



WISCONSIN HOSPITAL
ASSOCIATION

**SUMMARY OF THE PROPOSED
CALENDAR YEAR 2010
MEDICARE HOSPITAL
OUTPATIENT RULE**

July 2009

SUBMISSION OF COMMENTS

This document provides an overview of the Medicare proposed rule for the Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2010. The Centers for Medicare and Medicaid Services (CMS) must receive comments on the proposal by 5 p.m. on August 31. CMS requests that comments reference the file code CMS-1414-P. Comments can be submitted electronically at: <http://www.cms.hhs.gov/eRulemaking/> (attachments should be in Microsoft® Word, WordPerfect, or Excel format)

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I. OVERVIEW

CMS published the proposed Medicare OPPS rule for CY 2010 in the July 20 *Federal Register*. Changes are effective January 1, 2010 unless otherwise noted. Additional information regarding the OPPS is available on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

Note: Text in italics is extracted from the July 20 *Federal Register*.

The Proposed Rule Includes:

- **Marketbasket Factor:** CMS is proposing a full marketbasket update of 2.1 percentage points for CY 2010. Hospitals that are non-compliant with reporting outpatient quality measures will receive the full marketbasket update minus 2.0 percentage points. CMS is proposing to increase the conversion factor from \$66.059 in CY 2009 to \$67.439 in CY 2010.
- **Outliers:** CMS is proposing to increase the outlier fixed-dollar threshold from \$1,800 in CY 2009 to \$2,225 in CY 2010. Outlier payments would be provided when the procedure cost exceeds both 1.75 times the APC payment amount and the APC payment rate plus the fixed-dollar threshold.
- **Hold-Harmless Transitional Payments:** Existing hold-harmless transitional outpatient payments (TOPs) paid to rural hospitals and Sole Community Hospitals (SCHs) with 100 or fewer beds will expire on December 31, 2009. CMS does not have the authority to extend these payments beyond CY 2009 without legislation. However, the U.S House of Representatives tri-committee health care reform discussion draft legislation includes a provision that would extend hold-harmless TOPs through January 1, 2012.
- **Section 508 Reclassifications:** Existing Section 508 wage index reclassifications will sunset on September 30, 2009. CMS does not have the authority to extend Section 508 reclassifications without legislation. However, the U.S House of Representatives tri-committee health care reform discussion draft legislation includes a provision that would extend Section 508 reclassifications through December 31, 2011.
- **Quality Measures:** CMS proposes no changes to the current 11 outpatient quality measures that hospitals must report on for CY 2010. These measures include seven chart-abstracted emergency department and perioperative measures, and four existing claims-based imaging efficiency measures. Hospitals that failed to report the 11 measures in CY 2009 would receive a reduction of 2.0 percentage points to the full marketbasket update in CY 2010. CMS intends to publicly report OPPS measures sometime in 2010.
- **Validation of Quality Reporting:** CMS is proposing a quality reporting validation process for CY 2011. Hospitals would be required to participate in the validation process to receive their full annual payment update; however, the results of the data validation would not affect payment updates.
- **Health Care-Associated Conditions:** CMS is not proposing any health care-associated conditions for CY 2010 under the OPPS due to several operational challenges. CMS is seeking additional suggestions on alternatives for modifying OPPS payments for treating conditions that are generally preventable as health care delivery continues to evolve.
- **Composite Ambulatory Payment Classification (APC) Groups:** CMS proposes no changes to the current ten composite APCs for CY 2010. However, per the recommendation of the APC Panel, CMS will evaluate the implications of creating new composite APCs for cardiac resynchronization therapy with a defibrillator or pacemaker along with other potential composite APCs for future discussion.
- **APCs:** CMS is proposing to expand the list of procedures that would be payable under the OPPS to include pulmonary and intensive cardiac rehabilitation services.
- **Ambulatory Surgical Centers (ASCs):** CMS is proposing a number of provisions regarding ASCs including implementation of the third-year of a four-year phase-in to align ASC and OPPS payments. CMS is also proposing to expand the list of procedures that are payable under Medicare when performed in an ASC.

II. LEGISLATIVE MANDATES

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003; the Deficit Reduction Act of 2005 (DRA); the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006 (MIEA-TRHCA); the Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007 (MMSEA); and the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 each contain Medicare provisions that either currently affect or will begin to affect outpatient payment policy in upcoming calendar years. Where appropriate, legislative references are provided in the text below.

III. APC CLASSIFICATION PAYMENTS

CONVERSION FACTOR

Federal Register page 35291

Background: Outpatient payment rates are determined by multiplying the relative weight for an APC by the conversion factor. The CY 2009 conversion factor is \$66.059.

CMS' Proposal: *"The proposed marketbasket increase update factor of 2.1 percent for CY 2010 and the adjustment of 0.01 percent of projected OPSS spending for the difference in the pass-through spending set aside resulted in a full proposed marketbasket conversion factor for CY 2010 of \$67.439."*

For hospitals that did not meet the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) requirements for CY 2009, CMS will apply a reduction of 2.0 percentage points to the CY 2010 marketbasket update.

WAGE INDEX ADJUSTMENT

Federal Register pages 35291 - 35292

Background: To account for geographic differences, the labor portion of the conversion factor (60%) is adjusted by the hospital wage index. Currently, CMS applies the wage indexes used for the Inpatient Prospective Payment System (IPPS) to the OPSS conversion factor. These wage indexes also apply to Tax Equity Fiscal Responsibility Act of 1982 hospitals that participate in OPSS, but not in the IPPS.

CMS' Proposal: For CY 2010, CMS is *"... proposing to use the final FFY 2010 version of the IPPS wage indices used to pay IPPS hospitals to adjust the CY 2010 OPSS payment rates and copayment amounts for geographic differences in labor cost for all providers that participate in the OPSS, including providers that are not paid under the IPPS"*

In addition, existing Section 508 reclassifications are set to expire on September 30, 2009. CMS does not have the authority to extend Section 508 reclassifications without legislation. However, the U.S House of Representatives tri-committee health care reform discussion draft legislation includes a provision that would extend Section 508 reclassifications through December 31, 2011.

RURAL SOLE COMMUNITY HOSPITAL ADJUSTMENT

Federal Register page 35295

CMS' Proposal: For CY 2010, CMS is *"... proposing to continue our policy of a budget-neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs."*

TRANSITIONAL CORRIDOR PAYMENTS

Federal Register pages 35294 - 35295

Background: When the OPSS was implemented, transitional corridor payments were established to provide relief to hospitals that would receive less in payments under the OPSS methodology than they would have received under the prior payment system. Rural hospitals with 100 or fewer beds, cancer hospitals, and children's hospitals were held harmless and paid the full amount of the difference between the OPSS and the prior payment system. Other hospitals were eligible for partial relief.

For most hospitals, the transitional corridor payments were set to expire on December 31, 2003. The MMA extended transitional corridor payments through December 31, 2005 for rural hospitals with 100 or fewer beds and provided transitional corridor payments during the same period for SCHs located in rural areas. CMS does not have the authority to extend this provision without legislation. However, over the years legislation has provided relief by extending transitional corridor payments to rural hospitals and SCHs with 100 or fewer beds. Most recently, MIPPA extended the transitional payments for rural hospitals and SCHs with 100 or fewer beds through December 31, 2009. Cancer hospitals and children's hospitals are permanently held harmless from the impact of the OPSS.

CMS' Proposal: *"Effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds will no longer be eligible for hold harmless TOPs"*

However, the U.S House of Representatives tri-committee health care reform discussion draft legislation includes a provision that would extend hold-harmless TOPs through January 1, 2012.

COST OUTLIERS

Federal Register pages 35295 - 35297

Background: OPSS outlier payments are provided for individual services or procedures with extraordinarily high costs compared to the payment rates for their APC group. The outlier threshold is met when the cost of a service or procedure exceeds both 1.75 times the APC payment amount and the APC payment rate plus a fixed-dollar threshold. This dual test is intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures. Currently, the projected target for aggregate outlier payments is set at 1.0% of aggregate total OPSS payments.

CMS pays 50% of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met. For CY 2009, the outlier fixed-dollar threshold is \$1,800.

