APC were payable, the packaged services are not separately payable. In addition, the charges are not used to calculate TOPs payments.

## **C. Packaging Types Under the OPSS**

1. Unconditionally packaged services are services for which separate payment is never made because the payment for the service is always packaged into the payment for other services. Unconditionally packaged services are identified in the OPSS Addendum B with status indicator of N. See the OPSS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> for the most recent Addendum B (HCPCS codes with status indicators). In general, the charges for unconditionally packaged services are used to calculate outlier and TOPS payments when they appear on a claim with a service that is separately paid under the OPSS because the packaged service is considered to be part of the package of services for which payment is being made through the APC payment for the separately paid service.
2. STVX-packaged services are services for which separate payment is made only if there is no service with status indicator S, T, V or X reported with the same date of service on the same claim. If a claim includes a service that is assigned status indicator S, T, V, or X reported on the same date of service as the STVX-packaged service, the payment for the STVX-packaged service is packaged into the payment for the service(s) with status indicator S, T, V or X and no separate payment is made for the STVX-packaged service. STVX-packaged services are assigned status indicator Q/I. See the OPSS Webpage at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> for identification of STVX-packaged codes.
3. T-packaged services are services for which separate payment is made only if there is no service with status indicator T reported with the same date of service on the same claim. When there is a claim that includes a service that is assigned status

indicator T reported on the same date of service as the T-packaged service, the payment for the T-packaged service is packaged into the payment for the service(s) with status indicator T and no separate payment is made for the T-packaged service. T-packaged services are assigned status indicator Q2. See the OPPS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> for identification of T-packaged codes.

4. A service that is assigned to a composite APC is a major component of a single episode of care. The hospital receives one payment through a composite APC for multiple major separately identifiable services. Services mapped to composite APCs are assigned status indicator Q3. See the discussion of composite APCs in section 10.2.1.

### ***10.6.1 – Payment Adjustment for Certain Rural Hospitals***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Beginning January 1, 2006, rural sole community hospitals (SCHs), including essential access community hospitals (EACHs), receive a 7.1 percent increase in payments for most services, with certain exceptions. Services which are excepted from the increase in payments include, but are not limited to, separately paid drugs and biologicals and items paid at charges adjusted to cost. This adjustment is authorized under Section 1833(t)(13)(B) of the Act, and implemented in accordance with Section 419.43(g) of the regulations. The adjustment is automatically applied in Pricer.*

### ***10.6.2 – Payment Adjustment for Failure to Meet the Hospital Outpatient Quality Reporting Requirements***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Effective for services furnished on or after January 1, 2009, Section 1833(t)(17)(A) of the Act requires that “Subsection (d) hospitals” that have failed to meet the specified hospital outpatient quality reporting requirements for the relevant calendar year will receive payment under the OPPS that reflects a 2 percentage point reduction of the annual OPPS update factor. See [www.qualitynet.org](http://www.qualitynet.org) for information on complying with the reporting requirements and standards that must be met to receive the full update.*

#### ***10.6.2.1 -- Hospitals to Which the Payment Reduction Applies***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*The reduction applies only to hospitals that are identified as “Subsection (d) hospitals.” “Subsection (d) hospitals” have the same definition for hospitals paid under the OPPS as for hospitals paid under the IPPS. Specifically, “Subsection (d) hospitals” are defined under Section 1886(d)(1)(B) of the Act as hospitals that are located in the 50 states or the District of Columbia other than those categories of hospitals or hospital units that are*

*specifically excluded from the IPPS, including psychiatric, rehabilitation, long-term care, children's and cancer hospitals or hospital units. In other words, the provision does not apply to hospitals and hospital units excluded from the IPPS or to hospitals located in Maryland, Puerto Rico or the U.S. territories. Hospitals that are not required to submit quality data (i.e., those that are not Subsection (d) hospitals) will receive the full OPPS update. Similarly, the reduced update will not apply to Subpart (d) hospitals that are not paid under the OPPS (e.g., Indian Health Service hospitals).*

### ***10.6.2.2 -- Services to which the Payment Reduction Applies***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*The reduction to the annual update factor for failure to meet the quality reporting requirements applies to most, but not all, services paid under the OPPS. The reduction of payments does not apply to services paid under the OPPS if the payment amounts are not calculated using the conversion factor to which the annual update factor applies (e.g., drugs and biologicals paid based on the average sales price (ASP) methodology, new technology services paid at a fixed amount, and services paid at charges adjusted to cost). The reduction also does not apply to hospital outpatient services paid through other fee schedules or other mechanisms. Examples of these exceptions are services paid under the physician fee schedule (e.g., physical therapy and diagnostic and screening mammography), services paid at reasonable cost (e.g., influenza and pneumococcal vaccines), and services paid under other fee schedules (e.g., clinical laboratory services and durable medical equipment).*

*The specific services to which this policy applies can be identified by OPPS status indicator. CMS will identify the status indicators of the HCPCS codes to which the reduction applies each year in the change request that announces changes to the OPPS for the forthcoming calendar year. Also, the status indicators for the services (identified by HCPCS codes) to which the reduction applies can be found in the OPPS final rule for the year of interest under "Hospital Outpatient Regulations and Notices" at [www.cms.hhs.gov/HospitalOutpatientPPS/](http://www.cms.hhs.gov/HospitalOutpatientPPS/). The services excluded from the payment reduction may change each year if the method of calculating payment under the OPPS changes.*

### ***10.6.2.3 -- Contractor Responsibilities***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*CMS claims processing software will automatically reduce payment to "Subsection (d) hospitals" when those hospitals that fail to meet the quality reporting requirements bill for services to which the reduced update applies. However, contractors must update the Outpatient Provider Specific File (OPSF) quality reporting field when CMS furnishes the list of hospitals to which the payment reduction applies. The FISS auto-populates the Hospital Quality Indicator field of the OPSF field with a "1" for all hospitals. Once*

*CMS has issued the list of hospitals failing to meet the requirements, Medicare contractors must remove the '1' in the Hospital Quality Indicator field for each Subsection (d) hospital that fails to meet the quality reporting requirements. Contractors make no changes to the '1' indicator for hospitals that are not Subsection (d) hospitals providing OPSS services or for hospitals that are Subsection (d) hospitals providing OPSS services that are not listed as failing the requirements.*

*CMS sends Medicare contractors the file of hospitals to which the reduction applies for a given calendar year by a Joint Signature Memorandum/Technical Direction Letter as soon as the list is available. This will be sent as soon as possible, expected to be on or about December 1 of each year preceding the calendar year to which the payment reduction applies. Should a Subsection (d) hospital later be determined to have met the criteria after dissemination of this list, CMS will change the hospital's status. CMS will notify Medicare contractors of the change in status and contractors must update the OPSS as needed and must mass adjust paid claims.*

*For new hospitals, Medicare contractors must provide information to the Quality Contractor to be specified by CMS as soon as possible so that the Quality Contractor can enter the provider information into the Program Resource System and follow through with ensuring provider participation with the requirements for quality data reporting, if applicable. CMS will notify Medicare contractors of how to contact the Quality Contractor each year in the annual OPSS update change request. This allows the Quality Contractor the opportunity to contact new facilities as early as possible in the calendar year to inform them of the hospital outpatient quality reporting requirements. As soon as possible, Medicare contractors must provide the following information on newly participating hospitals to the Quality Contractor to be specified by CMS:*

- *State code;*
- *Provider name;*
- *Provider ID number;*
- *Medicare acceptance date;*
- *Contact name (if available); and*
- *Telephone number.*

#### ***10.6.2.4 - Application of the Payment Reduction Factor in Calculation of the Reduced Payment and Reduced Copayment***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*For services to which the payment adjustment applies, CMS calculates a payment reduction factor that is used in the OPSS Pricer to adjust the payments for hospitals that fail to meet the reporting requirements. **CMS calculates this factor by dividing the OPSS conversion factor that incorporates the reduced update factor by the OPSS***

*conversion factor that incorporates the full update factor for the applicable calendar year. This ratio is applied to the full national unadjusted payment amount for a service subject to the payment reduction in order to calculate the reduced payment amount. Similarly, this ratio is applied to the full national unadjusted copayment for an applicable service to calculate the reduced copayment that may be collected from the beneficiary by the hospital. The payment reduction factor will be included in the annual OPSS update change request and may also be found in the applicable OPSS final rule, which can be found at [www.cms.hhs.gov/HospitalOutpatientPPS/](http://www.cms.hhs.gov/HospitalOutpatientPPS/) under “Hospital Outpatient Regulations and Notices”.*

## **10.7 – Outliers**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

### **10.7.1 - Outlier Adjustments**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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/](http://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 OPPS 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 OPPS 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 OPPS 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 OPPS payment.

The total cost of all packaged items and services, including the cost of uncoded revenue code lines, that appear on a claim is allocated across all separately paid OPPS services that appear on the same claim. The proportional amount of total packaged cost allocated to each separately paid OPPS service is based on the percent of the APC payment rate for that service out of the total APC payment for all separately paid OPPS 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 OPPS services on the claim are \$200, \$300, and \$500 (total APC payments of \$1000). The first OPPS 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 OPPS service *is* allocated \$30 or 30 percent of the total cost of packaged services, and the third OPPS 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 – Outlier Reconciliation**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

### **10.7.2.1 – Identifying Hospitals and CMHCs Subject to Outlier Reconciliation**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Under Section 419.43(d)(6)(i), for hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009, OPPS 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 outlier reconciliation policies described in this section. 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 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 outlier payments, and*
- 2. Total hospital 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 outlier payments, and*
2. *Any CMHC 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 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 outlier reconciliation is complete. These hospital and CMHC cost reports will remain open until their claims have been processed for 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 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 reconciliation shall be reopened. Medicare contractors shall notify the CMS Central Office and regional office that the 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.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)**

*For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009, all hospitals and CMHCs are subject to the 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 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 outlier payments for this cost reporting period are reconciled using the correct CCR of 0.50.*

*In the event that multiple 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 reconciliation is required. Total 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*

<b>CCR</b>	<b>Days</b>	<b>Weight</b>	<b>Weighted CCR</b>
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)
<b>TOTAL</b>	365		(a)+(b) = 0.476

*The hospital meets the criteria for 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 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 outlier payments in a cost reporting period be reconciled if the hospital's most recent cost and charge data indicate that the 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 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.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)**

*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, outlier payment may be adjusted to account for the time value of money of any adjustments to outlier payments as a result of reconciliation. As described in Section 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 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:*

*(Rate from Web site as of the midpoint of the cost report being settled / 365 or 366) \*  
# of days from that midpoint until date of reconciliation.*

*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 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 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 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.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)**

*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 reconciliation should be performed and to record reconciled 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 reconciliation.*
- 2) *If the Medicare contractor receives approval from the CMS central office and regional office that 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 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 outlier claims are to be reconciled.*
- 5) *CMS will reprocess claims in an offline Pricer/FISS utility program to determine the correct 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 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 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.*

### **10.11.1 - Requirement to Calculate CCRs for Hospitals Paid under OPPS and for CMHCs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Medicare contractors must calculate overall cost-to-charge ratios for hospitals paid under OPPS and for CMHCs using the provider's most recent full year cost reporting period, whether tentatively settled or final settled, in accordance with the instructions in §§10.11.7, 10.11.8 or 10.11.9 as applicable. The contractor must calculate a provider

overall CCR whenever a more recent full year cost report becomes available. If a CCR is calculated based on the tentatively settled cost report, the contractor must calculate another overall CCR when the cost report is final or when a cost report for a subsequent cost reporting period is tentatively settled, whichever occurs first. If a CCR is based on a final settled cost report, the contractor must calculate the CCR when a cost report for a subsequent cost reporting period is tentatively settled.

