

# **FINAL RULE: MEDICARE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS FOR CY 2013**

## **SUMMARY**

The Centers for Medicare & Medicaid Services (CMS) released the CY 2013<sup>1</sup> final rule with comment on Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system, CMS-1589-P, on November 1, 2012; the rule was published in the November 15, 2012 *Federal Register*. The policies in this rule generally take effect on January 1, 2013.

The rule updates payment policies under the OPPS and applies to outpatient services furnished to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals as well as community mental health centers (CMHCs) for partial hospitalization services. It also makes updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. Other revisions affect the regulations governing Quality Improvement Organizations (QIOs).

Significant changes include:

- using the geometric mean costs of services of an Ambulatory Payment Classification (APC) to determine the relative payment weights of services, rather than the median costs that CMS has used since the inception of the OPPS;
- paying for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status at the statutory default of average sales price (ASP) plus 6 percent;
- continuing the cancer hospital adjustment policies finalized for 2012;
- implementing a new payment adjustment to cover hospitals' marginal cost of conversion to use non-highly enriched uranium (non-HEU) sources to obtain radioisotopes used in medical imaging;
- revising the regulations governing payments for new technology intraocular lens (NTIOLs) to require that the IOL's FDA-approved labeling contain a claim of a specific clinical benefit based on a new lens characteristic in comparison to currently available IOLs;
- extending the 2012 Medicare Electronic Health Record (EHR) Incentive Program Electronic Reporting Pilot for Eligible Hospitals and critical access hospitals (CAHs) through 2013, exactly as finalized for 2012; other changes to the Medicare and Medicaid EHR Incentive programs were finalized in a rule published in the *Federal Register* on September 4, 2012;
- clarifying the application of the supervision regulations to physical therapy, speech-language pathology, and occupational therapy services that are furnished in OPPS hospitals and CAHs and extending the non-enforcement instruction for CAHs and certain small rural hospitals for one final year through 2013.

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<sup>1</sup> Henceforth in this document, a year is a calendar year unless otherwise indicated.

With respect to outpatient observation services, CMS reports receiving roughly 350 comments from a wide variety of stakeholders, the majority of which ask that CMS refrain from implementing a comprehensive solution on the issue and instead seek an ongoing dialogue with interested parties. CMS does not respond to any of the comments in the final rule; rather it summarizes them by issue area and indicates that it may "potentially undertake [future actions] to provide more clarity and consensus regarding patient status for purposes of Medicare payment."

APC classifications with the comment indicator "NI" in the addenda listings and certain specific issues identified in the final rule are open to public comment, with a deadline of 5:00 p.m. Eastern time on December 31, 2012. Comments can be filed electronically. Details of the final rule are provided in the summary below.

The Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS Web site. Addenda relating to the OPSS are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1589-FC.html> and Addenda relating to the ASC payment system are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1589-FC.html>.

## TABLE OF CONTENTS

<b>I. Overview.....</b>	<b>1</b>
A. Estimated Impact of the Final Rule on Hospitals (p.1)	
<b>II. Updates Affecting OPPS Payments.....</b>	<b>2</b>
A. Recalibration of APC Relative Weights (p.2)	
1. Calculation and use of cost-to-charge ratios (CCRs); packaged revenue codes (p.2)	
2. Charge compression (p.3)	
3. Recalibration budget neutrality adjustment (p.3)	
4. Payment for APC 0606, Level III Clinic Visit (p.3)	
5. Calculation of single procedure APC criteria-based costs (p.3)	
6. Calculation of composite APC criteria-based costs (p.5)	
7. Geometric mean-based relative payment weights (p.9)	
8. Changes to packaged services (p.11)	
B. Conversion Factor Update (p.13)	
C. Wage Index Changes (p.14)	
D. Statewide Average Default Cost-to-Charge Ratios (CCRs) (p.14)	
E. OPPS Payment to Certain Rural and Other Hospitals (p.15)	
F. OPPS Payments to Cancer Hospitals (p.16)	
G. Hospital Outpatient Outlier Payments (p.17)	
H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment (p.18)	
I. Beneficiary Copayments (p.18)	
<b>III. OPPS Ambulatory Payment Classification (APC) Group Policies.....</b>	<b>20</b>
A. OPPS Treatment of New HCPCS and CPT Codes (p.20)	
B. OPPS Changes – Variations within APCs (p.21)	
C. New Technology APCs (p.22)	
D. OPPS APC-Specific Policies (p.24)	
<b>IV. OPPS Payment for Devices .....</b>	<b>33</b>
A. Pass-Through Payments for Devices (p.33)	
B. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices (p.35)	
<b>V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals .....</b>	<b>36</b>
A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals and Radiopharmaceuticals (p.36)	
1. Drugs and Biologicals with Expiring Pass-Through Status in 2013	

	(p.36)	
	2. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in 2013 (p.37)	
	3. Provision for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents to Offset Costs Packaged into APC Groups (p.37)	
B.	OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status (p.39)	
	1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals (p.39)	
	2. Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged (p.41)	
	a. Payment for Specified Covered Outpatient Drugs (SCODs) and other Separately Payable and Packaged Drugs and Biologicals (p.41)	
	b. Payment Policy for Therapeutic Radiopharmaceuticals (p.42)	
	c. Payment for Blood Clotting Factors (p.42)	
	d. Payment for New Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPPS Hospital Claims Data (p.42)	
<b>VI.</b>	<b>Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices.....</b>	<b>43</b>
	A. Devices (p.44)	
	B. Drugs and Biologicals (p.44)	
<b>VII.</b>	<b>OPPS Payment for Hospital Outpatient Visits .....</b>	<b>45</b>
	A. Codes (p.45)	
	B. Hospital Outpatient Visit Policies (p.45)	
	C. Transitional Care Management (p.46)	
<b>VIII.</b>	<b>Payment for Partial Hospitalization (PHP) Services .....</b>	<b>47</b>
	A. PHP APC Update for 2013 (p.47)	
	B. Separate Threshold for Outlier Payments to CMHCs (p.47)	
	C. Paladin Cmty. Mental Health Ctr. V. Sebelius (p.47)	
	D. Regulatory Impact (p.48)	
<b>IX.</b>	<b>Procedures That Would Be Paid Only as Inpatient Procedures .....</b>	<b>48</b>
<b>X.</b>	<b>Policies for the Supervision of Outpatient Services in Hospitals and CAHs.....</b>	<b>48</b>
	A. Conditions of Payment for Therapy Services in Hospitals and CAHs (p.48)	

B.	Extension of Nonenforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Small Rural Hospitals (p.49)	
<b>XI.</b>	<b>Outpatient Status: Solicitation of Public Comments .....</b>	<b>49</b>
<b>XII.</b>	<b>OPPS Payment Status and Comment Indicators.....</b>	<b>52</b>
<b>XIII.</b>	<b>OPPS Policy and Payment Recommendations.....</b>	<b>53</b>
<b>XIV.</b>	<b>Updates to the Ambulatory Surgical Center Payment System .....</b>	<b>53</b>
A.	Background (p.55)	
B.	Treatment of New Codes (p.55)	
C.	Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p.56)	
D.	Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services (p.59)	
E.	New Technology Intraocular Lenses (NTIOL) (p.60)	
F.	ASC Payment and Comment Indicators (p.62)	
G.	ASC Policy and Payment Recommendations (p.62)	
H.	Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates (p.62)	
<b>XV.</b>	<b>Hospital Outpatient Quality Reporting Program Updates .....</b>	<b>64</b>
A.	Background (p.64)	
B.	Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations (p.65)	
C.	Removal or Suspension of Quality Measures from the Hospital OQR Program Measure Set (p.65)	
D.	Quality Measures for the 2015 Payment Determination (p.67)	
E.	Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program (p.68)	
F.	Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the 2013 Payment Update (p.69)	
G.	Requirements for Reporting of Hospital OQR Program Data for the 2014 Payment Determination and Subsequent Years (p.69)	
H.	Reconsideration and Appeals Procedures for 2014 and Subsequent Years (p.71)	
I.	Extraordinary Circumstances Extension or Waiver for the 2013 Payment Determination and Subsequent Years (p.71)	
J.	Electronic Health Records (p.71)	
K.	2013 Measure EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (p.72)	

<b>XVI. Requirements for the Ambulatory Surgical Center Quality Reporting Program...</b>	<b>72</b>
A. Background (p.72)	
B. ASCQR Program Quality Measures (p.72)	
C. Requirements for Reporting ASC Quality Data (p.74)	
D. Payment Reduction for ASCs Failing to Meet ASCQR Program Requirements (p.74)	
<b>XVII. Inpatient Rehabilitation Facility Quality Reporting Program Updates.....</b>	<b>75</b>
A. Background (p.75)	
B. Updates to IRF QRP Measures Made as a Result of the NQF Review Process (p.75)	
C. Process for Retention of IRF Quality Measures (p.76)	
D. Measures for the FY 2014 Payment Determination (p.76)	
<b>XVIII. Revisions to Quality Improvement Organization (QIO) Regulations.....</b>	<b>77</b>
A. Immediate Advocacy (p.78)	
B. Beneficiary Complaint Review (p.79)	
C. General Quality of Care Review (p.81)	
D. Other Matters (p.82)	
E. Regulatory Impact (p.82)	
<b>Appendix: Tables Reproduced from the Proposed Rule.....</b>	<b>84</b>

**TABLE 57.—ESTIMATED IMPACT OF THE 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM (p.84)**

# **SUMMARY OF FINAL RULE: MEDICARE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS FOR 2013**

## **I. Overview**

### **A. Estimated Impact of the Final Rule on Hospitals**

CMS estimates that the final rule policies will increase expenditures under the OPSS for 2013 compared to 2012 by about \$600 million; together with changes in enrollment, utilization, and case-mix, CMS projects that OPSS expenditures will increase about \$4.6 billion in 2013, with total OPSS expenditures (including beneficiary cost-sharing) reaching about \$48.1 billion.

Hospitals' average payments per service will increase about 2.1 percent based on an annual update of 1.8 percent reflecting a market basket increase of 2.6 percent, a 0.7 percent offset for multifactor productivity as required by the ACA and an additional reduction of 0.1 percentage point also required by the ACA. Hospitals that satisfactorily report quality data will qualify for the full update of 1.8 percent, while hospitals that do not will be subject to the statutory reduction of 2.0 percentage points in the update factor resulting in a -0.2 percent update.

The regulation's impact analysis, highlighted below and included in the appendix to this summary, models the effect of the update and other changes to the conversion factor as well as the effects of changes outside the conversion factor. These include year-to-year variation in outlier payments, expiration of the section 508 wage index adjustment, and application of the frontier State wage adjustment, which is not budget neutral and increases average payments 0.10 percent.

Changes to the APC weights, wage indices, continuation of a payment adjustment for rural sole community hospitals (SCHs), including essential access community hospitals (EACHs), and the payment adjustment for cancer hospitals do not affect aggregate OPSS payments because these changes are budget neutral. Their effect on the conversion factor is discussed in section II.B below.

The impact analysis projects that the OPSS policies and rates for 2013 will increase payments by 1.9 percent for all hospitals and facilities. As shown in the table below, the analysis shows only small variations by major hospital category but this masks more substantial variation apparent in the detailed breakout of the impact analysis. The variation arises primarily due to the differential effect of the APC adjustments and APC recalibration based on the geometric mean. In general, the smallest hospitals based on bed size and hospitals with the lowest volume of outpatient services are relatively advantaged by the APC refinement and recalibration. These hospitals, both urban and rural, have projected payment increases from 2.7 percent to 6.8 percent. CMHCs, on the other hand, will see payments fall 4.4 percent overall due to a 5.7 percent reduction attributable to the new APC weights for partial hospitalization services.

All Facilities	1.9%
All Hospitals (except cancer and children's) and excluding CMHCs	1.9%
Urban	1.9%
Rural	2.2%
Major Teaching	1.8%
By type of ownership:	
Voluntary	1.9%
Proprietary	2.2%
Government	1.9%

## II. Updates Affecting OPSS Payments

### A. Recalibration of APC Relative Weights

CMS makes two significant changes in its methodology to calculate the Ambulatory Payment Classification (APC) relative weights for 2013. First, the cost of each APC is determined using geometric mean costs rather than median costs, which have been used since inception of the OPSS in 2000. Second, in calculating cost-to-charge (CCR) ratios, a separate cost center for implantable devices is incorporated. Additional information on each of these changes is shown below.

Other than these two changes, CMS continues the methodology that it has used for many years, including calculating the cost of each procedure only from single procedure claims or “pseudo” single claims created from bills containing multiple codes. The pseudo claim processes permit use of as much claims data as possible for rate-setting. For 2013, CMS used claims for HOPD services furnished from January 1, 2011 through December 31, 2011 (and processed through June 30, 2012). The hospital cost report data for the final rule were from cost report periods with fiscal year ends ranging from 2010 to 2011.

CMS provides the following link for a detailed description of the claims preparation process and an accounting of claims used in the development of the proposed payment rates, including the number of claims derived at each stage of the process: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

#### 1. Calculation and use of cost-to-charge ratios (CCRs); packaged revenue codes

To convert charges on the outpatient claims to estimated costs, CMS multiplies billed charges by the CCR associated with each revenue code. To calculate CCRs for 2013, CMS uses the same general approach that it has used beginning with APC payment rates for 2007. This process applies the appropriate hospital-specific CCR to the hospital's charges based on a revenue code-to-cost center crosswalk containing a hierarchy, for each revenue code, of CCRs used to estimate costs from charges. The current crosswalk, unchanged since October 2009, is available for review and continuous comment (outside of comments submitted in rule-making cycles) on the CMS Web site: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>



Table 2 of the final rule identifies the revenue codes for which CMS packages charges when the revenue code is reported but without HCPCS codes. No comments were received on this list of packaged codes, which is unchanged from the proposed rule.

CMS responds to commenters suggesting a “stability policy” that limits changes in OPPS payment rates from year to year, in particular capping decreases in payment rates at 5 percent. CMS believes such a policy would make payments less reflective of true costs and could unfairly reduce payments for other services. Further, it reviews past changes that aim to reduce volatility in year-to-year payment rates and states that larger payment packages and bundles will help stabilize payments.

## **2. Charge compression**

Citing support from many commenters, CMS finalizes its proposal to address the continuing issue of charge compression by using data from the “Implantable Devices Charged to Patients” cost center to create a distinct CCR for use in calculating the OPPS relative weights for 2013. The cost center for “Implantable Devices Charged to Patients” has been available for use for cost reporting periods beginning on or after May 1, 2009. Using cost reports in the December 31, 2011 quarter ending update of HCRIS, CMS determined that 2,063 hospitals, out of approximately 3,800 hospitals, utilized the “Implantable Devices Charged to Patients” cost center – judged by CMS to be a sufficient amount of data for meaningful analysis.

New standard cost centers for CT scans, MRIs, and cardiac catheterization were effective for cost report periods beginning on or after May 1, 2010, using the revised cost report Form CMS-2552-10. Although these cost report are not currently accessible in the HCRIS, CMS expects to have cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the 2014 OPPS rulemaking.

## **3. Recalibration Budget Neutrality Adjustment**

To make the APC reclassification and recalibration changes budget neutral, including the use of geometric means, CMS compares the estimated aggregate weight calculated using the final 2013 unscaled relative weights and service volume in the 2011 claims data to the aggregate weight using the final 2012 scaled relative weights and service volume using the same 2011 claims data. Based on this comparison, the final rule unscaled APC payment weights were adjusted by a weight scaler of 1.3596 for purposes of budget neutrality. CMS continues to include payments to CMHCs in the budget neutrality calculation for 2012 as well as payments for “specified covered outpatient drugs” (SCODs) and brachytherapy sources; these policies are the same as for 2012.

## **4. Payment for APC 0606, Level III Clinic Visit**

The rule provides a payment rate of \$96.96 for a Level 3 clinic visit (APC 0606) in 2013, an increase of \$1.76 or 1.8 percent compared to the October 1, 2012 payment rate of \$95.20.

## **5. Calculation of single procedure APC criteria-based costs**

The calculation of costs for several APCs follows various special rules, as described below.

Device-dependent APCs. CMS finalizes no policy changes for 2013. Costs for device-dependent APCs are calculated using only the subset of single bills from 2011 claims data that satisfy these criteria: 1) they pass the procedure-to-device edits validating that both the procedure and an appropriate device were billed; 2) they do not contain token charges (less than \$1.01) for the device; and 3) they do not contain the “FB” modifier (signifying that the device was furnished without cost to the provider, supplier, or practitioner, or where a full credit was received) or the “FC” modifier (indicating that the hospital received partial credit for the device). The procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code, while the device-to-procedure edits require that a claim that contains one of a specified set of device codes also contain an appropriate procedure code.

Subsequent to publication of the proposed rule, the American Medical Association CPT Editorial Panel created several new CPT codes describing services related to device-dependent APCs, to be effective January 1, 2013. Consistent with its standard process, CMS assigned these codes to the APC that it believes are comparable clinically and with respect to resource use. These codes are given the comment indicator “NI” in Addendum B of the final rule; the APC assignment for these new codes is open to public comment through December 31, 2012. CMS notes that the interim assignment of some of the new CPT codes for 2013 led it to change the titles of APCs 0107 and 0108, each relating to implantation of a cardiac defibrillator. In addition, the CPT Editorial Panel replacement of CPT codes 92980 and 92981 relating to coronary stent procedures led CMS to replace HCPCS codes G0290 and G0291 in order to maintain the existing policy of differentiating payment for intracoronary stent placement procedures involving nondrug-eluting and drug-eluting stents.

Table 3 of the final rule lists the APCs for which CMS used the standard device-dependent APC ratesetting methodology for 2013.

In response to comments, CMS strongly encourages hospitals to report a charge for each packaged service they furnish, either by billing the packaged HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions, by increasing the charge for the separately paid associated service to include the charge for the packaged service, or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code. CMS notes that any of these means of charging for the packaged service will result in the cost of the packaged service being incorporated into the cost estimate for the separately paid service.

In response to comments that the payment for the cochlear implant device (CPT code 69930) do not reflect the actual cost of the procedure and device because of potential coding errors by major hospital facilities between this code and the less expensive osseointegrated auditory device implant procedures, CMS reviewed the claims data and does not find evidence the inclusion of claims with coding errors is causing inaccurate procedure or APC estimates. CMS also disagreed with comments that osseointegrated auditory device implant procedures should not be

assigned to APC 0425. CMS believes that all the procedures in this APC involve the implantation of a prosthetic device into a bone, all procedures share similar clinical and resource similarities, and there is no evidence of a violation of the 2 times rule.

Blood and blood products. The final rule continues unchanged for 2013 the policy to set payment rates for blood and blood products using the blood-specific CCR methodology.

Brachytherapy Sources. As proposed, CMS continues for 2013 the policy of paying for brachytherapy sources at prospective payment rates based on source-specific costs calculated using the general OPPS rate-setting methodology, which for 2013 uses the geometric mean costs. The rule also continues other payment policies for brachytherapy sources. The “not otherwise specified” (NOS) codes for stranded and non-stranded sources (HCPCS codes C2698 and C2699, respectively) will be paid at the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis. For new brachytherapy sources for which the agency lacks claims data, CMS will assign HCPCS codes for new brachytherapy sources to their own APCs with payment rates based on external data and other information on expected hospital costs. Brachytherapy sources will continue to be subject to outlier payments and brachytherapy source payment weights will continue to be subject to scaling for budget neutrality.

A number of commenters opposed the proposal to base the payment for brachytherapy sources on geometric mean costs; other commenters supported the proposal. CMS disagrees with comments that the 2013 proposed payment rates for brachytherapy services based on geometric mean cost would change payment levels significantly from the 2012 payment rates. When CMS compares the payment rates they find increases or decreases of less than 10 percent, indicating stability for the majority of the brachytherapy sources.

## **6. Calculation of composite APC criteria-based costs**

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS does not add any new composite APCs for 2013. Policies for existing composites are discussed below.

### **a. Extended Assessment and Management Composite APCs (APCs 8002 and 8003)**

For 2013, CMS continues both the extended assessment and management composite APC payment methodology for APCs 8002 and 8003 and the general reporting requirements for observation services reported with HCPCS code G0378. The rule also maintains the 2012 methodology for combining services into the composite APCs for calculating costs. The final 2013 cost resulting from this methodology for composite APC 8002 is approximately \$453, which CMS calculated from 19,028 single and “pseudo” single bills, and the final 2013 cost for composite APC 8003 is approximately \$821, which CMS calculated from 284,861 single and “pseudo” single bills that met the required criteria.

At its August 2012 meeting, the APC Panel recommended that CMS:

- i) continue to report clinic/emergency department visit and observation claims data and, if CMS identifies changes in patterns of utilization or cost, that CMS bring those issues to the Visits and Observation Subcommittee; and
- ii) examine the costs and frequency for Level I and Level II Extended Assessment and Management Composite APCs associated with greater than 24 hours observation and if available report the findings to the Visits and Observation Subcommittee.

CMS accepts these recommendations and will provide the requested data to the Panel at a future meeting.

b. Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

For 2013, CMS continues as proposed the composite APC policy that has been applied since 2008 for Low Dose Rate (LDR) Prostate Brachytherapy. Under this policy, the OPSS provides a single payment when the composite service, identified by CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), is furnished in a single hospital encounter. CMS bases the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes which are not on the bypass list. When these services are billed individually, hospitals receive separate payments for the individual services. For 2013, CMS used 677 claims containing both CPT codes 5875 and 77778 to calculate a cost for composite APC 8001 of approximately \$3,348.

c. Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

CMS finalizes its proposal to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012, with modifications to accommodate changes made by the CPT Editorial Panel subsequent to the publication of the proposed rule. Specifically, the Panel added 5 new CPT codes describing cardiac electrophysiologic evaluation and ablation services and deleted 2 existing codes. Three new codes (93653, 93654 and 93656) are primary electrophysiologic services that encompass evaluation as well as ablation and are assigned to a new Group C in APC 8000 with no further requirement to have another electrophysiologic service furnished on the same date of service. The other two new codes (93655 and 93657) are dependent services that may only be performed as ancillary services to primary codes; CMS is packaging these with the primary procedures. Following the CPT panel decision, two codes (93651 and 93652) are removed from Group B, leaving only CPT 93650 in Group B at this time. CMS' assignment of these codes is open to public comment through December 31, 2012.

Table 4 in the final rule shows the three groups of procedures upon which APC 8000 is based. CMS used 12,235 claims containing a combination of Group A and Group B codes to calculate a final cost of approximately \$11,466 for composite APC 8000.

d. Mental Health Services Composite APC (APC 0034)

Having received no comments, for 2013 CMS continues as proposed its longstanding payment policy to limit the combined payment for specified less intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which the agency considers to be the most resource intensive of all outpatient mental health treatment. However, modifications are made from the proposed rule to accommodate changes subsequently made by the CPT Editorial Panel.

The CPT Editorial Panel has deleted 16 psychotherapy and psychiatric diagnostic evaluation CPT codes to which the mental health services composite APC applies and replaced them with 12 new codes. Table 5 in the final rule includes the deleted and new codes. CMS has assigned all the new codes to composite APC 0034; these assignments are open to public comment through December 31, 2012.

