



**SUMMARY OF THE
PROPOSED CALENDAR YEAR 2011
MEDICARE HOSPITAL OUTPATIENT
RULE**

July 2010

SUBMISSION OF COMMENTS

This document provides an overview of the proposed Medicare Outpatient Prospective Payment System (OPPS) rule for calendar year (CY) 2011. A display version of the proposed rule is available online at: http://www.ofr.gov/OFRUpload/OFRData/2010-16448_PI.pdf.

The Centers for Medicare and Medicaid Services (CMS) must receive comments on the proposed rule by 5 p.m. on August 31.

CMS requests that comments reference the file code CMS-1504-P.

Comments can be submitted electronically at: <http://www.cms.hhs.gov/eRulemaking/> (attachments should be in Microsoft® Word, WordPerfect, or Excel format).

Alternatively, one original and two copies can be delivered by:

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Department of Health and Human Services
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I. OVERVIEW

CMS published the display copy of the proposed Medicare OPSS rule for CY 2011 on July 2. CMS will accept comments on the proposal through August 31 and will publish a final payment rule in October. The changes proposed to the Medicare OPSS are effective January 1, 2011 unless otherwise noted. This document provides an overview of the proposed rule. A display version of the proposed rule is available online at http://www.ofr.gov/OFRUpload/OFRData/2010-16448_PI.pdf. Additional information regarding OPSS is available on CMS' Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS>.

Note: Text in italics is extracted from the July 2 display copy of the 2011 Medicare OPSS proposed rule.

HIGHLIGHTS OF THE PROPOSED RULE

Marketbasket Update: CMS proposes an OPSS marketbasket update of 2.15% for CY 2011, which reflects a marketbasket projection of 2.4% minus a Patient Protection and Affordable Care Act (PPACA) of 2010-mandated reduction of 0.25 percentage points. The CY 2011 conversion factor will increase from \$67.241 in CY 2010 to \$68.267. The net increase in the proposed conversion factor would be 1.5% after application of budget neutrality.

Quality Reporting: In addition to the 11 outpatient quality measures required to be reported by hospitals under the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) in CY 2010, CMS proposes that hospitals report data on an additional six measures in CY 2011. These measures include one structural health information technology (HIT) measure, four claims-based imaging efficiency measures, and one chart-abstracted measure for the emergency department (ED). Outpatient providers that fail to successfully report the 17 measures in CY 2011 will receive a reduction of 2.0 percentage points to the marketbasket update in CY 2012.

CMS proposes a quality reporting validation process for CY 2012 payment determinations using chart-abstracted data. CMS proposes to validate data from 800 randomly selected hospitals, randomly selecting up to 12 cases per quarter. Under the proposal, hospitals must achieve a minimum 75% validation score based on this process to receive the full OPSS marketbasket update in CY 2012.

Outlier Payments: CMS proposes to decrease the outlier fixed-dollar threshold from \$2,175 in CY 2010 to \$2,025 in CY 2011.

Packaging Threshold for Drugs, Biologicals, and Radiopharmaceuticals: CMS proposes to increase the packaging threshold for drugs, biologicals, and radiopharmaceuticals from \$65 in CY 2010 to \$70 in CY 2011.

Partial Hospitalization Services: CMS proposes to establish four separate partial hospitalization program (PHP) Ambulatory Payment Classification (APC) per diem payment rates; two for community mental health center (CMHC) PHPs and two for hospital-based PHPs, which are based on each provider type's data.

Section 508 Wage Index Reclassifications: Section 508 wage index reclassifications extended for one federal fiscal year by PPACA will sunset on September 30, 2010. CMS does not have the authority to extend Section 508 reclassifications beyond CY 2010 without legislation.

Medicare Wage Index Floor: As authorized by PPACA, CMS is implementing a wage index floor of 1.0 for outpatient hospitals located in "frontier" states (NV, ND, SD, MT, and WY) beginning January 1, 2011.

Hold-Harmless Transitional Outpatient Payments (TOPs): Hold-harmless TOPs paid to rural hospitals and Sole Community Hospitals (SCHs) with 100 or fewer beds that were extended for one-year by PPACA will expire on December 31, 2010. CMS does not have the authority to extend these payments beyond CY 2010 without legislation.

Supervision Requirements for Outpatient Services: CMS proposes to revise and further define current policies related to the supervision of outpatient services:

- **Outpatient Therapeutic Services:** CMS proposes to require “direct supervision” for the beginning of a service to stabilize the patient, followed by “general supervision” for the remainder of the service for a limited set of “non-surgical extended duration services,” including observation services and intravenous hydration. This provision would apply to both PPS hospitals and Critical Access Hospitals (CAHs) for CY 2011.
- **Outpatient Diagnostic Services:** CMS proposes to clarify current policy to state that clinical nurse-midwives are exempt from requiring physician supervision for the diagnostic tests that they are authorized to perform under the applicable State laws.

Cancer Hospital Adjustment: CMS proposes a hospital-specific adjustment under OPSS for eligible cancer hospitals if their outpatient costs are determined to be greater than the costs of other OPSS hospitals. Cancer hospitals remain eligible to receive outpatient hold-harmless payments.

II. LEGISLATIVE MANDATES

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003; Deficit Reduction Act (DRA) of 2005; Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006 (MIEA-TRHCA); Medicare, Medicaid, and State Children’s Health Insurance Program Extension Act (MMSEA) of 2007; the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008; and PPACA 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. OPSS PAYMENT UPDATES

CONVERSION FACTOR

Proposed Rule Display Version Pages 168 - 173

Background: Outpatient payment rates are determined by multiplying the relative weight for an APC by the conversion factor. The CY 2010 conversion factor is \$67.241.

CMS’ Proposal: *“The proposed OPD fee schedule increase factor of 2.15 percent for CY 2011, the required proposed wage index budget neutrality adjustment of approximately 1.0011, the proposed cancer hospital budget neutrality adjustment of 0.9934, and the proposed adjustment of 0.06 percent of projected OPSS spending for the difference in the pass-through spending result[s] in a proposed conversion factor for CY 2011 of \$68.267 . . .”*

For hospitals that did not meet HOP QDRP requirements for CY 2010, CMS will apply a reduction of 2.0 percentage points to the CY 2011 marketbasket update.