## **10.11.2 - Circumstances in Which CCRs are Used**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The contractors must apply CCRs prospectively to calculate outlier payments (for hospitals paid under OPPS and CMHCs), Transitional Outpatient Payment System (TOPS) payments (for hospitals paid under OPPS), device pass-through payments (for hospitals paid under OPPS), *and items and services paid at charges adjusted to cost (for hospitals paid under OPPS).*

## **10.11.3 - Selection of the CCR to be Used**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Contractors will use the CCR calculated for the most recent period of time, whether based on a tentatively settled cost report or a final settled cost report. For example, if the CCR being used is the tentatively settled CCR for FY 2008, and a tentatively settled CCR for FY 2009 is determined before the final settled CCR for FY 2008, then the contractor uses the CCR based on the tentatively settled 2009 cost report.

### ***10.11.3.1– CMS Specification of Alternative CCR***

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

*Effective January 1, 2009, the central office may direct Medicare contractors to use an alternative CCR if CMS believes this will result in a more accurate CCR. Also, if the Medicare contractor finds evidence that indicates that using data from the latest settled or tentatively settled cost report would not result in the most accurate CCR, then the Medicare contractor shall notify the CMS central office and CMS regional office to seek approval to use a CCR-based on alternative data. For example, CCRs may be revised more often if a change in a hospital or CMHC's operations occurs which materially affects a hospital or CMHC's costs and charges. The central and regional offices must approve the Medicare contractor's request before the Medicare contractor may use a CCR-based on alternative data. Revised CCRs are applied prospectively to all OPPS claims processed after the update. Medicare contractors shall send notification to the central office via the following address and e-mail address:*

*CMS*

*C/O Division of Outpatient Care – OPPTS Outlier Team  
7500 Security Blvd.  
Mail Stop C4-05-17  
Baltimore, MD 21244  
[outliersOPPS@cms.hhs.gov](mailto:outliersOPPS@cms.hhs.gov)*

***10.11.3.2 – Hospital or CMHC Request for Use of a Different CCR  
(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Effective January 1, 2009, CMS (or the Medicare contractor) may specify an alternative CCR if it believes that the CCR being applied is inaccurate. In addition, a hospital or CMHC has the opportunity to request that a different CCR be applied for outlier payment calculation in the event it believes the CCR being applied is inaccurate. The hospital or CMHC is required to present substantial evidence supporting its request. Such evidence should include documentation regarding its costs and charges that demonstrate its claim that an alternative ratio is more accurate. After the Medicare contractor has evaluated the evidence presented by the hospital or CMHC, the Medicare contractor notifies the CMS central office and CMS regional office of any such request. The CMS central and regional offices approve or deny any request by the hospital (or CMHC) or Medicare contractor for use of a different CCR. Medicare contractors shall send requests to the CMS central office using the address and e-mail address provided above.*

***10.11.3.3 – Notification to Hospitals Paid Under the OPPTS of a Change in the CCR  
(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*The Medicare contractor shall notify a hospital or CMHC whenever it makes a change to its CCR. When a CCR is changed as a result of a tentative settlement or a final settlement of the cost report, the change to the CCR can be included in the notice that is issued to each provider after a tentative or final settlement is completed. Medicare contractors can also issue separate notification to a hospital about a change to its CCR(s).*

***10.11.4 - Use of CCRs in Mergers, Acquisitions, Other Ownership Changes, or Errors Related to CCRs  
(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

The contractors use the CCR for the surviving provider in cases of provider merger, acquisition or other such changes.

Effective for hospitals experiencing a change of ownership after January 1, 2007, that have not accepted assignment of an existing hospital's provider agreement in accordance with 42 CFR 489.18, and do not yet have a Medicare cost report, the contractor *may* use the default *Statewide CCR* to determine cost-based payments until the hospital has submitted its first Medicare cost report. *See §10.11.10 for the location of the Statewide CCRs and the upper limit above which the contractor must use the Statewide CCR. For purposes of identifying a CCR for payment, Medicare contractors may apply a Statewide average to hospitals receiving a new provider number, such as hospitals converting from non-IPPS to IPPS status. Also, for purposes of identifying a CCR for payment, hospitals receiving a new provider number may request use of a different CCR based on substantial evidence. Use of an alternative CCR is subject to the approval of the CMS central and regional offices as discussed in §10.11.3.2.* For hospitals experiencing a change of ownership prior to January 1, 2007, the contractor should use the prior hospital's *CCR*.

*In instances where errors related to CCRs and/or outlier payments are discovered, the Medicare contractor shall contact the CMS central office to seek further guidance. Medicare contractors may contact the CMS central office via the address and e-mail address listed in §10.11.3.1 of this chapter.*

*If a cost report is reopened after final settlement and as a result of this reopening, there is a change to the CCR, Medicare contractors should contact the CMS regional and central office for further instructions. Medicare contractors may contact the CMS central office via the address and email address listed in §10.11.3.1.*

### **10.11.5 - New Providers and Providers with Cost Report Periods Less Than a Full Year**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The contractors must calculate a hospital CCR using the most recent full-year cost report if a hospital or CMHC has a short period cost report.

The contractors must use the Statewide CCR for all inclusive rate hospitals paid under OPSS, or when a new provider does not have a full year's cost report and has no cost report history.

See §10.11.10 for the location of the Statewide CCRs.

### **10.11.6 - Substitution of Statewide CCRs for Extreme OPSS Hospital Specific CCRs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The contractors must use the applicable Statewide average urban or rural hospital default ratio if the CCR calculated for a hospital paid under OPSS is greater than the upper limit CCR in the file of overall OPSS hospital CCR limits on the CMS Web site.

*In addition to the circumstances listed in §§10.11.6, 10.11.5, and 10.11.4 of this chapter, a Medicare contractor also should use a Statewide average CCR if it is unable to determine an accurate overall ancillary CCR for a hospital for whom accurate data with which to calculate an operating CCR is not available. Further, the policies of §§10.11.3.1 and 10.11.3.2 can be applied as an alternative to the Statewide average.*

See §10.11.10 for the location of the Statewide CCRs and the upper limit above which the contractor must use the Statewide CCR.

### **10.11.7 - Methodology for Calculation of Hospital Overall CCR for Hospitals That Do Not Have Nursing and Paramedical Education Programs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

In calculating the hospital's costs or charges, do not include departmental CCRs and charges for services that are not paid under the OPSS such as physical, occupational and speech language therapies, clinical diagnostic laboratory services, ambulance, rural health clinic services, non-implantable DME, etc.

See §10.11.10 for the location of the list of exact cost centers that shall be included in the calculation of the overall CCR.

**Step 1 – Determining Overall Costs:** Calculate costs for each cost center by multiplying the departmental CCR for each cost center (and subscripts thereof) that reflect services subject to the OPSS from Form CMS 2552-96, Worksheet C, Part I, Column 9 by the Medicare outpatient charges for that cost center (and subscripts thereof) from Worksheet D, Part V, Columns 2, 3, 4, and 5 (and subscripts thereof). Sum the costs calculated for each cost center to arrive at Medicare outpatient cost of services subject to OPSS.

**Step 2 – Determining Overall Charges:** Calculate charges by summing the Medicare outpatient charges from Form CMS 2552-96, Worksheet D, Part V, Columns 2, 3, 4, and 5 (and subscripts thereof) for each cost center (and subscripts thereof) that reflect services subject to the OPSS.

**Step 3 – Calculating the Overall CCR:** Divide the costs from Step 1 by the charges from Step 2 to calculate the hospital's Medicare outpatient CCR.

### **10.11.8 - Methodology for Calculation of Hospital Overall CCR for Hospitals That Have Nursing and Paramedical Education Programs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Do not include departmental CCRs and charges for services not subject to the OPSS (such as physical, occupational and speech language therapies, clinical diagnostic laboratory services, ambulance, rural health clinic services, non-implantable DME, etc.) in calculating the hospital's costs or charges.

See §10.11.10 for the location of the list of the exact cost centers that should be included in the overall CCR.

**Step 1 -- Determining costs for each department:** From Worksheet B, Part I – Column 27, deduct the nursing and paramedical education costs found on the applicable line in Columns 21, and 24 of Worksheet B, Part I to calculate a cost for each cost center. Exception: The costs for 6200 are not calculated on this worksheet. For cost center 6200, non-distinct unit observation beds, use the cost reported on Worksheet D-1, Part IV, line 85, and deduct the nursing and paramedical education costs found on Worksheet D-1, Part IV, line 89 and subscripts, column 5. See Step 3 below.

**Step 2 – Determining charges for each department:** From worksheet C, Part I – Column 8 (sum of columns 6 and 7), identify “total charges.”

**Step 3 – Determining the CCRs for each department without nursing and paramedical education costs:** For each line, divide the costs from Step 1 by the charges from Step 2 to acquire CCRs for each line, without inclusion of nursing and paramedical education costs. Exception: For cost center 6200, non-distinct unit observation beds, use the cost reported on Worksheet D-1, Part IV, line 85, and deduct the nursing and paramedical education costs found on Worksheet D-1, Part IV, line 89 and subscripts, column 5.

**Step 4 – Determining Overall Costs:** Multiply the CCR in step 3 by the Medicare outpatient charges for that cost center (and subscripts thereof) from Worksheet D Part V, Columns 2, 3, 4, and 5 (and subscripts thereof). Sum the costs calculated for each cost center to arrive at Medicare outpatient cost of services subject to OPSS.

**Step 5 – Determining Overall Charges:** Calculate charges by summing the Medicare outpatient charges from Form CMS 2552-96, Worksheet D, Part V, Columns 2, 3, 4, and 5 (and subscripts thereof) for each cost center (and subscripts thereof) that reflect service subject to the OPSS.

**Step 6 – Calculating the Overall CCR:** Divide the costs from Step 4 by the charges from step 5 to calculate the hospital's Medicare outpatient CCR.

### **10.11.9 - Methodology for Calculation of CCR for CMHCs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Calculate the CMHC's CCR using the provider's most recent full year cost report, Form CMS 2088-92, and Medicare cost and charges from Worksheet C, Page 2. Divide costs from line 39.01, Column 3 by charges from line 39.02, Column 3 to calculate the CCR.

If the CCR is above 1.0 enter the appropriate Statewide average urban or rural hospital default ratio that is in the OPSF for the CMHC. There is no lower limit for CMHC CCRs. Use the CCR you calculate and do not substitute the Statewide average urban or rural hospital default ratio in cases where the CCR is below 1.0.

Note that CCR reporting requirements in §10.11 apply to both hospitals paid under OPSS and to CMHCs.

### **10.11.10 - Location of Statewide CCRs, Tolerances for Use of Statewide CCRs in Lieu of Calculated CCRs and Cost Centers to be Used in the Calculation of CCRs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The file of OPSS hospital upper limit CCRs and the file of Statewide CCRs are located on the CMS Web site at [www.cms.hhs.gov/HospitalOutpatientPPS/](http://www.cms.hhs.gov/HospitalOutpatientPPS/) under "*Annual Policy Files.*" A spreadsheet listing the Statewide CCRs *also* can be found in the file containing the preamble tables that appears in the most recent OPSS/ASC final rule. The contractors must always use the most recent Statewide CCR.