Through the claims processing software, when the total payment for the individual services for specified mental health services – based on the payment rates associated with their APCs – provided by one hospital to a single beneficiary on one date of service exceeds the maximum per diem partial hospitalization payment, those specified mental health services are assigned to APC 0034 (Mental Health Services Composite). The hospital is paid one unit of APC 0034. CMS assigns the payment rate of APC 0176 to APC 0034 because APC 0176, applicable for partial hospitalization furnished in a hospital and involving 4 or more services, is the most resource intensive partial hospitalization service.

e. Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

For 2013, CMS finalizes its proposal to continue to apply the same multiple imaging composite APC policies that it has applied since 2009. (Prior to 2009, hospitals received a 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.) Under the multiple imaging policy:

- i. CMS defines five multiple imaging composite APCs:
  - APC 8004 (Ultrasound Composite); APC 8005 (CT and Computed tomographic angiography (CTA) without Contrast Composite);
  - APC 8006 (CT and CTA with Contrast Composite);
  - APC 8007 (MRI and magnetic resonance angiography (MRA) without Contrast Composite); and
  - APC 8008 (MRI and MRA with Contrast Composite).
- ii. CMS provides one composite APC payment when a hospital bills more than one procedure described by HCPCS codes within an OPPI imaging family (as designated in each year’s regulation) on a single date of service. If the hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital would receive payment for the “with contrast” composite APC.

- iii. When the conditions in ii. for a composite APC payment do not apply, CMS makes payment according to the standard OPPS methodology through the standard (sole service) imaging APCs; this rule applies when a single imaging procedure is performed, or when the imaging procedures performed have HCPCS codes assigned to different OPPS imaging families.
- iv. CMS continues current billing practices whereby hospitals use the same HCPCS codes to report imaging services and the integrated outpatient code editor (I/OCE) determines when combinations of imaging procedures would qualify for composite APC payment or would map to standard APCs for payment.

For 2013 will continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite payment methodology. Table 6 of the final rule lists the HCPCS codes that are subject to the policy, the approximate cost for each imaging composite APC, and the CPT codes included in each imaging family for 2013. In calculating costs for the 2013 final rule, CMS identified 1 million “single session” claims out of an estimated 1.6 million potential composite cases in the 2011 claims data used for rate-setting.

Several commenters supported CMS’ decision not to propose any new multiple imaging composite APCs. CMS notes that it will continue its’ usual practice to analyze claims data and provide public notice and seek comment for any new proposals through annual rulemaking.

f. Cardiac Resynchronization Therapy Composite APC (APC 0108)

Cardiac resynchronization therapy (CRT) uses a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD) to sequentially pace both sides of the heart to improve its output. “CRT–D” is performed with an ICD along with a pacing electrode while “CRT–P” involves a pacemaker and a pacing electrode. CRT procedures are described by combinations of CPT codes for the insertion of pulse generators, leads, and the pacing electrode.

In response to ongoing stakeholder comments and a prior APC panel recommendation, for 2012 CMS established a policy to recognize CPT codes 33225 and 33249 as a single, composite service when the procedures are performed on the same day and to assign them to APC 0108 (Insertion/Replacement/Repair of automatic ICD (AICD) Leads, Generator, and Pacing Electrodes) when they appear together on a claim with the same date of service. Hospitals continue to use the same CPT codes to report CRT-D implantation services, and the I/OCE identifies when the combination of CPT codes 33225 and 33249 on the same day qualify for composite service payment. CMS makes a single composite payment for such cases. When not performed on the same day as the service described by CPT code 33225, the service described by CPT code 33249 also is assigned to APC 0108. When not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 is assigned to APC 0655. CMS also implemented claims edits in 2012 to ensure that hospitals correctly code for CRT services. The edits return to providers incorrectly coded claims on which a pacing electrode insertion (the procedure described by CPT code 33225) is billed without one of

specified procedures to insert an ICD or pacemaker, as identified by the AMA in the CPT codebook.

For 2013, CMS finalizes its proposal to continue the policies established in 2012, with revisions to the claims edits reflecting changes in the CPT codebook. To calculate costs for the final rule payment rate for APC 0108, CMS identified 11,251 single claims having single procedure claims for the individual services assigned to APC 0108 as well as single procedure claims that contain the composite CRT-D service, defined as the combination of CPT codes 33225 and 33249 with the same date of service. CMS calculates a final cost of approximately \$31,561 for APC 0108.

## **7. Geometric Mean-Based Relative Payment Weights**

CMS finalizes its proposal to use geometric mean costs to calculate the APC relative weights. This is a change from the program's use of median costs, which has been in place since inception of the OPSS in 2000, when CMS chose not to exercise the statutory option to use mean costs. In making this change, CMS retains the claims development process without change as well as its processes for modeling the standard APCs and the criteria-based APCs described above. Use of geometric means applies to all APCs previously paid based on median costs, including brachytherapy sources, blood and blood products and the CMHC and hospital-based partial hospitalization program APCs. There are few exceptions to the application of the geometric mean-based relative payment weights, with these being the same exceptions that were previously made when median-based weights are applied. For example, payment for nonpass-through separately payable drugs and biologicals will continue to be developed through its own separate process. As required by law, adopting geometric means is done in a budget neutral manner.

CMS cites numerous reasons for the change from medians to geometric means, including:

- The change responds to commenters' persistent concerns such as the degree to which payment rates reflect the costs associated with providing a service, whether packaged items and services are appropriately reflected in the payment weights, and year-to-year variation in the weights.
- Medians do not reflect subtle changes in cost distributions, resulting in relative weight estimates being less sensitive to packaging decisions as well as to changes in the cost model due to factors such as the additional claims processed between the proposed rule and the final rule.
- Geometric means better encompass the variation in costs that occur when providing a service because, in addition to the individual cost values that are reflected by medians, geometric means reflect the magnitude of the cost measurements, and are thus more sensitive to changes in the data.
- Geometric mean costs better capture the range of costs associated with providing services, including those cases involving high cost packaged items or services, and those cases where very efficient hospitals have provided services at much lower costs.

- Geometric mean costs permit earlier detection of changes in the cost of services. Changes in cost often diffuse into the industry over time as opposed to impacting all hospitals equally at the same time. Medians and geometric means both capture the impact of uniform changes (those that influence all providers), but only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis.
- Geometric mean costs increase the sensitivity of the two times rule because it allows CMS to detect differences when higher costs occur in a subset of services even if the number of services does not change. CMS determined that the change to means would not significantly influence the application of the two times rule and would result in several more violations of the 2 times rule compared to use of median-based values.
- Geometric mean costs may promote better stability in the payment system.
- Use of mean costs brings the OPSS in line with the inpatient prospective payment system (IPPS), which uses mean costs rather than median costs to calculate the diagnosis related groups (DRG) weights. Note, however, that the IPPS uses arithmetic means rather than geometric means. Nevertheless, CMS states that using geometric means would achieve greater consistency between the methodologies used to calculate payment rates under the two programs and allow CMS to make more accurate and valid cross-system comparisons and to examine issues of payment parity.
- Geometric means improve CMS' ability to identify resource distinctions between previously homogeneous services. CMS believes that the cumulative effect of data shifts over the 12 years of OPSS introduced a number of inconsistencies in the APC groupings based on clinical and resource homogeneity. It intends to use the enhanced information based on geometric means over the next year to reexamine the APC structure and assignments and to consider further ways of increasing the stability of payments for individual services over time.

CMS also finalizes proposed changes in related regulations to reflect the change from median costs to geometric-mean based costs. Specifically, the regulation at 42 CFR 419.31 regarding the 2 times rule is modified.

CMS responds to numerous comments regarding the change to geometric mean-based relative payment weights. In doing so, CMS acknowledges that each metric (mean, median, geometric mean) has aspects that may make it preferable to the others, and reiterates the reasons enumerated above for its decision to use the geometric mean. In particular, CMS believes that many outlier observations in the data represent actual cost outliers and not errors as suggested by some commenters, and the geometric mean will better reflect packaging patterns and ranges in cost and will be an improvement in cost estimation.

Regarding suggestions for a phase-in to the new weights, CMS does not believe a transition period is necessary. It indicates that prior to proposing the change it analyzed the most recent 4 years of OPSS claims data and determined that there is no significant difference in payment fluctuations resulting from geometric (or arithmetic) means compared with medians, and that the



one-time differences resulting from the switch are typically small. Moreover, CMS believes that a phased in approach could distort the relativity of the system, under which cost fluctuations occur from year to year for various reasons. CMS discusses the potential use of the arithmetic mean, and notes that this change would be more sensitive toward outlier costs and also more volatile, with the short-term transition from medians to arithmetic means resulting in a wider range of provider impacts and the need for more reconfiguration of APCs to resolve the 2 times rule. CMS concludes that the use of geometric mean is a balanced approach between the strengths and weaknesses of using medians or arithmetic means.

CMS agrees that continued monitoring of changes in cost distributions and the frequency of services is important in understanding the impact of basing the APC relative payment weights on geometric mean costs. It notes, however, that the frequency of services may change from year to year based on a variety of factors, including issues unrelated to OPSS payments, and “situations where APC overpayments may have potentially led to inappropriate incentives to provide care”.

CMS analysis indicates that the change has a limited payment impact on most providers. CMS does not believe that observed declines or increases in the payment codes are typically associated with any individual specialty. The regulation’s impact table (attached to this summary) includes separate columns that identify the estimated impact of APC recalibration based on median costs using CY 2011 OPSS claims and updated historical cost report data, a column that estimates the impact of the change to geometric mean costs, and a column that shows the total impact of APC recalibration using geometric mean costs and OPSS CY 2011 claims and updated historical cost report data.

## **8. Changes to packaged services**

Beginning in 2008, CMS extended packaging to seven additional categories: guidance services, image processing services, intraoperative services, imaging supervision and interpretation, observation services, diagnostic radiopharmaceuticals and contrast media. Payment for these items or services is packaged into the payment for the primary diagnostic or therapeutic service with which they are billed and to which CMS believes they are typically ancillary and supportive. This 2013 final rule maintains the extended packaging with clarifications but no significant changes. CMS indicates that it is likely to develop additional payment bundles in future rulemaking. Additional payment to cover the cost of non-highly enriched uranium sources for radioisotopes used in medical imaging is discussed in section III.C of this summary.

Within the seven categories, the costs of some services are unconditionally packaged into the costs of the separately paid primary services with which they are billed; CMS believes that they are always integral to the performance of the primary modality. These services are assigned status indicator “N”. An “STVX-packaged code” describes a HCPCS code whose payment is packaged when one or more separately paid primary services with the status indicator of “S,” “T,” “V,” or “X” are furnished in the hospital outpatient encounter. A “T-packaged code” describes a code whose payment is packaged only when one or more separately paid surgical procedures (with a status indicator “T”) are provided during the hospital encounter. “STVX-packaged codes” and “T-packaged codes” are paid separately when they do not meet their respective criteria to be packaged. To signify that they are conditionally packaged services,

“STVX-packaged HCPCS codes” and “T-packaged HCPCS codes” are assigned status indicator “Q1” or “Q2” respectively. Status indicator “Q3” identifies codes that may be paid through a composite APC when the appropriate conditions are met.

With respect to drugs, biologicals, and radiopharmaceuticals, CMS continues to package five categories (unless temporary pass-through status applies): (1) those with per-day costs at or below the packaging threshold; (2) diagnostic radiopharmaceuticals; (3) contrast agents; (4) anesthesia drugs; and (5) drugs treated as surgical supplies. CMS refers to contrast agents and diagnostic radiopharmaceuticals as “policy-packaged” drugs because they are packaged regardless of their per-day costs.

CMS finalizes its proposal to continue for 2013 to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, and implantable biologicals that are surgically inserted or implanted through a surgical incision or a natural orifice into the body.

Packaging clarification. CMS clarifies the regulatory language at 42 CFR 419.2(b) to make explicit that the OPSS payments for the included costs of items and services covered under the OPSS are packaged into the payments for the related procedures or services with which such items and services are provided. The new regulatory language for 419.2(b) states:

*“(b) Determination of hospital outpatient prospective payment rates: Packaged costs. The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs include, but are not limited to, the following items and services, the payments for which are packaged into the payments for the related procedures or services.”*

Clarification of packaging policy for anesthesia drugs. Longstanding OPSS policy is to package “anesthesia” and “supplies and equipment for administering and monitoring anesthesia or sedation.” Recognizing that some anesthesia drugs may qualify for transitional pass-through status, CMS clarifies that the general policy is to package drugs used to produce anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status. The rule states that “drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality, and are included in our definition of ‘anesthesia’.”

Response to APC Panel Recommendations. In the proposed rule, CMS responded to recommendations made by the APC Panel at its February 2012 meeting on packaging policies. In this rule, CMS responds to public comments on its decisions regarding the recommendations, which remain unchanged. Discussion of recommendations made by the panel at its August 2012 meeting appears in section III.D of this summary.

## B. Conversion Factor Update

The OPPS conversion factor for 2013 is \$70.313. To set it, CMS begins with the 2012 conversion factor of \$70.016, adjusts it by the fee schedule increase factor and further applies various budget neutrality factors. The fee schedule increase factor equals the hospital inpatient market basket percentage increase, projected to be 2.6 percent for 2013, reduced by a multifactor productivity adjustment (MFP) of 0.7 percentage points as required by the ACA, and reduced an additional 0.1 percentage point as also required by the ACA. Thus, CMS finalizes a fee schedule increase factor of 1.8 percent for the 2013 OPPS (2.6 percent hospital market basket increase, less the proposed 0.7 percentage points MFP adjustment, less the 0.1 percentage point additional adjustment).

Hospitals that fail to meet the reporting requirements of the hospital Outpatient Quality Reporting program (OQR) are subject to a reduction of 2.0 percentage points, as discussed in section XV below, resulting in a fee schedule increase factor of -0.2 percent for such hospitals.

Additional adjustments apply for 2013: a wage index budget neutrality factor of 0.9998 and a budget neutrality adjustment of 1.000 for the rural adjustment and the cancer hospital adjustment. These factors are 1.000 – and therefore do not affect the conversion factor – because no change is made to the rural adjustment policy and the difference in the 2013 estimated payments due to applying the proposed 2013 cancer hospital payment adjustment relative to the CY 2012 final cancer hospital payment adjustment does not have a significant impact on the budget neutrality calculation. CMS estimates that CY 2013 pass-through spending for drugs and biological and devices will be \$74 million, or 0.15 percent of total spending, compared with 0.22 percent for CY 2012. Thus, an adjustment of -0.07 percent is made to reflect this differential. Estimated payments for outliers remain unchanged from 2012 at 1.0 percent. The table below shows the calculation of the 2013 conversion factor.

<b>2012 Final Rule Conversion Factor</b>	<b>Remove 2012 Pass - Through Adjustment</b>	<b>Apply 2013 Pass -Through Adjustment</b>	<b>Apply 2013 Wage Index Budget Neutrality Adjustment</b>	<b>Apply 2013 Fee Schedule Increase Factor</b>	<b>2013 Final Rule Conversion Factor</b>
\$70.016	0.9978	0.9985	0.9998	1.018	
	\$70.170	\$70.065	\$70.052	\$71.313	\$71.313

The combined effect of these factors is a total increase in the conversion factor of \$1.297, or 1.85 percent, yielding a conversion factor for 2013 of \$71.313 for hospitals satisfying the requirements of the quality reporting program. To calculate the 2013 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the OQR, the proposed rule applies a reduced fee schedule increase factor of -0.2 percent, rather than 1.8 percent, keeping all other adjustments the same, resulting in a reduced conversion factor for 2013 of \$69.887.

### **C. Wage Index Changes**

CMS finalizes its proposals to retain the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2013, and to retain its policy to adopt the final fiscal year IPPS wage index as the OPPS calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences.

CMS notes that some commenters expressed concern about the continuing use of the IPPS wage index, while others supported continuation of the use of that index. CMS responds that it believes that the IPPS wage index continues to be appropriate, given its long-standing use and because broader wage index reform is currently under development and consideration.

CMS notes that the Department has undertaken two studies in response to concerns that the current wage index system does not effectively reflect the true variation in labor costs. One was a report to Congress required under Section 3137(b) of the ACA, and the second was an Institute of Medicine (IOM) study commissioned by the Secretary. CMS refers readers to the preamble of the FY 2013 IPPS/LTCH PPS proposed rule for a review of the studies.

CMS finalizes its proposal to continue to implement the wage index adjustments called for in the ACA in the same manner as in 2012. That includes the “frontier state” adjustment requiring a wage index floor of 1.0 in certain cases if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality adjustment) is less than 1.0. In the case of a hospital outpatient department (HOPD) affiliated with a multicampus hospital system, the HOPD would continue to receive the wage index value of the specific inpatient hospital with which it is associated. If that hospital is in a frontier state, the frontier state wage index adjustment for that hospital would apply to the HOPD.

CMS notes that several section 508 reclassifications and special exceptions, most recently extended in P.L. 112-96 and amended by PL 112-78 expired as of March 31, 2012 under the IPPS and as of June 30, 2012 for the OPPS. Therefore, the final rule adopts the proposed policy that those provisions are not available in 2013.

CMS finalizes its proposal to retain its policy allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a county designated as an out-migration county under section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Those eligible for this out-migration adjustment, including the non-IPPS hospitals, are available at Addendum L to the final rule.

### **D. Statewide Average Default Cost-to-Charge Ratios (CCRs)**

CMS finalizes its proposal to update the statewide average default CCRs for 2013 using the most recent cost report data. The default CCRs are used for hospitals for which a CCR cannot be calculated, including certain hospitals that are new, hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR, and hospitals whose most recent cost report reflects all-inclusive rate status, such as those in Maryland.

One commenter expressed concern that Florida has the lowest CCR in the US for both rural and urban areas, and believes that that the data are skewed by hospitals in the Miami area. CMS responds that it uses only valid CCRs and that the Florida data have been stable for several years, and retains the proposed policy in the final rule.

CMS finalizes its proposal to continue its standard method for calculating the update for 2013, and notes that approximately 62 percent of the cost reports used for the update are for cost reporting periods ending in 2010, and 38 percent are for cost reporting periods ending in 2009. For Maryland, CMS continues to use an overall weighted average CCR for all hospitals in the nation. Table 8 in the final rule presents statewide default CCRs for urban and rural areas in each State for 2013 and the comparable CCRs for 2012.

### **E. OPSS Payment to Certain Rural and Other Hospitals**

Hold Harmless Transitional Payment Changes: Hold harmless transitional payment adjustments (reflecting the difference between OPSS payments and cost-based, pre-Budget Reconciliation Act (BBA) payments) were temporarily extended by statute since the promulgation of the 2012 final rule, but those temporary authorities have expired and are not applicable for 2013.

- P.L. 112-78 extended through February 29, 2012 the hold harmless payment adjustment for a sole community hospital (SCH), including an essential access community hospital (EACH), without bed size limitations. If the PPS amount is less than the provider's pre-BBA amount, the payment is increased by 85 percent of the difference.
- P.L. 112-96 extended through December 31, 2012 the hold harmless payment adjustment for a SCH, including an EACH, with no more than 100 beds. If the PPS amount is less than the provider's pre-BBA amount, the payment is increased by 85 percent of the difference.

CMS finalizes its proposal to revise the regulations to reflect those changes for OPSS payments made during 2012. Since the authority has expired for 2013, CMS finalizes its proposal to make no such transitional payments for 2013.

Proposed Adjustment for Rural SCHs and EACHs under Section 1833(t)(13)(B) of the Act: CMS finalizes its proposal to continue the 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. The adjustment is budget neutral and applied before calculating outliers and copayments. CMS again states an intention to reassess the 7.1 percent adjustment in the near future by examining differences between urban and rural hospitals' costs using updated claims, cost reports, and provider information.

CMS responds to comments suggesting that the adjustment also apply to urban SCHs and to Medicare Dependent Hospitals (MDHs) by noting that that statute directs the Secretary to apply the adjustment to rural hospitals.

## **F. OPSS Payments to Cancer Hospitals**

Medicare law exempts 11 cancer hospitals meeting statutory classification criteria under section 1886(d)(1)(B)(v) of the Act from payment under the IPPS. Since the inception of the OPSS, Medicare has paid these hospitals under the OPSS for covered outpatient hospital services. There is a permanent hold-harmless, under which the cancer hospitals receive the full difference between their OPSS payments and the amount they would have been paid prior to the implementation of the OPSS, a “pre-BBA” amount

The ACA requires a budget neutral adjustment to the extent that the Secretary determines that the 11 cancer hospitals’ OPSS costs are greater than other OPSS hospitals’ costs, including consideration of the cost of drugs and biologicals. Cancer hospitals remain eligible for transitional outpatient payments (TOPs), which are not budget neutral, and outlier payments, which are budget neutral.

CMS finalizes its proposal to continue its policy that started in 2012 to make additional payments to these 11 cancer hospitals sufficient to bring each hospital’s payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals. To avoid the higher copayments for beneficiaries that are associated with providing the adjustment on a claims basis through increased APC payments, the cancer hospital payment adjustment is applied in the form of an aggregate payment determined at cost report settlement to each cancer hospital, as opposed to an adjustment at the APC level. CMS examines each cancer hospital’s data at cost report settlement, determines the cancer hospital’s PCR (before the cancer hospital payment adjustment), and determines the lump sum amount necessary (if any) to make the cancer hospital’s PCR equal to the target PCR, which is defined as the PCR for all other hospitals. If a cancer hospital’s PCR (before the cancer hospital payment adjustment) is above the target PCR, the cancer hospital payment adjustment equals zero. CMS sets the target PCR in advance and calculates it using the most recent submitted or settled cost report data that are available at the time of the final rule.

For 2013, CMS finalizes its proposal to continue to set the target PCR at 0.91 for purposes of the cancer hospital payment adjustment.

Commenters suggested that CMS use a methodology to ensure that cancer hospitals’ losses not be greater than other PPS hospitals, that CMS should not recalculate the target PCR annually, and that the payment adjustment be effective for services furnished on or after January 1, 2011 (rather than 2012). CMS responds by reiterating the statutory rationale for the use of the PCR, and that annual updates to the PCR enable it to provide accurate adjustments each year. CMS further sets out its previously stated rationale for not finalizing the proposed rule for the adjustment that would have been effective in CY 2011, based on the comments received on that proposed rule.

Note: CMS does not comment in the final rule on its adoption of the proposed budget neutrality adjustment of 1.0 to the OPSS conversion factor, reflecting no significant change in payments in 2013 compared to 2012.

Table 9 in the final rule presents the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with estimated increases in OPSS payments for CY 2013 ranging from 10.0 percent to 44.9 percent.

## **G. Hospital Outpatient Outlier Payments**

The OPSS pays outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2013, CMS finalizes its proposal to continue to set aside 1.0 percent of the estimated aggregate total payments under the OPSS for outlier payments.

CMS calculates the fixed-dollar threshold using the same methodology as was used to set the threshold for 2012. CMS finalizes its proposal that the outlier threshold would be met when a hospital's cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a fixed-dollar threshold. That fixed dollar threshold was \$2,025 in CY 2011 and 2012, and CMS in the proposed rule had estimated it to be \$2,400 in 2013 in order to hit the 1.0 percent outlier set aside.

Several commenters expressed concern that the increase in the threshold would reduce outlier payments. CMS responds by reiterating the policy and the methodology, but based on updated data available since the issuance of the proposed rule, the final rule retains the fixed-dollar threshold for 2013 at the 2012 level of \$2,025.