WAGE-INDEX ADJUSTMENT

Proposed Rule Display Version Pages 173 - 180

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 adjust 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 IPPS.

CMS' Proposal: CMS will continue to its policy to use the IPPS wage indexes under OPSS. CMS will apply the final FFY 2011 IPPS wage indexes for calculating OPSS payments in CY 2011.

Section 10324 of PPACA established a wage index floor of 1.0000 for all hospitals located in "Frontier States." A Frontier State is defined as any state where at least half of its counties have a population density of less than six people per square mile. Based on this definition, CMS determined that Montana, Nevada, North Dakota, South Dakota, and Wyoming qualify as Frontier States. The wage index floor of 1.0000 is effective for outpatient services furnished on or after January 1, 2011. Only hospitals that are geographically located in a Frontier State qualify for the floor; hospitals that reclassify into these states are ineligible.

Section 10317 of PPACA also extended Section 508 wage index reclassifications for one additional year, through September 30, 2010. CMS does not have the authority to extend Section 508 reclassifications beyond CY 2010 without legislation.

RURAL SOLE COMMUNITY HOSPITAL ADJUSTMENT

Proposed Rule Display Version Pages 190 - 191

Background: As authorized by MMA, in the CY 2006 OPSS final rule, CMS established a 7.1% payment increase for rural SCHs for all services and procedures paid under OPSS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy.

CMS' Proposal: For CY 2011, CMS proposes ". . . to continue . . . a budget neutral 7.1 percent payment adjustment to 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."

HOLD HARMLESS TRANSITIONAL OUTPATIENT PAYMENTS

Proposed Rule Display Version Pages 186 - 189

Background: When OPSS was implemented, hold-harmless transitional outpatient payments (TOPs) 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 OPSS and the prior payment system. Other hospitals were eligible for partial relief.

Over the past several years, legislative extensions have maintained TOPs to rural hospitals and SCHs with 100 or fewer beds. Most recently, PPACA extended the transitional payments for rural hospitals and SCHs with 100 or fewer beds through December 31, 2010. Cancer hospitals and children's hospitals are permanently held harmless from the impact of OPSS. CMS does not have the authority to extend these payments beyond CY 2010 without legislation.

CMS' Proposal: "Effective for services provided on or after January 1, 2011, rural hospitals having 100 or fewer beds that are not SCHs and SCHs (including EACHs) will no longer be eligible for hold harmless TOPs . . ."

PAYMENT ADJUSTMENT FOR CERTAIN CANCER HOSPITALS

Proposed Rule Display Version Pages 191 - 206

Background: Since the inception of OPSS, Medicare has paid cancer hospitals under OPSS for covered outpatient hospital services. There are 11 cancer hospitals nationwide. Under OPSS, cancer hospitals are

permanently eligible for hold-harmless TOPs to ensure that they do not receive a payment that is lower under OPSS than the payment they would have received before implementation of OPSS.

Section 3138 of PPACA requires CMS to conduct a study to determine if the outpatient costs incurred by cancer hospitals exceed the costs of other OPSS hospitals. If appropriate, the law requires CMS to provide a payment adjustment to cancer hospitals for outpatient services furnished on or after January 1, 2011.

CMS' Proposal: Based on an analysis of Medicare outpatient claims data and Medicare cost report data, CMS found that cancer hospitals, as a group, have a significantly lower volume weighted average payment-to-cost ratio (PCR) than the volume weighted PCR of other OPSS hospitals. CMS also found that that the cancer hospitals cost per discounted unit standardized for service mix is higher than the standardized cost per discounted unit of all other hospitals.

CMS stated, “. . . we are proposing an adjustment for cancer hospitals to reflect these higher costs effective January 1, 2011, as mandated by section 3138 of the Affordable Care Act.

“We propose that this hospital-specific adjustment would be applied to the wage adjusted payments for all items, except for items and services paid at charges adjusted to cost or devices receiving pass-through status . . .

“We note that the proposed adjustment for all cancer hospitals would result in an estimated aggregate increase in OPSS payments to cancer hospitals of 41.2 percent for CY 2011”

Cancer hospitals remain eligible for both TOPs and outlier payments. The payment adjustment will be applied in a budget-neutral manner through a reduction to the conversion factor.

Table 11, on pages 204 - 205 of the proposed rule display version, lists OPSS payment adjustments available to cancer hospitals.

COST OUTLIERS

Proposed Rule Display Version Pages 207 - 212 and Pages 397 - 398

Background: Outlier payments are provided under OPSS 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, with a portion of that equal to 0.04 percent which is set aside to allocate partial hospitalization program (PHP) outlier payments to community mental health centers (CMHCs).

CMS pays outlier payments under OPSS at 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 threshold and the fixed-dollar threshold are met. For CY 2010, the outlier fixed-dollar threshold is \$2,175. For CMHCs, if the cost for partial hospitalization services exceeds 3.40 times the payment for APC 0173, the outlier payment is paid at 50% of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

CMS' Proposal: *“To ensure that the estimated CY 2011 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS . . . we are proposing to continue to make an outlier payment that equals 50 percent 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 proposed fixed-dollar \$2,025 threshold are met.”*

CMS proposes no change to the CMHC outlier threshold or calculation.

CALCULATION OF COST-TO-CHARGE RATIOS (CCRs)

Proposed Rule Display Version Pages 77 - 84

Background: Currently, to calculate the APC median costs on which APC payment rates are based, CMS converts charges to cost by calculating hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital using the most recent available OPSS claims data and Medicare cost reports.

Since the inception of OPSS, there has been concern that the use of cost-based weights could create a potential bias due to “charge compression.” Charge compression is the practice of applying a lower charge markup to higher-cost services and a higher charge markup to lower-cost services. This could cause cost-based weights to reflect an aggregation bias by undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center.