The file of standard and nonstandard cost centers to be used in the calculation of hospital outpatient CCRs is also found on the CMS Web site at [www.cms.hhs.gov/HospitalOutpatientPPS/](http://www.cms.hhs.gov/HospitalOutpatientPPS/) under "*Revenue Code to Cost Center Crosswalk.*"

### **10.11.11 - Reporting of CCRs for Hospitals Paid Under OPSS and for CMHCs**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The contractors shall report the OPSS hospital overall or CMHC CCR they calculate, or the Statewide CCR they select, for each provider to the Outpatient Provider Specific File (OPSF; see §50.1 of this chapter) within 30 days after the date of the calculation or selection of the Statewide CCR for the provider. If a cost report reopening results in adjustments that would change the CCR that is currently in effect, the contractor shall calculate and enter the CCR in the OPSF within 30 days of the date that the reopening is finalized. In such an instance, contractors must create an additional record in the OPSF for the provider. The contractor entries in the OPSF shall include the effective date of the CCR being entered. Entries in the OPSF shall not replace a pre-existing entry for the provider.

## 20.1 - General

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Reporting of HCPCS codes is required of acute care hospitals including those paid under alternate payment systems, e.g., Maryland, long-term care hospitals. HCPCS codes are also required of rehabilitation hospitals, psychiatric hospitals, hospital-based RHCs, hospital-based FQHCs, and CAHs reimbursed under Method II (HCPCS required to be billed for fee reimbursed services). This also includes all-inclusive rate hospitals. HCPCS includes the American Medical Association's "Current Procedural Terminology," 4th Edition, (CPT-4) for physician services and CMS developed codes for certain nonphysician services. All of the CPT-4 is contained within HCPCS, and is identified as Level I CPT codes consist of five numeric characters. The CMS developed codes are known as Level II. Level II codes are five-character codes that begin with an alpha character that is followed by either numeric or alpha characters.

Hospital-based and independent ESRD facilities must use HCPCS to bill for blood and blood products, and to bill for drugs and clinical laboratory services paid outside the composite rate. In addition, the hospital is required to report modifiers as applicable and as described in §20.6.

The CAHs are required to report HCPCS only for Part B services not paid to them on a reasonable cost basis, e.g., screening mammographies and bone mass measurements.

The HCPCS codes are required for all outpatient hospital services unless specifically excepted in manual instructions. This means that codes are required on surgery, radiology, other diagnostic procedures, clinical diagnostic laboratory, durable medical equipment, orthotic-prosthetic devices, take-home surgical dressings, therapies, preventative services, immunosuppressive drugs, other covered drugs, and most other services.

*When medical and surgical supplies (other than prosthetic and orthotic devices as described in the Medicare Claims Processing Manual, Chapter 20, §10.1) described by HCPCS codes with status indicators other than "H" or "N" are provided incident to a physician's service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent supplies. Claims containing charges for medical and surgical supplies used in providing hospital outpatient services are submitted to the Medicare contractor providing OPPS payment for the services in which they are used. The hospital should include charges associated with these medical and surgical supplies on claims so their costs are incorporated in ratesetting, and payment for the supplies is packaged into payment for the associated procedures under the OPPS in accordance with 42 CFR 419.2(b)(4).*

*For example, if the hospital staff in the emergency department initiate the intravenous administration of a drug through an infusion pump described by HCPCS code E0781 (Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient), complete the drug infusion, and*

*discontinue use of the infusion pump before the patient leaves the hospital outpatient department, HCPCS code E0781 should not be reported because the infusion pump was used as a supply and would be paid through OPPS payment for the drug administration service. The hospital should include the charge associated with the infusion pump on the claim.*

*In another example, if hospital outpatient staff perform a surgical procedure on a patient in which temporary bladder catheterization is necessary and use a catheter described by HCPCS code A4338 (Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each), the hospital should not report A4338 because the catheter was used as a supply and would be paid through OPPS payment for the surgical procedure. The hospital should include the charge associated with the urinary catheter on the claim.*

*When hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting, adjustment, or other services necessary for the patient's use of the item, the hospital should not bill a visit or procedure HCPCS code to report the charges associated with the fitting, adjustment, or other related services. Instead, the HCPCS code for the device already includes the fitting, adjustment or other similar services. For example, if the hospital outpatient staff provides the orthotic device described by HCPCS code L1830 (KO, immobilizer, canvas longitudinal, prefabricated, includes fitting and adjustment), the hospital should only bill HCPCS code L1830 and should not bill a visit or procedure HCPCS code to describe the fitting and adjustment.*

Claims with required HCPCS coding missing will be returned to the hospital for correction.

*Future updates will be issued in a Recurring Update Notification.*

## **20.6.9 - Use of HCPCS Modifier –FB**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

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)**”. See the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §61.3 for instructions regarding charges for items billed with the –FB modifier.

The OPPS hospitals must report modifier –FB on the same line as the procedure code (not the device code) for a service that requires a device for which neither the hospital, nor the beneficiary, is liable to the manufacturer. Hospitals must report modifier –FB on

the same line as the procedure code for a service that requires a device when the manufacturer gives credit for a device being replaced with a more costly device.

### 20.6.10 - Use of HCPCS Modifier –FC

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Effective January 1, 2008, the definition of modifier -FC is “**Partial credit received for replaced device.**” See the Medicare Claims Processing Manual, Pub 100-04, Chapter 4, §61.3 for instructions regarding charges for items billed with *modifier –FC*. OPSS hospitals must report modifier *–FC* for cases in which the hospital receives a partial credit of 50 percent or more of the cost of a new replacement device under warranty, recall, or field action. The hospital must append *modifier –FC* to the procedure code (not the device code) that reports the services provided to replace the device.

### 50.1 - Outpatient Provider Specific File

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The Outpatient Provider Specific File (OPSF) contains the required information about each provider to enable the pricing software to calculate the payment amount. Data elements and formats are shown below. Contractors must maintain the accuracy of the data, and update the file as changes occur in data element values, e.g., changes in metropolitan statistical area (MSA), bed size, cost to charge ratio. An update is accomplished by preparing and adding an additional complete record showing new current values and the effective date of the change. The old record is retained without change.

Contractors must also furnish CMS a quarterly file in the same format.

**NOTE:** All data elements, whether required or optional, must have a default value of “0” (zero) if numerical, or blank if alphanumeric.

File Position	Format	Title	Description
1-10	X(10)	National Provider Identifier (NPI)	Alpha-numeric 10 character provider number.
11-16	X(6)	Provider Oscar Number	Alpha-numeric 6 character provider number.
17-24	9(8)	Effective Date	Must be numeric, CCYYMMDD. This is the effective date of the provider's first OPSS period. For subsequent OPSS periods, the effective date is the date of a change to the PROV file. If a termination date is present for this record, the effective date must be equal to or less than the termination date.

25-32	9(8)	Fiscal Year Beginning Date	<p>Must be numeric, CCYYMMDD.</p> <p>Month: 01-12</p> <p>Day:01-31</p> <p>The date must be greater than 19990630.</p>
33-40	9(8)	Report Date	<p>Must be numeric, CCYYMMDD.</p> <p>Month: 01-12</p> <p>Day:01-31</p> <p>The created/run date of the PROV report for submittal to CO.</p>
41-48	9(8)	Termination Date	<p>Must be numeric, CCYYMMDD. Must be zeros or contain a termination date. <i>(once the official "tie-out" notice from CMS is received)</i>. Must be equal to or greater than the effective date. (Termination date is the date on which the reporting intermediary ceased servicing the provider in question).</p>
49	X(1)	Waiver Indicator	<p>Enter a "Y" or "N."</p> <p>Y = waived (provider is not under OPPS)</p> <p>N = not waived (provider is under OPPS)</p>
50-54	9(5)	Intermediary Number	<p>Enter the Intermediary #.</p>
55-56	X(2)	Provider Type	<p>This identifies providers that require special handling. Enter one of the following codes as appropriate.</p> <p>00 or blanks = Short Term Facility</p> <p>02 Long Term</p> <p>03 Psychiatric</p> <p>04 Rehabilitation Facility</p> <p>05 Pediatric</p> <p>06 Hospital Distinct Parts (Provider type "06" is effective until July 1, 2006. At that point, provider type "06" will no longer be</p>

			<p>used. Instead, contractors will assign a hospital distinct part as one of the following provider types: 49, 50, 51, 52, 53, or 54)</p> <p>07 Rural Referral Center</p> <p>08 Indian Health Service</p> <p>13 Cancer Facility</p> <p>14 Medicare Dependent Hospital (during cost reporting periods that began on or after April 1, 1990.</p> <p>15 Medicare Dependent Hospital/Referral Center (during cost reporting periods that began on or after April 1, 1990. Invalid October 1, 1994 through September 30, 1997).</p> <p>16 Re-based Sole Community Hospital</p> <p>17 Re-based Sole Community Hospital /Referral Center</p> <p>18 Medical Assistance Facility</p> <p>21 Essential Access Community Hospital</p> <p>22 Essential Access Community Hospital/Referral Center</p> <p>23 Rural Primary Care Hospital</p> <p>32 Nursing Home Case Mix Quality Demonstration Project – Phase II</p> <p>33 Nursing Home Case Mix Quality Demonstration Project – Phase III – Step 1</p> <p>34 Reserved</p> <p>35 Hospice</p> <p>36 Home Health Agency</p> <p>37 Critical Access Hospital</p>
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			<p>38 Skilled Nursing Facility (SNF) – For non-demo PPS SNFs – effective for cost reporting periods beginning on or after July 1, 1998</p> <p>40 Hospital Based ESRD Facility</p> <p>41 Independent ESRD Facility</p> <p>42 Federally Qualified Health Centers</p> <p>43 Religious Non-Medical Health Care Institutions</p> <p>44 Rural Health Clinics-Free Standing</p> <p>45 Rural Health Clinics-Provider Based</p> <p>46 Comprehensive Outpatient Rehab Facilities</p> <p>47 Community Mental Health Centers</p> <p>48 Outpatient Physical Therapy Services</p> <p>49 Psychiatric Distinct Part</p> <p>50 Rehabilitation Distinct Part</p> <p>51 Short-Term Hospital – Swing Bed</p> <p>52 Long-Term Care Hospital – Swing Bed</p> <p>53 Rehabilitation Facility – Swing Bed</p> <p>54 Critical Access Hospital – Swing Bed</p>
57	X(1)	Special Locality Indicator	Indicates the type of special locality provision that applies. Does not apply to ESRD Facilities.
58	X(1)	Change Code For Wage Index Reclassification	Enter “Y” if the hospital’s wage index location has been reclassified for the year. Enter “N” if it has not been reclassified for the year. Adjust annually. Does not apply to ESRD Facilities.
59-62	X(4)	Actual Geographic Location—MSA	Enter the appropriate code for MSA, 0040–9965, or the rural area, (blank)(blank) 2-digit numeric State code, such as __ 3 6 for Ohio, where the facility is physically located.