CMS finalizes its proposal to continue to make an outlier payment equal to 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 also finalizes its proposal that a portion of the 1.0 percent outlier set-aside, specifically 0.12 percent, be allocated to community mental health centers (CMHCs) for partial hospitalization program (PHP) outlier payments. This portion is determined by the amount of estimated outlier payments that would result from the CMHC outlier threshold as a proportion of total estimated outlier payments. CMS finalizes its proposal that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services)) or APC 0173 (Level II Partial Hospitalization (4 or more services)), exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

CMS finalizes its proposal to continue the policy that hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPSS annual payment update factor, resulting in reduced OPSS payments for most services. For hospitals that fail to satisfy the quality reporting requirements, CMS continues its policy that a hospital's costs will be compared to the reduced payments for purposes of determining outlier eligibility and payment amount (see sections H and I below).

Outlier payments are reconciled at cost report settlement. CMS finalizes its proposal to not incorporate any assumptions about the effects of reconciliation on the OPSS fixed-dollar threshold.

## H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

CMS notes that the 2.0 percent reduction in the annual payment update factor (see summary of section XV) for hospitals that fail to report required quality data will result in reduced national unadjusted payment rates for those hospitals. CMS finalizes its proposal for computing payment as follows. In addition, in section I below, it finalizes its policy for adjusting copayments for such hospitals.

CMS first reviews the terminology:

- The national unadjusted payment rate for hospitals that meet the quality reporting requirements is the “full” national unadjusted payment rate
- The “reduced” national unadjusted payment rate for hospitals that fail to meet the quality reporting requirements is the “full” national unadjusted rate multiplied by the “reporting ratio” of 0.98 (the 2% reduction).

The method for computing payment for hospitals is presented in the following table.

<b>Summary of methodology for computing payment for hospitals that meet and hospitals that fail to meet the quality reporting requirement</b>		
<b>Steps in calculation</b>	<b>Hospitals that meet the quality reporting requirement</b>	<b>Hospitals that fail to meet the quality reporting requirement</b>
1. Multiply 60% (labor-related share) times the national unadjusted payment rate	Use full national unadjusted payment rate for calculation	Use reduced (2% reduction) national unadjusted payment rate for calculation
2. Multiply result of step one by the applicable wage index for the hospital		
3. Multiply 40% (nonlabor-related share) times the national unadjusted payment rate	Use full national unadjusted payment rate for the calculation	Use reduced (2% reduction) national unadjusted payment rate for the calculation
4. Add results of steps 2 and 3: this is the adjusted Medicare payment		
5. If the provider is a sole community hospital (SCH) or essential access community hospital (EACH), and in a rural area or treated as such under the rules, multiply the result of step 4 times 1.071.		

## I. Beneficiary Copayments

Medicare law prescribes that the maximum coinsurance rate for any service is 40 percent of the total OPPS payment to the hospital and the minimum is 20 percent. The statute also limits a beneficiary’s actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is \$1,184 in 2013. The inpatient hospital deductible limit is applied to the actual co-payment amount after adjusting for the wage index. For this reason, the co-insurance



levels shown in the OPPS payment rate addenda of the final rule do not incorporate the hospital deductible limit.

Although the last scheduled reduction in the maximum coinsurance rate occurred in 2006, the methodology for calculating coinsurance rates ensures that beneficiary coinsurance amounts will continue to decrease gradually relative to the payment rates until all services have a coinsurance rate of 20 percent of the total payment for the service.

CMS estimates that total beneficiary liability for copayments under the final rule decrease as a percentage of total payments, from 22.0 percent in 2012 to 21.5 percent in 2013, due largely to changes in service mix

CMS finalizes its proposed copayment policy, which continues prior copayment requirements.

For 2013 as in 2012, CMS finalizes its proposal to reduce the beneficiary co-payment proportionately to the two percentage point conversion factor reduction when services are rendered in a hospital that chose not to report the required quality measures, or that reported them unsatisfactorily.

CMS presents in Addenda A and B the national unadjusted copayment amounts for services payable under the OPPS effective for CY 2013. CMS computes the adjusted copayment amounts as indicated in the following table.

<b>Summary of methodology for computing the adjusted copayment amount for an APC group for hospitals that meet and hospitals that fail to meet the quality reporting requirement</b>		
<b>Calculation</b>	<b>Hospitals that meet the quality reporting requirement</b>	<b>Hospitals that fail to meet the quality reporting requirement</b>
1. Divide the national unadjusted copayment amount by the national unadjusted payment rate to determine the beneficiary payment percentage	Use full national unadjusted payment rate for the calculation	Use reduced (2% reduction) national unadjusted payment rate for the calculation
2. Determine wage-adjusted copayment amount by multiplying the result of step one times the adjusted Medicare payment derived in steps 4 and 5 (if applicable for SCH and EACH provider) in the preceding table	Note: the adjusted Medicare payment in the preceding table was derived using the full national wage index-adjusted national unadjusted	Note: the unadjusted Medicare payment in the preceding table was derived using the reduced (2% reduction) national wage-index adjusted payment
3. Multiply the wage-adjusted copayment amount in step 2 by the 0.98 reporting ratio for hospitals that fail to meet the quality reporting requirement	The result of step 2 yields copayment amount	Multiply the result of step 2 by 0.98 (2% reduction) to derive copayment amount

### III. OPSS Ambulatory Payment Classification (APC) Group Policies

#### A. OPSS Treatment of New HCPCS and CPT Codes

Table 10 in the final rule (copied below) summarizes the CMS process for updating codes through OPSS quarterly update Change Requests (CRs), seeking public comment, and finalizing their treatment under the OPSS.

<b>OPSS Quarterly Update CR</b>	<b>Type of Code</b>	<b>Effective Date</b>	<b>Comments Sought</b>	<b>When Finalized</b>
April 1, 2012	Level II HCPCS Codes	April 1, 2012	2013 OPSS/ASC proposed rule	2013 OPSS/ASC final rule with comment period
July 1, 2012	Level II HCPCS Codes	July 1, 2012	2013 OPSS/ASC proposed rule	2013 OPSS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2012	2013 OPSS/ASC proposed rule	2013 OPSS/ASC final rule with comment period
October 1, 2012	Level II HCPCS Codes	October 1, 2012	2013 OPSS/ASC final rule with comment period	2014 OPSS/ASC final rule with comment period
January 1, 2013	Level II HCPCS Codes	January 1, 2013	2013 OPSS/ASC final rule with comment period	2014 OPSS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2013	2013 OPSS/ASC final rule with comment period	2014 OPSS/ASC final rule with comment period

Table 11 of the final rule lists the HCPCS codes that were assigned comment indicator “NI” (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in the 2012 OPSS final rule for which CMS received comments and the section in the 2013 OPSS final rule where the comments are addressed.

#### 1. Treatment of New 2012 Level II HCPCS Codes and CPT Codes Effective April 1 and July 1, 2012 for Which CMS Solicited Public Comments in the 2013 Proposed Rule

CMS finalizes the status indicators, APC assignments and payment rates, if applicable, for the 13 Level II HCPCS codes and 7 Category III CPT codes that were newly recognized in either the

April or July 2012 OPPS quarterly update CRs. Table 13 of the final rule, lists the final 2013 status indicator and APC assignments for the Level II HCPCS codes that were newly implemented in April 2012. Comments about HCPCS code C9733 (non-ophthalmic fluorescent vascular angiography) are discussed below in Section B, OPPS Changes – Variations within APCs. Table 15 of the final rule lists the final 2013 status indicator and APC assignments for the Level II HCPCS codes that were newly implemented in July 2012. As indicated in Table 15, two codes were not recognized because they are paid under a payment system other than OPPS. No public comments were received. Table 16 of the final rule, lists the Category III CCPT codes that were implemented in July 2012 with their final 2013 status indicators and APC assignments. The final payments for these codes are in Addendum B in this final rule. Comments about CPT code 0304T (Insertion/removal and replacement of intracardiac ischemia monitoring sys; device only) are discussed below in Section B, OPPS Changes – Variations within APCs.

## 2. Process for New Level II HCPCS Codes that will be Effective October 2012 and New CPT and Level II HCPCS Codes that will be Effective January 1, 2013 for Which CMS Solicits Public Comments in the 2013 Final Rule with Comment Period

CMS finalizes its practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for all CPT codes newly implemented in January 2013 and all HCPCS codes newly implemented in October 2012 or January 2013 in Addendum B in this final rule. These codes are flagged with comment indicator “NI”. They will be applicable in 2013 but are open to public comment and will be finalized in the 2014 OPPS/ASC final rule with comment period. CMS did not receive any comments about this process.

### **B. OPPS Changes – Variations within APCs**

The Secretary is required, on a recurring basis no less than annually, to review and revise the APCs, the relative payment weights and the wage and other adjustments to take into account changes in medical practice, technology, the addition of new services, new cost data and other relevant information and other factors. In addition, the Secretary is required to consult with an expert outside advisory panel to review the clinical integrity of the APC groups and their relative payment rates.

#### *Application of the 2 Times Rule*

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to comparability of the use of resources, if the median cost of the highest cost item or service within an APC group is more than 2 times greater than the median of the lowest cost item or service within that same group. In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers only those HCPCS codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant. Addendum B of the final rule identifies with comment indicator “CH” the final 2013 changes.

### *Exceptions to the 2 Times Rule*

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria to decide whether to propose exceptions: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for upcoding and code fragments.

CMS finalizes a list of 19 APCs exempted from the 2 times rule for 2013 ( Table 17 in the final rule). Based on comments and CMS' review of the 2011 costs from hospital claims and cost report data available for the final rule, CMS removed APCs from the proposed 2013 list that no longer violated the 2 times rule.

### **C. New Technology APCs**

CMS retains services within New Technology APC groups until sufficient claims data are gathered to enable CMS 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 2 years if sufficient data are available. It also allows CMS to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

CMS notes that each year it receives many requests for higher payment amounts under the New Technology APCs for specific procedures under the OPPI because they require the use of expensive equipment. CMS believes that Medicare payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries in cost-effective settings. These payment rates are based on Medicare beneficiary projected utilization, not on initial projections of low utilization for services in a transitional period.

In 2012, three procedures related to prostate saturation biopsy and described by HCPCS G-codes (G0417, G0418 and G0419) will have received payment through a New Technology APC since 2009. Analysis of hospital outpatient data for claims submitted for 2010 and 2011 indicates that prostate saturation biopsy procedures are rarely performed on Medicare beneficiaries. Given the continued lack of cost data for these HCPCS codes, CMS is reassigning these procedures to a clinically appropriate APC, APC 0661 (see Table 19 in the final rule). CMS did not receive any comments about this proposal.

### Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used, particularly for cardiac imaging for the Medicare population. The Administration established an agenda to eliminate domestic reliance on legacy reactors using highly enriched uranium (HEU) and is promoting the conversion of all medical radioisotopes production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are available and conversion to such production is expected to be completed within a 5-year time period. The cost of these alternative methods will be increased over the cost of medical radioisotopes produced using HEU because hospitals' payments to producers and

suppliers will have to cover capital expenses as well as all other new industry-specific ancillary costs.

CMS states that in the short term, some hospitals will be able to “depend on low cost legacy producers using aging subsidized reactors while other hospitals will be forced to absorb the full cost of non-HEU alternative sources.” CMS believes that these cost differentials and changes in supply source will create a significant payment inequity among hospitals resulting from factors outside of normal market forces.

Because of these concerns, CMS is exercising its authority under section 1833(t)(2)(E) of the Social Security Act to establish “other adjustments as determined to be necessary to ensure equitable payments” under the OPPI. CMS finalizes its proposed policy with modifications to provide an adjustment for the marginal cost for radioisotopes produced from non-HEU sources over the costs for radioisotopes produced by HEU sources. Specifically, **CMS finalizes:**

- A product that is identified as non-HEU sourced must be at least 95 percent derived from non-HEU sources.
- Establishment of a new HCPCS code, Q9969 (Tc-99 from non-HEU source, full cost recovery add-on, per study dose).
- Assignment of HCPCS code Q9969 to APC 1442 (Non-HEU TC-99M Add-On/Dose) with a status indicator of “K” and a 2013 payment rate of \$10.

The vast majority of commenters conceptually agreed with CMS’ proposed payment policy but differed in how CMS should implement this policy. CMS agrees with commenters that \$10 is not a large incentive to promote a conversion to non-HEU sources of Tc-99m but the proposed payment was not meant as an incentive (CMS notes this is outside the scope of the OPPI) but instead is to ensure payment equity among hospitals by creating an additional payment to address the incremental cost of obtaining Tc-99m from new sources of supply. In response to concerns that CMS did not account for the administrative costs involved in implementing this additional payment at the hospital level, at the radiopharmacy level and at the level of the generator manufacturer, CMS replies that the industry had indicated that the actual costs of conversion, separate from the administrative costs of billing, are confined to the producer, the processor and are then further passed down through the supply chain. CMS notes that its analysis is based on a payment calculation that would readily cover the additional cost of this change in supply as it is passed down the supply chain. CMS notes that due to small absolute differences in cost between non-HEU and HEU sourced Tc-99m, it does not believe significant inequities will exist in hospital costs until a significant amount of more expensive non-HEU enters the system, at which time the administrative costs would be spread over a large number of claims. CMS agrees with comments that the need for and the amount of this additional payment should be evaluated annually.

Additional discussion about the methodology used to determine the add-on payment is available in the final rule. In response to comments suggesting alternate payments, CMS notes that it does not have the statutory authority to create different types of payment such as a blended payment. CMS does, however, have the authority to deviate when it is necessary to adjust payments to ensure payment equity among hospitals, which is the basis for the add-on payment.

CMS agrees with commenters' concerns about the proposed policy that TC-99m doses must be derived 100 percent from non-HEU sources in order to receive the additional \$10 payment. CMS modifies the proposal to state that any dose of TC-99m that can be traced to a Mo-99 supply containing no more than 5 percent HEU sourced Mo-99 shall be considered to be completely derived from non-HEU sources.

In response to a comment about the administrative and financial burden the policy imposes on hospitals, CMS disagrees and notes that most hospitals have computerized inventory and billing systems that already track low-cost items such as needles and aspirins. CMS also notes that this additional payment is optional.

A few commenters were concerned about the compliance and liability burden this policy may place on hospitals; hospitals may be uncomfortable attesting that the supplies they receive are from non-HEU sources when there is no reliable guarantee that the products are from non-HEU sources. CMS states they do not expect hospitals to assay doses of drugs but their intent is to indicate that providers are expected to exercise due diligence and to ensure that their claims are supported by some internal records provided by a supplier (such as invoice, label and contract) regarding a non-HEU source as satisfactory proof.

To reduce the administrative overhead for hospitals, CMS is not proposing to require hospitals to separately track these additional costs but is proposing that hospitals include the cost of the radioisotope in the cost of the diagnostic radiopharmaceutical and report a token \$1 charge for the HCPCS Q9969 line. CMS states it would continue to calculate the total costs of radionuclide scans using claims data and periodically recalculate the estimated marginal costs of non-HEU Full Cost Recovery and adjust the code accordingly.

## **D. OPSS APC-Specific Policies**

### 1. Cardiovascular and Vascular Services

#### *Cardiac Telemetry (APC 0213)*

CMS finalizes its proposal with modification. Specifically, CMS is reassigning CPT code 93229 from APC 0209 to APC 0213 (instead of the proposed APC 0340) with a final 2013 geometric mean cost for APC 0213 of approximately \$178.

CMS disagrees with a commenter's concern that hospitals are incorrectly reporting the service and CMS should delay the reassignment of CPT code 93299. Based on claims data for the last 3 years, CMS believes it has sufficient information about this service and calculates a geometric mean cost of approximately \$172 for CPT code 923229. CMS does agree with concerns regarding reassigning the service to an APC that is labeled "Minor Ancillary Procedures" and based on clinical homogeneity and resource costs reassigns the code to APC 0213 (Level I Extended EEG, Sleep and Cardiovascular Studies).

#### *Mechanical Thrombectomy (APC 0653)*

CMS finalizes the continued assignment of CPT code 36860 to APC 0653, with a final 2013 geometric mean cost of approximately \$2,748.

Some commenters expressed concern that the proposed 19.7 percent payment reduction to APC 0653 would impede beneficiary's access to the procedure. CMS' analysis of the latest hospital outpatient data for claims submitted for services provided during 2011 shows a geometric mean cost for CPT code 36860 of approximately \$2,662 based on 539 single claims (out of 50,476 total claims) which is relatively similar to the proposed APC assignment. As with all codes, CMS will review this annually.

*Non-Congenital Cardiac Catherization (APC 0080)*

CMS finalizes the continued assignment of the entire cardiac catherization CPT codes to APC 0080 (Table 20 in the final rule), with a final 2013 geometric mean cost of approximately \$2,726.

In response to a commenter's concerns that two codes, CPT codes 93463 and 93464, are not cardiac catherization procedures, CMS notes these codes are included in this list because they are add-on codes that describe services performed in conjunction with cardiac catherization procedures.

*Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)*

Table 22 in the final rule provides the list of endovascular revascularization CPT codes assigned to APCs 0083, 0229, and 0319 for 2013.

- CMS finalizes the proposed continued assignment of CPT codes 37183 and 37210 to APC 0229, with a final 2013 geometric mean cost of approximately \$8,905.
- CMS finalizes the proposed continued assignment of CPT codes 37223, 37234 and 37235 to APC 0083, with a final 2013 geometric mean cost of approximately \$4,139.

Several commenters believed that the assignment of CPT code 37183 and 37210 to APC 0229 violated the 2 times rule. CMS' analysis of the 2011 claims data showed that CPT code 37183 and 37210 did not have significant claims data and that only 5 of the 12 procedures assigned to APC 0229 had significant claims to meet the required definition. CMS' analysis of the data for these procedures did not indicate a violation of the 2 times rule within APC 0029. Therefore, based on the clinical similarities to other procedures currently assigned to APC 0229 and because there is no determination of a violation of the 2 times rule, CMS does not reassign CPT codes 37183 and 37210.

Several commenters recommended the reassignment of add-on CPT code 37223 from APC 0083 to APC 0229 because of cost similarities and others argued that the assignment of the code created a violation of the 2 times rule. CMS replies that although many add-on codes are assigned to the same APC as their base code, there are some that are assigned to different APCs and APC assignment is based on clinical homogeneity and similarity in resource use. CMS does not agree that there is a violation of the 2 times rule in the composition of APC 0083 because there is insufficient claims data for CPT code 37223. CMS also disagrees that CPT codes 37234 and 37235 should be reassigned to APC 0229. CMS believes that although these procedures use stents they are still similar to the other procedures in APC 0083 and the outpatient claims data (one single claim for CPT code 37234 out of 153 total claims and no single claims for CPT code 37235 out of a total of 31 total claims) does not support an APC reassignment.

*External Electrocardiographic Monitoring (APC 0097)*

CMS finalizes the continued assignment of CPT code 0296T to APC 0097, with a final 2013 geometric mean cost of approximately \$68.

CMS disagrees with a comment that CPT code 0297T has similar resource use as CPT code 93271. CPT code 93271 includes 24-hour attended monitoring which is not included in CPT 0297T.

*Echocardiography (APCs 0177, 0178, 0269, 0270, and 0697)*

Table 23 in the final rule provides the list of echocardiography CPT codes, assigned APC and final 2013 geometric mean costs.

Based on CMS' review and comments, CMS agrees that APC 0128 (echocardiography procedures that utilize contrast agents) has a 2 times rule violation that cannot be exempted and finalizes the separation of APC 0128 to create two new level APCs:

APC 0177 (Level I Echocardiogram with Contrast and APC 0178 (Level II Echocardiogram with Contrast). The final 2013 geometric mean costs are approximately \$446 for APC 0177 and approximately \$595 for APC 0178. Table 23 in the final rule lists the 2013 APC assignments for echocardiography procedures.

## 2. Gastrointestinal Services

*Laparoscopic Adjustable Gastric Band (APC 0132)*

In response to comments, CMS revises the APC assignment for CPT code 43770 and finalizes assignment to APC 0132 instead of the proposed APC 0131. The final 2013 geometric mean cost for APC 0132 is approximately \$5,268.

CMS received conflicting statements on the issue of clinical comparability. Several commenters disagreed with the proposal to assign CPT code 43770 to APC 0131 because the procedure is different from other procedures assigned to this APC. Commenters thought the other procedures were less intense and stated that the procedure included the implantation of a gastric band device as well as a port device. Some commenters stated that assignment of CPT code 43770 to APC 0131 violated the 2 times rule and requested a new APC for the procedure. Although most commenters suggested that CMS establish a new APC code for CPT code 43770 some suggested assigning the procedure to APC 0132 as an interim APC assignment.

CMS disagrees that assigning CPT code 43770 to APC 0131 violates the 2 times rule. For the 2013 proposed rule the claims data for CPT code 433770 showed 171 single claims out of 216 total claims and comprised less than 1 percent of the claims for procedures within APC 0131. Although the HOP Panel recommended to continue to assign the code to APC 0131, in response to comments, CMS reviewed more recent claims data and the analysis indicated that the procedure would be more appropriate in APC 0132.



*Transoral Incisionless Fundoplication (APC 0422)*

CMS finalizes the continued assignment of HCPCS code C9724 to APC 0422, with a final 2013 geometric mean cost of approximately \$1,921.

CMS disagrees with comments that the payment rate for APC 0422 does not cover the cost of providing the service and states that claims data supports assignment of this code to APC 0422.

*Gastrointestinal Transit and Pressure Measurement (APC 0361)*

CMS finalizes the continued assignment of this procedure to APC 0361, with a 2013 final geometric mean cost of approximately \$613. As of January 1, 2013 the CPT Editorial panel is replacing CPT code 0242T with a Category I CPT code, 9112.

CMS disagrees with the HOP Panel recommendation to add CPT code 0242T to APC 0142. CMS' analysis of claims data does not support this recommendation and does support the continued assignment to APC 0361.

3. Integumentary System Services

*Extracorporeal Shock Wave Wound Treatment (APC 0340)*

Based on information provided by commenters, CMS reassigns CPT codes 0299T and 0300T from APC 0340 to APC 0133, which has a 2013 final geometric mean cost of approximately \$88. CMS will reevaluate the APC placement when claims data are available for CY 2014.

Several comments, including comments from several clinicians involved in the initial clinical trial, provided additional information about these services and the related resources.

*Application of Skin Substitute (APC 0133 and 0134)*

CMS finalizes the continued assignment of CPT codes 15272 and 15276 to APC 0133, which has a 2013 final geometric mean cost of approximately \$259, and CPT code 15274 and 15278 to APC 0134, which has a final geometric mean cost of approximately \$259. CMS will reevaluate the APC placement when claims data are available for CY 2014.

CMS disagrees with the request to reassign the 2012 new (replacement) CPT codes for the application of skin substitutes. CMS maintains that the assignment of these codes is most appropriate based on clinical homogeneity and estimated resource similarity.

*Low Frequency, Non-Contact, Non-Thermal Ultrasound (APC 0015)*

CMS finalizes the reassignment of CPT code 0183T from APC 0015 to APC 0013, with a final geometric mean cost of approximately \$74.

In response to comments CMS notes that the final rule geometric mean cost of CPT code 0183T (approximately \$88) and APC 0013 (approximately \$74) are very similar as compared to the final rule geometric mean cost of APC 0015 (approximately \$110). They note that merging the two APCs would create several 2-times rule violations.