CMS' Proposal: For CY 2010, CMS is *" . . . proposing that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$2,225 fixed dollar threshold."*

CMS' proposal increases the outlier fixed-dollar threshold from \$1,800 in CY 2009 to \$2,225 in CY 2010. Thresholds are set each year to target 1.0% of estimated total payments under the OPSS for outlier payments. CMS finds that 1.2% of total payments under OPSS were actually made for outliers in CY 2008. Currently, CMS estimates that outlier payments will represent 1.08% of total CY 2009 payments. CMS uses the CY 2009 estimate to justify the higher threshold in CY 2010, arguing that the projected overpayment in CY 2009 requires an increase in the CY 2010 threshold to avoid additional overpayments in CY 2010.

CALCULATION OF COST-TO-CHARGE RATIOS (CCRs)

Federal Register pages 35252 - 35262

Background: Since the inception of the OPSS, there has been concern about the OPSS cost-based weights, “charge compression,” and the distortion that could be caused by the lower charge markup that could be applied to higher-cost services. In August 2006, CMS contracted with RTI International to study charge compression, but limited the study to the IPPS relative weights. Subsequently, in August 2007, CMS contracted with RTI to evaluate the OPSS relative weights. The July 2009 RTI final report, *Refining Cost to Charge Ratios for Calculating APC and DRG Relative Payment Weights*, is available on the RTI Web site at <http://www.rti.org>. In this report, RTI made eight recommendations specific to non-IPPS that include short-term and long-term accounting changes to the cost report.

In the Inpatient PPS final rule for federal fiscal year (FFY) 2009, CMS added a cost center for Medical Supplies Charged to Patients” and one for “Implantable Devices Charged to Patients” to separate relatively inexpensive costs and charges for medical supplies from expensive implantable devices. CMS proposed in the CY 2009 OPSS rule, but did not adopt, a similar proposal for drugs by splitting the “Drugs Charged to Patients” cost center into two cost centers to separate the high pharmacy overhead costs from the low pharmacy overhead costs. However, CMS stated that it would continue to explore other potential approaches to improve the drug cost estimation methodology.

CMS’ Proposal: For CY 2010, CMS is “. . . proposing to continue using the hospital-specific overall ancillary and departmental CCRs to convert charges on the claims reported under specific revenue codes to estimated costs through application of a revenue code-to-cost center crosswalk.”

In addition, CMS is “. . . proposing an adjustment to our cost estimation methodology for drugs and biologicals in CY 2010 to address charge compression by proposing to shift a portion of the pharmacy overhead cost associated with packaged drugs and biologicals from those packaged drugs and biologicals to separately payable drugs and biologicals; proposing payment for separately payable drugs and biologicals at ASP+4 percent; and proposing a proportional reduction in the total amount of pharmacy overhead cost associated with packaged drugs and biologicals prior to our estimating the total resource costs of individual OPSS services.”

RECALIBRATION OF APC WEIGHTS

Federal Register page 35239

Background: CMS is required to review and revise the APC relative payment weights at least annually. The APC relative weights are based on the median hospital costs for services in the APC groups.

CMS’ Proposal: For CY 2010, CMS is proposing to use “. . . claims from CY 2008 that were processed before January 1, 2009, and continue to be based on the median hospital costs for services in the APC groups.”

IV. APC GROUP CHANGES

Federal Register pages 35299 - 35305

As required by law, the proposed rule revises the APC groups to take into account drugs and devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, changes in technologies, new services, and new cost data. In addition, the proposed rule includes input from the Advisory Panel on APC Groups (APC Panel)—an outside panel of experts established by the Balanced Budget Act of 1997.

A complete discussion of APC group changes can be found on the *Federal Register* pages referenced above. This summary shows the APCs per category for services other than pass-through drugs and biologicals.

APC Category	Status Indicator	2008	2009	2010
Clinic or Emergency Department Visit	V	12	16	17
Significant Procedures, Multiple Reduction Applies	T	188	183	181
Significant Procedures, No Multiple Reduction	S	128	130	130
Ancillary Services	X	39	40	39
Pass-Through Devices Categories	H	2	8	0
Non-Pass-Through Drugs/Biologicals	K	324	275	282
Partial Hospitalization	P	2	2	2
Observation	Q	0	0	0
Blood and Blood Products	R	Included in K	25	25
Brachytherapy Sources	U	Included in K	16	16
New Technology	S/T	Included in K	82	82
Total		695	777	774

CMS' Proposal: For CY 2010, CMS is “. . . proposing to reassign this electronic brachytherapy service from APC 1519 (New Technology - Level IXX (\$1700-\$1800)) to APC 0313 (Brachytherapy) . . .” The status indicator will remain “S” for CY 2010.

CMS seeks input on the proposed status indicators and the proposed APC assignments and payment rates, if applicable, for the 14 Level II HCPCS codes and the five Category I vaccine and Category III CPT codes that are new or have changed OPSS status indicator in April or July 2009 through the OPSS quarterly updates. The proposed codes and APCs can be found in Tables 14, 15, and 16 of the *Federal Register* on page 35301.

STATUS INDICATORS

Federal Register pages 35371 - 35375

Background: CMS assigns status indicators to HCPCS codes to indicate whether a service is payable under the OPSS or another payment system. In addition, status indicators signal the particular OPSS policies that apply to the code.

CMS was required under MIPPA to pay for therapeutic radiopharmaceuticals beginning July 1, 2008 through December 31, 2009, at hospitals' charges adjusted to costs and these were assigned a status indicator of “H.”

CMS' Proposal: For CY 2010, CMS is “. . . only proposing to change the definitions of status indicators ‘H’ and ‘K.’”

CMS is “. . . proposing to pay prospectively and separately for therapeutic radiopharmaceuticals with average per day costs greater than the proposed CY 2010 drug packaging threshold of \$65 under the OPSS. Therefore, we are proposing to change the status indicator for HCPCS codes used to report separately payable therapeutic radiopharmaceuticals from ‘H’ to ‘K,’ which indicates that an item is separately paid under the OPSS at the APC payment rate established for the item.”

In addition, CMS is “. . . proposing to consider implantable biologicals that are not on pass-through status as a biological before January 1, 2010, as devices beginning in CY 2010. Therefore, as devices, pass-

through implantable biologicals would be assigned a status indicator of ‘H,’ while non pass-through implantable biologicals would be assigned a status indicator of ‘N’ beginning in CY 2010.”

CMS is also “. . . proposing to assign status indicator ‘K’ to nonimplantable biologicals and to adjust the definition of status indicator ‘K’ accordingly.”

For a complete listing of HCPCS codes and their applicable status indicators and APC assignments for CY 2010, refer to Addendum B.

APPLICATION OF THE “2 TIMES RULE”

Federal Register page 35303

Background: CMS annually reviews APC groups to determine if the median cost of the highest cost item or service within an APC group is more than two times greater than the median of the lowest cost item or service within the same group. This is known as the “2 times rule.”

CMS’ Proposal: For CY 2010, CMS is proposing to exempt “. . . 14 APCs . . . from the 2 times rule . . .”

For a complete listing of the APC exceptions to the 2 times rules for CY 2010, refer to Table 17 on page 35303 of the *Federal Register*.

V. ENCOUNTER-BASED AND EPISODE-BASED PAYMENTS UNDER THE OPPTS

For OPPTS payments paid under APCs, packaging occurs when the payments for minor, ancillary services associated with a significant procedure are packaged into a single payment for the procedure. Bundling occurs when payments for multiple significant procedures related to an outpatient encounter or to an episode of care are bundled into a single unit of payment. CMS believes that packaging and bundling payments for multiple, interrelated services into a single payment creates incentives for providers to furnish services as efficiently as possible.

COMPOSITE APCS

Federal Register pages 35278 - 35286

Background: In CY 2008, CMS developed composite APCs to provide a single payment when a specified combination of HCPCS codes are reported on the same date of service, rather than paying for each service individually. CMS believes paying under composite APCs will enable hospitals to manage their resources with flexibility while adjusting the volume and efficiency of services themselves. For CY 2009, the following ten APCs were paid as composite APCs:

Composite APCs	
APC 8000	Cardiac Electrophysiologic Evaluation and Ablation Composite
APC 8001	Low Dose Rate (LDR) Prostate Brachytherapy Composite
APC 8002	Level I Extended Assessment and Management Composite
APC 8003	Level II Extended Assessment and Management Composite
APC 0034	Mental Health Services Composite
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
APC 8008	MRI and MRA with Contrast Composite

APC 8000—Cardiac Electrophysiologic Evaluation and Ablation Composite

Cardiac electrophysiologic evaluation and ablation services are frequently performed in varying combinations with one another during a single episode of care in a hospital outpatient setting.