63-66	X(4)	Wage Index Location—MSA	The appropriate code for the MSA, 0040-9965, or the rural area, (blank)(blank) (2 digit numeric State code) such as __ <u>3</u> <u>6</u> for Ohio, to which a hospital has been reclassified for wage index. Leave blank or enter the actual location MSA if not reclassified. Does not apply to ESRD Facilities.
67-70	9V9(3)	Payment-to-Cost Ratio	Enter the provider's payment-to-cost ratio. Does not apply to ESRD Facilities.
71-72	9(2)	State Code	Enter the 2-digit state where the provider is located. Enter only the first (lowest) code for a given state. For example, effective October 1, 2005, Florida has the following State Codes: 10, 68 and 69. Contractors shall enter a "10" for Florida's State Code.  List of valid State Codes is located in Pub. 100-07, Chapter 2, Section 2779A1.
73	X(1)	TOPs Indicator	Enter the code to indicate whether TOPs applies or not.  Y = qualifies for TOPs  N = does not qualify for TOPs
74	X(1)	<i>Hospital Quality Indicator Field</i>	<i>Enter the code to indicate whether the hospital meets data submission criteria per HOP QDRP requirements.</i>  <i>I = Hospital quality reporting standards have been met or hospital is not required to submit quality data (e.g., hospitals that are specifically excluded from the IPPS or which are not paid under the OPPS, including psychiatric, rehabilitation, long-term care and children's and cancer hospitals, Maryland hospitals, Indian Health Service hospitals, or hospital units; or hospitals that are located in Puerto Rico or the U.S. territories). The reduction does not apply to hospices, CORFs, HHAs, CMHCs, critical access hospitals or to any other provider type that is not a hospital.</i>  <i>Blank = Hospital does not meet criteria.</i>
75	X(1)	Filler	Blank.

76-79	9V9(3)	Outpatient Cost-to-Charge Ratio	Derived from the latest available cost report data. See §10.11 of this chapter for instructions on how to calculate and report the Cost-to-Charge Ratio. Does not apply to ESRD Facilities.
80-84	X(5)	Actual Geographic Location CBSA	00001-89999, or the rural area, (blank)(blank)(blank) 2 digit numeric State code such as ___ <u>3</u> <u>6</u> for Ohio, where the facility is physically located.
85-89	X(5)	Wage Index Location CBSA	Enter the appropriate code for the CBSA, 00001-89999, or the rural area, (blank)(blank)(blank) (2 digit numeric State code) such as ___ <u>3</u> <u>6</u> for Ohio, to which a hospital has been reclassified due to its prevailing wage rates. Leave blank or enter the Actual Geographic Location CBSA, if not reclassified. Pricer will automatically default to the actual location CBSA if this field is left blank. Does not apply to ESRD Facilities.
90-95	9(2) V9(4)	Special Wage Index	Enter the special wage index that certain providers may be assigned. Enter zeroes unless the Special Payment Indicator equals a “1” or “2.”
96	X(1)	Special Payment Indicator	The following codes indicate the type of special payment provision that applies.  Blank = not applicable  Y = reclassified  1 = special wage index indicator  2 = both special wage index indicator and reclassified
97-100	9(4)	Reduced Coinsurance Trailer Count	Enter the number of APCs the provider has elected to reduce coinsurance for. The number cannot be greater than 999.

The contractor enters the number of APCs for which the provider has elected to reduce coinsurance. Cannot be greater than 999. Reduced Coinsurance Trailer Record - Occurs 0-999 times depending on the reduced Coinsurance Trailer Count in positions 97-100. Due to systems capacity limitations the maximum number of reduced coinsurance trailers allowable is 999 at this time.

1-4	9(4)	APC Classification - Enter the 4-digit APC classification for which the provider has elected to reduce coinsurance.
5-10	9(4)V9(2)	Reduced Coinsurance Amount - Enter the reduced

		coinsurance amount elected by the provider
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The Shared system will verify that the last position of the record is equal to the number in file positions 97 through 100 multiplied by 10 plus 100 (last position of record = (# in file position 97-100)(10) + 100).

*Future updates will be issued in a Recurring Update Notification.*

## **61 - Billing for Devices Under the OPPS**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

*Future updates will be issued in a Recurring Update Notification.*

### **61.3 - Billing for Devices *Furnished* Without Cost to an OPPS Hospital or Beneficiary or for Which the Hospital Receives a Full or Partial Credit and Payment for OPPS Services Required to *Furnish* the Device**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

#### **61.3.1 - Reporting and Charging Requirements When a Device is *Furnished* Without Cost to the Hospital**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

*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**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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 6<sup>th</sup> 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**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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 OPSS 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 OPSS 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/](http://www.cms.hhs.gov/HospitalOutpatientPPS/).

## **70 - Transitional Corridor Payments**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) established transitional payments to limit provider's losses under *the* OPSS; the additional payments are for 3 1/2 years for *community mental health centers* (CMHCs) and most hospitals, and permanent for cancer hospitals effective August 1, 2000.

Section 405 of BIPA provides that children's hospitals described in §1886(d)(1)(B)(iii) *are* held harmless permanently for purposes of calculating TOP amounts, *retroactive to August 1, 2000. Some rural hospitals are also held harmless for several years after the implementation of the OPSS, as discussed in detail below. Contractors determine TOPs eligibility and calculate interim TOPs.*

Beginning September 1, 2000, and every month thereafter until further notice, the shared system maintainers must provide *contractors* with software that gathers all data required to calculate a TOP amount for each hospital and CMHC. The software must calculate and pay the TOP amount for OPSS services on claims processed during the preceding month, maintain an audit trail (including the ability to generate a hardcopy report) of these TOP amounts, and transfer to the PS&R system any necessary data. TOP amounts should be paid before the next month begins and they are not subject to normal payment floor requirements.

*Several* items contained in *the Inpatient or Outpatient Provider Specific File (IPSF or OPSF)* are needed to *determine TOP eligibility* for each hospital or CMHC. They are:

- The provider number;
- Fiscal year begin date;

- The provider type;
- Actual geographic location – *CBSA-(from the IPSF)*;
- Wage index location - *CBSA-(from the IPSF); and*
- Bed size *(from the IPSF)*

Pursuant to §403 of BIPA, a TOP may be made to hospitals and CMHCs that did not file a cost report for the cost reporting period ending in calendar year 1996. The law was amended to provide that if a hospital did not file a cost report for a cost reporting period ending in calendar year 1996, the payment-to-cost ratio used in calculating a TOP will be based on the hospital's first cost report for a period ending after calendar year 1996 and before calendar year 2001. This provision is effective retroactively to August 1, 2000.

*Future updates will be issued in a Recurring Update Notification.*

## **70.1 - Transitional Outpatient Payments (TOPs) for CY 2000 and CY 2001**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Monthly TOPs calculations that *contractors* are required to calculate are described below. This calculation is effective for services provided between August 1, 2000, and December 31, 2001.

Step 1 – Compute the pre-BBA amount for each month by first multiplying the total charges for covered services for all OPSS services on claims paid during the month and reduce the total charges to cost by multiplying them by the outpatient cost to charge ratio and then multiplying this amount by the provider-specific payment-to-cost ratio (PSPCR).

Step 2 – Add together the total Medicare program payments, unreduced coinsurance and deductible applied for all APCs, as well as all outlier payments and transitional pass-through payments for drugs, biologicals and/or devices for those same claims paid during the month as those used in Step 1. If the result is greater than the result of step 1, go to step 9. No transitional payment is due this month.

Step 3 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital, go to step 4. If any other type of hospital, divide the result of step 2 by the result of step 1, skip step 4 and perform step 5, 6, 7, or 8 as appropriate.

Step 4 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital, subtract the result of step 2 from the result of step 1 and pay .85 times this amount. Do not perform steps 5-8.

Step 5 - If the result of step 3 is equal to or greater than .9 but less than 1.0, subtract the result of step 2 from the result of step 1, and multiply the difference by .8 and pay .85 times this amount.

Step 6 - If the result of step 3 is equal to or greater than .8 but less than .9, subtract .7 times the result of step 2 from .71 times the result of step 1, and pay .85 times this amount.

Step 7 - If the result of step 3 is equal to or greater than .7 but less than .8, subtract .6 times the result of step 2 from .63 times the result of step 1, and pay .85 times this amount.

Step 8 - If the result of step 3 is less than .7, multiply the result of step 1 by .21 and pay .85 times this amount.

Step 9 - When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.

## **70.2 - Transitional Outpatient Payments (TOPs) for CY 2002**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

For services provided during calendar years 2002, TOPs were gradually reduced for all providers except those hospitals that receive hold harmless TOPs (cancer hospitals, children's hospitals, and rural hospitals having 100 or fewer beds). To avoid TOP overpayments, *contractors* were instructed to revise the monthly interim TOP calculations to reflect the new calculation.

Monthly TOPs calculations that *contractors* are required to calculate are described below. This calculation is effective for services provided between January 1, 2002, and December 31, 2002.

Step 1 – Compute the pre-BBA amount for each month by first multiplying the total charges for covered services for all OPSS services on claims paid during the month and reduce the total charges to cost by multiplying them by the outpatient cost-to-charge ratio and then multiplying this amount by the provider-specific payment-to-cost ratio (PSPCR).

Step 2 – Add together the total Medicare program payments, unreduced coinsurance and deductible applied for all APCs, as well as all outlier payments and transitional

pass-through payments for drugs, biologicals and/or devices for those same claims paid during the month as those used in Step 1. If the result is greater than the result of step 1, go to step 8. No transitional payment is due this month.

Step 3 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital go to step 4. If any other type of hospital, divide the result of step 2 by the result of step 1, skip step 4 and perform steps 5, 6, or 7 as appropriate.

Step 4 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital, subtract the result of step 2 from the result of step 1 and pay .85 times this amount. Do not perform steps 5-7.

Step 5 - If the result of step 3 is equal to or greater than .9 but less than 1.0, subtract the result of step 2 from the result of step 1, and multiply the difference by .7 and pay .85 times this amount.

Step 6 - If the result of step 3 is equal to or greater than .8 but less than .9, subtract .6 times the result of step 2 from .61 times the result of step 1, and pay .85 times this amount.

Step 7 - If the result of step 3 is less than .8, multiply the result of step 1 by .13 and pay .85 times this amount.

Step 8 - When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.

### **70.3 - Transitional Outpatient Payments (TOPs) for CY 2003**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

For services provided during calendar years 2003, TOPs continued to decrease for all providers except those hospitals that receive hold harmless TOPs (cancer hospitals, children's hospitals, and rural hospitals having 100 or fewer beds). To avoid TOP overpayments, *contractors* were instructed to revise the monthly interim TOP calculations to reflect the new calculation.

Monthly TOPs calculations that *contractors* are required to calculate are described below. This calculation is effective for services provided between January 1, 2003, and December 31, 2003.

Step 1 – Compute the pre-BBA amount for each month by first multiplying the total charges for covered services for all OPPS services on claims paid during the month and reduce the total charges to cost by multiplying them by the outpatient cost to

charge ratio and then multiplying this amount by the provider-specific payment-to-cost ratio (PSPCR).

Step 2 – Add together the total Medicare program payments, unreduced coinsurance and deductible applied for all APCs, as well as all outlier payments and transitional pass-through payments for drugs, biologicals and/or devices for those same claims paid during the month as those used in Step 1. If the result is greater than the result of step 1, go to step 7. No transitional payment is due this month.

Step 3 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital go to step 4. If any other type of hospital, divide the result of step 2 by the result of step 1, skip step 4 and perform step 5 or 6 as appropriate.

Step 4 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital, subtract the result of step 2 from the result of step 1 and pay .85 times this amount. Do not perform steps 5-6.

Step 5 - If the result of step 3 is equal to or greater than .9 but less than 1.0, subtract the result of step 2 from the result of step 1, and multiply the difference by .6 and pay .85 times this amount.