#### 4. Nervous System Services

##### *Scrambler Therapy (APC 0215)*

CMS finalizes the proposed assignment of CPT code 0278T to APC 0215, with a final geometric mean cost of approximately \$44.

Effective January 1, 2012 the CPT Editorial Panel established a Category III code 0278T (Transcutaneous electrical modulation pain repro.) and for 2012 this code was assigned a comment indicator “NI” and assigned on an interim basis to APC 0215. In response to comments requesting reassignment, CMS notes that as a new Category III CPT code for 2012, they do not have hospital claims data for this procedure. Under the OPSS, CMS assigns a payment rate to a new Category III code based on input from a variety of sources such as information from specialty societies, input from CMS medical advisors, and a review of costs and clinical homogeneity of the service to the existing procedure. Based on the information provided, CMS does not believe there is sufficient clinical or cost information to justify a reassignment to a different APC but will reevaluate for the 2014 update.

##### *Transcranial Magnetic Stimulation Therapy (TMS) (APC 0216)*

CMS modifies its proposal and finalizes reassignment of CPT codes 90867, 90868, and 90869 from APC 0218 to APC 0216, with a final 2013 geometric mean cost of approximately \$189. (Summarized in Table 24 in the final rule.)

A commenter disagreed with the proposed APC assignment to APC 0218 and stated that the TMS therapy codes are not similar to the services assigned to APC 0218. Based on CMS’ review of the latest claims data, CMS agrees with one of the commenter’s suggestions that APC 0216 would be the more appropriate APC assignment for the three TMS therapy codes. CMS also agrees with the commenter’s suggestion to revise the APC titles of 0215, 0216, and 0218 to appropriately reflect the services within each APC. These APC titles have been changed from different level of “Nerve and Muscle Tests” to “Nerve and Muscle Services”.

##### *Paravertebral Neurolytic Agent (APC 0207)*

CMS finalizes the continued assignment of CPT code 64633 to APC 0207, with a final 2013 geometric mean cost of approximately \$582.

For 2012, CMS assigned the new CPT code 64633 a comment indicator of “NI” and assigned it on an interim basis to APC 0207. A commenter believed the payment rate substantially underpays providers. CMS notes it does not have any claims data to validate this comment and will reevaluate for the 2014 rulemaking cycle.

##### *Programmable Implantable Pump (APC 0691)*

CMS finalizes the continued assignment of CPT codes 62369 and 62370 to APC 0691, with a final 2013 geometric mean cost of approximately \$197.

For 2012, CMS assigned the new CPT codes 62369 and 62370 a comment indicator of “NI” and assigned it on an interim basis to APC 0691. A commenter believed the payment rate

substantially underpays providers. CMS notes it does not have any claims data to validate this comment and will reevaluate for the 2014 rulemaking cycle.

*Revision/Removal of Neurostimulator Electrodes (APC 0687)*

CMS modifies its proposal and finalizes reassignment of CPT code 64569 from APC 0687 to APC 0040, with a final 2013 geometric mean cost of approximately \$4,526.

Commenters objected to the assignment of CPT code 64569 in APC 0687 because the code is used to report both the revision and replacement of neurostimulator electrodes. Commenters noted that hospital resources are substantially greater when neurostimulator electrodes are being replaced rather than revised. CMS agrees with the commenters.

5. Ocular Services: Placement of Amniotic Membrane (APC 0233)

CMS finalizes the continued assignment of CPT code 65778 to its conditionally packaged status of “Q2” and the reassignment of the status indicator for CPT code 65779 from “T” to “Q2”. When CPT code 65779 is furnished with a separately payable surgical procedure with status indicator “T” on the same day, the code is packaged. CMS also will continue to assign both CPT codes to APC 0233, which has a final 2013 geometric mean cost of approximately \$1,162. (Summarized in Table 25 in the final rule.)

In response to a comment, CMS states that it believes that the revision in the status indicator for CPT code 65779 would enable hospitals to perform either procedure, CPT code 65778 or 65779, when appropriate, and would not differentiate between procedures based on the status indicator. In addition, CMS’ review of claims data supports the assignment to APC 0233.

6. Radiology Oncology

*Proton Beam Therapy (APCs 0664 and 0667)*

CMS modifies its proposal and maintains the current APC structure for APC 0664 and 0667. CMS however, finalizes the updates for the 2013 payment rates for proton beam therapy to reflect recently available claims data from all providers. The 2013 final geometric mean cost of APC 0664 (including CPT codes 77520 and 77522) is approximately \$1,169 and the final geometric mean cost of APC 0667 (including CPT codes 77523 and 77525) is approximately \$702.

Commenters requested that CMS forego using any 2011 claims data to set the 2013 rates because they are based, in part, on inaccurate data reported by one of the few billing providers (only 3 providers bill Medicare for these services). They requested that CMS maintain both the 2012 payment rates and the 2012 APC configuration. CMS maintains the 2012 APC configuration but uses all the available data to determine 2013 payment rates.

*Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)*

CMS finalizes the continued assignment of CPT code 77338 to APC 0305, with a final 2013 geometric mean cost of approximately \$299.

CMS disagrees with a comment that providers are inappropriately coding the service, which is contributing to the low estimated cost of this service as compared to its predecessor code and will continue to use claims data for determining the payment level for this code. CMS will reevaluate for 2014 rulemaking.

*Other Radiation Oncology Services (APCs 0310 and 0412)*

CMS finalizes the payment rates for the following services:

- CPT code 77418 is assigned to APC 0412 with a 2013 final geometric mean cost of approximately \$498.
- CPT code 77295 is assigned to APC 0310 with a 2013 final geometric mean cost of approximately \$991.
- CPT code 77373 is assigned a status indicator of “B” (Not covered under the OPSS). Hospitals should report this service using HCPCS code G0251; code G0251 is assigned to APC 0065 with a 2013 final geometric mean cost of approximately \$1,007.
- CPT code 77014 is assigned a status indicator of “N” and is packaged (a policy implemented in 2008).

CMS disagrees with a commenter’s concern about a perceived decrease in payment for these services and notes a slight payment increase in 2013.

*Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067, and 0127)*

CMS finalizes the continued assignment of CPT code 77371 to APC 0127 with a 2013 final geometric mean cost of approximately \$8,138 and the continued assignment of HCPCS code G0339 to APC 0067 with a 2013 final geometric mean cost of approximately \$3,395.

CMS disagrees with a comment that the APC assignments for the linear acceleration-based (LINAC) and robotic Cobalt-60 based stereotactic radiosurgery HCPCS codes should be the same because they have similar resource costs. CMS’ analysis of the updated 2011 claims data indicates that the code-specific geometric mean costs for these systems are different and different APC assignments are appropriate.

*Intraoperative Radiation Therapy (IORT) (APC 0412)*

CMS modifies the proposed assignment and finalizes the assignment of CPT codes 77424 and 77425 to APC 0065 with a 2013 final geometric mean cost of approximately \$1,006. CMS will review the APC assignment of each code individually once OPSS claims data are available and will also provide this information to the HOP Panel. CMS finalizes the status indicator for CPT code 77469 as “B”, codes that have nonpayable status under the OPSS.

Many commenters supported the proposal to unpackage 77424 and 77425, but objected to the proposed assignment of these codes to APC 0412 because of the differences in clinical characteristics and resource use. Some commenters, including a recommendation from the HOP Panel, requested an assignment to APC 0313 (Brachytherapy) and other commenters requested an assignment to APC 0067 (Level III Stereotactic Radiosurgery). CMS notes that IORT services are not the typical intraoperative packaged services as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes

IORT. CMS agrees with commenters that the resource costs of APC 0412 do not fit with IORT and based on the range of claimed costs provided by the commenters, will assign the codes to APC 0065.

## 7. Imaging

### *Non-Ophthalmic Fluorescent Vascular Angiography (FVA) (APC 0397)*

CMS finalizes its proposal to assign HCPCS code C9733 to APC 0397 and to continue to assign the code to status indicator “Q2”; APC 0397 has a 2013 final geometric mean cost of approximately \$340.

CMS disagrees with commenters and believes that when the non-ophthalmic FVA procedure is performed with a surgical procedure, it is ancillary to the surgical service by providing imaging services that are supportive and adjunctive to the surgical service and the status indicator “Q2” is appropriate. When the service is performed as a stand-alone service, it is separately paid. CMS also notes that the assumed monthly use of the related equipment markedly affects the estimated cost of the procedure and that low utilization of a new technology can result in aberrantly higher case cost estimates. CMS will continue to evaluate this in future ratesetting.

### *Level II Nervous System Imaging (APC 0402)*

CMS finalizes the continued assignment of CPT code 78607 to APC 0402 with a 2013 final geometric mean cost of approximately \$472.

In response to commenters’ concerns about the proposed 22 percent payment reduction, CMS notes that the proposed payment rate using either the geometric mean or median based methodology resulted in a decreased payment rate with a median cost of approximately \$497 and a geometric mean cost of approximately \$477. CMS did an additional examination of the claims data and notes that CPT code 78607 represents 75 percent of the claims for services assigned to APC 0402.

### *Computed Tomography (CT) of the Abdomen/Pelvis (APCs 0331 and 0334)*

As summarized in Table 28 in the final rule (copied below), CMS finalizes the continued assignment of these CPT codes to a single and composite APC for CT and CTA. Status indicator “Q3” indicates they are eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other CT procedures performed on the same patient on the same day.

**Table 28. APC Assignments for the Computed Tomography of Abdomen and Pelvis  
CPT Codes for 2013**

<b>CY 2013 CPT Code</b>	<b>CY 2013 Short Descriptor</b>	<b>CY 2013 SI</b>	<b>CY 2013 Single Code APC</b>	<b>CY 2013 Composite APC</b>
74176	Ct abd & pelvis	Q3	0331	8005
74177	Ct abd & pelv w/contrast	Q3	0334	8006

74178	Ct abd & pelv 1/> regns	Q3	0334	8006
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Several commenters expressed concerns about the proposed decrease in payment rates for APC 0331 and 0334 and that hospitals had not had enough time to appropriately adjust their charge masters to accurately reflect the 2011 coding changes. CMS disagrees and notes that there are hundreds of coding changes every year and hospitals make changes to their internal systems to ensure their claims are processed timely and accurately. CMS also notes that because of the substantial claims data for these procedures, it has no reason to delay the use of the claims data in determining the costs for these codes.

## 8. Respiratory Services

### *Bronchoscopy (APC 0415)*

CMS finalizes its proposal to reassign CPT codes 31629 and 31634 from APC 0076 to APC 0415 with a final 2013 geometric mean cost of approximately \$1,1617.

CMS disagrees with commenters requesting alternative reassignment for CPT codes 31629 and 31634. CMS proposed the revised APC assignments because analysis of the claims data revealed a 2 times rule violation in APC 0076. Based on claims data analysis and the recommendation from the HOP Panel, CMS states that reassignment of these codes to APC 0415 is appropriate. CMS will reevaluate the clinical similarity and resource use of the procedures in APC 0415 for the 2014 rulemaking.

### *Upper Airway Endoscopy (APC 0075)*

CMS finalizes continued assignment of CPT codes 31295, 31296, and 31297 to APC 0075, and reassigns CPT code 31541 to APC 0075, with a final 2013 geometric mean cost of approximately \$2,085.

CMS disagrees with comments that the payment rate for APC 0075 substantially underpays providers. CMS also disagrees with a request to separate APC 0075 into an APC for sinus surgery with balloon catheter (device-dependent) and an APC for sinus surgery without balloon catheter. CMS notes that the commenters assert costs of approximately \$4,000 for the device-dependent procedures; CMS calculates that the highest geometric mean cost of all the procedures assigned to this APC is approximately \$4,000, which includes the “nonclaims data” cost estimate offered by commenters. CMS notes there is currently no 2 times rule violation in APC 0075 supporting its decision not to split the APC. CMS also does not agree with commenters that CPT code 41541 should remain in APC 0074 since the clinical characteristics and geometric mean cost justify its reassignment from APC 0074 to APC 0075.

## 9. Other Services

### *Payment for Molecular Pathology Services*

CMS finalizes the assignment of the 101 molecular pathology services CPT code to status indicator “A” for 2013. Status indicator “A” indicates that the codes will be paid under a Medicare fee schedule and not under the OPPS. For 2013, CMS will also assign status indicator

“A” to the 14 new Tier I Molecular Pathology Procedure CPT codes that the CPT Editorial Panel established effective January 1, 2013. These codes will be paid under the CLFS.

HCPCS code G0452 (Molecular pathology procedure; physician interpretation and report) will be assigned status indicator “B” under the OPPS for 2013. Status indicator “B” indicates the code describes a professional component-only service paid under the MPFS.

CMS disagrees with comments and notes that molecular pathology services are currently billed using stacking codes that are paid under the CLFS. In response to comments that this issue was not discussed in the preamble of the OPPS proposed rule, CMS notes that the codes were assigned status indicator “A” in Addendum B in the proposed rule and were subject to comment.

#### *Bone Marrow (APC 0112)*

CMS finalizes the continued assignment of CPT codes 38240 and 38241 to APC 01112, with a final 2013 geometric mean cost of approximately \$2,972.

CMS disagrees with a comment that CMS create separate APCs for autologous and allogeneic transplants because of the cost differences between the two procedures.

### **IV. OPPS Payment for Devices**

#### **A. Pass-Through Payments for Devices**

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. CMS’ established policy is to base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device. Further, except for brachytherapy sources, for devices that are no longer eligible for pass-through payments CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates. CMS proposes and finalizes the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

#### *Expiration of Transitional Pass-Through Payments for Certain Devices*

CMS finalizes the expiration date for the four device categories currently eligible for pass-through payment:

- HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)), pass through payment expires after December 31, 2012;
- HCPCS code C1830 (Powered bone marrow biopsy needle), pass through payment expires after December 31, 2013;
- HCPCS code C1840 (Lens, intraocular (telescopic)), pass through payment expires after December 31, 2013; and
- HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), pass through payment expires after December 31, 2013.

Therefore, after December 31, 2012, CMS will package the C1749 device costs into the costs of the procedure with which the devices are reported on hospitals' bills. Beginning January 1, 2014, device categories C1830, C1840, and C1886 will no longer be eligible for pass-through payments, and their respective device costs will be packaged into the costs of the procedures with which the devices are reported in the claims data.

In response to a commenter's concerns that there were few claims for HCPCS code C1886 in 2011, CMS agrees but reports there are over 300 units of the code reported in the first 8 months of 2012 which provides sufficient information to base payment rates. CMS disagrees that packaging C1749 will not provide adequate payment for the device. CMS notes it will be able to track utilization of the device as hospitals are required to include code C1749 and its costs on claims with the corresponding billed procedure.

#### *Provisions for Reducing Transitional Pass-through Payments to Offset Costs Packaged into APC Groups*

For 2013, CMS finalizes its proposal to continue the following policies related to pass-through payment for devices:

- 1) treating implantable biologicals, which are surgically inserted or implanted (through a surgical incision or a natural orifice) and which are newly approved for pass-through status on or after January 1, 2010, as devices for purposes of the OPSS pass-through evaluation process and payment methodology;
- 2) including implantable biologicals in calculating the device APC offset amounts;
- 3) using the device APC offset amounts to evaluate whether the cost of a device (defined to include implantable biologicals) in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices; and
- 4) reducing device pass-through payments based on device costs already included in the associated procedural APCs when it is determined that device costs associated with the new category are already packaged into the existing APC structure.

CMS finalizes the proposal to place on the CMS web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>, the list of all procedural APCs with the final 2013 portions of the APC payment amounts that it determines are associated with the cost of devices.

CMS disagrees with a commenter's recommendation that all biologicals, including implantable biologicals approved by FDA under biological license applications, be treated as drugs. CMS reiterates their policy to exclude from consideration for drug and biological pass-through status any biological that has an indication it may function as a surgically implanted or inserted biological, even if there also are indications in which the biological is not surgically implanted or inserted. This language is on the device application web site and CMS will add similar language to the device and drug pass-through application web sites.

#### *Clarification of Existing Device Category Criterion*

In order to determine if a new device is appropriately described by any existing or previously in effect category of devices, CMS applies two tests based upon the evaluation of information



provided in the device category application:

1. An applicant for a new device category must show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update.
2. An applicant must demonstrate that utilization of its device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments, including procedures utilizing devices in any existing or previously in effect device categories.

CMS considers a new device that meets both of these tests not to be appropriately described by any existing or previously in effect pass-through device categories.

For 2013, CMS finalizes its proposal and clarifies that a candidate device may not be considered to be appropriately described by any existing or previously in effect pass-through device categories if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) that belong or once belonged to an existing or any previously in effect device category, and that the candidate device is not similar to devices whose costs are reflected in the OPPS claims data in the most recent OPPS update. The substantial clinical improvement criterion, which also must be satisfied in every case, is separate from the criterion that a candidate device not be similar to devices in any existing or previously in effect pass-through categories. CMS did not receive any comments about this proposal.

## **B. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices**

CMS finalizes its proposal to continue all of its current policies.

Under current policy, CMS reduces the payment for selected device-dependent APCs when the hospital receives certain replacement devices without cost or receives a full credit for the device being replaced. Hospitals are instructed to report such full credit/no cost cases using the “FB” modifier on the line with the procedure code in which the free device is used. Payment is also reduced when hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals are instructed to append the “FC” modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device.

CMS applies three criteria when determining the APCs to which the policy should apply:

- All procedures assigned to the selected APCs must require implantable devices that would be reported if device replacement procedures were performed.
- The required device must be surgically inserted or be an implanted device that remains in the patient's body after the conclusion of the procedure (at least temporarily).
- The device offset amount must be significant, defined as exceeding 40 percent of the APC cost.

Table 29 of the final rule lists the APCs to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in 2013 and displays the payment adjustment percentages for both no cost/full credit and partial credit circumstances. Table

30 lists the devices to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in 2013.

CMS finalizes its proposal for 2013 that OPSS payment for the implantation procedure to which the “FB” modifier is appended are reduced by 100 percent of the device offset amount for full credit/no cost cases when both a specified device code (Table 30) is present on the claim and the procedure code maps to a specified APC (Table 29). CMS also finalizes its proposal that OPSS payments for the implantation procedures to which the “FC” modifier is appended are reduced by 50 percent of the device offset amount for partial credit cases when both a specified device code (Table 30) is present on the claim and the procedure code maps to a specified APC (Table 29). Beneficiary copayment is based on the reduced payment amount when either the “FB” or “FC” modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

CMS disagrees with commenters that there is a problem because sometimes hospitals receive a full credit for only one component of a pacemaker or ICD replacement procedure that involves both a lead and a generator. CMS reiterates that averaging is inherent in a prospective payment system and in some cases, the estimated device cost and, therefore, the amount of the payment reduction will be more or less than the cost a hospital would otherwise incur. For clarification of the “FB/FC” modifier, CMS refers interested individuals to the Medicare Claims Processing Manual, Chapter 4, Sections 61.3.1 and 61.3.3. In response to a comment, CMS also notes that not all device-dependent APCs are included on the list of APCs to which the no cost/full credit and partial credit device adjustment policy apply.

## **V. OPSS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**

### **A. OPSS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals and Radiopharmaceuticals**

#### **1. Drugs and Biologicals with Expiring Pass-Through Status in 2013**

CMS finalizes its proposal to let the pass-through status expire for the 23 drugs and biologicals listed in Table 31 of the final rule on December 31, 2012. By that date, all of these drugs and biologicals will have received OPSS pass-through payment for at least 2 years and no more than 3 years. Except for drugs and biologicals that are always packaged when they do not have pass-through status (diagnostic radiopharmaceuticals and contrast agents), CMS will continue to make a separate payment if the product’s estimated per day cost exceeds the OPSS drug packaging threshold, which is finalized at \$80. Table 31 indicates that 21 of the 23 drugs would qualify for separate payment at ASP+6 percent (CMS acknowledges that J7183 was erroneously assigned to status indicator “N” in the proposed rule.); 3 products will be packaged in 2013.

In response to several commenters requesting pass-through status for 3 years CMS reiterates its longstanding practice to begin pass-through payment on a quarterly basis based on when applications are submitted but let pass-through status expire only on an annual basis. CMS disagreed with a wide-range of commenters requesting that HCPCS code C9275 (Injection, hexaminolevulinic acid hydrochloride) continue to be paid separately to ensure payment and

utilization. CMS states that hospitals may bill an unlisted code for the accompanying blue light cystoscopy procedure and include costs for C9275 on the claim. This information would be included in future ratesetting for these products.

## **2. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in 2013**

CMS finalizes its proposal to continue pass-through status in 2013 for the 26 drugs and biologicals listed in Table 32 of the final rule. **For 2013, CMS finalizes payment for drugs and biologicals with pass-through status at ASP+6 percent.**

The pass-through payment portion of the payment is the difference between the rate that CMS pays in 2013 for nonpass-through, separately payable drugs and the pass-through drug rate of ASP+6 percent. Excluding policy-packaged drugs, the pass-through portion is zero since CMS will pay both pass-through and nonpass-through drugs at ASP+6 percent. For pass-through contrast agents and diagnostic radiopharmaceuticals, the pass-through payment portion of the payment is the full payment, which equals ASP+6 percent less any “policy-packaged” drug offset (described in the next subsection) because, if not on pass-through status, payment for these products would be packaged into the associated procedures. Determining the pass-through portion of a drug’s payment is important, in part, because this is the portion that is counted in calculating total pass-through payments for the purpose of the conversion factor offset.

CMS finalizes its proposal to continue its 2012 policy for radiopharmaceutical in 2013. All pass-through diagnostic and therapeutic radiopharmaceuticals will continue to be paid based on the ASP methodology. If ASP data are not available for a radiopharmaceutical, CMS proposes to set the payment rate at wholesale acquisition cost (WAC)+6 percent, as applies to pass-through drugs and biologicals without ASP information. If WAC information is also not available, CMS will pay the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

CMS finalizes its proposal to continue to set the copayment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals at zero for 2013. Similarly, CMS finalizes its proposal that the copayment amount for pass-through anesthesia drugs that would otherwise be packaged will be zero for 2013. If these items did not have pass-through status, they would be packaged and no separate payment would be made for their use.

CMS notes that several commenters supported CMS’ proposal to provide payment at ASP+6 for drugs, biologicals, contrast agents and radiopharmaceuticals that are granted pass-through status. CMS rejects comments requesting additional payment and changes in pass-through status for specific drugs.

## **3. Provision for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents to Offset Costs Packaged into APC Groups**

*Payment Offset Policy for Diagnostic Radiopharmaceuticals:* For 2013, CMS finalizes its proposal to continue current policies for the “policy-packaged” drug offset. CMS deducts from the payment for pass-through radiopharmaceuticals an amount that reflects the portion of the

APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made. In 2009, CMS established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals.

CMS utilizes 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). To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPSS payment amount, CMS 1) multiplies 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 2) reduces the separate OPSS payment for the pass-through diagnostic radiopharmaceutical by this amount. The radiolabeled product edits in the I/OCE require a hospital to report a diagnostic radiopharmaceutical with a nuclear medicine scan in order to receive payment for the nuclear medicine scan.

For 2013, CMS will continue to require hospitals to append modifier “FB” to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. When the diagnostic radiopharmaceutical is furnished without cost or with full credit, CMS will continue to instruct the hospital to report a token charge of less than \$1.01. When a hospital bills an “FB” with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table 33 of the final rule will be reduced by the full “policy-packaged” offset amount appropriate for diagnostic radiopharmaceuticals.