APC 8001—Low Dose Rate (LDR) Prostate Brachytherapy Composite

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate.

APCs 8002/8003—Level I and II Extended Assessment and Management Composite

Composite APCs 8002 and 8003 are used for high levels of care provided to patients in conjunction with observation services of substantial duration. More specifically, APC 8002 is for a high level (Level 5) clinic visit or direct referral to observation and APC 8003 is for 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. Therefore, in situations when observation services are provided in conjunction with a high level visit or direct referral and is an integral part of a patient's extended delivery of care, payment is made for the entire care encounter through one of the two composite APCs, as appropriate.

APC 0034—Mental Health Services Composite

CMS believes that costs associated with administering a partial hospitalization program are most resource-intensive of all outpatient mental health treatment. Therefore, CMS will not pay more for a day of individual mental health services under the OPSS than the partial hospitalization two-tiered payment approach.

APCs 8004/8005/8006/8007/8008-Multiple Imaging Composite APCs

Before CY 2009, CMS paid the full APC payment for each imaging service on a claim, regardless of how many procedures were performed during a single session using the same imaging modality or whether the procedures were performed on contiguous body areas.

Per recommendations from the Medicare Payment Advisory Commission to improve accuracy for imaging services under the OPSS, CMS adopted five multiple imaging composite APCs in the final OPSS rule for CY 2009. CMS will make a single payment for APCs 8004, 8005, 8006, 8007, and 8008, as well as any packaged services furnished on the same date of service.

CMS' Proposal-Composite APCs: For CY 2010, CMS is proposing to continue using the current composite APCs until claims data are available to evaluate the impact on payments. However, per the recommendation of the APC Panel, CMS will evaluate the implications of creating new composite APCs for cardiac resynchronization therapy with a defibrillator or pacemaker along with other potential composite APCs for future discussion.

In addition, even though CMS is proposing no changes to the multiple imaging composite APCs, CMS is accepting the APC Panel recommendations to seek further input and examine different options for APCs with multiple imaging sessions and multiple imaging procedures.

PACKAGED SERVICES

Federal Register pages 35286 - 35291

Background: Before CY 2008, the OPPS APC assignments reflected a modest degree of packaging for minor ancillary services, inexpensive drugs, medical supplies, implantable devices, capital-related costs, operating and recovery room use, and anesthesia services.

In CY 2008, CMS expanded its packaging of services to create incentives for hospitals to monitor and adjust the volume and efficiency of services delivered. Over time, CMS intends to contain growth in volume and spending by moving away from service specific-based payments and creating more packaged APCs.

As an initial step toward creating larger payment groups for outpatient care in CY 2008, CMS began packaging payments for items and services in the following seven categories:

- guidance services;
- image processing services;
- intraoperative services;
- imaging supervision and interpretation services;
- diagnostic radiopharmaceuticals;
- contrast media; and
- observation services.

Packaged services are not paid separately and instead are included in the payment for the primary diagnostic or therapeutic modality to which these items and services are typically ancillary or supportive. In these cases, CMS assigns one of two status indicators to these HCPCS codes.

- CMS assigns a status indicator of “N” for procedures that changed from separately paid to unconditionally packaged. CMS always packages the cost of the procedure into the costs of the separately paid primary services with which they are billed.
- CMS assigns a status indicator of “Q1” (“STVX-Packaged Codes”), “Q2” (“T-Packaged Codes”), or “Q3” (codes that may be paid through a composite APC) for procedures that changed from separately paid to conditionally packaged. In this case, the procedure is either packaged or separately paid, depending on the services with which it is reported (refer to the “Status Indicator” section).

As a result of expanding packaging in CY 2008, the APC Panel recommended that CMS report its findings of the impact of packaging on net payments for patient care. CMS reported to the APC Panel that hospitals in aggregate did not appear to have significantly changed their service reporting patterns due to expanding packaging under OPPS in CY 2008. The APC Panel’s Packaging subcommittee also made recommendations to the APC Panel, which CMS will consider.

CMS’ Proposal: For CY 2010, CMS is proposing no change to the current packaging of payments. CMS will evaluate the APC Panel recommendations for future rulemaking.

VI. PULMONARY, CARDIAC, AND INTENSIVE CARDIAC REHABILITATION SERVICES

MIPPA created new Medicare Part B coverage and payment policies for items and services furnished under cardiac rehabilitation (CR), pulmonary rehabilitation (PR), and intensive cardiac rehabilitation (ICR) programs, effective January 1, 2010. Covered services include physician-prescribed exercise, psycho-social assessment and outcomes assessment; cardiac risk factor modification, including education, counseling, and behavioral intervention for cardiac rehabilitation programs; and education or training for pulmonary rehabilitation programs.

PULMONARY REHABILITATION

Federal Register pages 35360 - 35361

Background: Historically, individual services that comprise comprehensive PR have been reported separately with existing HCPCS codes that are paid under the OPSS through the individual APC that is most appropriate for each service described by the specific HCPCS code reported. CMS does believe that there is an existing clinical APC for PR that could be assigned appropriately under OPSS based on the information currently available.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to create one new Level II HCPCS code for hospitals to report and bill for the services furnished under a PR program as . . . Specifically, we would use HCPCS code GXX30 (Pulmonary rehabilitation, including aerobic exercise (includes monitoring), per session, per day). . . This proposed new HCPCS G-code would be used by hospitals to report PR services furnished to patients performing physician-prescribed exercises that are targeted to improving the patient's physical functioning and may also include the provision of other aspects of PR, such as education and training.”

In addition, CMS is “. . . proposing that hospitals would use proposed HCPCS code GXX30 to report sessions lasting a minimum of 60 minutes each, generally for two to three sessions of PR per week, under the OPSS. We also are proposing to allow no more than one session per day because individuals who are furnished services in a PR program have significant respiratory compromise and would not typically be capable of performing more than one session of exercise per day.”

Due to the lack of outpatient hospital data available for the PR program, CMS is proposing “. . . to assign HCPCS code GXX30 to New Technology APC 1492 (New Technology—Level IB (\$10-\$20)), the New Technology APC that provides payment for new services with estimated facility costs between \$10 and \$20 and for which no existing clinical APC is appropriate.” CMS believes that payment under New Technology APC 1492 is similar to the corresponding physician's office payment amount.

CARDIAC REHABILITATION AND INTENSIVE CARDIAC REHABILITATION

Federal Register page 35361

Background: Currently, cardiac rehabilitation (CR) furnished by hospitals are reported using CPT codes 93797 and 93798. Both CR and ICR programs consist of exercise, cardiac risk factor modification, psycho-social assessment, outcomes assessment, and other services. Although more sessions per day for a beneficiary may be provided in an ICR program than a CR program, CMS believes the hospital costs for a single session would be similar, and OPSS payment for CR and ICR would be provided on a per-session basis.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to create two new Level II HCPCS codes to report the services of an ICR program that are furnished to hospital outpatients . . . proposed HCPCS code GXX28 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session) and

proposed HCPCS code GXX29 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session)."

Furthermore, CMS is ". . . proposing to assign proposed HCPCS codes GXX28 and GXX29 to APC 0095 (Cardiac Rehabilitation) with a status indicator of 'S.' The proposed median cost of APC 0095 for CY 2010 is approximately \$39. This proposed median cost reflects historical hospital cost data for one session of general CR services reported with CPT code 93797 or 93798."

Under the OPSS, CMS is proposing no additional changes to the CR program; however, CMS is proposing changes under the proposed CY 2010 Medicare physician fee schedule (MPFS) that affect CR services. Specifically, CMS is proposing under the MPFS for CY 2010 ". . . that each day CR items and services are furnished to a patient, aerobic exercises along with other exercises must be included (that is, a patient must exercise aerobically every day he or she attends a CR session). In addition, we are proposing that each session must be a minimum of 60 minutes and patients must participate in a minimum of two CR sessions a week, with a maximum of two CR sessions a day."