In August 2007, CMS contracted with RTI International 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 at <http://www.rti.org>. In this report, RTI made eight recommendations specific to non-IPPS payment settings that include short-term and long-term accounting changes to the cost report. As a result of RTI’s findings, CMS modified its cost report software, incorporated new standard and non-standard cost centers, and eliminated outdated requirements in an attempt to improve the accuracy of the cost data in the Medicare cost report used to calculate the OPSS relative weights.

CMS’ Proposal: CMS proposes no change to its policy to use hospital-specific overall ancillary and departmental CCRs to convert charges to cost for the calculation of APC median costs. CMS notes that it will continue to examine ways in which it can improve the accuracy of the cost estimation process.

PAYMENT STATUS AND COMMENT INDICATORS

Proposed Rule Display Version Pages 447 - 456

Background: Payment status indicators assigned to Healthcare Common Procedure Coding System (HCPCS) codes and APCs play an important role in determining payment for services under OPSS. Payment status indicators specify whether a service represented by a HCPCS code is payable under OPSS or another payment system and also whether particular OPSS policies apply to the code.

CMS’ Proposal: *“We are not proposing any changes to the status indicators . . . for the CY 2011 OPSS We are not proposing any changes to the definitions of the OPSS comment indicators for CY 2011”*

The payment status and comment indicators that will be used for CY 2011 are available on pages 447 - 456 of the proposed rule display version.

IV. REPORTING HOSPITAL OUTPATIENT QUALITY DATA

CY 2011 PAYMENT DETERMINATIONS (BASED ON CY 2010 QUALITY MEASURES AND PARTICIPATION REQUIREMENTS)

Proposed Rule Display Version Pages 592 - 597

Background: MIEA-TRHCA 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.

For hospitals that fail to meet the HOP QDRP reporting requirements, CMS currently applies a reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates for all services with the status indicators “P,” “Q1,” “Q2,” “Q3,” “R,” “S,” “T,” “V,” “U,” or “X.” New Technology APCs assigned a status indicator of “S” or “T” are exempt from this reduction since the outpatient fee schedule increase factor is not used to update payment rates for these APCs. Brachytherapy sources, exempt from payment reduction in 2009, are currently subject to the reduction.

CMS’ Proposal: *“For the CY 2011 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the reduced conversion factor of \$66.930 by the full conversion factor of \$68.267. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor.”*

CY 2011 QUALITY MEASURES (MEASURES FOR CY 2012 PAYMENT DETERMINATIONS)

Proposed Rule Display Version Pages 559 - 570

Background: In CY 2008, CMS adopted seven outpatient quality measures that had been endorsed by the National Quality Forum under HOP QDRP. These outpatient measures included five ED acute myocardial infarction (ED-AMI) measures and two perioperative care measures. In CY 2009, CMS adopted four additional imaging measures for CY 2010 payment determinations. In the CY 2010 final rule, CMS did not adopt any new measures for CY 2011 payment determinations. Hospitals that fail to successfully report the 11 measures in CY 2010 will receive a reduction of 2.0 percentage points to the marketbasket update in CY 2011.

CMS’ Proposal: *“. . . for the CY 2012 payment determination, we are proposing to retain the 11 existing HOP QDRP measures for the CY 2011 payment determination, to add one new structural measure, four new claims-based imaging efficiency measures, and one new chart-abstracted measure for the ED AMI population.*

“Submission of data regarding the new structural measure would begin with January 1, 2011 discharges using a Web-based collection tool available on the QualityNet Web site.

“We are proposing to calculate the four imaging measures using Medicare claims from calendar year 2010.

“Data collection for the chart-abstracted measure would begin with January 1, 2011 discharges, and data would be submitted quarterly beginning with the first quarter of 2011, as with all other chart-abstracted measures.”

The table below lists quality measures to be reported in CY 2011 and used for CY 2012 payment determinations. Hospitals that fail to successfully report the 17 measures in CY 2011 will receive a reduction of 2.0 percentage points to the marketbasket update in CY 2012.

HOP QDRP Quality Measures for CY 2012 Payment Determination
(The New HOP QDRP Measures for CY 2012 Payment Determinations Are Highlighted in the Chart)

Topic	Measure	Potential Data Sources
AMI	OP-1: Median Time to Fibrinolysis	Chart, Electronic Health Record
	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Arrival	
	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	
	OP-4: Aspirin at Arrival	
	OP-5: Median Time to Electrocardiogram (ECG)	
Surgery	OP-6: Timing of Antibiotic Prophylaxis	Chart, Electronic Health Record
	OP-7: Prophylactic Antibiotic Selection for Surgical Patients	
Imaging Efficiency	OP-8: MRI Lumbar Spine for Low Back Pain	Claims
	OP-9: Mammography Follow-up Rates	
	OP-10: Abdomen CT - Use of Contrast Material	
	OP-11: Throat CT - Use of Contrast Material	
Electronic Health Record	The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data	Electronic Health Record
Imaging Efficiency	Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment	Claims
	Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG	
	Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	
	Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache	
AMI/Chest Pain	Troponin Results for Emergency Department Acute Myocardial Infarction (AMI) Patients or Chest Pain Patients (with Probable Cardiac Chest Pain) Received Within 60 Minutes of Arrival	Chart, Electronic Health Record

HOP QDRP PARTICIPATION REQUIREMENTS FOR CY 2012 (REQUIREMENTS FOR CY 2012 PAYMENT DETERMINATIONS)

Proposed Rule Display Version Pages 597 - 623

Background: To participate in the HOP QDRP, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). For the most part, these procedures and requirements mirror those currently in place under the IPSS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

CMS’ Proposal—Administrative Requirements: *“To participate in the HOP QDRP, we are proposing that several administrative steps be completed. These steps would require the hospital to:*

- *“Identify a QualityNet security administrator who follows the registration process located on the QualityNet Web site (<http://www.QualityNet.org>) and submits the information to the appropriate CMS-designated contractor.*
- *“Register with QualityNet, regardless of the method used for data submission.*
- *“Complete and submit an online participation form if this form (or a paper Notice of Participation form) has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a*

new CCN. For HOP QDRP decisions affecting the CY 2012 payment determination, hospitals that share the same CCN would be required complete a single online participation form.”