There is currently one radiopharmaceutical with pass-through status under the OPSS, HCPCS code A9584 (Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries). This product was granted pass-through status using HCPCS code C9406 beginning July 1, 2011. CMS finalizes its proposal to continue pass-through status for this product in 2013 and will apply the radiopharmaceutical payment offset policy to pass-through payment for this product.

In response to comments, CMS states that although not discussed in the proposed rule, it will continue to annually update and implement the radiopharmaceutical edits for nuclear medicine procedures using radiopharmaceuticals as long as diagnostic radiopharmaceuticals are packaged. Specific instructions are contained within the I/OCE CMS specification on the web site at <http://www.cms.gov/OutpatientCodeEdit/02OCEQtrReleaseSpecs.asp#TopOfPage>. In response to comments CMS notes that the exact data used to calculate all the proposed and final payment rates, including the associated offset amounts for the CY 2013 OPSS are available for purchase under a CMS data use agreement at <http://www.cms.gov/Medicare?Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

*Payment Offset Policy for Contrast Agents:* For 2013, CMS finalizes its proposal to continue to deduct from the OPSS payment for pass-through contrast agents an amount that reflects the portion of the APC payment associated with predecessor contrast agents in order to ensure no duplicate contrast agent payment is made. To determine the actual APC offset amount, CMS applies the same methodology that is used for radiopharmaceuticals, as described above.

Procedural APCs for which CMS expects a pass-through contrast agent offset could be applicable have been identified as any procedural APC with a “policy-packaged” drug amount greater than \$20 that is not a nuclear medicine APC identified in Table 33 of the final rule. The APCs meeting these criteria are displayed in Table 34 of the final rule. CMS did not receive any comments about these polices.

There are currently no contrast agents with pass-through status under the OPSS.

## **B. OPSS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status**

### **1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals**

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged into the payment for the associated service; or separate payment (individual APCs). Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPSS payment rate for the associated procedure or service.

*Cost Threshold for Packaging of “Threshold-Packaged Drugs:”* “Threshold-packaged drugs” under OPSS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If their cost per day exceeds the threshold, they are separately payable and if not, they are packaged. For 2012, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was \$75. **For 2013, CMS finalizes a packaging threshold of \$80.**

In calculating the packaging threshold for the 2013 final rule, CMS used updated four quarter moving average producer price index (PPI) for prescription drugs to trend the \$50 threshold forward from the third quarter of 2005 to the third quarter of 2013 and rounded the resulting dollar amount (\$81.91) to the nearest \$5 increment.

CMS disagrees with commenters’ objections to the proposed increase in the OPSS packaging threshold from \$75 to \$80. CMS believes that updating the threshold is consistent with industry and government practices and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Because of all the numerous price proxies in the market basket update, CMS does not consider this an appropriate mechanism for determining the outpatient drug packaging threshold amount. In response to comments that drugs should not be packaged and instead, should be paid separately, similar to the Physician Fee Schedule (PFS), CMS states that OPSS and the PFS are fundamentally different payment systems with essential differences in their payment policies and structures (prospective payments related to costs of resources used for services as compared to a fee schedule based on the relative value of each component). CMS also notes that the growing utilization associated with packaged drugs and biologicals in the claims data suggests beneficiaries have sufficient access to these items.

CMS also disagrees with comments recommending separate payment for any drug used in anticancer regimens and specifically for 5-HT3 antiemetics, a class of drugs used as part of anticancer treatment to treat nausea. CMS states this is not consistent with a prospective payment system and it can not find any evidence of beneficiary access issues.

*Use of quarterly ASP data:* CMS finalizes to continue their standard methodology and to use quarterly ASP updates as follows:

- 4<sup>th</sup> quarter of 2011: budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2013 OPPS proposed rule;
- 2<sup>nd</sup> quarter of 2012: payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the 2013 OPPS final rule;
- 3<sup>rd</sup> quarter of 2012: payment rates effective January 1, 2013 for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B; these are the same ASP data used to calculate payment rates effective January 1, 2013 for drugs and biologicals furnished in the physician's office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using ASP data with a two-quarter lag. CMS finalizes its proposal to continue its policy to make an annual packaging determination for a HCPCS code when it develops the OPPS final rule. Only HCPCS codes that are identified as separately payable in the final rule will be subject to quarterly updates.

The proposed rule noted that the packaging status of some threshold-packaged drugs may change based on more current data used for the final rule. CMS finalizes its proposal to continue to use the following rules, which are unchanged from past years, for determining packaging status:

- HCPCS codes that were separately payable in 2012 and were proposed for separate payment in 2013 would continue to be separately payable in 2013 even if the updated data used for the 2013 final rule indicate per day costs equal to or less than \$80. Therefore, HCPCS codes J2700 and J9218 will continue to be paid separately in 2013.
- HCPCS codes that were packaged in 2012, proposed for separate payment in 2013, and then have per day costs equal to or less than \$80 based on the updated data used for the 2012 final rule would remain packaged in 2013.
- HCPCS codes for which CMS proposed packaged payment in 2013 but then have per day costs greater than \$80 based on the updated data used for the 2013 final rule would be separately payable in 2013. Therefore, HCPCS codes J0365, J1560, J7183, and Q4105 will be paid separately in 2013.

CMS also finalizes its proposal that HCPCS codes J1452 and J1835 will be assigned a status indicator of "K" for 2013 and will be paid separately.

*Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages:* For 2013, CMS finalizes its proposal to continue its policy of making

packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy would apply are listed in Table 35 of the final rule. CMS did not receive any comments on this proposal.

*Packaging of Payment for Nonpass-through Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals (“Policy-Packaged” Drugs and Devices):*

Similar to the policies applicable to pass-through drugs and biologicals, for 2013 CMS finalizes its proposal to continue these policies for nonpass-through drugs and biologicals:

- package payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as “policy-packaged” drugs, regardless of their per day costs;
- package payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and package the payment for contrast agents into the payment of the associated echocardiography imaging procedure, regardless of whether the contrast agent meets the OPDS drug packaging threshold; and
- package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body.

For nonpass-through biologicals that may sometimes be used as implantable devices, CMS will continue to instruct hospitals not to bill separately for the HCPCS codes for the products when they are used as implantable devices.

## **2. Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged**

*a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals:*

Section 1833(t)(14)(A)(iii) of the Act requires that payment for a SCOD for 2006 and succeeding years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology used to pay for drugs furnished in a physician’s office, as described in sections 1842(o), 1847A, or 1847B of the Act and as calculated and adjusted by the Secretary. Most Part B drugs administered in physicians’ offices are paid at ASP+6 percent.

For 2013, **CMS finalizes its proposal to pay separately payable drugs at the statutory default rate of ASP+6 percent** and abandon its standard rate setting methodology.

CMS encourages hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged, and to ensure that drug costs are completely reported, using appropriate revenue codes. CMS does not accept a recommendation made by the APC Panel in February 2012 to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636. CMS indicates that drugs and biologicals may also be appropriately reported in revenue code categories other than revenue code 0636, including but not limited to, revenue codes 025x and 062x.

Commenters strongly supported CMS' proposal. CMS disagrees with several commenters' concern that this payment level is not sufficient to cover both drug acquisition and pharmacy overhead costs.

*b. Payment Policy for Therapeutic Radiopharmaceuticals*

For 2013, CMS finalizes its proposal to continue to pay for all nonpass-through, separately payable therapeutic radiopharmaceuticals under the same ASP methodology that is adopted for separately payable drugs and biologicals, or ASP+6 percent, when manufacturers submit the necessary ASP information for a "patient ready" dose. The payment rate will be updated quarterly using the most recently available ASP data reported by manufacturers. Reporting ASP information remains optional for manufacturers. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS proposes to determine payment rates based on 2011 mean unit cost data derived from hospital claims data.

Commenters supported CMS' proposal. CMS disagrees with a request that CMS create a HCPCS J-code for tositumomab, currently provided under a radioimmunotherapy regimen and billed as part of HCPCS code G3001. CMS states that unlabeled tositumomab is not approved as either a drug or a radiopharmaceutical and that it is a supply that is required as part of the radioimmunotherapy treatment regimen.

*c. Payment for Blood Clotting Factors*

For 2013, CMS finalizes its proposal to continue to pay for blood clotting factors using the same methodology used to pay other nonpass-through separately payable drugs and biologicals under the OPSS, or ASP+6 percent. CMS will update the furnishing fee based on the percentage increase in the Consumer Price Index (CPI) for medical care following the same methodology it has used since 2008. For 2013, the updated amount will be based on the percentage increase in the CPI for medical care for the 12-month period ending in June 2012. CMS will announce the actual fee through program instructions and posting on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>. When blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee also is applied to the payment. Commenters supported this proposal.

*d. Payment for New Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPSS Hospital Claims Data*

For 2013, CMS finalizes its proposal to continue to pay for new 2013 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+6 percent, the same method used for other nonpass-through separately payable drugs and biologicals.

For 2013, CMS will continue to package payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data (those new 2013 diagnostic radiopharmaceutical, contrast agent, and



implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes), consistent with the packaging of all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents and implantable biologicals. CMS will continue to assign status indicator “K” to HCPCS codes for new drugs and biologicals without OPSS claims data for which CMS has not granted pass-through status (Table 36 in the final rule).

In the absence of ASP data, for 2013 CMS will continue the policy first implemented in 2005 of using WACs to establish the initial payment rate for new nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals which have HCPCS codes and are separately payable. If the WAC also is unavailable, CMS will pay at 95 percent of the product’s most recent AWP. Once ASP data become available in later quarter submissions, payment rates under the OPSS will be adjusted based on the ASP methodology using the ASP+6 payment amount.

New 2013 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals, which were not available at the time of development of the proposed rule, are included in Addendum B to the 2013 OPSS final rule and are assigned comment indicator “NI” to reflect that their interim final OPSS treatment is open to public comment.

CMS continues its existing methodology for determining the 2013 packaging status of nonpass-through drugs and biologicals that were payable in 2011 and/or 2012 but for which CMS does not have 2011 hospital claims data. If CMS has pricing information available for the ASP methodology, it calculates the per day cost of the drug or biological by multiplying the payment rate for each product based on ASP+6 percent by an estimated average number of units of each product that would typically be furnished to a patient during one administration in the hospital outpatient setting.

CMS finalizes its proposal to continue to assign status indicator “E” to drugs and biologicals that were payable in 2011 but for which CMS lacks both 2011 claims data and pricing information for the ASP methodology. The 19 products that fall into this category are listed in Table 37 of the final rule. If pricing information becomes available for these products, CMS will assign the products status indicator “K” and pay for them separately for the remainder of 2013.

CMS did not receive any comments about these proposals. CMS disagrees with a comment that the status indicator for HCPCS code Q4128 was erroneously assigned a status indicator of “E” instead of “K” and should have been assigned “K” effective January 1, 2012. CMS notes that the status indicator was changed to “K” when pricing information was received during 2012.

## **VI. Estimate of OPSS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices**

CMS estimates that total pass-through spending for drug and device pass-through payments during 2013 will equal about \$74 million, or 0.15 percent of total OPSS projected payments for 2013. The final rule aggregate estimate is \$10 million less than the estimate in the proposed rule, which is attributed to lower estimated spending for drugs and nonimplantable biologicals for 2013. CMS notes that it did not receive comments on any of its proposed estimation methodologies and thus finalizes them as proposed to develop estimates for the final rule.

## **A. Devices**

Using its established methodology, CMS projects \$52 million in pass-through spending attributable to device categories in 2013. The estimate for the first group of device categories is \$42 million. The first group consists of those device categories receiving pass-through payments in 2012 that would continue for payment in 2013, and there are three device categories in this group: C1830 (Powered bone marrow biopsy needle), C1840 (Lens, intraocular (telescopic)), and C1886 (Catheter, extravascular tissue ablation, any modality (insertable)).

The estimate for the second group of device categories is \$10 million. The second group consists of those device categories CMS knows or projects may be approved for pass-through status in 2013, and includes contingent projections for new device categories in the second through fourth quarters of 2013. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for the second group.

## **B. Drugs and Biologicals**

CMS projects \$32 million in pass-through spending attributable to drugs and nonimplantable biologicals in both groups in 2013. CMS considers radiopharmaceuticals as drugs for pass-through purposes and includes them in their estimates for drugs and biologicals.

The final estimate for the first group of drugs and nonimplantable biologicals is \$15 million which reflects an increase of \$2 million in the proposed rule. The first group consists of drugs and biologicals recently eligible for pass-through payments that would continue in 2013. CMS projects utilization based on physician office data, information in pass-through applications, historical hospital claims data, as well as other data sources.

The final estimate for the second group of drugs and nonimplantable biologicals is \$7 million which reflects a decrease of \$12 million from the proposed estimate for this group. This group consists of those drugs and biologicals CMS knows or projects could be approved for pass-through status in 2012, and includes contingent projections for new drugs and nonimplantable biologicals that could initially be eligible in the second through fourth quarters of 2013.

Because CMS will pay for most non-pass-through and all pass-through drugs and biologicals at the same rate (ASP+6 percent), its estimates for this group of items is zero. However, the estimate of pass-through payment amounts for diagnostic radiopharmaceuticals and contrast agents with pass-through status approved before 2013 is not zero because they would be paid at ASP+6 percent in lieu of being packaged into associated procedures as is the case for non-pass-through radiopharmaceuticals and contrast agents. Please refer to section V of the summary for a description of the methodology used to determine whether the cost of certain "policy-packaged" drugs are already packaged in the existing APC structure.

## **VII. OPSS Payment for Hospital Outpatient Visits**

### **A. Codes**

CMS continues to recognize the CPT and HCPCS codes that describe clinic visits, Type A and B emergency department visits, critical care services, and trauma team activation provided in association with critical care services for 2013. The list of HCPCS codes for hospital reporting is presented in Table 38 of the final rule.

### **B. Hospital Outpatient Visit Policies**

CMS finalizes all its proposals related to hospital outpatient visits with one modification. The agency moves HCPCS code G0379 (Direct admission from patient for hospital observation care) to APC 0608 (Level 5 Hospital Clinic Visits) based on a recommendation from the Hospital Outpatient Payment (HOP) Panel. Thus, CMS continues the following policies related to outpatient visits:

1. The definitions of “new” and “established” patients are based on whether the patient had been registered as an inpatient or outpatient of the hospital, including its off-campus provider-based clinic or emergency department, within the past 3 years prior to the patient’s visit.
2. CMS calculates median costs for five levels of clinic visit APCs (0604 through 0608) under the OPSS using historical hospital claims data.
3. It recognizes two different types of emergency departments under OPSS: Type A Emergency Departments and Type B Emergency Departments. CMS will pay for emergency department visits in 2013 based on median costs through five levels of APCs: APCs 0609 and 0613 through 0616 for Type A and 0626-0630 for Type B emergency department visits. The APC assignments and payment rates for these hospital visits can be found in Addendum B to the final rule at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.
4. Hospitals should report visits during 2013 according to their own internal hospital coding guidelines which should comport with principals listed in the 2008 OPSS/ASC final rule with comment period; hospitals with specific questions on the creation of internal guidelines should contact their servicing fiscal intermediary or MAC. CMS reminds hospitals that it will vigorously enforce its payment policies and pursue appropriate enforcement actions for billing inaccuracies.

CMS notes one commenter’s observation that the agency should not move to national guidelines for visits in CY 2013 because many hospitals have developed their own internal guidelines. CMS seems grateful for the comment but does observe that national guidelines could be helpful to many hospitals.

As proposed, for 2013 CMS will continue 1) to recognize existing CPT codes for critical care services; 2) to set the payment rate based on historical data; and 3) to package the costs of care and ancillary services notwithstanding the AMA CPT Editorial Panel revision that requires hospitals to report ancillary services and associated charges separately. CMS reiterates the rationale stated in the proposed rule that, based on a review of 2011 hospital claims data (which for the first time reflects the revised coding guidance), CMS found that both the mean and

median line item costs and charges increased (by more than 10 percent) as compared to 2010 hospital claims data. Additionally, those data show no substantial change in ancillary services present on critical care claims while also showing continued low volumes of many ancillary services. CMS believes that many hospitals did not change billing practices for CPT code 99291; thus CMS continues to find separate payment for these ancillary services inappropriate. It will continue to implement claims processing edits that conditionally package payment for ancillary services furnished on the same date as critical care services, and will continue to monitor claims data for CPT code 99291 for potential revisions to this policy.

In response to commenters who suggest that the CMS methodology to estimate costs of packaged ancillary services should include a review of multiple cost report revenue centers, CMS believes its methodology is consistent with that goal.

### C. Transitional Care Management

As part of a multi-year strategy to encourage primary care and care coordination for Medicare beneficiaries, CMS had proposed to assign HCPCS code (GXXX1) with a status indicator “N” for certain elements of transitional care coordination services furnished to hospital outpatients as ancillary or supportive services. CMS instead adopts the following CPT transitional care management codes:

CPT Transitional Care Management Codes	Required Elements
99495 (Transitional care management services with moderate medical decision complexity; Face to face visit within 14 days)	<ul style="list-style-type: none"> <li>● Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge;</li> <li>● Medical decisionmaking of at least moderate complexity during the service period; and</li> <li>● Face-to-face visit, within 14 calendar days of discharge.</li> </ul>
99496 (Transitional care management services with high medical decision complexity; Face to face visit within 7 days)	<ul style="list-style-type: none"> <li>● Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge;</li> <li>● Medical decision-making of high complexity during the service period; and</li> <li>● Face-to-face visit, within 7 calendar days of discharge.</li> </ul>

The codes are for use in the case of established patients with medical and/or psychosocial problems requiring moderate or high complexity medical decisionmaking during transitions of care from institutional to community settings. Transitional care management begins on date of discharge and continues for the next 29 days; and includes one face-to-face visit in conjunction with non-face-to-face services performed by a physician or, under the direction of the physician, by qualified health care professionals and/or clinical staff. CMS believes that the inclusion of the face-to-face visit requirement merits separate payment under the OPSS as it represents a primary, independent service. In response to comments, CMS notes that it sought to keep billing requirements simple as well as to avoid duplication with discharge day management services

described by other CPT codes. The codes are open for comment during the 60-day period following publication of the final rule.

## **VIII. Payment for Partial Hospitalization (PHP) Services**

### **A. PHP APC Update for 2013**

CMS finalizes its proposal to calculate relative payment weights for OPPS APCs using geometric means in lieu of median costs for services in APC groups, including for the four PHP APCs (days with 3 services and days with 4 or more services separately for Community Mental Health Center (CMHC)-based PHPs and hospital-based PHPs). The geometric mean per diem costs are contained in Tables 39 and 40 of the final rule and reproduced below:

<b>2013 Geometric Mean Per Diem Costs for PHP Services</b>				
<b>Category</b>	<b>CMHC PHPs</b>		<b>Hospital-Based PHPs</b>	
Level I (days with 3 services)	APC 0172	\$87.39	APC 0175	\$185.90
Level II (days with 4 or more services)	APC 0173	\$112.82	APC 0176	\$234.81

CMS notes that under the new geometric mean methodology using 2011 data, the per diem costs are higher in both levels for hospitals than the median costs calculated under the current methodology. For CMHCs, CMS notes the new methodology results in roughly the same rate for Level I services and approximately a \$9 decrease for Level II services. Median per diem costs continue to decrease significantly for CMHCs which underscores the agency's belief that separate payment computation by provider type is important. Hospitals are supportive of using geometric means while CMHCs feel disadvantaged by the new methodology as well as by the policy to calculate separate APCs for the two provider types.

### **B. Coding Changes**

After publication of the proposed rule, the AMA's CPT Editorial Panel deleted 28 psychiatric CPT codes and replaced them with 12 new CPT codes, which require corresponding changes to the codes used to bill and document PHP services. Changes made include 1) separating initial E/M codes by provider (physicians versus nonphysician practitioners); 2) substituting specific times (30, 45 and 60 minutes, respectively) for psychotherapy codes in lieu of range of times; 3) use of time add-on CPT codes when psychotherapy is provided during an E/M service encounter; 4) use of add-on codes for interactive complexity in lieu of separate codes for interactive psychotherapy (which CMS notes requires precise articulation of what the complexity is). Table 42 in the final rule provides a crosswalk of deleted and new PHP CPT and HCPCS billable codes for 2013, which are effective January 1, 2013.

### **C. Separate Threshold for Outlier Payments to CMHCs**

CMS did not receive any comments on its proposal to continue its policy of identifying 1.0 percent of the aggregate payments under the OPPS for aggregate outlier payments for 2013, of which 0.12 percent would be allocated to CMHCs for PHP outliers. Thus, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the

service and the product of 3.40 times the APC 0173 payment rate. CMS does not set a dollar threshold for CHMC outlier payments.

#### **D. Regulatory Impact**

CMS estimates that payments to CMHCs will decline by 4.4 percent, primarily due to the impact of the geometric mean methodology on APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) as well as due to the continuation of the four separate APC method of payment calculation (based on cost report and claims data submitted by CMHCs), and other adjustments.

#### **IX. Procedures That Would Be Paid Only as Inpatient Procedures**

Of the two procedures CMS had proposed to remove from the current inpatient list, only one, CPT code 22856 (Total disc arthroplasty)<sup>2</sup>, is finalized as payable in the hospital outpatient setting. CMS assigns that code, as well as CPT codes 22551 and 22554, to APC 0208 notwithstanding requests to assign them to a different or new APC.

Based on concerns from commenters, CMS decides not to remove CPT code 27447 (Arthroplasty, knee, condyle and plateau)<sup>3</sup> from the inpatient list. Using its longstanding methodology for this evaluation, CMS believes that performing the procedure in the hospital outpatient setting may be inappropriate for Medicare beneficiaries.

Commenters requested that CMS remove an additional 39 procedures (found in Table 44 of the final rule) from the inpatient list; CMS does not remove any of those procedures. Conversely, commenters requested that four laparoscopy procedures (CPT codes 44206, 44207, 44208, and 44213) be reassigned to the inpatient list, but CMS declines noting that they had been performed in the outpatient department for several years without significant concerns. One significant concern expressed by commenters was that Recovery Audit Contractors (RACs) target procedures removed from the inpatient list for audit; CMS dismisses the concern believing that there is sufficient time for hospitals to make adjustments to prepare for any RAC audit of these types of claims. The list of codes paid in 2013 only as inpatient procedures is included as Addendum E to the final rule and is available on the CMS Website.

#### **X. Policies for the Supervision of Outpatient Services in Hospitals and CAHs**

##### **A. Conditions of Payment for Therapy Services in Hospitals and CAHs**

CMS clarifies that the supervision and other requirements of §410.27 of the regulations apply to facility services paid to hospitals under the OPPS and to CAHs paid on a reasonable cost basis. §410.27 requirements do not apply to professional services separately billed under the physician

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<sup>2</sup> CPT Code 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical).

<sup>3</sup> CPT Code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)).

fee schedule (MPFS) or to physical therapy (PT), speech-language pathology (SLP), and occupational therapy (OT) billed by the hospital as therapy services and paid based on the MPFS. Similarly, these requirements do not apply to those same services when furnished in a CAH. CMS reiterates that it does not intend to establish different requirements for hospitals and CAHs under that regulation for the same services. However, CMS notes that §410.27 supervision and other requirements do apply to PT, SLP, and OT services when those services are not furnished under a certified therapy plan of care (referred to as “sometimes therapy” services). Table 46 in the final rule lists “sometime therapy” services which include negative pressure wound therapies.