VII. REPORTING OF HOSPITAL OUTPATIENT QUALITY DATA

Federal Register pages 35394 - 35405

The MIEA-TRHCA of 2006 required CMS, by January 1, 2009, to establish a quality reporting program specific to hospital outpatient care using standardized measures of care to receive the full annual update to the OPSS payment rate.

REPORTING REQUIREMENTS TO RECEIVE THE FULL OPSS UPDATE

Background: In CY 2008, CMS adopted seven outpatient quality measures that had been endorsed by the National Quality Forum under the HOP QDRP. These outpatient measures included: five emergency department-acute myocardial infarction (ED-AMI) measures and two perioperative care measures. In CY 2009, CMS adopted four additional imaging measures. To receive the full OPSS payment update for services, providers must submit data on the 11 outpatient measures. Non-compliant providers in CY 2009 will receive the OPSS marketbasket conversion factor update reduced by 2.0 percentage points for all OPSS payments in CY 2010. In addition, CMS proposed to reduce the beneficiary payment for non-compliant hospitals in CY 2010.

Application of a reduced outpatient fee schedule increase results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality measures and that fail to meet the HOP QDRP requirements. Therefore, status indicators "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," "U," or "X," would be affected by the reduction of the national unadjusted payment rates for applicable hospitals. However, New Technology APCs, assigned a status indicator of "S" or "T," and brachytherapy sources, assigned status indicator "U" are exempt from this reduction since the outpatient fee schedule increase factor is not used to update payment rates for these APCs.

CY 2010 HOP QDRP PROGRAM

Currently, the following 11 outpatient quality measures are reported:

CY 2010 Designations	CY 2009 Designations	Endorsed by NQF
OP-1: Median Time to Fibrinolysis	ED-AMI-2	yes
OP-2: Fibrinolytic Therapy Received within 30 Minutes of Arrival	ED-AMI-3	yes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	ED-AMI-5	yes
OP-4: Aspirin at Arrival	ED-AMI-1	yes
OP-5: Median Time to Electrocardiogram (ECG)	ED-AMI-4	yes
OP-6: Timing of Antibiotic Prophylaxis	PQRI #20	yes
OP-7: Prophylactic Antibiotic Selection for Surgical Patients	PQRI #21	yes
OP-8: MRI Lumbar Spine for Low Back Pain	NA	yes
OP-9: Mammography Follow-up Rates	NA	no
OP-10: Abdomen CT - Use of Contrast Material	NA	no
OP-11: Throat CT - Use of Contrast Material	NA	yes

CMS' Proposal—HOP QDRP Quality Measures: For CY 2010, CMS proposes to continue submission of data on the 11 outpatient measures listed above.

CMS' Proposal—Reporting Ratio: For CY 2010, CMS is proposing “. . . reporting ratio is 0.980, calculated by dividing the reduced conversion factor of \$66.118 by the full conversion factor of \$67.439.” “We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the HOP QDRP requirements for the full CY 2010 annual payment update factor.”

In addition, CMS is “. . . proposing that the CY 2010 payment for brachytherapy sources would be based on the conversion factor and the quality reporting reduction policy would be applicable to brachytherapy sources, which are assigned status indicator ‘U.’”

Participation Procedures and Requirements

To participate in the HOP QDRP each year, hospitals must meet administrative and data collection/submission requirements. For the most part, these procedures and requirements mirror those currently in place under the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. In the CY 2009 final rule, CMS established that hospitals sharing the same CMS certification number (CCN) must combine data collection and submission across their multiple campuses for the clinical measures for public reporting purposes.

Data Collection and Submission Requirements

Currently, data are submitted through the QualityNet secure Web site at <http://www.qualitynet.org>. Submission deadlines are four months after the last day of each calendar quarter for measures finalized in the current OPSS final rule.

CMS' Proposal-Data Collection: For CY 2010, CMS is proposing “. . . to make data collected for quarters beginning with third quarter of CY 2008 (July - September 2008) under the HOP QDRP publicly available, regardless of whether those data have been validated for payment determination purposes.”

Retirement of HOP QDRP Measures

CMS does not believe that it is appropriate to wait for an annual rulemaking cycle to retire a measure if evidence proves that it raises patient safety concerns. In FFY 2010 IPPS proposed rule, CMS proposed a process to immediately retire measures of the RHQDAPU program if they raised patient safety concerns.

CMS' Proposal—Retirement of Measures: For CY 2010, CMS is proposing the same immediate retirement policy for the HOP QDRP as proposed under IPPS. “Specifically, we are proposing that if we

receive evidence that continued collection of a measure that has been adopted for the HOP QDRP raises patient safety concerns, we would promptly retire the measure and notify hospitals and the public of the retirement of the measure and the reasons for its retirement through the usual means by which we communicate with hospitals, including but not limited to hospital e-mail blasts and the QualityNet Web site.”

Validation Requirement

CMS has not required data validation for CY 2010 payment update determinations. However, CMS believes that validation is intended to provide assurance of the accuracy of the hospital abstracted data.

CMS stated it will publicly report, sometime in 2010, third quarter (July through September) 2008 OPDS quality data that have not been validated.

Reconsideration and Appeals Procedures

In the CY 2009 final rule, CMS implemented a reconsideration submission process for HOP QDRP modeled after the reconsideration process implemented under the IPPS RHQDAPU program. Under this proposed process, hospitals must submit to CMS, via QualityNet, a reconsideration request form that will be made available on the QualityNet Web site. This form must be submitted by February 3, 2011 and must contain the following information:

- hospital CMS CCN;
- hospital name;
- CMS-identified reason for failure;
- hospital basis for requesting reconsideration;
- chief executive officer and any additional designated hospital personnel contact information; and
- a copy of all materials that the hospital submitted to receive the full payment update.

CMS will notify the contact person regarding the outcome of the reconsideration process. A hospital may file an appeal if it is dissatisfied with CMS’ outcome.

CY 2011 HOP QDRP PROGRAM

Program Expansion

CMS’ Proposal—Program Expansion: For CY 2011, CMS is proposing no additional OPDS quality measures. Therefore, CMS will “. . . continue requiring that hospitals submit data on the existing 11 HOP QDRP measures.”

“. . . we are sensitive to the burden upon hospital outpatient departments associated with chart abstraction, and believe that adopting such measures at this time would not be consistent with our stated goal to minimize the collection burden associated with quality measurement.”

CMS seeks public comment on its proposal to retain the existing 11 HOP QDRP measures and to not adopt additional measures for the CY 2011 payment determination.

Administrative Requirements

For hospitals to participate in the HOP QDRP, they must:

- register on QualityNet;
- name a QualityNet administrator; and
- complete a Notice of Participation form.

Under current regulations, hospitals have 30 days to submit the participation form following receipt of a CCN form from CMS.

CMS' Proposal—Administrative Requirements: *“For the CY 2011 payment update, we are proposing that any hospital that has a Medicare **acceptance date on or after January 1, 2010** (including a new hospital and hospitals that have merged) must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date on the CMS Online System Certification and Reporting (OSCAR) system.”*

*“For the CY 2011 payment update, we are proposing that any hospital that has a Medicare **acceptance date on or before December 31, 2009** that wants to withdraw from participation in the CY 2011 HOP QDRP or that is not currently participating in the HOP QDRP and wishes to participate in the CY 2011 HOP QDRP must submit a participation form by March 31, 2010.”*

Data Collection and Submission Requirements

CMS' Proposal—Data Collection: For the CY 2011 payment update, CMS is proposing the following data submissions:

- third quarter (July - September) of 2009;
- fourth quarter (October - December) of 2009;
- first quarter (January - March) of 2010; and
- second quarter (April - June) of 2010.

CMS stated, *“Hospitals that did not participate in the CY 2010 HOP QDRP, but would like to participate in the CY 2011 HOP QDRP, and that have a Medicare acceptance date on the OSCAR system before January 1, 2010, must begin data submission for 1st quarter CY 2010 services using the CY 2011 measure set that will be finalized in the CY 2010 OPPS/ASC final rule with comment period.”*

Waiver for Reporting Quality Data

Some hospitals have been unable to submit the required quality data due to circumstances beyond their control. CMS' goal is not to penalize these hospitals under extreme circumstances and not to create more of a burden during these times.