CMS’ Proposal—Data Collection and Submission Requirements: *“We are proposing that, to be eligible for the full CY 2012 OPSS payment update, hospitals would be required to . . . submit data for each applicable quarter by the deadline posted on the QualityNet Web site; there must be no lapse in data submission.”*

“For the CY 2012 annual payment update, the applicable quarters would be as follows: 3rd quarter CY 2010, 4th quarter CY 2010, 1st quarter CY 2011, and 2nd quarter CY 2011.

“For the claims-based measures, we would calculate the measures using the hospital’s Medicare claims data. For the CY 2012 payment update, we would utilize paid Medicare fee-for-service (FFS) claims submitted prior to January 1, 2011, to calculate these measures.

“For the structural measure to be used for the CY 2012 payment determination, hospitals would be required to submit data beginning with January 1, 2011 discharges using a Web-based tool available on QualityNet beginning in 2011.”

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.

Additional information regarding case sampling and case thresholds related to HOP QDRP, along with information regarding extraordinary circumstance extensions and waivers for reporting quality measures is available on proposed rule display version pages 603 - 610.

CMS’ Proposal—Validation Requirements: *“Similar to our proposal for the FY 2012 RHQDAPU program . . . we are proposing to validate data from 800 randomly selected hospitals (approximately 20 percent of all participating HOP QDRP hospitals) each year, beginning with CY 2012 payment determination.”*

“For each selected hospital, we are proposing to randomly select up to a total of 48 self-reported cases from the total number of cases (12 per quarter) that the hospital successfully submitted to the OPSS Clinical Warehouse. However, if a selected hospital has submitted less than 12 cases in any quarter, only those cases available would be validated.”

“We are proposing to sample data for April 1, 2010 to March 31, 2011 . . . to make the CY 2012 payment determinations.”

“To receive the full OPSS payment update, we are proposing that hospitals must attain at least a 75 percent validation score, based upon our validation process, for the designated time period.”

CMS’ Proposal—Reconsideration and Appeals Procedures: In 2009, CMS implemented a reconsideration submission process for HOP QDRP modeled after the reconsideration process implemented under the IPSS RHQDAPU program. Under this process, hospitals must submit to CMS, via QualityNet, a reconsideration request form that will be made available on the QualityNet Web site. For CY 2012 payment determinations, this form must be submitted by February 3, 2012.

CY 2012 AND 2013 QUALITY MEASURES (MEASURES FOR CY 2013 AND 2014 PAYMENT DETERMINATIONS)

Proposed Rule Display Version Pages 570 -592

Background: In prior years, CMS proposed measures for one payment determination in a given rulemaking cycle. Beginning with the CY 2011 rulemaking cycle and going forward, CMS will propose the addition of new measures over a three-year period.

CMS' Proposal—CY 2012 Quality Measures (Measures for CY 2013 Payment Determinations): “. . . for the CY 2013 payment determination, we are proposing to retain all of the measures adopted for the CY 2012 payment determination, and to adopt one new structural measure, and six new chart-abstracted measures . . . on the topics of HOPD care transitions and ED efficiency.

“Submission of the new structural measure would begin with first quarter CY 2012 discharges to be submitted via a Web-based tool on the QualityNet Web site in 2012.

“The submission of the new chart-abstracted measures for the CY 2013 payment determination would begin with first quarter CY 2012 discharges, to be submitted in 2012.”

The table on pages 579 - 580 of the proposed rule display version lists the 24 proposed quality measures to be reported in CY 2012 and used for CY 2013 payment determinations.

CMS' Proposal—CY 2013 Quality Measures (Measures for CY 2014 Payment Determinations): “. . . for the CY 2014 payment determination, we are proposing to retain all of the measures adopted for the CY 2013 payment determination, and to adopt six new chart-abstracted measures . . . on the topics of diabetes care and exposure time for procedures using fluoroscopy.”

“We are proposing that submission of the new chart-abstracted measures for the CY 2014 payment determination begin with first quarter CY 2013 discharges to be submitted in 2013.”

The table on pages 588 - 589 of the proposed rule display version lists the 30 proposed quality measures to be reported in CY 2013 and used for CY 2014 payment determinations.

HEALTH CARE-ASSOCIATED CONDITIONS

No Proposed Rule Display Version Pages Available on this Topic

In 2005, Congress authorized CMS to adjust Medicare IPPS hospital payments to encourage the prevention hospital-acquired conditions (HACs). Since October 1, 2008, the Medicare program has reduced inpatient payments to hospitals for certain cases where one of the conditions recognized under the HAC categories was not present on admission (POA) and, therefore, was considered to be acquired in the hospital. CMS currently recognizes 12 Medicare HAC categories as preventable under IPPS.

There is currently no HAC payment policy under OPSS. In past OPSS proposed rules, CMS considered implementing a Medicare HAC payment policy more broadly to other Medicare payment settings, including OPSS, and has solicited public comment on options and considerations for such a policy, including the statutory authority related to expanding the IPPS HAC provision to OPSS. CMS did not include a discussion of HACs in the 2011 OPSS proposed rule.

V. APC GROUPS AND WEIGHTS

RECALIBRATION OF APC WEIGHTS

Proposed Rule Display Version Pages 54 - 168

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

CMS' Proposal: *“The proposed APC relative weights . . . were calculated using claims from CY 2009 that were processed before January 1, 2010, and continue to be based on the median hospital costs for services in the APC*

groups. We selected claims for services paid under the OPPS and matched these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the median costs underpinning the APC relative payment weights . . .”

APC GROUP REVISIONS

Proposed Rule Display Version Pages 54 - 168

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.