## **B. Extension of Nonenforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Small Rural Hospitals**

CMS extends for another year through 2013 its nonenforcement policy for direct supervision of outpatient therapeutic services in CAHs and small rural hospitals; CMS expects this will be the final year of this nonenforcement policy. The Hospital Outpatient Payment (HOP) Panel considered several requests for changes to the applicable minimum supervision level for certain services, including 1) observation services; 2) administration of certain drugs and agents; and 3) certain bladder, skin/wound care, injection/infusion, intravenous and central venous access services. CMS is reviewing the requests and the HOP Panel's recommendations and will issue final decisions before January 1, 2013 on its Website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

## **XI. Outpatient Status: Solicitation of Public Comments**

CMS used its demonstration authority to implement a 3-year Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration project, beginning with 2012, which permits up to 380 hospitals to rebill a Part A short stay claim that is denied because the inpatient admission was deemed not reasonable and necessary. Participating hospitals can receive 90 percent of allowable payment for all Part B services that would have been medically necessary had the beneficiary been treated as an outpatient in lieu of the current limited set of Part B services (viz. “Inpatient Part B” or “Part B Only” services and outpatient services furnished during the 3-day window prior to admission). Under the demonstration, participating hospitals 1) may rebill outside the usual timely filing requirements; 2) must waive appeal rights for the denied inpatient claim that is eligible for rebilling; and 3) may not bill beneficiaries for additional cost-sharing or self-administered drugs. CMS notes that hospitals may not rebill for observation services because they must be ordered prospectively to determine whether an inpatient admission is necessary.

In the proposed rule, CMS sought comment generally on policy changes the agency could implement to improve clarity and consensus among the various stakeholders (hospitals, beneficiaries, and program integrity and other contractors) with respect to inpatient admissions and appropriate Medicare payment while taking into account the impact of any changes on beneficiary liability, spending under the program, and feasibility of implementation. CMS made no policy proposals, but was clearly concerned about the impact on Medicare beneficiaries of what it describes as a growing trend among hospitals to treat beneficiaries as outpatients

receiving observation services for longer periods of time in lieu of admitting them. Beneficiaries in this outpatient status face the likelihood that their aggregate copayments for all outpatient services received will exceed the inpatient hospital deductible, and Part B does not usually cover self-administered drugs furnished in outpatient settings. More concerning is the fact that time spent as a hospital outpatient does not count toward the 3-day qualifying inpatient stay for Part A coverage of post-acute care in a skilled nursing facility (SNF).

CMS reports receiving roughly 350 comments from a wide variety of stakeholders, the majority of which ask that CMS refrain from implementing a comprehensive solution on the issue and instead seek an ongoing dialogue with interested parties. CMS does not respond to any of the comments; rather it summarizes them by issue area and indicates that it may "potentially undertake [future actions] to provide more clarity and consensus regarding patient status for purposes of Medicare payment."

Part A to Part B Rebilling. Many commenters support the AB Rebilling Demonstration, pointing to beneficiary protections against changes in liability and increased hospital part B payments, though there was dissatisfaction with the requirement to forego claim appeal rights. Commenters disagree on the wisdom of a national policy to permit rebilling of all Part B services; some believe a more generous rebilling policy would remove incentives for hospitals to admit beneficiaries inappropriately. Others saw this type of policy as 1) removing the incentive to bill properly; 2) undermining the designs of the OPDS and IPPS systems which could lead to miscalibration of payment rates; and 3) providing an unfair market advantage to those providers who make inappropriate inpatient admissions. Concerns are also raised with respect to timely filing requirements; some commenters believe permitting full Part B rebilling would have limited utility since the timely filing period would have lapsed before an inpatient claim would be denied. Additionally, the manual process of recoding the claim as an outpatient claim is costly. Some commenters suggest extending the timely filing deadlines or permitting a hospital to change beneficiary status after discharge.

Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria. CMS reports widespread understanding and agreement among commenters with its guidance that an inpatient admission is a complex medical judgment involving consideration of many factors. Many emphasize that physician judgment should take precedence over other criteria, especially given concerns over decision-making tools that fail to account for patient risk. Commenters feel strongly that Medicare contractors both disregard physician judgment and fail to employ physicians for their claims review; there are also concerns over the accuracy and validity of proprietary screening tools. Many commenters believe that the AHRQ National Clearinghouse Guidelines or other guidelines developed with physician societies could serve as national criteria. Some commenters urge physicians to improve their documentation to support patient status, such as indicating need for admission in an electronic health record; others urge hospitals to be clear in selecting patient status designation.

Hospital Utilization Review. Commenters had mixed views on the utility of hospital utilization review (UR); some believe UR or case management staff should be available 24/7 as a hospital best practice while others thought CMS should require it. Still others believe UR should be eliminated from current CoPs either because of the added hospital administrative costs or that the



accuracy of admissions is not commensurate with costs to maintain the UR. Additionally, some believe that as long as admission criteria are unclear, hospital UR will have limited utility; a physician association objects to other physicians in the hospital overruling the judgment of the admitting physician.

Prior Authorization. While comments indicate great concern with mandatory prior authorization, especially in the case of patients in emergency departments or receiving critical care, its targeted application holds some appeal, such as for selected elective procedures or for conditions at high risk for inappropriate inpatient admission. Others object to its use altogether, arguing that it is an additional administrative burden and would not be particularly effective absent a guarantee for payment. One commenter observes that prior authorization is often subject to review by commercial insurers; thus requiring it would add significant cost to the program without eliminating the inpatient error rate.

Time-Based Criteria for Inpatient Admission. CMS currently does not specify a time limit for the receipt of observation services, though in the past it has limited payment for those services to a specific timeframe (from 24 to 48 hours). CMS sought comment on whether there should be a time limit for receipt of observation services before the hospital encounter becomes inpatient. Some commenters support a strict time limit (24, 48, or 72 hours) where others suggest a default time limit of 24 hours with exceptions at the discretion of the physician or requiring additional assessments. Still others believe that patients who cannot be safely discharged after 24 or 48 hours of observation services should be treated as inpatients even if they do not technically meet the criteria. In contrast, other comments posit that inpatient and outpatient services are different in nature, for example due to advanced technology and availability of nursing staff in the inpatient setting. There is also concern that a time-based policy may affect hospital payment because level of service would no longer be taken into account. Additional concerns about this type of policy include 1) that it would undermine physician judgment; 2) that the absence of objective clinical criteria for choosing the timeframe would render it arbitrary; 3) that hospitals require more time to evaluate diagnostic testing and prepare a treatment plan; and 4) that it may conflict with inpatient surgical care for patients who only require a short admission. Other commenters suggested furnishing observation services only in dedicated observation units of an emergency department.

Payment Alignment. CMS reports that commenters expressed a great deal of interest in various methods to align payment for "equivalent outpatient and short stay inpatient hospital stays". Suggestions included the development of a DRG for short inpatient stays, an expanded outpatient APC, and a short stay inpatient admissions DRG payment that would be adjusted based on the percentage of the length of stay. Other commenters believe that payment alignment would reduce but not eliminate the financial risk of claim denial.

Other Topics. Commenters had much to say about Medicare contractors and the criteria used to determine medical necessity as well as the personnel making these decisions (i.e., physicians are not always making these determinations for the contractors). Commenters also believe that reviewing contractors inappropriately base their judgment on information that was neither predictable nor available to the physicians at the time of admission. Commenters want CMS to

increase its oversight of its medical review contractors and all review contractors to use the same criteria physicians and hospitals are required to use for these admissions.

Some commenters recommend that physicians not be paid whenever an inpatient hospital payment is denied, while physicians indicated unhappiness with proprietary tools hospitals use to identify allegedly inappropriate admissions and then change a patient's status to outpatient without informing the physician.

Beneficiary organizations recommend that CMS clarify and strengthen beneficiary notice requirements and appeals rights on the issues of changes of patient status and receipt of observation care, arguing that beneficiaries need a clear explanation of the cost-sharing implications of inpatient status versus outpatient status receiving observation services. Other suggestions include 1) the waiver by hospitals of any increases in cost-sharing; 2) CMS coverage of self-administered drugs in hospital outpatient departments; 3) capping total cost-sharing at the inpatient deductible; and 4) establishing annual maximum out-of-pocket costs. Commenters also recommend penalizing hospitals for inappropriate admissions patterns, using appropriate quality measures, and improving physician education on potential beneficiary liabilities.

With respect to the 3-day hospital inpatient stay criteria for coverage of SNF services, commenters recommend that Congress revise and modernize the SNF stay requirements, such as by counting observation days, given that the length of hospital inpatient stays have reduced over time. Others believe that CMS has the authority to waive the 3-day rule under section 1812(f) of the Act.

## **XII. OPPS Payment Status and Comment Indicators**

CMS did not receive comments on either its proposed OPPS Payment Status Indicator Definitions or proposed Comment Indicator Definitions. CMS does not make any changes to the definitions of OPPS payment status indicators that were listed in Addendum D1 of the 2012 OPPS/ACS final rule with comment period for 2013. The complete list of 2013 status indicator assignments for APCs and HCPCS codes (displayed in Addendum A and Addendum B, respectively of the final rule) and of 2013 status indicators and their definitions (displayed in Addendum D1 of the final rule) is available from the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Similarly, for 2013 CMS uses the same two comment indicators that were in effect for the 2012 OPPS:

- “CH” – Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS codes that will be discontinued at the end of the current calendar year.
- “NI” – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

Use of the “CH” indicator in the final rule identifies

- changes in payment status indicator and/or APC assignment for HCPCS codes for 2013 compared to their assignment as of June 30, 2012; and
- for composite APC indicators, a change to the configuration of the composite APC in the final rule.

CMS uses the “CH” indicator in the final rule to indicate HCPCS codes for which the status indicator, APC assignment, or both, would change in 2013 compared to their assignment as of December 31, 2012.

CMS makes no changes regarding the use of the comment indicator “NI”. Existing HCPCS code numbers with substantial revisions to the code descriptors will be labeled with the comment indicator “NI” in Addendum B to this final rule. CMS notes that use of the comment indicator “NI” is for a significant revision to the code descriptor—meaning that the new code descriptor describes a new service or procedure for which OPPS treatment may change. CMS continues to assign the comment indicator “NI” to those codes to allow for comment on the final payment for substantially revised codes, and CMS will respond to those comments and finalize their OPPS treatment in the 2014 OPPS/ASC final rule with comment period. CMS continues to use the definitions of the OPPS comment indicators for 2012 which are listed in Addendum D2 on the CMS Web site found at the link above.

### **XIII. OPPS Policy and Payment Recommendations**

MedPAC recommended that Congress increase payment rates for the OPPS by 1.0 in 2013 and enact legislation to pay for E/M office visits in hospital outpatient departments at the same rate that applies to those visits in physician offices. With respect to the latter, MedPAC recommended that the resulting payment reduction be phased-in over a three-year period and be limited to two percent in the case of hospitals with disproportionate share patient percentages above the median. Neither GAO nor the HHS OIG has released any reports or recommendations relating to the hospital OPPS since the 2012 OPPS/ASC final rule.

### **XIV. Updates to the Ambulatory Surgical Center Payment System**

CMS finalizes an update to ACS payment rates of 0.6 percent, using the same methodology as in the past and included in the proposed rule but using updated economic data compared with the proposed rule. When coupled with the final wage index budget neutrality adjustment of 1.0008, it yields a CY 2013 conversion factor of \$42.917, computed as follows:

#### Summary, key factors in calculating CY 2013 conversion factor

CY 2012 conversion factor:		\$42.627
Wage index budget neutrality adjustment		1.0008
CPI-U update	1.4%	
Minus multifactor productivity adjustment	<u>-0.8%</u>	
Net payment update		0.6 %
CY 2013 conversion factor		\$42.917

CMS sets out estimated increases by surgical specialty group in Table 58 of the final rule, replicated below. The eye and ocular adnexa group remains the largest source of payments, but with no increase in total payments in 2013. The nervous system group is estimated to see the greatest percentage increase in payments (3 percent) while the integumentary, respiratory, and cardiovascular systems groups are each estimated to see a 3 percent decrease.

**Table 58: Estimated Impact of the Final 2013 Update to the ASC Payment System on Aggregate 2013 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group**

<b>Surgical Specialty Group</b>	<b>Estimated 2012 ACS Payments (in Millions)</b>	<b>Estimated 2013 Percent Change</b>
Total	\$3,480	1%
Eye and ocular adnexa	\$1,453	0%
Digestive system	\$719	2%
Nervous system	\$471	3%
Musculoskeletal system	\$433	-2%
Genitourinary system	\$160	0%
Integumentary system	\$131	-3%
Respiratory system	\$45	-3%
Cardiovascular system	\$31	-3%
Ancillary items and services	\$21	0%
Auditory system	\$11	1%
Hematologic & lymphatic systems	\$5	0%

CMS sets out estimated increases for selected procedures in Table 59 in the final rule, replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest procedure by far, and is estimated to see a 1 percent increase in total payments. Two procedures are estimated to experience an 8 percent increase in total payments: code 63685 (Insert/redo spine neurostimulator generator) and code 64590 (Insert/redo peripheral or gastric neurostimulator). The largest decrease, 6 percent, is estimated for code 29827 (Arthroscopic rotator cuff repair).

**Table 59: Estimated Impact of the Final 2013 Update to the ASC Payment System on Aggregate Payments for Selected Procedures**

<b>CPT/ HCPS Code*</b>	<b>Short Descriptor</b>	<b>Estimated 2012 ACS Payments (in Millions)</b>	<b>Estimated 2013 Percent Change</b>
66984	Cataract surg w/iol, 1 stage	\$1,079	1%
43239	Upper GI endoscopy, biopsy	\$157	2%
45380	Colonoscopy and biopsy	\$144	2%
45385	Lesion removal colonoscopy	\$92	2%
45378	Diagnostic colonoscopy	\$89	2%

<b>CPT/ HCPS Code*</b>	<b>Short Descriptor</b>	<b>Estimated 2012 ACS Payments (in Millions)</b>	<b>Estimated 2013 Percent Change</b>
66982	Cataract surgery, complex	\$83	1%
64483	Inj foramen epidural l/s	\$73	5%
62311	Inject spine l/s (cd)	\$68	5%
66821	After cataract laser surgery	\$55	5%
63650	Implant neuroelectrodes	\$40	-2%
15823	Revision of upper eyelid	\$39	-2%
G0105	Colorectal scrn; hi risk ind	\$38	2%
64493	Inj paravert f jnt l/s 1 lev	\$36	5%
29827	Arthroscop rotator cuff repr	\$36	-6%
64721	Carpal tunnel surgery	\$31	-1%
G0121	Colon ca scrn not hi rsk ind	\$30	2%
29881	Knee arthroscopy/surgery	\$30	-1%
63685	Insrt/redo spine n generator	\$28	8%
64590	Insrt/redo pn/gastr stimul	\$25	8%
29880	Knee arthroscopy/surgery	\$25	-1%
45384	Lesion remove colonoscopy	\$23	2%
43235	Uppr gi endoscopy diagnosis	\$23	2%
52000	Cystoscopy	\$20	4%
28285	Repair of hammertoe	\$19	-1%
62310	Inject spine c/t	\$18	5%
26055	Incise finger tendon sheath	\$17	-4%
67042	Vit for macular hole	\$17	-1%
29826	Shoulder arthroscopy/surgery	\$17	-1%
67904	Repair eyelid defect	\$17	-3%
50590	Fragmenting of kidney stone	\$17	-4%
* * HCPCS codes CMS is deleting for 2013 are not displayed			

## **A. Background**

CMS reviews the legislative history and regulatory policies regarding changes to the lists of codes and payment rates for ASC covered surgical procedures and covered ancillary services.

## **B. Treatment of New Codes**

*Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2012 for Which CMS Solicited Public Comments in the Proposed Rule*

CMS in April and July of 2012 change requests (CRs) made effective 12 new Level II HCPCS codes describing covered ancillary services, and 5 new Category III CPT codes that were not included in the 2012 OP/AS final rule. CMS finalizes the proposed rule's inclusion of these codes, and Tables 47, 48 and 49 in the final rule set out the codes and descriptors, and the 2013 payment indicators.

*Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which CMS is Soliciting Public Comments in the 2013 OPPTS/ASC Final Rule with Comment Period*

CMS finalizes its proposal to include in Addenda AA and BB to the 2013 OPPTS/ASC final rule with comment period **and solicit public comment** on:

- new Category I and III CPT codes effective January 1, 2013 that would be incorporated in the January 2013 ASC quarterly update CR; and
- new level II HCPCS codes, effective October 1, 2012 or January 1, 2013, that would be released in the October 2012 or January 2013 quarterly CRs.

**C. Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services**

*Additions to the List of ASC Covered Surgical Procedures*

CMS finalizes with modifications based on comments the addition of 25 covered ASC surgical procedures, after determining that they would not be expected to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

CMS had included in the proposed rule the addition of 16 procedures. Commenters raised a number of points.

Commenters identified a list of 57 additional CPT codes that they believe are as safe as procedures currently on the ASC covered procedures list. Further, in a survey, ASCs reported positive outcomes when the procedures are performed on non-Medicare patients. Table 50 in the final rule identifies those 57 procedures. CMS reviewed the list and responds as follows:

- 22 are on the OPPTS inpatient list and not paid under the OPPTS, and another is not paid under the OPPTS. Those 23 are therefore not eligible for addition to the list of ASC covered procedures.
- In reviewing the remaining 34 procedures, CMS determined that most (25) either may be expected to pose a threat to beneficiary safety or require active medical monitoring at midnight following the procedure, and thus are not eligible for addition to the list of ASC covered procedures.
- CMS determined that 9 of the 57 procedures did meet its criteria for inclusion.

The final rule includes 25 new procedures: the 16 initially proposed and the nine additional procedures requested by the commenters. Table 51 in the final rule provides the list of new ASC covered surgical procedures for CY 2013, including the HCPCS code, the long description and the payment indicator.

CMS also responded to but rejected several additional comments. One commenter believed that two of the 16 listed procedures should not be added because additional clinical information on clinical efficacy and outcomes was needed: CPT codes 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care;

initial wound); and 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care). CMS responds that it makes the decision for inclusion on the ASC coverage list based on whether the procedure would pose a significant safety risk or require an overnight stay if performed in an ASC, not based on data regarding clinical efficacy.

One commenter suggested that six additional “unlisted procedure” codes be included: CPT code 66999 (unlisted procedure, anterior segment of the eye); CPT code 67299 (Unlisted procedure, posterior segment); CPT code 67399 (Unlisted procedure, ocular muscle); CPT code 67999 (Unlisted procedure, eyelids); CPT code 68399 (Unlisted procedure, conjunctiva); and CPT code 68899 (Unlisted procedure, lacrimal system). CMS responds that its regulatory policy precludes the inclusion of unlisted codes because it is not able to evaluate unlisted codes to determine if they meet the criteria for inclusion as an ASC covered procedure.

#### *Surgical Procedures Designated as Office Based*

CMS annually reviews volume and utilization data to identify office-based procedures that are performed more than 50 percent of the time in physicians’ offices and that CMS’ medical advisors believe are of a level of complexity consistent with other procedures performed routinely in physicians’ offices. CMS finalizes its proposal to permanently identify six additional CPT codes as office-based. Table 52 lists the procedures and 2013 ASC payment indicators.

CMS also reviewed information for the eight procedures finalized for temporary office-based status in last year’s final rule. CMS identified very little claims data for six of the procedures, and finalizes its proposal to retain them as temporarily office-based for 2013. CMS finalizes its proposal to remove from the office-based designation two procedures because they are not performed predominantly in physicians’ offices:

- CPT code 37761 (ligation of perforator vein(s), subfacial, open, including ultrasound guidance, when performed, 1 leg); and
- CPT code 0232T (injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed).

Table 53 lists the eight procedures and CMS’ final decisions for payment indicators 2013.

#### *ASC Covered Surgical Procedures Designated as Device-Intensive*

CMS updates the ASC covered procedures eligible for payment according to the device-intensive procedure payment methodology, for the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS payment system. CMS finalizes in Table 54 the procedures that it identifies as device-intensive, including the CPT code and short descriptor, the proposed payment indicator, the proposed 2013 OPPS APC assignment and device offset percentage, and an indication of whether the full credit or partial credit device adjustment policy (see below) would apply. The final rule includes as device intensive, with an interim payment status, six of the new CPT codes added effective October 1, 2012 and January 1, 2013, that were added to the list of covered ACS procedures for comment in this final rule (see

discussion in section XIV.B): codes 0316T, 0319T, 0321T, 0323T, 24370, and 24371. CMS solicits comments on the interim device-dependent payment status for these procedures.

Commenters questioned the sufficiency of the ASC device-intensive payment methodology. They suggested that CMS should apply the methodology to all procedures for which CMS can establish a median device cost regardless of whether they are classified as device-intensive. Commenters also suggested that the threshold to determine device-intensive procedures should be 50 percent of the unadjusted ASC payment rate. CMS responds that it continues to believe that its criteria are adequate to ensure that ASC payment rates are adequate to provide packaged payment for high cost implantable devices and ensure beneficiary access.

#### *Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices*

CMS refers readers to the 2009 OPPS/ASC final rule for a full discussion of the ASC policy, which adopts OPPS policy, for payment when a specified device is furnished without cost or with full or partial credit from the manufacturer for the cost of the device.

When such a device is provided as part of a device-intensive procedure listed in Table 54, CMS finalizes its proposed policy for payment as follows:

- When the device is furnished at no cost or with full credit from the manufacturer, CMS proposes that the contractor would reduce payment to the ASC by the device offset amount that would apply under the OPPS in that circumstance, which is the amount that CMS estimates as the cost of the device.
- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, CMS proposes that the contractor would reduce payments to the ASC by one-half of the device offset amount that would be applied if the device were furnished at no cost or with full credit.

CMS finalizes in Table 55 the specific devices for which the FB or FC modifier must be reported when the device is furnished at no cost or with full or partial credit.

#### *ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for 2013*

CMS finalizes with modification its proposal that two procedures proposed for removal from the OPPS inpatient list should continue to be excluded from the ASC list of covered surgical procedures for 2013 because they would be expected to pose a significant risk to beneficiary safety or require an overnight stay in ASCs.

- CPT code 27447: Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty) is not being finalized for removal from the OPPS inpatient list and thus is not subject to this review.
- CMS finalizes its proposal to exclude from the ASC covered list CPT code 22856: Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical



### *Covered Ancillary Services*

CMS finalizes its proposal to update the list of covered ancillary services to reflect the payment status for the services under the 2013 OPPS. Addendum BB provides the final ASC covered ancillary services and their payment indicators for 2013.

### **D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services**

#### *Proposed Payment for Covered Surgical Procedures*

#### *Proposed Update to ASC Covered Surgical Procedure Payment Rates for 2013*

CMS finalizes its proposal to update ASC payment rates using its previously established methodologies. It notes that, because it finalizes in the OPPS section of this rule its proposal to base the OPPS relative payment rates on geometric mean costs, the ASC system too would shift to the use of geometric means to determine relative payment rates.

CMS finalizes its proposal to update payments for office-based procedures and device-intensive procedures using its previously established methodology, including the updated OPPS device offset percentages. That means that CMS will make payment for office-based procedures at the lesser of the 2013 MPFS nonfacility PE RVU-based amount, or the 2013 ASC payment amount calculated according to the standard methodology.