CMS' Proposal—Waiver: CMS is *“. . . proposing a process for hospitals to follow so that we may consider granting extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital.”*

Specifically, for a hospital to receive consideration for an extension or waiver to submit quality data for one or more quarters, a hospital must submit a request form to CMS explaining reasons for requesting this extension waiver. *“The request form must be signed by the hospital's CEO. A request form must be submitted within 30 days of the date that the extraordinary circumstance occurred.”*

Validation Requirements

CMS' Proposal—Validation Requirements: *“For the CY 2011 payment determination, we are proposing to implement a validation program that will require hospitals to supply requested medical documentation to a CMS contractor for purposes of being validated. However, the results of the validation will not affect the CY 2011 payment update for any hospital.”*

In addition, CMS is proposing *“. . . to select a random sample of 7,300 cases from all cases successfully submitted to the OPPS Clinical Warehouse”* *“A sample size of 7,300 was chosen because it will enable us to detect a relative difference of 10 percent in the measured overall accuracy rate with a 95 percent (two-tailed) confidence interval and should provide sufficient data to conduct post-hoc stratified analyses that provide meaningful feedback.”*

“We are proposing to request medical documentation from hospitals for April 1, 2009 through March 31, 2010 episodes of care, which will allow us to gather one full year of submitted data for validation purposes.” Hospitals have 45 days from the date of the initial request for medical documentation to respond to CMS, otherwise a “zero” score will be assigned to each data element for each selected case and the case will fail for all measures in the same topic.

“. . . hospitals must supply the medical documentation for each requested case; failure to provide this documentation may result in a 2.0 percentage point reduction in a hospital’s CY 2011 annual payment update.”

CY 2012 (AND SUBSEQUENT YEARS) HOP QDRP PROGRAM

Program Expansion

CMS’ Proposal—Program Expansion: For CY 2012 payment determinations and subsequent years, CMS is proposing 16 additional outpatient quality measures. The proposed measures are as follows:

Topic	Measure	Potential Data Sources
Cancer	1 Adjuvant chemotherapy is considered or administered within 4 months of surgery to patients under age 80 with AJCC III colon cancer	Registry
	2 Adjuvant hormonal therapy for patients with breast cancer	Claims, Registry
	3 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection	Claims, Registry
ED Throughput	4 Median time from ED arrival to ED departure for discharged ED patients	Chart, EHR
Diabetes	5 Low density lipoprotein control in type 1 or 2 diabetes mellitus	Claims, EHR
	6 Urine protein screening or medical attention for nephrology during at least one office visit within the last year for a patient with diabetes mellitus	
	7 Eligible diabetes patients with documentation of an eye exam or referral for an eye exam within the last 24 months	
	8 Patients who received at least one complete foot exam (visual inspection, sensory exam with monofilament wna pulse exam within the last 12 months	
Medication Reconciliation	9 Medication reconciliation	Claims, EHR
Immunizations	10 Pneumococcal vaccination status - overall rate	Chart, EHR
	11 Influenza vaccination status - overall rate	
Imaging Efficiency	12 SPECT MPI and stress echocardiography for preoperative evaluation for low-risk non-cardiac surgery risk assessment	Claims
	13 Use of stress echocardiography or SPECT MPI post-revascularization coronary artery bypass graft	
	14 Use of computed tomography in emergency department for headache	
	15 Simultaneous use of brain computed tomography and sinus computed tomography	
	16 Appropriate surgical site hair removal	
Surgery	16 Appropriate surgical site hair removal	Chart, EHR

Validation Requirement

CMS’ Proposal—Validation Requirements: For CY 2012 payment determinations, CMS is proposing to “. . . validate data from 800 randomly selected hospitals (approximately 20 percent of all participating HOP QDRP hospitals) each year”

“For each selected hospital, we are proposing to randomly validate per year up to 48 patient episodes of care (12 per quarter) from the total number of cases that the hospital successfully submitted to the OPDS Clinical Warehouse.”

“We are proposing to sample data for April 1, 2010 to March 31, 2011 services because this will provide a full year of the most recent data possible to use for purposes of completing the validation in time to make the CY 2012 payment determinations.”

“For the CY 2012 and subsequent years’ payment determinations, we would use the validation methodology proposed for the CY 2011 payment update with validation being done for each selected hospital. Specifically, we would conduct a measures level validation by calculating each measure within a submitted record using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement will then be calculated”

“To receive the full OPSS payment update, we are proposing that hospitals must attain at least a 90 percent reliability score, based upon our validation process, for the designated time period. We will use the lower bound of a two-tailed 95 percent confidence interval to estimate the validation score. If the calculated upper limit is above the required 90 percent reliability threshold, we will consider a hospital’s data to be “validated” for payment purposes.”

CMS also seeks input on the specified targeted criteria they list on *Federal Register* pages 35403 - 35404 or another approach that could be used for validation in future years.

HEALTH CARE-ASSOCIATED CONDITIONS

Federal Register pages 35405 - 35407

Background: In 2005, Congress authorized CMS to adjust Medicare IPPS hospital payments to encourage the prevention of eight selected hospital-acquired conditions (HACs), based on the following criteria:

- high-cost, high-volume, or both;
- result in the assignment of a case to a Diagnosis Related Group (DRG) that has a higher payment when present as a secondary diagnosis; and
- could reasonably have been prevented through the application of evidence-based guidelines.

Since October 1, 2008, Medicare no longer assigns a hospital inpatient discharge to a higher paying MS-DRG if the specified IPPS HACs were not present on admission.

CMS has evaluated, but not adopted similar conditions under OPSS, but plans to apply these strategies across the continuum of care for Medicare beneficiaries. CMS will refer to these conditions in other settings across the continuum excluding inpatient as “health care-associated conditions.” In the CY 2009 proposed rule, CMS did seek input from the public on health care-associated conditions as they relate to OPSS but did not adopt any new Medicare policy in the final rule.

CMS’ Proposal: For CY 2010, CMS is “. . . *not proposing to expand the principles behind the IPPS HAC payment provision to the OPSS through a HOP-HAC program. While we continue to believe that it may be appropriate to expand the principles of the IPPS HAC payment provision to the OPSS in the future, we acknowledge that, at this time, there are many operational challenges to such an expansion that will require further consideration and infrastructure development.*”

VIII. TRANSITIONAL PASS-THROUGH PAYMENTS

PASS-THROUGH SPENDING

Federal Register pages 35339 - 35340

Background: The BBRA provides transitional pass-through payments for certain drugs, pharmaceuticals, biologicals, and medical devices. The cap on the total amount of pass-through spending is 2.0% of total OPSS payments. Estimated pass-through spending that does not exceed the 2.0% cap is returned to the conversion factor.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to set the applicable percentage limit at 2.0 percent of the total OPSS projected payments for CY 2010, consistent with our OPSS policy from CY 2004 through 2009.

PAYMENT FOR PASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Federal Register pages 35310 - 35318

Background: The law limits payments for pass-through drugs for between two and three years. It has been CMS' policy to remove drugs from pass-through status as quickly as possible and most are incorporated into the APC rates after two years. There are two groups who are eligible for pass-through payments: “current” or “new,” depending on when they were first paid.

The MMA requires pass-through drugs and biologicals to be paid at the average sales price (ASP) + 6% for 2005 and thereafter, unless the drug or biological is covered under the Competitive Acquisition Program (CAP). In the latter case, the payment rate is equal to the average price for the drug or biological for all competitive acquisition areas and the year established as calculated and adjusted by the Secretary of Health and Human Services (HHS). However, in the CY 2009 final rule CMS suspended the CAP program, effective January 1, 2009.

Payment for drugs and biologicals with pass-through status is equal to the difference between ASP + 6% and the applicable fee schedule portion associated with the drug or biological.

Tables identifying the drugs and biologicals, both continuing and expiring, with pass-through status for CY 2010 are available in the *Federal Register* pages referenced above.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2010.”

“Proposed CY 2010 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” as indicated in Addenda A and B to this proposed rule.”