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

APC Category	Status Indicator	2009	2010	2011
Clinic or Emergency Department Visit	V	16	17	17
Significant Procedures, Multiple Reduction Applies	T	183	181	182
Significant Procedures, No Multiple Reduction	S	130	131	130
Ancillary Services	X	40	39	39
Pass-Through Devices Categories	H	8	0	0
Non-Pass-Through Drugs/Biologicals	K	275	293	289
Partial Hospitalization	P	2	2	4
Blood and Blood Products	R	25	34	34
Brachytherapy Sources	U	16	16	16
New Technology	S/T	82	82	82
Total		777	795	793

APPLICATION OF THE “2 TIMES RULE”

Proposed Rule Display Version Pages 234 - 241

Background: The “2 times rule” provides CMS guidance as it assigns new procedures or reassigns existing procedures into an APC group. Under OPPS, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost for an item or service in the group is more than double the lowest median cost for an item or service within the same group. Subject to certain exceptions, APC groups cannot violate the 2 times rule.

Each year, CMS reviews the items and services within an APC group to determine violations of the 2 times rule and proposes exceptions to this limit in unusual cases.

CMS’ Proposal: For CY 2011, CMS proposes to exempt “. . . 17 APCs . . . from the 2 times rule . . .”

A complete list of the proposed APC exceptions to the 2 times rule is available on Table 16, located on pages 240 – 241 of the proposed rule display version.

NEW TECHNOLOGY APCS

Proposed Rule Display Version Pages 241 - 253

Background: Since CY 2002, CMS retains services within new technology APC groups until sufficient claims data are available to assign the service to a clinically appropriate APC. This policy allows CMS to move a service from a new technology APC in less than two years if sufficient data are available or retain a service in a new

technology APC for more than three years if sufficient data are not available. Currently, new technologies are assigned to cost bands that range from:

- \$0 to \$50 in increments of \$10;
- \$50 to \$100 in an increment of \$50;
- \$100 through \$2,000 in intervals of \$100; and
- \$2,000 through \$10,000 in intervals of \$500.

The cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under OPSS. Payment for each APC is made at the mid-point of the APC's assigned cost band.

CMS retains two parallel sets of New Technology APCs, one set with a status indicator of "S" (Significant Procedures, Not Discounted when Multiple) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies). Currently, there are 82 New Technology APCs.

CMS' Proposal: ". . . we are proposing to reassign HCPCS G-code G0416 from New Technology APC 1505 to clinical APC 0661 (Level V Pathology), which has an APC median cost of approximately \$165, and HCPCS G-code G0417 from New Technology APC 1507 (New Technology – Level VII (\$500 to \$600)) to New Technology APC 1506 (New Technology - Level VI (\$400 - \$500))."

Table 17, on page 247 of the proposed rule display version, lists the reassignment of the two new technology procedures.

CMS is also proposing APC-specific policy changes related to the application of Apligraf, Dermagraft, and Oasis skin substitutes (APCs 0134 and 0135).

VI. ENCOUNTER-BASED AND EPISODE-BASED PAYMENTS UNDER OPSS

For OPSS 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. Under OPSS, 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

Proposed Rule Display Version Pages 120 - 144

Background: In CY 2008, CMS established several composite APCs to provide a single payment when a specified combination of procedures is performed on the same date of service (based on reported HCPCS codes), rather than paying for each service individually. CMS believes that paying for composite APCs will enable hospitals to manage their resources with flexibility while adjusting the volume and efficiency of services themselves.

Currently, CMS has composite APC policies for extended assessment and management services, low-dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services.

CMS' Proposal: For CY 2011, CMS proposes no change to its current policy. The table below lists the ten APCs that are 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

At the recommendation of the APC Panel, CMS will consider, for future rulemaking, creating a composite APC or custom APC that captures the costs of stem cell acquisition performed in conjunction with recipient transplantation. CMS will also study the feasibility of expanding the extended assessment and management composite APC methodology to include services commonly furnished in conjunction with visits and observation services, such as drug infusion, electrocardiogram, and chest X-ray.

PACKAGED SERVICES

Proposed Rule Display Version Pages 144 - 165

Background: In CY 2008, CMS expanded its practice of packaging 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 individual service-based payments and creating more packaged services.

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. CMS assigns one of two status indicators to these HCPCS codes:

- Status indicator “N” denotes procedures that are unconditionally packaged. CMS always packages the cost of the procedure into the costs of the separately paid primary services with which they are billed.
- Status indicators “Q1” (“STVX-Packaged Codes”), “Q2” (“T-Packaged Codes”), and “Q3” (codes that may be paid through a composite APC) denote procedures that are conditionally packaged. In these cases, the procedure is either packaged or separately paid, depending on the services with which it is reported.

As a result of the expansion of packaged services 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 as a result of the expansion of packaging in CY 2008.

CMS' Proposal: For CY 2011, CMS is not proposing further expansion of its packaging policy.

VII. TRANSITIONAL PASS-THROUGH PAYMENTS FOR DRUGS AND DEVICES

TRANSITIONAL PASS-THROUGH SPENDING

Proposed Rule Display Version Pages 345 - 357

Background: BBRA provides for temporary additional payments or “transitional pass-through payments” under OPSS 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: *“We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPSS payments for CY 2011 we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2011 and those device categories, drugs, and non-implantable biologicals that first become eligible for pass-through payment during CY 2011 would be approximately \$86.9 million, which represents 0.20 percent of total OPSS projected total payments for CY 2011. We estimate that pass-through spending in CY 2011 would not amount to 2.0 percent of total projected OPSS CY 2011 program spending.”*

TRANSITIONAL PASS-THROUGH PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Proposed Rule Display Version Pages 266 - 287

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

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, CMS suspended the CAP program in the CY 2009 final rule.

Therefore, for drugs and biologicals, the pass-through payment equals the difference between ASP + 6% and the applicable fee schedule portion associated with the drug or biological.

CMS' Proposal: *“We are proposing that the pass-through status of 18 drugs and biologicals would expire on December 31, 2010”*

Table 20, on pages 270 - 271 of the proposed rule display version, lists 18 drugs and biologicals for which pass-through status will expire in CY 2011.

“We are proposing to continue pass-through status in CY 2011 for 31 drugs and biologicals.”