#### *Waiver of Coinsurance and Deductibles for Certain Preventive Services*

CMS refers to the 2011 OPPS/ASC final rule for a discussion of its policies and list of preventive services for which the coinsurance and deductible are waived. CMS finalizes its proposal to make no changes to its policies or the list of preventive services for 2013.

#### *Payment for Cardiac Resynchronization Therapy (CRT) Composite*

CMS finalizes its proposal to make no changes in its policy for CRT services, and refers the reader to the 2012 OPPS/ASC final rule for a discussion of the policy.

#### *Payment for Low Dose Rate (LDR) Prostrate Brachytherapy Composite*

CMS finalizes its proposal to establish an ASC composite payment rate based on the OPPS relative payment weight applicable to APC 8001 (LDR Prostrate Brachytherapy Composite) when CPT codes 55875 (Transperineal placement of needles or catheters into prostrate for interstitial radioelement application, with or without cystoscopy) and 77778 (Interstitial radiation source application; complex) are performed on the same date of service in an ASC. When not performed on the same day, the service described by CPT code 77778 will continue to be assigned to APC 0651, and the service described by CPT code 55875 will continue to be assigned to APC 0163.

### *Proposed Payment for Covered Ancillary Services*

CMS finalizes its proposal to set the 2013 payments for brachytherapy sources and separately payable drugs and biological equal to the final 2013 OPPS rates, discussed separately in this summary.

CMS finalizes its proposal to continue to base payment for separately payable covered radiology services based on the lower of the 2013 MPFS nonfacility PE RVU-based amounts and the 2013 ASC standard rate-setting methodology (except in the case of nuclear medicine procedures and services that use contrast agents). If the radiology service is packaged under the OPPS, payment for the radiology service may be packaged into the payment for the ASC. Addendum BB indicates the payment status for each radiology service.

In the case of nuclear medicine procedures designated as radiology services paid separately when provided integral to a surgical procedure on the ASC list, CMS finalizes its proposal to continue to set payments based on the OPPS relative payment weights, regardless of whether the MPFS nonfacility PE RV-based amount is lower. In the case of radiology services that use contrast agents, CMS finalizes its proposal to continue to set payment based on the OPPS relative payment rate, and will, therefore, include the cost of the contrast agent.

One commenter suggested that ASC payment policy for nuclear medicine procedures would be further improved by providing separate payment for diagnostic radiopharmaceuticals that are used in nuclear medicine procedures. CMS responds that it does not agree because CMS follows the OPPS packaging policies which require that payment for these items always is packaged.

### **E. New Technology Intraocular Lenses (NTIOL)**

CMS finalizes what it describes as “significant revisions” to the regulatory criteria for approving new NTIOL classes, with the stated purpose of improving the quality of the NTIOL applications.

First, CMS finalizes its proposal to require that the IOL’s FDA-approved labeling contain a claim of a specific clinical benefit imparted by a new lens characteristic, and notes that this must be a new characteristic in comparison to currently available IOLs. CMS’ stated justification is that recent NTIOL applications have not included FDA labeling claims of clinical benefit, and the low quality evidence submitted has been insufficient for NTIOL status. CMS believes that the quality of evidence would improve if applicants were required to obtain a labeling claim for the benefit and have the evidence for such benefit evaluated by the FDA. CMS believes that this would have multiple advantages: any ultimate grant of an NTIOL would be supported by a labeling claim; the manufacturer could advertise the benefit without deviating from FDA advertising limitations; and CMS would have the benefit of an FDA review of the relevant evidence.

CMS reviews a comment that disagreed substantively with the proposed requirement to obtain a label claim. The commenter noted that:

- Obtaining such a claim is difficult and time-consuming;
- It is not the FDA’s job to review evidence related to an NTIOL application;

- FDA does not typically evaluate claims of comparative clinical benefit and is not obligated to do so.
- Clinical studies to support a claim require time and resources, and there is no guarantee of success.
- Other new technology programs do not require a claim of clinical benefit.
- Requiring a claim of clinical benefit would provide extended exclusivity to the first company to establish an NTIOL class.
- Requiring such a claim will limit patient access to new technology.

CMS responds point by point in finalizing the proposed policy. It says that its current regulations require FDA-approved label information to contain information about clinical benefit; that this is a core function of the FDA; that various new technology programs have different requirements depending on the statutory authority and purposes of the program; and that if the requirement results in a longer period of a single manufacturer using a new NTIOL class exclusively, that would serve as an additional inducement to innovate. CMS agrees that seeking a label claim will require time and effort but believes that this will better serve applicants and increase the likelihood of NTIOL approval. Finally, CMS disagrees that the policy will reduce beneficiary access to new IOL technology, and says that having NTIOLs supported by such a labeling claim will increase patient confidence.

Second, CMS finalizes its proposal to require that any specific clinical benefit claimed must be supported by evidence that demonstrates the IOL results in a measurable, clinically meaningful, improved outcome. CMS finalizes its proposal to retain the current language, from the 1994 statutory language, that such improved outcomes include: (i) reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

In the proposed rule, CMS noted the changes in modern cataract surgery have made the first five items in the list of limited clinical relevance, and solicited comments on what potential benefits associated with a new IOL could be considered under (vi) above as a “comparable clinical advantage.” Commenters supported retention of that open-ended category, and made suggestions of particular clinical advantages. CMS responds that it appreciates the range of potential issues that could be addressed through new IOL technology, but that questions remain, and notes that innovations that provide greater surgical convenience but no direct patient benefit would not qualify for NTIOL status. Further, CMS notes that vision improvements cannot be merely improved optical performance, but must relate to meaningful improved outcome in visual performance. Finally CMS notes that the list of six outcomes is statutory.

CMS notes that it did not receive any requests for review to establish a new NTIOL class for CY 2013 by the March 2, 2012 due date.

## **F. ASC Payment and Comment Indicators**

CMS finalizes its proposal to not make changes to the definitions in the ASC payment and comment indicators for 2013. Addenda DD1 and DD2 provide the complete lists of ASC payment and comment indicators for 2013.

## **G. ASC Policy and Payment Recommendations**

The Medicare Payment Advisory Commission (MedPAC) recommended that the Congress update ASC rates by 0.5 percent for 2013 and require ASCs to submit cost data.

CMS notes that the Congress has not acted on these recommendations, and that CMS is proposing to continue its current policy to update the ACS conversion factor by the CPI-U (see section that follows), with statutory adjustments.

## **H. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates**

### *Updating the ASC Relative Payment Rates for 2013 and Future Years*

CMS finalizes its proposal to continue to update relative weights using the national OPPS relative weights, and the MPFS nonfacility PE RVU-based amounts when applicable. Because CMS is finalizing its proposal to base the OPPS relative weights on the geometric mean, the ASC system will also shift to the use of geometric means.

CMS finalizes its proposal to scale the relative weights as under prior policy. Holding ASC use and mix of services constant from 2011, CMS computes the ratio of:

- Total payments using the 2012 relative payment rates, to
- Total payments using the 2013 relative payment rates.

The resulting ratio, 0.9324, is the final weight scaler for 2013 (the calculation in the proposed rule yielded a proposed scaler of 0.9331). The scaler would apply to the payment for covered surgical procedures and covered radiology services for which the ASC payments are based on OPPS relative weights. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights. That includes drugs and biologicals that are separately paid, and services that are contractor-priced or paid at reasonable cost in ASCs.

### *Updating the ASC Conversion Factor*

CMS finalizes its proposal to compute the budget neutrality adjustment factor for changes in wage index values as under prior policy. Holding ASC use and mix of services and the proposed 2013 national payment rates after application of the weight scaler constant, CMS computes the ratio of:

- Total ASC payments using the 2012 pre-floor and pre-reclassified hospital wage indices, to
- Total ASC payments using the 2013 pre-floor and pre-reclassified hospital wage indices.

The resulting ratio, 1.0008, is the proposed wage index budget neutrality adjustment for 2013 (the calculation in the proposed rule yielded a proposed budget neutrality adjustment of 1.0002).

CMS finalizes its proposal to continue its policy of updating the conversion factor by the CPI-U estimated for the 12 month period ending with the mid-point for 2013, minus the multi-factor productivity (MFP) adjustment called for under the ACA.

Because of the availability of updated information since the issuance of the proposed rule, that yields a final MFP-adjusted ASC update of 0.6 percent instead the 1.3 percent update derived in the proposed rule. The proposed and final factors are set out below.

<b>Calculation of CY 2013 Update to ASC payments: proposed and final rule</b>		
	<b>Proposed rule</b>	<b>Final rule</b>
CPI-U update	2.2 %	1.4 %
Minus multifactor productivity adjustment (MFP)	-0.9 %	-0.8 %
Net MFP adjusted ASC update	1.3%	0.6%

The resulting 2013 ASC conversion factor is \$43.917. The computations in the proposed and final rules are as follows.

<b>Calculation of CY 2013 ASC conversion factors: proposed and final rule</b>		
	<b>Proposed rule</b>	<b>Final rule</b>
CY 2012 ASC conversion factor	\$42.627	\$42.627
Wage adjustment for budget neutrality	x 1.0002	x 1.0008
Net MFP-adjusted update	x 1.013	x 1.006
CY 2013 ASC conversion factor	\$43.190	\$42.917

CMS notes that stakeholders have commented that the CPI-U may not be the best measure of inflation for ASCs. CMS reviewed in the proposed rule the options of using the hospital market basket update, the physician’s practice expense (PE) component of the Medicare Economic Index, and an average of the two. CMS finalizes its proposal to continue to use the CPI-U: it notes that until it has more information regarding the cost inputs of ASCs, it is not confident that any of the alternatives are a better proxy for ASC costs.

CMS notes that, beginning on October 1, 2012 ASCs are required to submit data on quality measures for services for the 2014 payment determination as part of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. As noted in the summary of Section XVI, CMS finalizes its proposal to implement a 2.0 percent reduction to the update factor in 2014 (not 2013) for an ASC that fails to meet the ASCCR requirements.

*Display of CY 2013 ASC Payment Rates*

Addenda AA and BB display the final updated ASC payment rates for CY 2013 for covered surgical procedures and covered ancillary services, respectively. Addendum EE provides the

HCPCDS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2013

## **XV. Hospital Outpatient Quality Reporting Program Updates**

### **A. Background**

CMS finalizes changes to the Hospital Outpatient Quality Reporting (OQR) Program, including retention, suspension and removal of OQR Program measures, data reporting requirements and other administrative program procedures and requirements. No additions are made to the OQR Program measure set.

In the final rule, CMS discusses the principles applied to this and other quality reporting programs for measure development and use, including support of the National Quality Strategy; reliance on a mix of process, outcome, efficiency, and patient experience of care measures; alignment of measures across programs; reporting burden on hospitals; consideration of the views of the Measure Application Partnership and other stakeholder input; and the HHS and CMS strategic plans. Policies with respect to publication of hospital OQR Program data on the *Hospital Compare* website are reiterated.

Some commenters supported reliance on NQF-endorsed measures or called for delay in adoption of measures until specification problems are fully addressed. In response, CMS states that when it develops new measures it proceeds with caution and uses a rigorous consensus-based development and field testing process that involves stakeholder input. They view that measures developed in this way are reasonable for adoption to the program whether or not they achieve NQF endorsement. CMS goes on to say that when a measure is developed by others, specifications may be finalized after the measure is adopted for a reporting program.

Although CMS indicates that coding updates are normally incorporated using a subregulatory process, it will solicit public comment on the ICD-10 versions of measure specifications in future rulemaking prior to their implementation. This is because moving to ICD-10 coding may involve nuances in the measure that result in unanticipated changes in performance.

Regarding comments that the communication of changes to measure via email blasts does not always reach the appropriate quality personnel, CMS notes that the emails are not intended to substitute for the QualityNet website, and that the email blasts are available there along with other information.

In response to a comment expressing concern that the acceptable quality range and benchmark data on outpatient imaging efficiency measures might alarm consumers, CMS indicates that it will emphasize rates “within range” and facility outlier results. It will consult stakeholder and focus groups in determining how to present information on quality measurement to the public.

## **B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations**

Under this final rule, once a measure is adopted for the hospital OQR program for a payment determination year it will automatically be adopted for subsequent years until CMS proposes to remove, suspend or replace it. Prior policy adopted measures on a year-by-year basis.

## **C. Removal or Suspension of Quality Measures from the Hospital OQR Program Measure Set**

In this rule, application is made to the OQR Program of several provisions regarding removal of quality measures that are consistent with changes made to the Inpatient Quality Reporting (IQR) Program. First, CMS will use the term “remove” rather than “retire” to refer to the action of no longer including a measure in the IQR Program. In addition, the criteria for removal of measures are established. These seven criteria involve (1) high and unvarying measure performance among hospitals (“topped out” measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) lack of alignment with current clinical guidelines or practice; (4) availability of a more broadly applicable measure; (5) availability of a measure that is more proximal in time to desired patient outcomes; (6) availability of a measure that is more strongly associated with desired patient outcomes; and (7) collection or public reporting of the measure leads to negative unintended consequences such as patient harm. In addition, CMS indicates that the views of the Measures Application Partnership (MAP) will be considered as part of its evaluation of whether or not a measure should be removed from the OQR Program. CMS clarifies that in considering whether to remove a measure it intends to assess whether the removal criteria are relevant and to take a balanced approach in assessing the value of each criterion in each situation.

CMS discusses removal of the measure OP-16, *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*, which occurred subsequent to publication of the proposed rule through a memorandum issued on August 13, 2012. The memorandum is available on the QualityNet.org website in the outpatient section under “email notifications.” CMS will not publicly report, validate or use in the payment determination for 2013 any data collected on this measure. It was removed due to patient safety concerns resulting from the Food and Drug Administration recall of several point of care testing kits, including those that provide Troponin results. CMS emphasizes that hospitals should not cease testing Troponin and other cardiac markers or otherwise stop following clinical guidelines for diagnosis and treatment of cardiac patients due to the decision to remove OP-16 from the OQR program.

Importantly, although OP-16 has been removed from the OQR program, CMS says that due to system limitations it is unable to cease data collection on this measure prior to January 1, 2013. Submission of a blank value for this measure prior to that date will lead the system to reject the case which could result in the hospital failing to meet OQR program requirements. Hospitals may choose to submit a meaningless value for this measure through the end of December. Hospitals are encouraged to work with their vendors to determine options for populating the OP-16 data field through December 31, 2012. CMS reports that it is working with its contractor on a

future version of the data collection system that will add functionality that enables the removal of a measure without delay. In addition, CMS has said that priority to fixing the problem as soon as possible and that it has been “prioritized as high as possible given all the competing demands on contract programmers.”

CMS finalizes its proposal to defer the start of data collection on *OP-24: Patient Referral from an Outpatient Setting* from January 1, 2013 to January 1, 2014. The measure will be included in the 2015 payment determination. CMS anticipates that detailed data abstraction instructions will be available for inclusion in the July 2013 release of the Specifications Manual. In responding to comments, CMS indicates its belief that it is “highly unlikely that hospitals would have spent resources preparing for this measure” because it has not yet been added to the Specifications Manual.

In the proposed rule, CMS discussed suspension or deferral of two additional measures which occurred prior to publication of that rule. The measures are:

- *OP-19: Transition Record with Specified Elements Received by Discharged Patients.* CMS issued a memorandum in April 2012 giving notice of suspension of data collection on this measure effective January 1, 2012 until further notice. In this rule, CMS indicates that it is working with the measure steward, the American Medical Association Physician Consortium for Performance Improvement, to clarify the specifications and address specific concerns raised by commenters. Like with measure OP-16 discussed above, although data collection for this measure is suspended, CMS recommends that hospitals continue to report a value for OP-19 during the time it is suspended because its data collection systems require a populated value for this measure. Data submitted for OP-19 will not be publicly reported or used for payment determinations.
- *OP-15, Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache.* This measure was finalized for inclusion in the OQR Program along with other imaging efficiency measures beginning with the 2012 payment determination. In this final rule, CMS clarifies that public reporting on this measure is not planned until July 2013 at the earliest and confirms that this measure will not be used in the 2014 payment determination. CMS does not discuss any comments regarding this measure. It plans to discuss its intent to include or exclude this measure in the 2015 payment determination in future rulemaking.

CMS responds to comments requesting information on the process for re-instating a removed or suspended measure. A measure that has been removed must be proposed for reinstatement through rulemaking. For a measure that has been suspended, however, CMS says that it will strive to align reinstatement with the quarterly data collection cycle, and will provide at least 3 months’ notice prior to resuming data collection. This will occur through the same notification process used when a measure is suspended: QualityNet.org memoranda and email blasts. In addition, CMS plans to issue addenda to Specifications Manual releases. If CMS determines that a measure’s specifications have been substantively changed, however, it will use rulemaking to formally propose replacing the suspended measure.



## D. Quality Measures for the 2015 Payment Determination

The final OQR Program measure set for the CY 2015 payment determination includes 25 measures, all of which have been previously adopted for inclusion; this rule adds no new measures. For reference, the OQR Program measures for 2013 through 2015 are shown in the table below. Technical specifications for the Hospital OQR Program measures are available on the [QualityNet.org](http://QualityNet.org) website. A Hospital OQR Specifications Manual is published every 6 months with addenda issued as necessary.

<b>Hospital OQR Measurement Sets</b>					
	<b>Payment Determination Year</b>				
	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
OP-1: Median Time to Fibrinolysis	X	X	X	X	X
OP-2: Fibrinolytic Therapy Received Within 30 Minutes	X	X	X	X	X
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	X
OP-4: Aspirin at Arrival	X	X	X	X	X
OP-5: Median Time to ECG	X	X	X	X	X
OP-6: Timing of Antibiotic Prophylaxis	X	X	X	X	X
OP-7: Prophylactic Antibiotic Selection for Surgical Patients	X	X	X	X	X
OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X
OP-9: Mammography Follow-up Rates	X	X	X	X	X
OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X
OP-11: Thorax CT – Use of Contrast Material	X	X	X	X	X
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data		X	X	X	X
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery		X	X	X	X
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)		X	X	X	X
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache		Public reporting delayed at least until July 2013			(earliest)
OP-17: Tracking Clinical Results between Visits			X	X	X
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients			X	X	X

Hospital OQR Measurement Sets					
	Payment Determination Year				
	2011	2012	2013	2014	2015
OP-19: Transition Record with Specified Elements Received by Discharged Patients			Suspended effective with 1/1/12 encounters until further notice		
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional			X	X	X
OP-21: ED- Median Time to Pain Management for Long Bone Fracture			X	X	X
OP-22: ED- Patient Left Without Being Seen			X	X	X
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival			X	X	X
OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting					X
OP-25: Safe Surgery Checklist Use				X	X
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures				X	X
<i>OP 26- Procedure Category</i>	<i>OP 26 - Corresponding HCPCS Codes</i>				
<i>Gastrointestinal</i>	<i>40000 through 49999, G0104, 0105,G0121,C9716, C9724, C9725, 0170T</i>				
<i>Eye</i>	<i>65000 through 68999, G0186, 0124T, 0099T, 0017T,0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T,0191T, 0192T, 76510, 0099T</i>				
<i>Nervous System</i>	<i>61000 through 64999, G0260, 0027T, 0213T, 0214T,0215T, 0216T, 0217T, 0218T, 0062T</i>				
<i>Musculoskeletal</i>	<i>20000 through 29999, 0101T, 0102T, 0062T, 0200T,0201T</i>				
<i>Skin</i>	<i>10000 through 19999, G0247, 0046T, 0268T, G0127,C9726, C9727</i>				
<i>Genitourinary</i>	<i>50000 through 58999, 0193T, 58805</i>				
<i>Cardiovascular</i>	<i>33000 through 37999</i>				
<i>Respiratory</i>	<i>30000 through 32999</i>				

**E. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program**

With respect to possible future measures, CMS emphasizes its expectation that a transition to EHR-based reporting of Hospital OQR Program measures in future years will reduce administrative burden on hospitals of the IQR program. CMS recognizes that much work remains to reach this point including developing electronic specifications, pilot testing, reliability and validity testing and completing other implementation work.

In addition, CMS is considering initiating a call for input to assess six measure domains which it believes will promote better care and align the OQR Program with the IQR Program and the ASC Quality Reporting Program. CMS will consider suggestions offered by commenters for possible new measures for future rulemaking.

#### **F. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the 2013 Payment Update**

CMS proposes to continue for the 2013 update the existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements. The reporting ratio is 0.98, calculated by dividing the reduced conversion factor of \$69.887 by the proposed full conversion factor of \$71.313. Continuing previous policies, when applicable the reporting ratio is applied to all services calculated using the OPSS conversion factor. It is applied to all HCPCS codes to which CMS has assigned status indicators P, Q1, Q2, Q3, R, S, T, U, V, and X, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T. The reporting ratio is applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services, all other applicable standard adjustments to the OPSS national unadjusted payment rates apply, and OPSS outlier eligibility and outlier payment are based on the reduced payment rates.

In the regulatory impact analysis of this proposed rule, CMS reports that 114 hospitals failed to meet the Hospital OQR Program requirements for the full 2012 update. Most of these hospitals (106 of the 114) received little or no OPSS payment on an annual basis and did not participate in the Hospital OQR Program. CMS estimates that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2014.

#### **G. Requirements for Reporting of Hospital OQR Program Data for the 2014 Payment Determination and Subsequent Years**

CMS proposes administrative, data collection and submission and data validation requirements for participation in the Hospital OQR Program for the 2014 payment determination. Most of the requirements are unchanged from those previously in place.

*Notice of Participation.* CMS finalizes its proposal to change the deadlines for certain hospitals to give notice of participation in the OQR Program. Hospitals with a Medicare acceptance date prior to January 1 of the year prior to the effected annual update (e.g., 2013 for the 2014 determination) will have until July 1 to submit a notice of participation form instead of the previous deadline of March 31.

*Data Submission Requirements.* For chart-abstracted measures, the applicable quarters for which hospitals must submit data for the 2014 payment determination are the 3<sup>rd</sup> and 4<sup>th</sup> quarters of 2012 and the 1<sup>st</sup> and 2<sup>nd</sup> quarters of 2013. Hospitals with a Medicare acceptance date on or after January 1, 2013 will submit data with the first full quarter following submission of a participation form. Hospitals that have a Medicare acceptance date before January 1, 2013 that

did not participate in the 2013 Hospital OQR Program will begin data submission with the 1<sup>st</sup> quarter 2013 encounters using the 2013 measure set.

Similarly, for the 2015 payment determination, the applicable quarters for data submission will be the 3<sup>rd</sup> and 4<sup>th</sup> quarters of 2013 and the 1<sup>st</sup> and 2<sup>nd</sup> quarters of 2014. Hospitals with a Medicare acceptance date on or after January 1, 2014 will begin submitting data with the first full quarter following submission of a participation form. Hospitals that have a Medicare acceptance date before January 1, 2014 that did not participate in the 2014 Hospital OQR Program would begin data submission with the 1<sup>st</sup> quarter 2014 encounters using the 2014 measure set.

For the 2015 payment update, CMS will not continue to use a calendar year basis for the calculation of claims-based measures. Instead, data for the period July 1, 2012 to June 30, 2013 will be used. CMS says this will align the data periods for inpatient and outpatient claims based measures on the *Hospital Compare* website and will allow for the posting of more recent data on imaging efficiency on *Hospital Compare*.