Step 6 - If the result of step 3 is less than .9, multiply the result of step 1 by .06 and pay .85 times this amount.

Step 7 - When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.

## **70.4 - Transitional Outpatient Payments (TOPs) for CY 2004 and CY 2005**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Section 411 of the Medicare Modernization Act (MMA) provided that for services provided on or after January 1, 2004, TOPs are discontinued for all CMHCs and all hospitals except for rural hospitals having 100 or fewer beds, sole community hospitals (SCHs) which are located in rural areas, and cancer and children's hospitals. For CMHCs and hospitals for which TOPs will be discontinued, interim TOPs are to be paid for services furnished through December 31, 2003.

Hold harmless TOPs shall continue for services rendered through December 31, 2005, for rural hospitals having 100 or fewer beds. Cancer hospitals and children's hospitals are permanently held harmless. In addition, hold harmless TOPs are paid to sole community hospitals that are located in rural areas, with respect to services furnished during the

period that begins with the provider's first cost reporting period beginning on or after January 1, 2004, and ends on December 31, 2005. **NOTE:** If a qualifying SCH has a cost reporting period that begins on a date other than January 1, TOPs and interim TOPs payments will not be paid for services furnished after December 31, 2003, and before the beginning of the provider's next cost reporting period. If a hospital qualifies as both a rural hospital having 100 or fewer beds and as a SCH located in a rural area, for purposes of § 70.4, the hospital will be treated as a rural hospital having 100 or fewer beds, thereby avoiding a gap in payment if the cost reporting period does not begin on January 1.

If the *contractor* identifies additional hospitals that are eligible for TOPs payments, the *contractor* shall make the appropriate interim payments retroactive to January 1, 2004, for small rural hospitals and retroactive to the provider's first day of the cost reporting period beginning on or after January 1, 2004 for rural SCHs having greater than 100 beds.

For 2004-2005, providers will receive interim TOPs payments of 85 *percent*, and will receive the additional 15 *percent* (to reach 100 *percent*) at cost report settlement.

*Monthly TOPs calculations that contractors are required to calculate are described below. This calculation is effective for services provided between January 1, 2004, and December 31, 2005.*

*Step 1 – Compute the pre-BBA amount for each month by first multiplying the total charges for covered services for all OPSS services on claims paid during the month and reduce the total charges to cost by multiplying them by the outpatient cost-to-charge ratio and then multiplying this amount by the provider-specific payment-to-cost ratio (PSPCR).*

*Step 2 – Add together the total Medicare program payments, unreduced coinsurance and deductible applied for all APCs, as well as all outlier payments and transitional pass-through payments for drugs, biologicals and/or devices for those same claims paid during the month as those used in Step 1. If the result is greater than the result of step 1, go to step 4. No transitional payment is due this month.*

*Step 3 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds, a rural sole community hospital, or a cancer hospital, subtract the result of step 2 from the result of step 1 and pay .85 times this amount.*

*Step 4 - When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.*

## 70.5 - Transitional Outpatient Payments (TOPs) for CY 2006-CY 2008

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Hold harmless transitional outpatient payments (TOPs) to small rural hospitals and rural sole community hospitals were scheduled to expire December 31, 2005. Section 5105 of The Deficit Reduction Act (DRA) of 2005 reinstated these hold harmless payments through December 31, 2008, for rural hospitals having 100 or fewer beds that are not sole community hospitals. Small rural hospitals will continue to receive TOPs payments through December 31, 2008. Sole community hospitals are no longer eligible for TOPs payments. Essential Access Community Hospitals (EACHs) are considered to be sole community hospitals under section 1886(d)(5)(D)(iii)(III) of the Act. Therefore, EACHs are not eligible for TOPs payments for CY 2006-CY 2008. If a hospital qualifies as both a small rural hospital and a rural SCH, for purposes of receiving TOPs and interim TOPs in §70.5, the hospital will be treated as a rural SCH. These providers are not eligible for TOPs for services furnished on or after January 1, 2006.

The DRA specifies that providers will receive 95 *percent* of the hold harmless amount during 2006, 90% of the hold harmless amount in 2007, and 85 *percent* of the hold harmless amount in 2008. Interim TOPs payments will continue at 85 *percent*, and the provider will continue to receive additional payments at cost report settlement, similar to past policy.

For 2006, providers will continue to receive interim TOPS payments of 85 *percent* and will receive the additional 10 *percent* (to reach 95 *percent*) at cost report settlement. For 2007, providers will receive the additional 5 *percent* (to reach 90 *percent*) at cost report settlement. For 2008, providers will not receive any additional money at cost report settlement.

Cancer and children's hospitals are permanently held harmless and will continue to receive TOPs payments in 2006 and beyond.

Monthly TOPs calculations that *contractors* are required to calculate are described below. This calculation is effective for services provided between January 1, 2006, and December 31, 2008.

Step 1 – Compute the pre-BBA amount for each month by first multiplying the total charges for covered services for all OPSS services on claims paid during the month and reduce the total charges to cost by multiplying them by the outpatient cost-to-charge ratio and then multiplying this amount by the provider-specific payment-to-cost ratio (PSPCR).

Step 2 – Add together the total Medicare program payments, unreduced coinsurance and deductible applied for all APCs, as well as all outlier payments and transitional pass-through payments for drugs, biologicals and/or devices for those same claims paid during the month as those used in Step 1. If the

result is greater than the result of step 1, go to step 59. No transitional payment is due this month.

Step 3 - If the hospital is a children's hospital, a small rural hospital that is not also a SCH, EACH, or a cancer hospital, go to step 4.

Step 4 - If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital, subtract the result of step 2 from the result of step 1 and pay .85 times this amount.

Step 5 - When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.

### ***70.6 - Transitional Outpatient Payments (TOPs) for CY 2009***

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Hold harmless transitional outpatient payments (TOPs) to small rural hospitals and rural sole community hospitals that were scheduled to expire December 31, 2008. Section 147 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) extends the hold harmless provision for small rural hospitals with 100 or fewer beds through December 31, 2009, at 85 percent of the hold harmless amount. Section 147 also provides 85 percent of the hold harmless amount from January 1, 2009, through December 31, 2009, to sole community hospitals with 100 or fewer beds. Essential Access Community Hospitals (EACHs) are considered to be sole community hospitals under section 1886(d)(5)(D)(iii)(III) of the Act. Therefore, EACHs are also eligible for TOPs for CY 2009.*

*Cancer and children's hospitals are permanently held harmless and continue to receive TOPs payments in CY 2009.*

*Monthly TOPs calculations that contractors are required to calculate are described below. This calculation is effective for services provided between January 1, 2009, and December 31, 2009.*

*Step 1 – Compute the pre-BBA amount for each month by first multiplying the total charges for covered services for all OPSS services on claims paid during the month and reduce the total charges to cost by multiplying them by the outpatient cost-to-charge ratio and then multiplying this amount by the provider-specific payment-to-cost ratio (PSPCR).*

*Step 2 – Add together the total Medicare program payments, unreduced coinsurance and deductible applied for all APCs, as well as all outlier payments*

*(including reconciled outlier payments and the time value of money) and transitional pass-through payments for drugs, biologicals and/or devices for those same claims paid during the month as those used in Step 1. If the result is greater than the result of step 1, go to step 4. No transitional payment is due this month.*

*Step 3 - If the hospital is a children's hospital, a cancer hospital, a rural hospital with 100 or fewer beds, or a sole community hospital (including EACHs) with 100 or fewer beds, subtract the result of step 2 from the result of step 1 and pay .85 times this amount. If the hospital is not one of the hospital types listed above, no payment is made.*

*Step 4 - When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.*

## **70.7 - TOPs Overpayments**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Because the revised TOP calculations are often implemented in the system after their effective date, overpayments or underpayments in interim TOPs to providers are expected.*

*Unless directed by CMS, retroactive calculations of monthly interim TOP amounts are not necessary because any difference in interim TOP payments and actual TOP amounts determined on the cost report will be taken into account in the cost report settlement process, including tentative settlements.*

*If mutually agreed upon by both the contractor and the provider, the contractor can pay less than 85 percent of the monthly TOP payment to that provider, to avoid significant overpayments throughout the year that must be paid back to the contractor at cost report settlement.*

*Contractors should advise providers of the revised TOP calculations and other changes in OPSS using their normal communication protocols (Web site, regularly scheduled bulletins, electronic bulletin boards, or listserv).*

## **160.1 - Critical Care Services**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Hospitals should separately report all HCPCS codes in accordance with correct coding principles, CPT code descriptions, and any additional CMS guidance, when available. Specifically with respect to CPT code 99291 (Critical care, evaluation and management*

*of the critically ill or critically injured patient; first 30-74 minutes), hospitals must follow the CPT instructions related to reporting that CPT code. Any services that CPT indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by CPT) should not be billed separately by the hospital. Instead, hospitals should report charges for any services provided as part of the critical care services. In establishing payment rates for critical care services, and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services and other services, according to the standard OPSS methodology for packaging costs.*

Beginning January 1, 2007, critical care services will be paid at two levels, depending on the presence or absence of trauma activation. Providers will receive one payment rate for critical care without trauma activation and will receive additional payment when critical care is associated with trauma activation.

To determine whether trauma activation occurs, follow the National Uniform Billing Committee (NUBC) guidelines in the Claims Processing Manual, Pub 100-04, Chapter 25, §75.4 related to the reporting of the trauma revenue codes in the 68x series. The revenue code series 68x can be used only by trauma centers/hospitals as licensed or designated by the state or local government authority authorized to do so, or as verified by the American College of Surgeons. Different subcategory revenue codes are reported by designated Level 1-4 hospital trauma centers. Only patients for whom there has been prehospital notification based on triage information from prehospital caregivers, who meet either local, state or American College of Surgeons field triage criteria, or are delivered by inter-hospital transfers, and are given the appropriate team response can be billed a trauma activation charge.

When critical care services are provided without trauma activation, the hospital may bill CPT code 99291, Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes (and 99292, if appropriate). If trauma activation occurs under the circumstances described by the NUBC guidelines that would permit reporting a charge under 68x, the hospital may also bill one unit of code G0390, which describes trauma activation associated with hospital critical care services. Revenue code 68x must be reported on the same date of service. The OCE will edit to ensure that G0390 appears with revenue code 68x on the same date of service and that only one unit of G0390 is billed. CMS believes that trauma activation is a one-time occurrence in association with critical care services, and therefore, CMS will only pay for one unit of G0390 per day.

The CPT code 99291 is defined by CPT as the first 30-74 minutes of critical care. This 30 minute minimum has always applied under the OPSS. The CPT code 99292, Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes, remains a packaged service under the OPSS, so that hospitals do not have the ongoing administrative burden of reporting precisely the time for each critical service provided. As the CPT guidelines indicate, hospitals that provide less than 30 minutes of critical care should bill for a visit, typically an emergency department visit, at a level consistent with their own internal guidelines.

Under the OPPS, the time that can be reported as critical care is the time spent by a physician and/or hospital staff engaged in active face-to-face critical care of a critically ill or critically injured patient. If the physician and hospital staff or multiple hospital staff members are simultaneously engaged in this active face-to-face care, the time involved can only be counted once.