“ . . . we are 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 2011.”

For CY 2011, the pass-through payment amount for most pass-through drugs and biologicals will be \$0.00 because the difference between ASP + 6 percent and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP + 6 percent is \$0.

Table 21, on pages 276 – 277 of the proposed rule display version, lists 31 drugs and biologicals for which pass-through status will continue in CY 2011.

“ . . . one radiopharmaceutical with pass-through status under the OPPS . . . will continue on pass-through status in CY 2011.”

For CY 2011, new pass-through diagnostic radiopharmaceuticals will be paid at ASP + 6 percent, while those without ASP information will be paid at wholesale acquisition cost (WAC) + 6 percent or, if WAC is not available, payment will be based on 95% of the product’s most recently published average wholesale price (AWP).

TRANSITIONAL PASS-THROUGH PAYMENT FOR DEVICES

Proposed Rule Display Version Pages 253 - 259

Background: The law limits OPPS 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 OPPS payment rate associated with the device. There are currently no device categories eligible for pass-through payment.

CMS’ Proposal: For CY 2011, CMS proposes no change to its current policy. There continues to be no device categories eligible for pass-through payment.

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

PACKAGING CRITERIA FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Proposed Rule Display Version Pages 287 - 290

Background: Under OPPS, CMS currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment into the payment for the associated service; or separate payment (individual APCs). Generally, packaging status is based on a comparison of CMS-calculated per-day cost of the item to a packaging threshold. For CY 2010, the packaging threshold was set at \$65.

CMS’ Proposal: For CY 2011, CMS is *“ . . . proposing a packaging threshold . . . of \$70.”*

PAYMENT FOR SEPARATELY PAYABLE DRUGS, BIOLOGICALS, AND THERAPEUTIC RADIOPHARMACEUTICALS (THOSE WITHOUT PASS-THROUGH STATUS THAT ARE NOT PACKAGED)

Proposed Rule Display Version Pages 305 - 336

Background: For separately payable drugs, biologicals, and therapeutic radiopharmaceuticals, CMS has used various methodologies to establish payment rates that account for acquisition and pharmacy overhead costs. CMS has often used ASP plus a specified percentage as a proxy to establish a combined payment rate for drug and biological acquisition and pharmacy overhead costs. Therapeutic radiopharmaceuticals have typically been paid at charges adjusted to cost.

In CY 2010, CMS developed a refined methodology in an attempt to better account for pharmacy overhead costs and using claims data and Medicare cost report data established payment for separately payable drugs, biologicals, and therapeutic radiopharmaceuticals at ASP + 4%. For therapeutic radiopharmaceuticals where no ASP information was available, payment was based on mean unit cost data derived from hospital claims.

CMS' Proposal: For CY 2011, CMS proposes to provide payment for separately payable drugs, biologicals, and therapeutic radiopharmaceutical at *"ASP+6 percent."*

CMS will use the same methodology used in CY 2010 to account for pharmacy overhead costs in establishing payment rates for separately drugs, biologicals, and therapeutic radiopharmaceuticals. For therapeutic radiopharmaceuticals where no ASP information is available, payment will continue to be based on mean unit cost data derived from hospital claims. In addition, CMS will continue to pay 340B hospitals at the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program.

PAYMENT FOR BLOOD CLOTTING FACTORS

Proposed Rule Display Version Pages 336 - 337

Background: Currently, CMS provides payment for blood clotting factors at ASP + 4% plus an additional payment for the furnishing fee. The furnishing fee is currently \$0.170 per unit. The furnishing fee provided under OPFS is updated each year in the Medicare Physician Fee Schedule (MPFS) final rule.

CMS' Proposal: For CY 2011, CMS proposes *" . . . to pay for blood clotting factors at ASP+6 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 OPFS HOSPITAL CLAIMS DATA

Proposed Rule Display Version Pages 337 - 345

Background: Since CY 2005, CMS has established varying policies and payment rates to pay for separately payable non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without OPFS hospital claims data.

Currently, CMS provides payment for new drugs (excluding contrast agents), non-implantable biologicals, and therapeutic radiopharmaceutical with HCPCS codes that do not have pass-through status and are without OPFS hospital claims data, at ASP + 4%, consistent with the CY 2010 payment methodology for other separately payable non-pass-through drugs, and non-implantable biologicals.

CMS' Proposal: *"We are proposing to provide payment for new CY 2011 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals , at ASP+6*

percent, consistent with the proposed CY 2011 payment methodology for other separately payable non pass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals.”

“In accordance with the OPPTS ASP methodology, in the absence of ASP data, for CY 2011, we are proposing to continue the policy we 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 [and new therapeutic radiopharmaceuticals] with HCPCS codes, but which are without OPPTS 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.”

IX. OTHER

PHYSICIAN SUPERVISION

Proposed Rule Display Version Pages 402 - 430

Background: In CY 2000, CMS established, as a condition of payment, the requirements for physician supervision of diagnostic and therapeutic services provided to hospital outpatients incident to a physician’s service.

CMS has defined supervision in the hospital outpatient setting by drawing on the three levels of supervision defined under the MPFS: general, direct, and personal supervision. Generally, CMS defines these levels of supervision as follows:

- General Supervision: Services furnished under the overall direction and control of the physician, but his or her physical presence is not required during the performance of the procedure.
- Direct Supervision: The physician is physically present on site and is immediately available to furnish assistance and direction throughout the performance of the procedure. However, it does not mean the physician must be present in the same room when the procedure is being performed.
- Personal Supervision: The physician is present in the room when the service is being performed.

Outpatient Therapeutic Services

For outpatient therapeutic services, CMS has defined and clarified that “direct supervision” is the standard for physician supervision. The direct supervision standard applies to all hospital outpatient therapeutic services, regardless of their on-campus or off-campus location.

Non-physician practitioners, including clinical psychologists, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, and licensed clinical social workers, may directly supervise outpatient therapeutic services that they are able to personally furnish in accordance with state law and all additional requirements, including the Medicare coverage rules relating to their services.