“. . . proposing that the pass-through status of 6 drugs and biologicals would expire on December 31, 2009, as listed in Table 21”

“We are proposing to continue pass-through status in CY 2010 for 31 drugs and biologicals The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator “G” in Addenda A and B”

CMS' Proposal—Eligibility Period: For CY 2010, CMS is “. . . proposing to change the start date of the pass-through payment eligibility period for a drug or biological from the first date on which pass-through payment is made to the date on which payment is first made for a drug or biological as an outpatient hospital service under Part B.”

Diagnostic Radiopharmaceuticals

Payment for radiopharmaceuticals with pass-through status would be paid at ASP + 6%, while those without ASP information would be paid at wholesale acquisition cost (WAC) + 6% or, if WAC is not available, based on 95% of the product's most recently published average wholesale price (AWP).

Diagnostic radiopharmaceuticals without pass-through status are packaged into payment for nuclear medicine procedures; the pass-through payment is then reduced by an amount that reflects the diagnostic radiopharmaceutical portion of the APC payment amount for the associated nuclear medicine procedure (the “policy-packaged” drug APC offset) that CMS determines is associated with the cost of predecessor

diagnostic radiopharmaceuticals. CMS believes an APC payment offset is necessary to provide an appropriate transitional pass-through payment and to ensure there are no duplicate radiopharmaceutical payments. CMS determines the actual APC offset amount for pass-through diagnostic radiopharmaceuticals by taking into consideration the otherwise applicable OPSS payment amount, and multiplying the “policy-packaged” drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reducing the separate OPSS payment for the pass-through diagnostic radiopharmaceutical by this amount.

In CY 2009, CMS established a policy that would utilize the “policy-packaged” drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for “policy-packaged” drugs divided by the cost from single procedure claims in the APC).

Contrast Agents

CMS’ Proposal: For CY 2010, CMS is proposing to apply the same policy that was adopted in CY 2009 for diagnostic radiopharmaceuticals, to contrast agents. *“Specifically, we are proposing to utilize the “policy-packaged” drug offset fraction for clinical APCs calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for “policy-packaged” drugs divided by the cost from single procedure claims in the APC).*

PASS-THROUGH DEVICES

Federal Register pages 35305 - 35306

Background: The law limits payments for pass-through devices for between two and three years. It has been CMS’ policy to remove devices from pass-through status as quickly as possible and most are incorporated into the APC rates after two years. For devices, the pass-through payment equals the amount by which the hospital’s charges, adjusted to cost, exceeds the OPSS payment rate associated with the device.

For CY 2009 there were no device categories eligible for pass-through status. In addition, the costs of implantable biologicals that were not eligible for pass-through payment were packaged into the costs of the procedures in which they were implanted because non pass-through implantable biologicals are not separately paid.

As required by law, CMS deducts from the pass-through payments for the identified devices an amount that reflects the portion of the APC payment amount that CMS determines is associated with the cost of the device, referred to as the APC offset amount.

CMS’ Proposal: For CY 2010, CMS is proposing “. . . *the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be the device pass-through process and payment methodology only As a result, implantable biologicals would no longer be eligible to submit biological pass through applications and to receive biological pass-through payment at ASP+6 percent . . . payment for implantable biologicals eligible for pass-through payment beginning on or after January 1, 2010, would be based on hospital charges adjusted to cost, rather than the ASP methodology that is applicable to pass-through drugs and biologicals.*”

IX. PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS WITHOUT PASS-THROUGH STATUS

PAYMENT FOR NON PASS-THROUGH DRUGS

Federal Register page 35326

CMS' Proposal: For CY 2010, CMS is “. . . *proposing that, for CY 2010, we would make payment for separately payable drugs and biologicals not receiving pass-through payment at ASP+4 percent, which would continue to include payment for both the acquisition costs of separately payable drugs and biologicals and the pharmacy overhead costs applicable to these separately payable drugs and biologicals.*”

CMS is also “. . . *proposing a pharmacy overhead adjustment for separately payable drugs and biologicals in CY 2010 that would result in their payment at ASP+4 percent.*”

PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS— PACKAGING CRITERIA

Federal Register pages 35319 - 35324

Background: The costs of drugs, biologicals, and radiopharmaceuticals are generally packaged into the APC rate for their related procedures or services, unless they are determined to be relatively expensive or are rarely used. Items such as single indication “orphan” drugs, certain vaccines, and blood and blood products are excluded from the packaging policy. In addition, oral and injectable forms of 5HT3 anti-emetic products are exempt.

Packaging status is based on a comparison of CMS-calculated per-day cost of the item to a packaging threshold. For CY 2009, the packaging threshold was set at \$60.

As a result of the enactment of MIPPA, hospital claims can no longer be used to establish the packaging status of therapeutic radiopharmaceuticals. Instead, all radiopharmaceuticals will be paid separately in CY 2009 at hospital charges adjusted to cost.

CMS' Proposal: For CY 2010, CMS is “. . . *proposing a packaging threshold . . . of \$65.*”

In addition, CMS is “. . . *proposing to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as “policy-packaged” drugs, regardless of their per day costs . . .*”

REPORTING OF HCPCS CODES FOR PART B DRUGS

Federal Register pages 35321 - 35323

Background: Before CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug and biological. In the CY 2008 final rule, CMS adopted a policy that recognized multiple HCPCS codes that report different dosages for the same covered Part B drugs and biologicals.

Based on CMS' analysis using the first year of claims data available for CY 2008, CMS concluded that using multiple HCPCS codes for the same drug or biological by different costs associated with the varying dosages for the same drug or biological could lead to payment incentives for hospitals to report certain HCPCS codes instead of others.

CMS' Proposal: For CY 2010, CMS is “. . . *proposing to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages.*”

For a complete listing of the proposed drugs and biologicals HCPCS codes that are subject to this drug-specific packaging determination methodology, refer to Table 24 of the *Federal Register* on pages 35321 - 35322.

PAYMENT FOR RADIOPHARMACEUTICALS

Federal Register pages 35333 - 35336

Background: Per the MMA, radiopharmaceuticals are exempt from ASP pricing. Radiopharmaceuticals are considered specified covered outpatient drugs; payments must be made at average acquisition cost as determined by the HHS Secretary and subject to any adjustment for overhead costs. However, CMS does not have ASP data for radiopharmaceuticals.

In the CY 2008 OPSS final rule, CMS adopted a prospective payment for therapeutic radiopharmaceuticals using mean costs derived from the most current claims data, where the costs are determined using the standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.

The enactment of MIPPA further extends the payment period for therapeutic radiopharmaceuticals based on hospital's charges adjusted to cost through December 31, 2009.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to allow manufacturers to submit ASP information for any separately payable therapeutic radiopharmaceutical in order for therapeutic radiopharmaceuticals to be paid based on ASP. . . . in order for a therapeutic radiopharmaceutical to receive payment based on ASP beginning January 1, 2010, we would need to receive ASP information from the manufacturer no later than November 1, 2009, that would reflect therapeutic radiopharmaceutical sales in the third quarter of CY 2009 (July 1, 2009, through September 30, 2009).”

CMS is “. . . proposing to provide payment at the ASP rate if ASP information is available for a given calendar year quarter or, if ASP information is not available, we are proposing to provide payment based on the most recent hospital mean unit cost data that we have available.”

PAYMENT FOR BLOOD CLOTTING FACTORS

Federal Register page 35333

Background: For CY 2009, CMS provides payment for blood clotting factors at ASP + 4% plus an additional payment for the furnishing fee. The furnishing fee is currently \$0.164 per unit. The furnishing fee provided under the OPSS is updated each year in the MPFS final rule.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to pay for blood clotting factors at ASP+4 percent, consistent with our proposed payment policy for other non pass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount.”

PAYMENT FOR NON PASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS WITH HCPCS CODES, BUT WITHOUT OPSS HOSPITAL CLAIMS DATA

Federal Register pages 35336 - 35337

Background: Beginning in CY 2005, CMS paid separately for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but which did not have pass-through status at a rate that was equivalent to the payment they received in the physician office setting. In CY 2009, CMS paid for these at ASP + 4%.