- *Beginning in* CY 2007 hospitals may continue to report a charge with RC 68x without any HCPCS code when trauma team activation occurs. In order to receive additional payment when critical care services are associated with trauma activation, the hospital must report G0390 on the same date of service as RC 68x, in addition to CPT code 99291 (or 99292, if appropriate.)
- *Beginning in* CY 2007 hospitals should continue to report 99291 (and 99292 as appropriate) for critical care services furnished without trauma team activation. CPT 99291 maps to APC 0617 (Critical Care). (CPT 99292 is packaged and not paid separately, but should be reported if provided.)

Critical care services are paid in some cases separately and in other cases as part of a composite APC payment. See Section 10.2.1 of this chapter for further details.

*Future updates will be issued in a Recurring Update Notification.*

### **180.3 - Unlisted Service or Procedure**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*An unlisted HCPCS code represents an item, service, or procedure for which there is no specific CPT or Level II alphanumeric HCPCS code. The CPT code book lists a number of unlisted service or procedure codes, which can be found at the end of a section or subsection. Alternatively, a summary list of the unlisted CPT codes can be found in the Guidelines section for each chapter of the CPT code book. The long descriptors for these codes start with the term “Unlisted” and the last 2 digits of the codes often end in “99.”*

*Under the OPPS, CMS generally assigns the unlisted service or procedure codes to the lowest level APC within the most appropriate clinically related series of APCs. Payment for items reported with unlisted codes is often packaged.*

*For non-OPPS payment purposes, when an unlisted service or procedure code is reported, a report describing the service or procedure shall be submitted with the claim. Pertinent information includes a definition or description of the nature, extent, and need for the procedure or service, as well as the provider’s time, effort, and equipment necessary to provide the service.*

*When a Medicare contractor receives a claim with an unlisted HCPCS code for non-OPPS payment, the contractor shall verify that no existing HCPCS code adequately describes the procedure or service. Unlisted codes should be reported only if no other*

*specific HCPCS codes adequately describe the procedure or service. If an unlisted code is submitted on a claim and the contractor has verified that the code submitted is correct, the contractor pays the claim using the unlisted code, based on the applicable non-OPPS payment methodology. However, if it is determined that an unlisted code was submitted in error because the procedure or service is described by a specific HCPCS code, the contractor shall advise the hospital or CAH of the appropriate code and process the claim. If a procedure or service reported with an unlisted code is reported frequently, the contractor shall advise the provider that a request for a specific CPT code or alphanumeric HCPCS code should be made.*

*The latest list of “Unlisted” CPT codes for procedures and services can be found at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>. Medicare contractors shall review this list once a year since it is updated annually on or about January 1 of the calendar year.*

*Future updates will be issued in a Recurring Update Notification.*

## **200.7.2 - Cardiac Echocardiography With Contrast**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

Hospitals are instructed to bill for echocardiograms with contrast using the applicable HCPCS code(s) included in Table 200.7.2 below. Hospitals should also report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms.

**Table 200.7.2 – HCPCS Codes For Echocardiograms With Contrast**

<b><i>HCPCS</i></b>	<b><i>Long Descriptor</i></b>
<i>C8921</i>	<i>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete</i>
<i>C8922</i>	<i>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study</i>
<i>C8923</i>	<i>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography</i>
<i>C8924</i>	<i>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study</i>
<i>C8925</i>	<i>Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, real time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report</i>
<i>C8926</i>	<i>Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies;</i>

	<i>including probe placement, image acquisition, interpretation and report</i>
<i>C8927</i>	<i>Transesophageal echocardiography (TEE) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis</i>
<i>C8928</i>	<i>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report</i>
<i>C8929</i>	<i>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography</i>
<i>C8930</i>	<i>Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision</i>

## **200.8 - Billing for Nuclear Medicine Procedures**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Beginning January 1, 2008, the I/OCE began editing for the presence of a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. Hospitals should include radiolabeled product HCPCS codes on the same claim as a nuclear medicine procedure beginning on January 1, 2008.*

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 OPSS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

*Hospitals are instructed to use HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) on outpatient claims for nuclear medicine procedures to indicate that a radiolabeled product that provides the radioactivity necessary for the reported diagnostic nuclear medicine procedure was provided during a hospital inpatient*

*stay. This HCPCS code is assigned status indicator “N” because no separate payment is made for the code under the OPPTS. The effective date of the code is January 1, 2008, the date the nuclear medicine procedure-to-radiolabeled product edits were initially implemented. Because the Medicare claims processing system requires that there be a charge for each HCPCS code reported on the claim, hospitals should always report a token charge of less than \$1.01 for HCPCS code C9898. The date of service reported on the claim for HCPCS code C9898 should be the same as the date of service for the nuclear medicine procedure HCPCS code, which should always accompany the reporting of HCPCS code C9898. HCPCS code C9898 should never be reported on a claim without a diagnostic nuclear medicine procedure that is subject to the nuclear medicine procedure-to-radiolabeled product edits.*

*More information regarding these edits is available on the OPPTS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS>*

Future updates to this section will be communicated in a Recurring Update Notification.

## **260.1 - Special Partial Hospitalization Billing Requirements for Hospitals, Community Mental Health Centers, and Critical Access Hospitals**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

Medicare Part B coverage is available for hospital outpatient partial hospitalization services.

### **A. Billing Requirement**

Section 1861 of the Act defines the services under the partial hospitalization benefit in a hospital.

Section 1866(e)(2) of the Act recognizes CMHCs as “providers of services” but only for furnishing partial hospitalization services. See §261.1.1 for CMHC partial hospitalization bill review directions.

Hospitals and CAHs report condition code 41 in FLs **18-28** (or electronic equivalent) to indicate the claim is for partial hospitalization services. They must also report a revenue code and the charge for each individual covered service furnished. In addition, hospital outpatient departments are required to report HCPCS codes. CAHs are not required to HCPCS code for this benefit.

Under component billing, hospitals are required to report a revenue code and the charge for each individual covered service furnished under a partial hospitalization program. In addition, hospital outpatient departments are required to report HCPCS codes. Component billing assures that only those partial hospitalization services covered under §1861(ff) of the Act are paid by the Medicare program.

All hospitals are required to report condition code 41 in FLs *18-28* to indicate the claim is for partial hospitalization services. Hospitals use bill type 13X and CAHs use bill type 85X. The following special procedures apply.

Bills must contain an acceptable revenue code. They are as follows:

Revenue Code	Description
0250	Drugs and Biologicals
043X	Occupational Therapy
0900	Behavioral Health Treatment/Services
0904	Activity Therapy
0910	Psychiatric/Psychological Services (Dates of Service prior to October 16, 2003)
0914	Individual Therapy
0915	Group Therapy
0916	Family Therapy
0918	Testing
0942	Education Training

Hospitals other than CAHs are also required to report appropriate HCPCS codes as follows:

Revenue Code	Description	HCPCS Code
043X	Occupational Therapy	*G0129
0900	Behavioral Health Treatment/Services	90801 <i>or</i> 90802
0904	Activity Therapy (Partial Hospitalization)	**G0176
0910	Psychiatric General Services (Dates of Service prior to October 16, 2003)	90801, 90802, 90899
0914	Individual Psychotherapy	90816, 90817, 90818, 90819, 90821, 90822, 90823, 90824, 90826,

Revenue Code	Description	HCPCS Code
		90827, 90828, 90829 90845, 90865, or 90880
0915	Group Therapy	<i>G0410 or G0411</i>
0916	Family Psychotherapy	90846 <i>or</i> 90847
0918	Psychiatric Testing	96101, 96102, 96103, 96116, 96118, 96119, or 96120
0942	Education Training	***G0177

The FI will edit to assure that HCPCS are present when the above revenue codes are billed and that they are valid HCPCS codes. The FI will not edit for matching the revenue code to HCPCS.

\*The definition of code G0129 is as follows:

Occupational therapy services requiring skills of a qualified occupational therapist, furnished as a component of a partial hospitalization treatment program, per session (45 minutes or more).

\*\*The definition of code G0176 is as follows:

Activity therapy, such as music, dance, art or play therapies not for recreation, related to care and treatment of patient's disabling mental problems, per session (45 minutes or more).

\*\*\*The definition of code G0177 is as follows:

Training and educational services related to the care and treatment of patient's disabling mental health problems, per session (45 minutes or more).

Codes G0129 and G0176 are used only for partial hospitalization programs.

Code G0177 may be used in both partial hospitalization program and outpatient mental health settings.

Revenue code 250 does not require HCPCS coding. However, Medicare does not cover drugs that can be self-administered.

Edit to assure that HCPCS are present when the above revenue codes are billed and that they are valid HCPCS codes. Do not edit for the matching of revenue code to HCPCS.

**B. Professional Services**

The professional services listed below when provided in all hospital outpatient departments are separately covered and paid as the professional services of physicians and other practitioners. These professional services are unbundled and these practitioners (other than physician assistants (PA) bill the Medicare Part B carrier directly for the professional services furnished to hospital outpatient partial hospitalization patients. The hospital can also serve as a billing agent for these professionals by billing the Part B carrier on their behalf under their billing number for their professional services. The professional services of a PA can be billed to the carrier only by the PAs employer. The following direct professional services are unbundled and not paid as partial hospitalization services.

- Physician services that meet the criteria of 42 CFR 415.102, for payment on a fee schedule basis;
- Physician assistant (PA) services as defined in §1861(s)(2)(K)(i) of the Act;
- Nurse practitioner and clinical nurse specialist services, as defined in §1861(s)(2)(K)(ii) of the Act; and
- Clinical psychologist services as defined in §1861(ii) of the Act.

The services of other practitioners (including clinical social workers and occupational therapists), are bundled when furnished to hospital patients, including partial hospitalization patients. The hospital must bill you for such nonphysician practitioner services as partial hospitalization services. Make payment for the services to the hospital.

PA services can only be billed by the actual employer of the PA. The employer of a PA may be such entities or individuals such as a physician, medical group, professional corporation, hospital, SNF, or nursing facility. For example, if a physician is the employer of the PA and the PA renders services in the hospital, the physician and not the hospital would be responsible for billing the carrier on Form CMS-1500 for the services of the PA.

### **C. Outpatient Mental Health Treatment Limitation**

The outpatient mental health treatment limitation may apply to services to treat mental, psychoneurotic, and personality disorders when furnished by physicians, clinical psychologists, NPs, CNSs, and PAs to partial hospitalization patients. However, the outpatient mental health treatment limitation does not apply to such mental health treatment services billed to the intermediary by a CMHC or hospital outpatient department as partial hospitalization services.

### **D. Reporting of Service Units**

Hospitals report number of times the service or procedure, as defined by the HCPCS code, was performed. CAHs report the number of times the revenue code visit was performed.

**NOTE:** Service units are not required to be reported for drugs and biologicals (Revenue Code 250).

**E. Line Item Date of Service Reporting**

Hospitals other than CAHs are required to report line item dates of service per revenue code line for partial hospitalization claims. This means each service (revenue code) provided must be repeated on a separate line item along with the specific date the service was provided for every occurrence. Line item dates of service are reported in FL 45 "Service Date" (MMDDYY). See §260.5 for a detailed explanation.

**F. Payment**

Beginning with services provided on or after August 1, 2000, for hospital outpatient departments, make payment under the hospital outpatient prospective payment system for partial hospitalization services. *Effective January 1, 2009, there are two separate APC payment rates for PHP: one for days with three services and one for days with four or more services.*

<i>APC</i>	<i>Group Title</i>
<i>0172</i>	<i>Level I Partial Hospitalization (3 services)</i>
<i>0173</i>	<i>Level II Partial Hospitalization (4 or more services)</i>

Apply Part B deductible, if any, and coinsurance.