The direct supervision requirement for payment of hospital outpatient therapeutic services incident to a physician or non-physician practitioner service applies to both hospitals and CAHs.

Outpatient Diagnostic Services

For outpatient diagnostic services, the supervision standard (direct, general, or personal) follows the physician supervision levels for the individual tests as listed in the MPFS Relative Value File. The applicable supervision standard applies regardless of whether the outpatient diagnostic services were provided in a hospital, in a provider-based department of hospital, or at a non-hospital location. Physician supervision of outpatient diagnostic services is required unless a non-physician practitioner is specified as exempt. The supervision requirements for payment of hospital outpatient diagnostic services do not apply to CAHs.

CMS' Proposal—Supervision of Outpatient Therapeutic Services: “. . . we are proposing modest changes to our supervision policy for therapeutic services . . . in the hospital outpatient setting as a requirement for payment.

“. . . we are proposing to require, for a limited set of nonsurgical extended duration therapeutic services, direct supervision during the initiation of the service followed by general supervision for the remainder of the service.

“We are proposing to define ‘initiation of the service’ as the beginning portion of a service ending when the patient is stable and the supervising physician or appropriate nonphysician practitioner believes the remainder of the service can be delivered safely under their general direction and control without their physical presence on the hospital campus or in the PBD of the hospital.

“We are proposing to adopt the definition of ‘general supervision’ in §410.32(b)(3)(i), which is the same definition of general supervision that we already recognize as appropriate for diagnostic services with a general supervision level requirement under the MPFS.”

Table 37, on pages 424 - 425 of the proposed rule display version, lists the proposed nonsurgical extended duration therapeutic services to which the revised outpatient therapeutic services supervision policy will apply.

This change would apply to both PPS hospitals and CAHs for CY 2011. CMS is seeking input as to whether to exempt CAHs from a direct supervision requirement for outpatient therapeutic services.

CMS' Proposal—Supervision of Outpatient Diagnostic Services: “. . . we are making a clarifying proposal in the CY 2011 MPFS proposed rule that clinical nurse-midwives should be excepted from requiring physician supervision for the diagnostic tests that they are authorized to perform under applicable State laws.”

PAYMENT FOR PARTIAL HOSPITALIZATION

Proposed Rule Display Version Pages 388 - 398

Background: Partial hospitalization is an intensive outpatient psychiatric program of services 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 OPSS, 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.

Over the years, CMS has implemented refinements to the methodology used for computing the PHP median, to control median per diem costs. In CY 2009, CMS began using 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).

In 2010, CMS is using only hospital-based PHP data to determine the appropriate per diem rates since CMHCs' data have fluctuated significantly each year.

CMS' Proposal: “. . . we believe that we can no longer . . . continue to base the PHP payment rates using only hospital-based data.”

“We believe that the results of our analysis of the claims data indicate a need to establish payment rates for each provider type based on its own unique cost structures.”

“. . . for CY 2011, we are proposing to compute four separate PHP APC per diem payment rates, two for CMHC PHPs (for Level I and Level II services using only CMHC data) and two for hospital-based PHPs (Level I and Level II services using only hospital-based PHP data).”

“Creating the proposed four payment rates (two for CMHC PHPs and two for hospital-based PHPs) would support continued access to the PHP benefit, including a more intensive level of care, while also providing appropriate payment based on the unique cost structures of CMHC PHPs and hospital-based PHPs.”

The table below lists the proposed CY 2011 APCs median per diem costs for PHP services by provider type.

APC	Group Title	Per Diem Rate
0172	Level I Partial Hospitalization (3 services) for CMHCs	\$118.19
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	\$123.35
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	\$184.47
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	\$235.58

Section 1301 of PPACA revised the statutory definition of a CMHC and the description of what constitutes a PHP. Beginning April 1, 2011, CMHCs must provide at least 40% of its services to individuals who are not Medicare beneficiaries. For PHPs, the description of a PHP has been modified by PPACA to specify that the program must be a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care “other than in an individual’s home or in an inpatient or residential setting.”

PAYMENT FOR BRACHYTHERAPY SOURCES

Proposed Rule Display Version Pages 357 - 367

Background: Currently, CMS pays for separately payable brachytherapy sources under the general OPPTS methodology using median costs based on claims data to set the relative payment weights. As required by law, CMS established separate payment groups for “stranded and non-stranded” brachytherapy sources furnished on or after July 1, 2007. CMS currently pays for the stranded and non-stranded not-otherwise-specified (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. Brachytherapy sources are eligible to be used in determining outlier payments under OPPTS and payment weights are scaled for the purposes of budget neutrality.

Before CY 2010 (from CY 2004 through 2009), legislation required that all devices of brachytherapy consisting of a seed or seeds (or radioactive source) be classified separately from other services or groups of services and be paid based on a facility’s charges adjusted to cost. Because brachytherapy sources were paid at cost, they were not eligible to be used in determining outlier payments under OPPTS and payments for these sources were exempt from budget neutrality requirements.

CMS’ Proposal: For CY 2011, CMS proposes no change to its current policy.

Table 29, on pages 365 - 366 of the proposed rule display version, lists the proposed separately payable brachytherapy sources for CY 2011.

PAYMENT FOR DRUG ADMINISTRATION SERVICES

Proposed Rule Display Version Pages 370 - 376

Background: In CY 2007, CMS adopted the use of a full set of CPT codes for the reporting of drug administration services. Currently, CMS pays separately for the drug administration codes and assigns the separately paid drug administration codes to five APCs.

CMS' Proposal: For CY 2011, CMS proposes no change to its current policy. CMS believes the current assignment of separately paid drug administration codes to five APCs continues to appropriately reflect the relative resources required to furnish these services.

Table 30, on pages 372 - 376 of the proposed rule display version, lists the proposed configuration of the five drug administration APCs for CY 2011.

Addendum B, proposed rule display version pages 1043 – 1529, lists the payment rate for each of the proposed drug administration APCs.