CMS' Proposal—New Drugs and Biologicals: For CY 2010, CMS is “. . . proposing to provide payment for new drugs (excluding contrast agents), nonimplantable biologicals, and therapeutic radiopharmaceuticals with HCPCS codes (those new CY 2010 drug (excluding contrast agents), nonimplantable biological, and therapeutic radiopharmaceutical HCPCS codes that do not crosswalk to CY

2009 HCPCS codes), but which do not have pass-through status and are without OPPS hospital claims data, ASP+4 percent . . .”

In absence of ASP data, for CY 2010, CMS is proposing to “. . . continue the policy . . . implemented beginning in CY 2005 of using the WAC for the product to establish the initial payment rate for new non pass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the product’s most recent AWP.”

For a list of the non pass-through drugs and biologicals without available CY 2008 claims data, refer to Table 30 on page 35337 of the *Federal Register*.

X. OTHER

CLINIC VISITS, ED VISITS, AND CRITICAL CARE SERVICES

Federal Register pages 35349 - 35354

Currently, CMS instructs hospitals to report visit HCPCS codes for three types of OPPS services: clinic visits, emergency department (ED) visits, and critical care services. However, CMS believes that CPT Evaluation and Management (E/M) codes were defined to reflect the activities of physicians and do not describe well the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters.

Visit Reporting Guidelines

Since CY 2000, CMS has been trying to develop national guidelines to determine the assignment of E/M codes. In the absence of the national guidelines, CMS has instructed hospitals to report facility resources for clinic and emergency department visits using CPT E/M codes and to develop internal hospital guidelines to determine what level of visit to report for each patient. CMS has advised that each hospital’s internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes. Due to the complexity and challenges in developing national guidelines, CMS has evaluated both clinic and emergency department visit distributions and found that hospitals were billing in an appropriate and consistent manner between visit levels, resulting in normal distributions nationally under the OPPS.

CMS’ Proposal: For CY 2010, CMS is proposing not to implement national guidelines for clinic and emergency department visits. CMS “. . . will continue to regularly reevaluate patterns of hospital outpatient visit reporting at varying levels of disaggregation below the national level to ensure that hospitals continue to bill appropriately and differentially for these services.”

Clinic Visits, New and Established Patient Visits

In the CY 2009 final rule, CMS refined the definition to distinguish between a “new” and “established” patient visit. A patient who has been registered as an inpatient or outpatient of the hospital within the three years prior to a visit would be considered an “established” patient for that visit. Otherwise the patient would be considered “new.”

Type B Emergency Department (ED) Visits

“Type B” EDs offer emergency level services but are not open “24/7.” As of CY 2007, these services were reported using five specific G-codes and paid based upon clinic APCs. The G-codes would serve as a means to distinguish between a Type B ED from a Type A ED (ED that must be available to provide services 24/7 and meet one or both of the EMTALA requirements).

In CY 2009, CMS had its first year of claims data available to adjust charges appropriately to reflect differences between a Type B ED and a Type A ED. Therefore, in the CY 2009 final rule, CMS adopted the APC Panel recommendation to assign levels 1, 2, 3, and 4 Type B emergency department visits to their own APCs and to assign the level 5 Type B emergency department to the same APC as the level 5 Type A emergency department visit.

For CY 2010, CMS has more data available to analyze on Type B emergency department visits and has concluded that relative cost differences between Type A and Type B emergency departments visits is consistent with what CMS observed last year. CMS continues to believe that median costs for Type B emergency department visits are less than the median costs of Type A emergency department visits across all levels.

CMS' Proposal—Type B ED Visits: For CY 2010, CMS is proposing “. . . to pay levels 1 through 4 Type B emergency department visits through four levels of APCs: APC 0626 (Level 1 Type B Emergency Visits), APC 0627 (Level 2 Type B Emergency Visits), APC 0628 (Level 3 Type B Emergency Visits), and APC 0629 (Level 4 Type B Emergency Visits). In addition, we are proposing to create new APC 0630 (Level 5 Type B Emergency Visits) and pay level 5 Type B emergency department visits through this new APC.”

“We are proposing to assign HCPCS codes G0380, G0381, G0382, G0383, and G0384 (the levels 1, 2, 3, 4, and 5 Type B emergency department visit Level II HCPCS codes) to APCs 0626, 0627, 0628, 0629, and 0630, respectively, for CY 2010.”

“. . . to distinguish new APC 0630 from the APC for the level 5 Type A emergency visits, we are proposing to modify the title of the current level 5 Type A emergency visit APC to incorporate Type A in the title. Therefore, the proposed revised title of APC 0616 would be “Level 5 Type A Emergency Visits.”

PAYMENT FOR BRACHYTHERAPY SOURCES

Federal Register pages 35340 - 35343

Background: In CY 2004, MMA required that all devices of brachytherapy consisting of a seed or seeds (or radioactive source) be paid based on a facility's charges for the service, adjusted to cost. In addition, because brachytherapy sources are paid at cost, they are excluded from outlier payments and from any budget neutrality requirements. To accommodate this MMA requirement, CMS revised the status codes for brachytherapy sources to “H” and revised the definition of status code “H” to include non-pass-through brachytherapy sources paid on a cost basis. This provision was set to expire at the end of CY 2006.

For CY 2007, CMS finalized a policy of prospective payment based on median costs for brachytherapy sources. However, MIEA-TRHCA provided a one-year extension through December 31, 2007, paying for brachytherapy based on charges adjusted to cost. In addition, MIEA-TRHCA established separate payment groups for “stranded and non-stranded” brachytherapy sources furnished on or after July 1, 2007. As a result, CMS created HCPCS code C2698 (brachytherapy source, stranded, not otherwise specified (NOS), per source) for stranded NOS sources and HCPCS code C2699 (brachytherapy source, non-stranded, NOS, per source) for non-stranded NOS sources.

In CY 2008, CMS again finalized a policy to pay for brachytherapy sources at prospective payment rates, which was later rescinded by the enactment of MMSEA, which extended the payment for brachytherapy sources based on charges adjusted to costs until December 31, 2009.

In CY 2009, CMS discontinued using status indicator “H” and replaced it with status indicator “U” for brachytherapy sources.

CMS' Proposal: For CY 2010, CMS is “. . . proposing to pay for brachytherapy sources at prospective payment rates based on their source-specific median costs for CY 2010.” In addition, CMS is “. . .

proposing to subject brachytherapy sources to outlier . . . and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality.”

CMS is “. . . proposing to pay for the stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis”

PARTIAL HOSPITALIZATION

Federal Register pages 35354 - 35357

Background: Partial hospitalization is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care. A partial hospitalization program (PHP) may be provided by a hospital to its outpatients or by a freestanding Community Mental Health Center (CMHC). Under the OPPTS, providers are paid on a per diem basis for partial hospitalization services.

Generally, CMS is required to establish relative payment weights based on median costs. Historically, the median per diem cost for CMHCs has greatly exceeded the median per diem cost for hospital-based PHPs. CMS indicates that hospital-based PHPs are Medicare providers that are required to maintain uniform charges for all payers and therefore are less likely to significantly change their charges for PHP from year to year, while many CMHCs have indicated that Medicare is their only payer and as a result may have increased and decreased their charges in response to Medicare payment policies, including the manipulation of charges to inappropriately receive outlier payments. As a result, there has been a significant fluctuation in the CMHC median per diem costs over the past few years, while hospital-based median per diem costs have remained relatively stable.

In the CY 2008 final rule, CMS implemented two refinements to the methodology used for computing the PHP median, to control median per diem costs. In addition, CMS explored regulatory changes and alterations to claims processing systems to deny payments for low intensity days. As a result, CMS in the CY 2009 final rule adopted several regulatory and payment changes, including a two-tiered approach for PHP services in which CMS would pay one amount for days with three units of service (APC 0172) and a slightly higher amount for days with four or more units of service (APC 0173).

CMS’ Proposal: For CY 2010, CMS is proposing “. . . to use only hospital-based PHP data to develop the two proposed PHP APC per diem payment rates for CY 2010 . . .” CMS is proposing the following per diem rates:

APC	Group Title	Per Diem Rate
0172	Level I Partial Hospitalization (3 services)	\$149
0173	Level II Partial Hospitalization (4 or more services)	\$213

CMS is seeking “. . . public comment about the possibility of using both CMHC and hospital-based PHP data to develop the PHP payment rates for CY 2010.”