**G. Data for CWF and PS&R**

Include revenue codes, HCPCS/CPT codes, units, and covered charges in the financial data section (fields 65a - 65j), as appropriate. Report the billed charges in field 65h, "Charges," of the CWF record.

Include in the financial data portion of the PS&R UNIBILL, revenue codes, HCPCS/CPT codes, units, and charges, as appropriate.

*Future updates will be issued in a Recurring Update Notification.*

## **260.1.1 - Bill Review for Partial Hospitalization Services Provided in Community Mental Health Centers (CMHC)**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

### **A. General**

Medicare Part B coverage for partial hospitalization services provided by CMHCs is available effective for services provided on or after October 1, 1991.

### **B. Special Requirements**

Section 1866(e)(2) of the Act recognizes CMHCs as “providers of services” but only for furnishing partial hospitalization services. Applicable provider ranges are 1400-1499, 4600-4799, and 4900-4999.

### **C. Billing Requirements**

The CMHCs bill for partial hospitalization services on Form CMS-1450 or electronic equivalent under bill type 76X. The FIs follow bill review instructions in Chapter 25 except for those listed below.

The acceptable revenue codes are as follows:

<b>Code</b>	<b>Description</b>
0250	Drugs and Biologicals
043X	Occupational Therapy
0900	Behavioral Health Treatments/Services
0904	Activity Therapy
0910	Psychiatric/Psychological Services (Dates of Service prior to October 16, 2003)
0914	Individual Therapy
0915	Group Therapy
0916	Family Therapy
0918	Testing
0942	Education Training

The CMHCs are also required to report appropriate HCPCS codes as follows:

<b>Revenue Codes</b>	<b>Description</b>	<b>HCPCS Code</b>
043X	Occupational Therapy (Partial Hospitalization)	*G0129
0900	Behavioral Health Treatments/Services	90801 <i>or</i> 90802
0904	Activity Therapy (Partial Hospitalization)	**G0176
0910	Psychiatric General Services (Dates of Service prior to October 16, 2003)	90801, 90802, 90899
0914	Individual Psychotherapy	90816, 90817, 90818, 90819, 90821, 90822, 90823, 90824, 90826, 90827, 90828, 90829, <i>90845, 90865, or</i> <i>90880</i>
0915	Group Psychotherapy	<i>G0410 or G0411</i>
0916	Family Psychotherapy	90846 <i>or</i> 90847
0918	Psychiatric Testing	<i>96101, 96102, 96103, 96116, 96118,</i> <i>96119, or 96120</i>
0942	Education Training	***G0177

The FIs edit to assure that HCPCS are present when the above revenue codes are billed and that they are valid HCPCS codes. They do not edit for the matching of revenue codes to HCPCS.

\*The definition of code G0129 is as follows:

Occupational therapy services requiring the skills of a qualified occupational therapist, furnished as a component of a partial hospitalization treatment program, per session (45 minutes or more).

\*\*The definition of code G0176 is as follows:

Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient's disabling mental health problems, per session (45 minutes or more).

\*\*\*The definition of code G0177 is as follows:

Training and educational services related to the care and treatment of patient's disabling mental health problems, per session (45 minutes or more).

Codes G0129 and G0176 are used only for partial hospitalization programs.

Code G0177 may be used in both partial hospitalization program and outpatient mental health settings.

Revenue code 0250 does not require HCPCS coding. However, drugs that can be self-administered are not covered by Medicare.

HCPCS includes CPT-4 codes. CMHCs report HCPCS codes in FL44, "HCPCS/Rates." HCPCS code reporting is effective for claims with dates of service on or after April 1, 2000.

The FIs are to advise their CMHCs of these requirements. CMHCs should complete the remaining items on Form CMS-1450 in accordance with the bill completion instructions in Chapter 25.

The professional services listed below are separately covered and are paid as the professional services of physicians and other practitioners. These professional services are unbundled and these practitioners (other than physician assistants (PAs)) bill the Medicare Part B carrier directly for the professional services furnished to CMHC partial hospitalization patients. The CMHC can also serve as a billing agent for these professionals by billing the Part B carrier on their behalf for their professional services. The professional services of a PA can be billed to the carrier only by the PAs employer.

The following professional services are unbundled and not paid as partial hospitalization services:

- Physician services that meet the criteria of 42 CFR 415.102, for payment on a fee schedule basis;
- PA services, as defined in §1861(s)(2)(K)(i) of the Act;
- Nurse practitioner and clinical nurse specialist services, as defined in §1861(s)(2)(K)(ii) of the Act; and,
- Clinical psychologist services, as defined in §1861(ii) of the Act.

The services of other practitioners (including clinical social workers and occupational therapists) are bundled when furnished to CMHC patients. The CMHC must bill the FI

for such nonphysician practitioner services as partial hospitalization services. The FI makes payment for the services to the CMHC.

The PA services can be billed only by the actual employer of the PA. The employer of a PA may be such entities or individuals as a physician, medical group, professional corporation, hospital, SNF, or nursing facility. For example, if a physician is the employer of the PA and the PA renders services in the CMHC, the physician and not the CMHC would be responsible for billing the carrier on Form CMS-1500 for the services of the PA.

#### **D. Outpatient Mental Health Treatment Limitation**

The outpatient mental health treatment limitation **may apply** to services to treat mental, psychoneurotic, and personality disorders when furnished by physicians, clinical psychologists, NPs, CNSs, and PAs to partial hospitalization patients. However, the outpatient mental health treatment limitation **does not** apply to such mental health treatment services billed to the FI as partial hospitalization services.

#### **E. Reporting of Service Units**

Visits should no longer be reported as units. Instead, CMHCs report in the field, "Service Units," the number of times the service or procedure, as defined by the HCPCS code, was performed when billing for partial hospitalization services identified by revenue code in subsection C.

**EXAMPLE:** A beneficiary received psychological testing (HCPCS code 96100, which is defined in 1 hour intervals) for a total of 3 hours during one day. The CMHC reports revenue code 0918, HCPCS code 96100, and "3".

When reporting service units for HCPCS codes where the definition of the procedure does not include any reference to time (either minutes, hours or days), CMHCs should not bill for sessions of less than 45 minutes.

The CMHC need not report service units for drugs and biologicals (Revenue Code 0250)

**NOTE:** Information regarding the claim form locators that correspond with these fields and a table to crosswalk the CMS-1450 form locators to the 837 transaction is found in Chapter 25.

#### **F. Line Item Date of Service Reporting**

Dates of service per revenue code line for partial hospitalization claims that span two or more dates. This means each service (revenue code) provided must be repeated on a separate line item along with the specific date the service was provided for every occurrence. Line item dates of service are reported in "Service Date". See examples

below of reporting line item dates of service. These examples are for group therapy services provided twice during a billing period.

For *claims*, report as follows:

Revenue Code	HCPCS	Dates of Service	Units	Total Charges
0915	<i>G0176</i>	<i>20090505</i>	1	\$80
0915	<i>G0176</i>	<i>20090529</i>	2	\$160

**NOTE:** Information regarding the claim form locators that correspond with these fields and a table to crosswalk the CMS-1450 form locators to the 837 transaction is found in Chapter 25.

The FIs return to provider claims that span two or more dates if a line item date of service is not entered for each HCPCS code reported or if the line item dates of service reported are outside of the statement covers period. Line item date of service reporting is effective for claims with dates of service on or after June 05, 2000.

### G. Payment

Section 1833(a)(2)(B) of the Act provides the statutory authority governing payment for partial hospitalization services provided by a CMHC. FIs made payment on a reasonable cost basis until OPSS was implemented. The Part B deductible and coinsurance applied.

Payment principles applicable to partial hospitalization services furnished in CMHCs are contained in §2400 of the Medicare Provider Reimbursement Manual.

The FIs make payment on a per diem basis under the hospital outpatient prospective payment system for partial hospitalization services. CMHCs must continue to maintain documentation to support medical necessity of each service provided, including the beginning and ending time.

*Effective January 1, 2009, there are two separate APC payment rates for PHP: one for days with three services and one for days with four or more services.*

<i>APC</i>	<i>Group Title</i>
<i>0172</i>	<i>Level I Partial Hospitalization (3 services)</i>
<i>0173</i>	<i>Level II Partial Hospitalization (4 or more services)</i>

**NOTE:** Occupational therapy services provided to partial hospitalization patients are not subject to the prospective payment system for outpatient rehabilitation services, and therefore the financial limitation required under §4541 of the Balanced Budget Act (BBA) does not apply.

## **H. Medical Review**

The FIs follow medical review guidelines in the Medicare Program Integrity Manual.

## **I. Coordination With CWF**

See Chapter 27. All edits for bill type 74X apply, except provider number ranges 4600-4799 are acceptable only for services provided on or after October 1, 1991.

### **260.4 - Reporting Service Units for Partial Hospitalization**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Hospitals report number of times the service or procedure, as defined by the HCPCS code, was performed. CAHs report the number of times the revenue code visit was performed.

**EXAMPLE:** A beneficiary received psychological testing (HCPCS code 96100 which is defined in one-hour intervals) for a total of three hours during one day. The hospital reports revenue code 0918 in FL 42, HCPCS code 96100 in FL 44, and three units in FL 46. The CAH would report revenue code 0918, leave HCPCS blanks, and report 1 unit in FL 46.

When reporting service units for HCPCS codes where the definition of the procedure does not include any reference to time (either in minutes, hours, or days), hospital outpatient departments do not bill for sessions of less than 45 minutes.

The FI must return to the provider claims other than CAH claims that do not contain service units for each HCPCS code.

**NOTE:** Service units do not need to be reported for drugs and biologicals (Revenue Code 0250).

Hospitals must retain documentation to support the medical necessity of each service provided, including beginning and ending time.

### **260.5 - Line Item Date of Service Reporting for Partial Hospitalization**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Hospitals other than CAHs are required to report line item dates of service per revenue code line for partial hospitalization claims. Where services are provided on more than one day included in the billing period, the date of service must be identified. Each service (revenue code) provided must be repeated on a separate line item along with the specific date the service was provided for every occurrence. See examples below of reporting line item dates of service. These examples are for group therapy services provided twice during a billing period.

For the *claims*, report as follows:

Revenue Code	HCPCS	Dates of Service	Units	Total Charges
0915	<i>G0176</i>	<i>20090505</i>	1	\$80.00
0915	<i>G0176</i>	<i>20090529</i>	2	\$160.00

**NOTE:** Information regarding the claim form locators that correspond with these fields and a table to crosswalk the CMS-1450 form locators to the 837 transaction is found in Chapter 25.

The FI must return to the hospital (RTP) claims where a line item date of service is not entered for each HCPCS code reported, or if the line item dates of service reported are outside of the statement covers period. Line item date of service reporting is effective for claims with dates of service on or after June 5, 2000.

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

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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 direct admission 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 admission to 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. A beneficiary's time in observation (and hospital billing) begins with the beneficiary's admission to an observation bed.
- c. A beneficiary's time in observation (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 admission to observation 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 admission, 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 observation services will be packaged or will meet the criteria for extended assessment and management composite payment.

Only 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 admission to 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 Change Request 4047, Transmittal 763, issued on November 25, 2005.

If a claim for services providing 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.