PAYMENT FOR THERAPY SERVICES

Proposed Rule Display Version Pages 446 - 447

Background: By law, outpatient physical therapy (including speech language pathology services) and outpatient occupational therapy services are excluded from payment under OPSS. Hospitals are paid for these services under MPFS.

CMS' Proposal: *“For CY 2011, we are proposing to revise the MPFS to apply a multiple procedure reduction to payment for all outpatient physical and occupational therapy services paid under the MPFS.”*

CMS also included this proposal in the CY 2011 MPFS rule. Because hospitals are paid for therapy services under MPFS, the expansion of the multiple procedure reduction to these services under MPFS will apply to hospital payment.

PAYMENT FOR NO-COST/FULL CREDIT AND PARTIAL CREDIT DEVICES

Proposed Rule Display Version Pages 259 - 266

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.

Currently, hospitals are required to report an “FB” modifier on the line with the procedure code in which a device was furnished without cost or with a full credit. OPSS payments for implantation procedures are reduced by 100% of the device offset for no cost/full credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC.

In addition, hospitals are required to report an “FC” modifier on the line with the procedure code in which a device was furnished with partial credit of 50% or more of the cost of the new device. OPSS payments for implantation procedures are reduced by 50% of the device offset for partial credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC.

To set rates for device-dependent APCs under OPSS, CMS uses only claims that contain the correct device code for the procedure, do not contain token charges (a device charge of less than \$1.01 in cases where the device is furnished without cost or full credit), do not contain the “FB” modifier, and do not contain the “FC” modifier.

Beneficiary copayment is based on the reduced payment amount when either the “FB” or the “FC” modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

CMS uses the three criteria for determining the APCs to which this policy applies. Specifically, (1) all procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient’s body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40% of the APC cost.

CMS' Proposal: For CY 2011, CMS proposes no change to the existing policy.

Table 18 on page 264 of the display version of the proposed rule lists the proposed APCs to which the payment adjustment policy would apply in CY 2011. Table 19 on page 265 of the display version of the proposed rule lists the proposed devices to which this policy would apply in CY 2011.

PAYMENT FOR PULMONARY, CARDIAC, AND INTENSIVE CARDIAC REHABILITATION SERVICES

Proposed Rule Display Version Pages 445 - 446

Background: MIPPA of 2008 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.

Historically, individual services that comprise comprehensive PR have been reported separately with existing HCPCS codes that are paid under OPSS based on the resulting APC assignment. CMS believes that there is an existing clinical APC for PR that could be assigned appropriately under OPSS based on the information currently available.

Currently, CR furnished by hospitals is 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 should be similar, and OPSS payment for CR and ICR should be provided on a per-session basis.

Since the CY 2010 final rule, CMS has received several inquiries as to whether a CAH outpatient department is a covered setting for services furnished under these programs.

CMS' Proposal: For CY 2011, CMS is “. . . clarifying that a CAH outpatient department is considered a covered setting for PR, CR and ICR programs, provided that the programs meet all of the regulatory requirements, including, but not limited to, direct supervision of all services by a physician . . .”

UPDATES TO THE “INPATIENT-ONLY” LIST

Proposed Rule Display Version Pages 400 - 402

Background: Under OPSS, CMS identifies procedures that are typically provided only in an inpatient setting, and therefore would not be paid under OPSS. These procedures comprise what is referred to as the “inpatient-only” list. The inpatient-only list specifies those services that only will 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 paid under OPSS.

CMS' Proposal: For CY 2011, CMS proposes to remove “. . . the following three procedures from the . . . inpatient list: CPT codes 21193 (Reconstruction of mandibular rami; horizontal, vertical, C, or L osteotomy; without bone graft); 21395 (Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)); and 25909 (Amputation, forearm, through radius and ulna; reamputation).”

VISIT CODES FOR CLINIC VISITS, ED VISITS, AND CRITICAL CARE SERVICES

Proposed Rule Display Version Pages 376 - 388

Background: Currently, CMS instructs hospitals to report visit codes for three types of OPPS services: clinic visits, ED visits, and critical care services. Under OPPS, CMS recognizes:

- **Clinic Visit Codes:** Codes defined in the CPT code book to report evaluation and management (E/M) services provided in the physician’s office or in an outpatient or other ambulatory facility.
- **ED Visit Codes:** Codes used to report E/M services provided in the ED. ED visit codes consist of five CPT codes that apply to Type A EDs and five Level II HCPCS codes that apply to Type B EDs.
- **Critical Care Codes:** CPT codes used by hospitals to report critical care services that involve the “direct delivery by a physician(s) of medical care for a critically ill or critically injured patient,” as defined by the CPT code book. CMS also recognizes HCPCS code G0390 (Trauma response team associated with hospital critical care service) for the reporting of a trauma response in association with critical care services.

CMS believes that CPT 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. 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 ED 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 ED visit distributions and found that hospitals were billing in an appropriate and consistent manner between visit levels, resulting in normal distributions nationally under OPPS.

CMS’ Proposal: *“We continue to believe that, based on the use of their own internal guidelines, hospitals are generally billing in an appropriate and consistent manner that distinguishes among different levels of visits based on their required hospital resources.”*

“As a result of our updated analyses, we are encouraging hospitals to continue to report visits during CY 2011 according to their own internal hospital guidelines.”

“. . . we continue to expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits for purposes of extended assessment and management composite APC payment.”

“Because of our commitment to provide hospitals with 6 to 12 months notice prior to implementation of national guidelines, we would not implement national guidelines prior to CY 2012.”

Table 31, on pages 377 – 378 of the proposed rule display version, lists the proposed CPT and HCPCS codes for reporting clinic and ED visits and critical care services.

BENEFICIARY COPAYMENTS

Proposed Rule Display Version Pages 218 - 221

BBRA mandated 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. However, a 25% copayment is applied for screening flexible sigmoidoscopies and screening colonoscopies.

Section 4104 of PPACA of 2010 eliminated the copayment for preventive services that meet certain requirements, including screening flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure.

The national unadjusted copayment amounts for services payable under OPSS that will be effective January 1, 2011 are shown in Addendum A and B of the proposed rule.