INPATIENT-ONLY PROCEDURES PAYMENT

Federal Register pages 35357 - 35358

Background: CMS identifies procedures that are typically provided only in an inpatient setting, and therefore would not be paid by Medicare under the OPPTS. These procedures comprise what is referred to as the “inpatient-only list.” The inpatient-only list specifies those services that will only be paid when provided in an inpatient setting because of the nature of the procedure and the need for at least 24 hours of post-operative recovery time or monitoring before the patient can be safely discharged. These procedures are assigned a status code of “C” and hospitals are advised to admit beneficiaries requiring these procedures to receive payment. Each year, CMS, with input from the APC Panel, reviews the inpatient only list using

specific criteria to determine whether any procedures should be moved from the inpatient only list and assigned to an APC.

CMS' Proposal: For CY 2010, CMS is proposing to “. . . remove the procedures described by CPT codes 21256, 27179, and 51060 from the inpatient list”

For a detailed list of the three procedures removed from the inpatient-only list, refer to Table 37 on *Federal Register* page 35358.

DEVICES REPLACED WITH NO COST OR HOSPITAL RECEIVES CREDIT

Federal Register pages 35306 - 35308

Background: In recent years, there have been several field actions and recalls with regard to failure of implantable devices. In many of these cases, the manufacturers have offered replacement devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device.

In CY 2008, hospitals were required to add the “FC” modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50% or more of the cost of the new devices. In addition, when a specified device code is present on the claim and the procedure code maps to a specific APC, the OPSS payment is reduced by 100% of the device offset for full credit or no cost cases and 50% for partial credit cases.

CMS' Proposal: For CY 2010, CMS is proposing “. . . to continue the policy of reducing OPSS payment for specified APCs by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.”

The APCs impacted and the device offset amounts applicable in cases of no cost or full or partial credit for replaced devices for CY 2010 can be found in Tables 19 and 20 of the *Federal Register* on pages 35307 - 35308.

PHYSICIAN SUPERVISION

Federal Register pages 35361 - 35370

Background: Long-standing Medicare policy allows payment for hospital outpatient services “incident to” the services of physicians in the treatment of patients if they are provided “as an integral though incidental part of a physician's services.” These services must be furnished on a physician’s order and delivered under physician supervision. This policy applies to both hospitals and Critical Access Hospitals (CAHs).

In the CY 2009 final rule CMS clarified its policy regarding physician supervision of outpatient hospital and CAH diagnostic and therapeutic services. The CY 2009 rule specified that direct supervision requires that the physician be present on the same campus, in the hospital or the on-campus provider-based department of the hospital, and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed, but must be immediately available to furnish assistance and direction. CMS stated that it expects direct physician supervision of all hospital outpatient therapeutic services, regardless of their on-campus or off-campus location, but would continue to emphasize the physician supervision requirement for off-campus provider-based departments.

CMS further clarified that non-physician practitioners, such as nurse practitioners (NPs), or physician assistants (PAs), may not provide physician supervision in a provider-based department, even if their professional service was being billed as a NP or PA service and not as a physician service. According to

CMS, the law only allows payment for services incident to a physician's services and not services incident to a non-physician practitioner's services. The law does provide an exception for supervision of certain services by clinical psychologists.

A number of organizations and hospitals responded to the CY 2009 rules, indicating problems that would be encountered when the policies were implemented. In the CY 2010 proposed rule, CMS responds to a number of these concerns and proposes modifications to the policy for CY 2010. However, CMS is not revising the policy for CY 2009. According to CMS “. . . physician supervision policies for hospital outpatient diagnostic and therapeutic services as described in the CY 2009 OPPS/ASC final rule with comment period . . . continue to be in effect for CY 2009. We have not instructed contractors to delay initiation of enforcement actions or to discontinue pursuing pending enforcement actions regarding the physician supervision of hospital outpatient services.”

Supervision of Outpatient Therapeutic Services

CMS is proposing to modify the supervision policies for CY 2010 to allow for supervision of therapeutic services by non-physician practitioners.

CMS' Proposal: For CY 2010, CMS is “. . . proposing that non physician practitioners, defined for the purpose of proposed revised §410.27 of the regulations as clinical psychologists, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives, may directly supervise all hospital outpatient therapeutic services that they may perform themselves within their State scope of practice and hospital-granted privileges, provided that they meet all additional requirements, including any collaboration or supervision requirements as specified in §§410.71, 410.74, 410.75, 410.76, and 410.77.”

CMS notes that the non-physician practitioner supervision policy would not apply to cardiac rehabilitation, pulmonary rehabilitation, or intensive cardiac rehabilitation programs. Physician supervision will continue to be required for these programs.

CMS is also proposing to refine the definition of direct supervision of hospital outpatient therapeutic services for those services furnished in a hospital and in on-campus departments of a hospital for CY 2010. As a result, requirements will differ in on-campus from the requirements for off-campus provider-based departments (PBDs).

CMS is not proposing modification to the requirements for off-campus provider-based departments. For off-campus provider-based departments of hospitals, direct supervision will continue to mean that the physician or non-physician practitioner must be present in the off-campus provider-based departments and immediately available to furnish assistance and direction throughout the performance of the procedure.

CMS Proposal for On-Campus Provider-Based Departments: “For services furnished on a hospital's main campus, we are proposing that direct supervision means that the supervisory physician or non physician practitioner must be present on the same campus, in the hospital or the on-campus PBD of the hospital as defined in §413.65, and immediately available to furnish assistance and direction throughout the performance of the procedure. . . . We also are proposing to define “in the hospital” . . . as meaning areas in the main building(s) of a hospital that are under the ownership, financial, and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital's CCN.”

“Therefore, to be present in the hospital or the on-campus PBD of the hospital and immediately available requires that the physician or non physician practitioner must be physically present in areas on the campus of the hospital that are part of the hospital, including on-campus PBDs, that are operated by the hospital, and where services furnished in those areas are billed under the hospital's CCN. The supervisory physician or non physician practitioner of the hospital's outpatient therapeutic services may not be located in any other entity, such as a physician's office, IDTF, co-located hospital, or hospital-operated provider or supplier such as a skilled nursing facility (SNF), end stage renal disease (ESRD) facility, or home health

agency (HHA), or any other nonhospital space that may be co-located on the hospital's campus, as "hospital campus" is defined in §413.65(a)(2) of the regulations."

CMS further specifies that ". . . direct supervision requires immediate physical presence. While we also have not specifically defined the word 'immediate' for direct supervision in terms of time or distance, the general definition of the word means 'without interval of time.' Therefore, the supervisory physician or non physician practitioner could not be immediately available while, for example, performing another procedure or service that he or she could not interrupt. In addition, we understand that advances in medical technology, changes in the patterns of health care delivery, and changes in the organizational structure of hospitals have led to the development of extensive hospital campuses, sometimes spanning several city blocks. However, in the context of direct physician or non physician practitioner supervision, we believe that it would be neither appropriate nor 'immediate' for the supervisory physician or non physician practitioner to be so physically far away on the main campus from the location where hospital outpatient services are being furnished that he or she could not intervene right away."

"In addition, the definition of direct supervision . . . has included and would continue to specify under our CY 2010 proposal that the physician or non physician practitioner must be available to furnish assistance and direction throughout the performance of the procedure. This means that the physician or non physician practitioner must be prepared to step in and perform the service, not just to respond to an emergency. This includes the ability to take over performance of a procedure and, as appropriate to both the supervisory physician or non physician practitioner and the patient, to change a procedure or the course of treatment being provided to a particular patient."

BENEFICIARY COPAYMENTS

Federal Register page 35298

Background: The BBRA requires rules for determining copayment amounts to be paid by beneficiaries for covered outpatient department (OPD) services. The national unadjusted copayment amount for a covered OPD service provided in a year must be reduced so that the effective copayment rate for that service does not exceed a specified percentage. The national unadjusted copayment amount cannot be less than 20% of the OPD fee schedule amount.

CMS' Proposal: For CY 2010, CMS is proposing that ". . . the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service."

The national unadjusted copayment amounts for services payable under the OPDS that will be effective January 1, 2010 are shown in Addendum A and B of the proposed rule.