# Medicare Claims Processing Manual

## Chapter 17 - Drugs and Biologicals

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### 90.2 - Drugs, Biologicals, and Radiopharmaceuticals

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

#### **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 OPSS 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 OPSS, 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 OPSS 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. Correct Reporting of Biologicals When Used As Implantable Devices**

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

### **C. 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](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 Web site at: <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>.

### **D. 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.

## **E. Radiopharmaceuticals**

### **1. General**

Beginning in CY 2008, the OPSS 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 OPSS 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 OPSS will continue to pay for therapeutic radiopharmaceuticals at charges adjusted to cost *f*rom January 1, 2008 through December 31, 2009.

# Medicare Claims Processing Manual

## Chapter 32 – Billing Requirements for Special Services

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### 67.1 – Practitioner Billing for No Cost Items

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Practitioners *typically* should not bill for no cost items as there is no *non-covered* charges field on the claim and there are also no system edits in place to require providers to do so. *However, practitioners are required to report Category A IDE devices received at no cost on claims as specified in §68.3 of this chapter (although they will not receive payment).*

### 67.2 – Institutional Billing for No Cost Items

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

*Generally speaking, institutional, providers should not have to report the usage of a no cost item. However, for some claims (e.g., hospital Outpatient Prospective Payment System (OPPS) claims), providers may be required to bill a no cost item due to claims processing edits that require an item (even if received at no cost) to be billed along with an associated service (e.g., a specified device must be reported along with a specified implantation procedure).*

*For OPPS claims, providers must report a token charge of less than \$1.01 for the item in the covered charge field, along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service requiring a device. For more information on billing no cost items under the OPPS, refer to Chapter 4, §20.6.9 and 61.3.1 of this manual.*

By *billing in this way*, the provider is accomplishing four things:

- 1) Communicating to the contractor that the provider is not seeking *payment* for the no cost item;
- 2) Reflecting, with completeness and accuracy, all services provided to the patient;
- 3) Preventing the line item or claim from being rejected/denied by system edits that require an item to be billed in conjunction with an associated procedure (such as *implantation* or administration *procedures*);

- 4) Assuring that the patient and provider are not held liable for any charges for the no cost item.

*Future updates will be issued in a Recurring Update Notification.*

## **67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

*Currently, institutional providers that use the Healthcare Common Procedural Coding System (HCPCS) bill device HCPCS codes for no cost or full credit items with token charges in order for claims to pass OPSS claims processing edits that require certain devices to be billed with their associated procedures so that payment can be made. Effective January 1, 2006, modifier –FB is used to indicate that an item used in a procedure was furnished without cost to the provider, and, therefore, it is not being charged to Medicare or the beneficiary. More information on billing HCPCS modifier –FB can be located in Chapter 4, §20.6.9 and 61.3.1 of this manual.*

*Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes are used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due to warranty for a malfunction or recall.*

<b>Table 1: New Condition Codes and Descriptions</b>		
<b>Condition Code</b>	<b>Description</b>	
<b>49</b>	Product Replacement within Product Lifecycle	A medical device is replaced before "end-of-life" because there is an indication that the device is not functioning properly. (This is a warranty situation.)
<b>50</b>	Product Replacement for Known Recall of a Product	A medical device is replaced because of a manufacturer or FDA recall.

- Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty or recall. These condition codes will be used to track no cost/full credit devices replaced due to recall or warranty.*
- Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty or recall are met.*

**NOTE:** *OPPS hospitals billing no cost/full credit devices must append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 1 above), in instances when claims processing edits require that certain devices be billed with their associated procedures. The modifier identifies the procedure code line for the no cost/full credit device, while the condition code explains if the device was provided free of cost due to warranty or recall.*

## 68.1 – General

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

CMS determines Medicare device coverage based on which category the FDA assigns the device. Devices are either designated as a Category A IDE or a Category B IDE.

**NOTE:** For purposes of these instructions, IDEs will be referred to as “studies” instead of “trials” to help distinguish clinical trial instructions from IDE study instructions.

### Category A Devices

Category A *IDE* devices are considered experimental *and*, therefore, *are* not eligible for payment. *Institutional providers should not bill for Category A IDE devices, while practitioners are required to report the Category A IDE number on the claim as specified in §68.3 of this chapter (although they will not receive payment). Practitioners must report the Category A IDE number on the claim because the contractor must validate that the IDE number is part of a current clinical trial by reviewing a monthly file provided by CMS.*

*Effective January 1, 2005, routine costs (as described in [The National Coverage Determinations Manual, section 310.1](#)) of clinical trials involving a Category A IDE devices are covered when the Medicare contractors determine that the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. *Both institutional providers and practitioners are required to bill for the routine costs of clinical trials involving Category A devices as specified in §68.3 of this chapter.**

### Category B Devices

Unlike Category A devices, Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved. Category B devices may be covered under Medicare as long as it meets the billing requirements listed in *section 68.2* below. If the device is billed under a Category B IDE study, and it meets the billing requirements for IDEs, the device itself and the routine costs associated with its use are eligible for payment (*Payment* for the device may not

exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

More information regarding these two categories of IDEs can be located in [The Benefit Policy Manual, Chapter 14](#).

*Future updates will be issued in a Recurring Update Notification.*

## **68.2 – Notifying Contractors of an IDE Device Trial**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

**Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare contractor. The following information must be furnished prior to submission of a claim for payment:**

- A copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number must be on the letter;
- The name of the device (both trade, common or usual, and classification name);
- Any action taken to conform to any applicable IDE special controls;
- A narrative description of the device sufficient to make a payment determination;
- A statement indicating how the device is similar to and/or different from other comparable products;
- Indication of whether the device will be billed on an inpatient or outpatient claim;
- A brief summary of the study design or a copy of the actual trial protocol;
- The provider's protocol for obtaining informed consents for beneficiaries participating in the clinical trial.

**NOTE:** Potential Medicare coverage of Category B IDE devices is predicated, in part, on the device's status with the FDA. If a sponsor loses its Category B status for the device or violates relevant IDE requirements necessitating the FDA's withdrawal *of* approval, all payment will cease. Providers must notify their contractor within 30 days of any change in status for an IDE. By billing for an IDE, whether it is for a Category B *IDE* device or for the routine costs of clinical trials involving a Category A *IDE* device, the provider attests that the device was approved at the time the services were rendered.

## **68.3 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of *the Category A IDE device trial*, as listed in section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A *IDE* device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the contractor determines that the device does, in fact, meet the requirements of coverage, then the provider may begin billing the routine costs of a clinical trial involving a Category A *IDE* device.

### **Institutional *Inpatient* Billing**

#### *Routine Costs*

*Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.*

### ***Institutional Outpatient Billing***

#### *Routine Costs*

*Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.*

### **Practitioner Billing**

#### *Routine Costs*

*Practitioners shall submit claims for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.*

#### *Category A Device*

*Effective for dates of service on or before December 31, 2007, practitioners must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device along with the IDE number.*

Effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter o) modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category A IDE number on practitioner claims:

<b>Data</b>	<b>CMS-1500</b>	<b>837i and 837p</b>
IDE #	<u>Item 23</u>	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category A device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. Remark code MA50 is used

(Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication).

## **68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE**

***(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)***

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDE *devices and the routine costs of clinical trials involving Category B IDE devices*. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may *bill* Category B IDE *claims*.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE *device* and the routine costs associated with its use are eligible for payment under Medicare. (*payment* for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

### **Institutional *Inpatient* Billing**

#### *Routine Costs*

*Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter*

### *Category B Device*

Institutional providers must bill the Category B IDE *number* on a 0624 revenue code line with charges in the covered charges field. *Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free of charge.*

### ***Institutional Outpatient Billing***

#### *Routine Costs*

*Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.*

#### *Category B Device*

*On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:*

- *Category B IDE device HCPCS code, if applicable.*
- *The appropriate HCPCS modifier:*
  - *Q0 (numeral 0 versus the letter o) modifier for claims with dates of service on or after January 1, 2008; or*
  - *QA modifier for claims with dates of service prior to January 1, 2008.*
- *The Category B IDE number.*
- *Charges for the device billed as covered charges.*

**NOTE:** *If the Category B IDE device is provided at no cost, OPSS providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPSS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.*

### **Practitioner Billing**

#### *Routine Costs*

*Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.*

#### *Category B Device*

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE *device* on a line with a QA modifier (FDA IDE) along with the IDE

number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (*numeral 0 versus the letter o*) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

*The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:*

<b>Data</b>	<b>CMS-1450</b>	<b>CMS-1500</b>	<b>837i and 837p</b>
<b>IDE #</b>	<u><b>FL 43</b></u>	<u><b>Item 23</b></u>	<b>Segment 2300, REF02(REF01=LX)</b>

Contractors will validate the IDE number for *the* Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. (Remark code MA50 is used (Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication)).

## **69.5 - Billing Requirements – General**

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

Instruct *practitioners and institutional providers* to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free of charge by research sponsors *generally* may not be billed to be paid by Medicare, and providers are not required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free of charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as non-covered at the time of entry, while also assuring that the beneficiary is not held liable. This instruction applies to all hospitals including hospitals located in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC).

*For OPPS claims, providers must report a token charge for a no cost item in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service provided to furnish the no cost item, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.*

*Future updates will be issued in a Recurring Update Notification.*

## 69.6 - Requirements *for Billing Routine Costs of Clinical Trials*

*(Rev.1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

### *Routine Costs Submitted by Practitioners*

Claims with dates of service before January 1, 2008:

- HCPCS modifier ‘QV’
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier ‘Q1’ *(numeral 1 instead of the letter i); and*
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis.

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to change request (CR) 5790 for more information regarding the 8-digit number. Below are the claim locators that providers should use to bill the 8-digit number:

- CMS-1500 paper form-place in Field 19 (preceded by ‘CT’); and
- 837 P—Loop 2300, REF02, REF01-P4 (do not use ‘CT’ on the electronic claim).

### Routine Costs Submitted by Institutional Providers

#### *All Institutional Clinical Trial Claims*

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to CR 5790 for more information regarding the 8-digit number. To bill the 8-digit clinical trial number, institutional providers shall code value code ‘D4’---where the value code amount equals the 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- CMS-1450—Form Locator 39-41
- 837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)

**NOTE:** The QV/Q1 modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary’s participation in a Medicare-covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV/Q1 modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV/Q1 modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/Q1 modifier will serve as the provider’s attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

### Inpatient Clinical Trial Claims

*Institutional provider billing clinical trial service(s) must report a diagnosis code V70.7 and a condition code 30 regardless of whether all services are related to the clinical trial or not.*

**NOTE:** *HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.*

### Outpatient Clinical Trial Claims

*A) All services on the claim related to the trial - Institutional providers billing clinical trial claims that contain only clinical trial line item services do not have to report the routine modifiers, QV or Q1. The presence of condition code 30, along with the absence of the QV or Q1 modifier, is the provider’s attestation that all line item services on the claim are routine clinical trial services (with the exception of any investigational item on the claim that would be identified with a Q0 modifier on or after January 1, 2008, or a QA modifier before January 1, 2008.*

*B) Claim contains both services related and unrelated to the trial - Institutional providers billing clinical trial claims that contain both clinical trial line item services and non-clinical trial line item services, must bill the following elements:*

*Claims with dates of service before January 1, 2008:*

- *HCPCS modifier ‘QV’ only on line items related to the clinical trial;*
- *Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis; and*

- *Condition Code 30.*

*Claims with dates of service on or after January 1, 2008:*

- *HCPCS modifier 'Q1' only on line items related to the clinical trial; and*
- *Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis Condition Code 30.*