Beginning with the 2014 payment determination, the data submission period for structural measures is extended. Instead of reporting with respect to calendar year 2012 during the period July 1, 2013 through August 15, 2013, hospitals will have from July 1, 2013 to November 1, 2013 to submit required information on the structural measures. The July to November period will similarly apply with respect to structural measure data submissions for the 2015 payment determination.

The same July-November data submission period adopted for structural measure reporting will apply to reporting requirements for measure OP-22: Patient Left Without Being Seen. Although this is technically a chart-abstracted measure, CMS has previously finalized data submission requirements for OP-22 that are similar to those used for the structural measures. That is, hospitals will report aggregate numerator and denominator counts on this measure once a year using a web-based tool via the QualityNet website.

Voluntary quarterly reporting is continued for aggregate population and sample size counts with respect to each chart-abstracted measure. For hospitals that choose to report these data, they would be submitted under the same deadlines that apply to reporting chart-abstracted measures under the data submission schedule posted on the QualityNet website. In the past, CMS has not finalized its proposals to require population and sample size reporting in response to comments from hospitals regarding reporting burden.

*Data Validation Requirements.* The final rule continues for 2014 the OQR Program data validation requirements adopted in last year's rulemaking for 2013, which included a reduction in the number of randomly selected hospitals from 800 to 450 and selection of up to 50 additional hospitals for validation based on targeting criteria. For 2014, the targeting criteria remain unchanged and will continue to include hospitals that either fail the validation requirement for the 2012 payment determination or have an outlier value based on the data submitted. Other features of the validation procedures also continue, including the process for validation of up to 48 randomly selected encounters (12 per quarter) and the method for calculating the validation score. In response to comments, CMS indicates that if a hospital seeks

to learn under which criterion it was selected for validation it may call the support contractor (using contact information on QualityNet.org) to request this information.

In response to a comment regarding validation of ED throughput measures, CMS finalizes that for CY 2014 and subsequent years, a 5 minute variance between the times abstracted by the hospital and the Clinical Data Abstraction Center will be allowed when scoring each of the six measures OP-18 through OP-23. That is, these measures will not be required to have matching numerator and denominator states.

## **H. Reconsideration and Appeals Procedures for 2014 and Subsequent Years**

CMS continues for the 2014 payment determination, with modifications, the reconsideration and appeals procedures that were finalized in last year's rulemaking for the 2013 payment determination. The changes require that the hospital designate a contact on the reconsideration request form, and that the designated contact sign the reconsideration request. (Last year, CMS eliminated a previous requirement that the hospital CEO sign the reconsideration request, but failed to include any requirement that the request be signed.)

## **I. Extraordinary Circumstances Extension or Waiver for the 2013 Payment Determination and Subsequent Years**

One change is made with respect to the procedures for a hospital to request from CMS an extension or waiver from OQR Program requirements in the case of extraordinary circumstances not within the hospital's control. Instead of requiring that the hospital submit contact information for the CEO and other designated personnel, with the CEO signing the request form, the hospital must submit contact information for the CEO or other designated personnel. The CEO or the hospital's designated contact must sign the request form.

## **J. Electronic Health Records**

As in the proposed rule, CMS reiterates its intention that the hospital IQR and OQR programs will transition to the use of certified EHR technology for submission of data on those measures that require information from the clinical record. It notes that 2015 was identified in the FY 2012 IPPS/LTCH proposed rule as a potential transition date for moving from chart-abstracted data to EHR-based data submission. CMS anticipates that the transition for reporting on Hospital OQR Program measures will likely be somewhat later because the clinical quality measures in the EHR Incentive Program are primarily aligned with Hospital IQR Program measures rather than the Hospital OQR Program measures.

CMS discusses the conflicting requirements under the OQR and Stage 2 Medicare EHR Incentive Program final rule, and responds to invited comments. Under Stage 2, electronic reporting of clinical quality measures is required beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use. Because electronic reporting will not begin for the OQR program at that time, eligible hospitals may be using two different methods to report similar information to the two programs. In the proposed rule, CMS indicated that it had considered allowing but not requiring EHR-based submission for the OQR program at

the earliest possible date. However, this was not proposed because CMS believes that measure results that are publicly reported should be based on consistent, comparable results among reporting hospitals. Moreover, CMS indicates its first priority is alignment of EHR-based submissions under the IQR Program.

In this rule CMS summarizes its vision for electronic reporting as using the same electronically specified quality measures for different programs, standardizing measure development and electronic specification process across programs, coordinating stakeholder involvement in quality measurement efforts and identifying ways to minimize multiple data submission requirements and mechanisms. CMS believes a staggered transition to electronic reporting in order to monitor the infrastructure and data integrity during the process.

#### **K. 2013 Measure EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs**

CMS finalizes its proposal to continue for the 2013 payment year the Electronic Reporting Pilot that was finalized for 2012. Regulations are revised to reflect continuation of the program and to conform to proposed changes included in the EHR Incentive Program Stage 2 final rule. Eligible hospitals and CAHs may continue to report clinical quality measure results by attestation under the Medicare EHR Incentive Program.

### **XVI. Requirements for the Ambulatory Surgical Center Quality Reporting Program**

#### **A. Background**

In the 2012 OPPS/ASC final rule, CMS finalized the implementation of an ASC Quality Reporting (ASCQR) Program beginning with the 2014 payment determination. That rule adopted quality measures for 2014, 2015 and 2016 and adopted data collection and reporting requirements and timeframes for 2014. In that rule, CMS indicated that the FY 2013 IPPS rulemaking process would be used to issue proposals for other ASCQR Program requirements. Following through on this, in the FY 2013 IPPS final rule (77 FR 28101), CMS finalized requirements regarding administrative issues, data validation and completeness, and reconsideration and appeals processes.

In this rule, CMS finalizes reporting requirements for the ASCQR Program for 2015 and subsequent years, data completeness requirements for 2015, and a methodology for implementing the payment reduction for ASCs that fail to meet the ASCQR Program requirements.

#### **B. ASCQR Program Quality Measures**

No additions or deletions are made with respect to the measures adopted in last year's rulemaking for 2014, 2015 and 2016. For reference, the measures previously adopted and proposed to be unchanged are shown in a table below. Technical specifications for quality measures are available on the QualityNet website.

CMS discusses the considerations in the selection of measures for the ASCQR Program, which follow those related to the OQR Program and other similar quality reporting programs. These considerations include support for the National Quality Strategy; seeking a mix of process, outcome and patient experience of care measures with a goal of emphasizing the latter two categories over process of care measures; reporting burden; views of the MAP; stakeholder views; and the HHS and CMS strategic plans. Alignment of measures across providers is also a consideration, particularly with respect to harmonizing measures across ASCs and HOPDs. CMS states its view that ASC facilities are similar to HOPDs, that both provide many of the same surgical procedures, and therefore similar standards and guidelines with respect to surgical care improvement can be applied to both settings.

CMS clarifies that the process adopted in last year’s rulemaking for updating the ASCQR Program measures includes the same subregulatory process adopted for updating measures in the OQR Program. Under that process, when NQF (or other national consensus building entity) updates the specifications for a measure included in the OQR Program, CMS updates specifications accordingly. For other measures, the subregulatory process is used to update measures based on scientific advances as determined necessary by CMS through the measure maintenance process involving Technical Expert Panels. According to the 2012 OPPI/ASC final rule, notification for substantial changes, such as changes to ICD-9, CPT, NUBC and HCPCS codes, will be provided via the QualityNet website and Specifications Manual at least 3 months before the effective date of specification changes, and at least 6 months notice will be provided for substantive changes to data elements requiring significant systems changes.

As noted earlier, CMS is considering initiating a call for input to assess six measure domains which it believes will promote better care and align the OQR Program with the IQR Program and the ASC Quality Reporting Program.

<b>ASC Program Measurement Sets for the 2014-2016 Payment Determinations</b>			
	<b>Payment Determination Year</b>		
	<b>2014</b>	<b>2015</b>	<b>2016</b>
ASC-1: Patient Burn*	X	X	X
ASC-2: Patient Fall*	X	X	X
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*	X	X	X
ASC-4: Hospital Transfer/Admission*	X	X	X
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing*	X	X	X
ASC-6: Safe Surgery Checklist Use**		X	X
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures**		X	X
<i>ASC-7 Procedure Category</i>	<i>ASC-7 Corresponding HCPCS Codes</i>		
<i>Gastrointestinal</i>	<i>40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T</i>		
<i>Eye</i>	<i>65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T</i>		
<i>Nervous System</i>	<i>61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T</i>		

<b>ASC Program Measurement Sets for the 2014-2016 Payment Determinations</b>			
<i>Musculoskeletal</i>	<i>20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T</i>		
<i>Skin</i>	<i>10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727</i>		
<i>Genitourinary</i>	<i>50000 through 58999, 0193T, 58805</i>		
ASC-8: Influenza Vaccination Coverage among Healthcare Personnel***			X

### **C. Requirements for Reporting ASC Quality Data**

For claims-based measures in 2015, the same reporting process adopted for 2014 will be used. ASCs WILL submit data on the claims-based quality measures by including the appropriate Quality Data Code (QDC) on the Medicare claim. The data collection period for the claims-based measures is the calendar year 2 years prior to the payment determination (i.e., for 2015, the data collection period will be calendar year 2013) for those claims paid by April 30<sup>th</sup> of the following year (i.e., calendar year 2013 claims paid by April 30, 2014). In response to comments, CMS reiterates that April 30 is the latest date that would allow CMS the time to acquire and analyze the data and make payment determinations and to allow MACs the time to program systems. As CMS gains experience it will consider changing the dates; any changes would be made through notice and comment rulemaking.

CMS extends for 2015 and later the data completeness standard established in last year's rulemaking for 2014. Under that requirement, data completeness is determined by comparing the number of Medicare claims meeting measure specifications with the number of Medicare claims that would meet measure specifications but did not have the appropriate QDC code. Claims include those for which Medicare is the primary or secondary payer. (However, in the FY 2013 IPPS finale rule, CMS determined that for 2014 only claims with Medicare as the primary payer will be used to establish ASC data completeness because private payers will not have QDCs in their required HCPCS data files prior to January 1, 2013.) In response to a commenter's suggestion, CMS will provide ASCs with preliminary data completeness percentages prior to the April 30<sup>th</sup> data submission deadline. This will be provided either electronically or by mailing a facility-specific report. CMS indicates that ASCs can also use remittance information to assess whether QDCs are being successfully processed by MACs.

### **D. Payment Reduction for ASCs Failing to Meet ASCQR Program Requirements**

Although the Secretary has discretion as to whether to implement an ASCQR Program, if she elects to do so the program must provide for a 2.0 percentage point reduction to the update factor of an ASC that fails to meet the program's requirements for a year. This rule establishes the method by which the 2.0 percentage point update factor reduction will be implemented. Having received no comments, the methodology is finalized as proposed.

The method that CMS finalizes for implementing a payment reduction for ASC failing to meet quality reporting requirements parallels the approach used in the Hospital OQR Program. Two conversion factors are calculated: a full update conversion factor and an ASCQR Program



reduced update conversion factor that reflects application of the 2.0 percentage point reduction. The reduced update conversion factor could result in a net update that is less than zero prior to application of the multifactor productivity adjustment. Payment for all services assigned the payment indicators A2, G2, P2, R2, Z2, and the service portion of device intensive procedures identified by J8 are subject to the reduction. ASC payment rates for certain separately payable services will not be subject to the reduction because the conversion factor and update factor do not apply to payments for these services. These include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPFS payment rates, and certain office-based procedures and radiology services where payment is based on the physician fee schedule amounts, and a few other specific services that receive cost-based payment.

Office-based surgical procedures and separately paid radiology services are paid at the lesser of the MPFS non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. The standard ASC ratesetting methodology used for the purpose of determining these payments will use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, Medicare beneficiary copayments will be based on the reduced national unadjusted payment rate.

All other applicable adjustments to the ASC national unadjusted payment rates will apply when the annual update is reduced for an ASC that fails to meet ASCQR Program requirements. These include the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost.

## **XVII. Inpatient Rehabilitation Facility Quality Reporting Program Updates**

### **A. Background**

Pursuant to the Affordable Care Act, a quality reporting program (QRP) for inpatient rehabilitation facilities (IRFs) was established in the FY 2012 IRF PPS final rule. Because no proposed rule for the IRF PPS will be issued this year, CMS elected to propose updates to the IRF QRP that require notice and comment in the OPFS/ASC proposed rule.

CMS proposals for the IRF QRP included in this rule relate to 1) updates of previously adopted measures, 2) retaining previously adopted measures, and 3) use of notice and comment rulemaking for updating the two measures previously adopted for the program.

### **B. Updates to IRF QRP Measures Made as a Result of the NQF Review Process**

CMS finalizes with modifications its proposal to use a subregulatory process for updating a measure when as a result of its review process the NQF updates an endorsed measure that has been adopted for the IRF QRP in a manner that CMS considers does not “substantially change” the nature of the measure. CMS intends to revise the information on the measure included on the

CMS IRF QRP website and provide “sufficient lead time” for IRFs to implement changes to the data collection process, if necessary. The modifications to the proposed rule reflect parallel policies adopted in the FY 2013 IPPS/LTCH final rule for the IQR Program and other quality reporting programs, and CMS offers both there and in this final rule examples of changes that might generally be considered to be substantive and non-substantive, noting that changes would be evaluated on a case-by-case basis.

### **C. Process for Retention of IRF Quality Measures**

Measures adopted for the IRF QRP for a payment determination year will be automatically adopted for all subsequent payment determinations until CMS proposes and finalizes its removal, suspension or replacement. This policy is finalized in general and specifically with respect to the two measures adopted for the IRF QRP for FY 2013. These are Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and Percent of Residents with Pressure Ulcers that are New or Worsened (NQF # 0678).

In response to comments, CMS notes that IRFs may submit comments regarding quality measures already in use through the IRF QWRP helpdesk and email box ([irf.questions@cms.hhs.gov](mailto:irf.questions@cms.hhs.gov)). CMS discusses the potential reasons for removal of a measure and notes that measure removal will be subject to notice and comment rulemaking unless there are safety concerns in which case CMS will take immediate action to remove a measure.

### **D. Measures for the FY 2014 Payment Determination**

*CAUTI.* When CMS adopted the CAUTI measure for the IRF QRP, it was not specified for the IRF setting, applying only to patients in intensive care units (ICUs). The measure was adopted under the exception authority which allows the Secretary to adopt a measure that is not NQF endorsed when no similar endorsed measure is available. Subsequent to its adoption, the NQF endorsed expansion of the scope of the CAUTI measure to non-ICU settings, including rehabilitation hospitals. In addition, the calculation of the measure was changed from a simple rate per 1,000 days to a standardized infection ratio methodology.

CMS finalizes its proposal to modify the IRF QRP CAUTI measure by adopting the changes made by the NQF to measure #0138 for the FY 2014 payment determination. In addition, the revised measure is adopted for the FY 2015 payment determination and subsequent years, and any future changes to the measure will be incorporated consistent with the proposed approach to updating measures discussed above.

*Pressure Ulcers.* The measure Percent of Residents with Pressure Ulcers that are New or Worsened (NQF # 0678) was previously adopted for the IRF QRP, under the exception authority because the measure was specified for short-stay nursing home patients. In April 2012, CMS requested that NQF undertake a review of the measure and endorse it for other settings. In the proposed rule, CMS states that if NQF expands the scope of the measure to include the IRF setting, it would update the measure following the process proposed above. In the meantime, CMS proposed to proceed to implement the measure as finalized in last year’s rulemaking.

CMS indicates that concerns raised by commenters reflect ongoing discussions that have occurred during stakeholder calls and forums. These primarily involve concerns about limitations of the amount and type of pressure ulcer data that can be collected on the IRF-PAI. CMS indicates that it would not benefit IRFs to delay the start of data reporting on this measure, because evaluating the initial pressure ulcer data that is reported will be helpful to CMS in determining needed modifications in the IRF-PAI needed to calculate risk-adjusted rates, and because many providers have already incurred a significant financial burden to prepare their EHR systems and staff for implementation on October 1, 2012.

After consideration of numerous comments regarding the pressure ulcer measure, the final rule adopts a non risk-adjusted version of NQF# 0678, which consists of numerator and denominator data only. The pressure ulcer measure will be collected using the current version of the IRF Patient Assessment Instrument (PAI). Public reporting on this measure will not begin until CMS has 1) conducted research and consulted experts, 2) made appropriate modifications to the quality indicator section of the IRF-PAI to add the risk adjustment items and 3) adopted the NQF endorsed pressure-ulcer measure and notified stakeholders through the rulemaking process.

CMS indicates that it is working to develop and implement two measures recommended by MedPAC for addition to the IRF QRP. One is a measure of risk-adjusted readmissions and the other a measure of functional improvement.

## **XVIII. Revisions to Quality Improvement Organization (QIO) Regulations**

CMS finalizes its proposed changes to the operations of Quality Improvement Organizations (QIOs) with only minor modifications which generally afford slightly more time than would have applied under its proposed deadlines for the various stages of the review process. The goals of the changes are to make QIOs more responsive to beneficiary complaints about quality of care and to improve the efficiency with which QIOs carry out their duties.

CMS provides for three avenues for quality of care review: 1) immediate advocacy, 2) beneficiary complaint review, and 3) general quality of care review. Immediate advocacy is the most significant change. It is based on an alternative dispute resolution model, and a beneficiary may orally communicate certain complaints or quality of care concerns to a QIO for resolution. Under this less formal process, the QIO contacts the provider or practitioner in question directly to achieve a prompt resolution of the concern. CMS notes that these concerns may relate to access to an item or service that he or she feels should be provided, such as a wheelchair, but would not be used for significant quality of care concerns (a defined term described below). CMS seeks to ensure QIO ability to review a considerable variation and scope of complaints and related factors. For example, in response to commenters' concerns that complaints relating to impolite staff, room temperatures of facilities, and reception processes in waiting rooms could now be raised, CMS observes that these types of concerns may well contribute to a QIO's overall assessment of whether a particular standard of care is met. QIOs will use evidence-based standards of care in their reviews to the maximum extent practicable. CMS declines to define episode of care with any specificity fearing that it may limit a QIO's flexibility to link different settings or services for a particular complaint.

CMS responds to another complaint frequently voiced about the current QIO program—that beneficiaries have little or no information about the review process, including specifics relating to the complaint resolution, the standard of review used by the QIO, statements of the pertinent facts used by the QIO to make its determination, the status of the review, and the right to request a reconsideration, if any. QIO determinations will now generally include this type of information and also be required to adhere to a strict timetable for initial determinations and reconsiderations. CMS reiterates that there are no changes to QIO sanction authority, process or activities under this final rule.

### **A. Immediate Advocacy**

CMS codifies in regulations the immediate advocacy process under which a beneficiary may orally file a complaint with a QIO on certain quality of care concerns. Upon receipt of an oral communication from a beneficiary on a quality of care concern (defined as care that does not meet a professionally recognized standard of health care), a QIO representative will directly contact the provider or practitioner involved to resolve the issue; CMS believes this could be as efficient as "same day resolution". Immediate advocacy may not be used for situations that involve gross and flagrant, substantial, or significant quality of care concerns, which CMS continues to believe should be resolved using the more formal written beneficiary complaint review process. Many commenters agree that this process should not be used for significant quality of care concerns which are described as neither gross and flagrant nor substantial, but still are a noticeable departure from the standard of care that could reasonably be expected to have a negative impact on beneficiary health. However, CMS will evaluate the potential use of immediate advocacy for significant quality of care concerns in the future.

All parties to a complaint under the immediate advocacy process must orally consent to use the process and also agree that all written and oral communications may not be “rediscovered” absent agreement of all parties. A beneficiary must make an oral complaint to the QIO not later than 6 months after the date of care at issue, and the beneficiary must agree to the disclosure of his or her name to the provider or practitioner. Immediate advocacy may be used if the QIO determines either that 1) while unrelated to clinical quality of care, the complaint relates to items or services accompanying or incidental to that care; or 2) the complaint is related to clinical quality of care but is not a gross and flagrant, substantial, or significant quality of care concern.

The QIO or either party may discontinue immediate advocacy at any time, for example upon discovery of more serious concerns. The QIO must notify all parties of the termination of the process and advise the beneficiary that he or she may file a written complaint which will be resolved through the beneficiary complaint review process. Likewise, should any party abandon or fail to comply with requirements of the immediate advocacy process, the QIO may terminate the process and provide the same notice.

CMS also permits a QIO to determine whether to conduct a general quality of care review for those situations where a beneficiary who makes an oral complaint that is not resolvable under the immediate advocacy process due to the nature of the quality of care concern (i.e., gross and flagrant, substantial, or significant) does not follow up by filing a written complaint.

## **B. Beneficiary Complaint Review**

CMS modifies the process for review of written complaints received from beneficiaries claiming the quality of health care furnished was not consistent with professionally recognized standards of care (beneficiary complaint review).

A QIO must receive the written complaint, which includes via electronic submission, not later than 3 years after the date of care at issue. If a new concern related to the same complaint reported to the QIO is raised after its initial determination, the QIO will treat it as a new complaint; the QIO may process a new concern raised before its initial determination as part of the original complaint or address it as a separate complaint.

A QIO's scope of review involves consideration of all information and materials submitted by all parties; the QIO must hold as confidential any information or material that meets the definition of confidential information under §480.101. The focus of the review is the episode of care at issue (which CMS declines to define with specificity), the specific beneficiary concerns raised, and any concerns the QIO may identify. CMS continues to believe this reduces the burden on providers and practitioners and timeframes for resolving complaints. QIOs may separate concerns into different complaints if they relate to different episodes of care. QIOs apply evidence-based standards of care in the review to the maximum extent practicable; otherwise existing norms, best practices, and established guidelines are used to establish the standard. CMS emphasizes that the standard used by the QIO in its review is not be appealable and notes, in response to concerns, that QIOs have successfully done this for decades.

CMS finalizes an expeditious process with shortened timeframes for each step in the review process. For example, in the case of a medical information request from a QIO, providers and practitioners must deliver all requested medical information within 14 calendar days (a slight increase from the 10-day deadline in the proposed rule). Additionally, QIOs may shorten that deadline in cases of potential gross and flagrant, or substantial, quality of care concerns. As it proposed, CMS applies the same timeframes or deadlines to practitioners as it does for providers. When a QIO requests medical information of practitioners or providers, it must 1) notify them that the medical record is sought in connection with a beneficiary complaint; 2) explain their right to discuss the QIO's interim initial determination; and 3) request a contact person for purposes of that discussion. A practitioner or provider's failure to timely deliver requested information to the QIO could result in the denial of a claim for payment.

QIOs must 1) complete their interim initial determination with 10 days after receipt of all requested information (an increase from the 7-day deadline in the proposed rule); 2) notify the provider and practitioner, by phone, of the determination; and 3) afford an additional 7-day period to discuss, orally or in writing, any findings made against the provider or practitioner. CMS finalizes its proposed policy to prohibit providers or practitioners from submitting new or additional medical evidence in response to an offer for a discussion; CMS believes that because a QIO request for medical records must now indicate that the request is in response to a beneficiary complaint, the practitioner or provider will likely provide all relevant medical information in response to that request. The QIO may grant additional time to complete the

discussion or for the submission of a written statement in lieu of discussion, but CMS emphasizes that this is in rare circumstances.

QIOs must issue a final initial determination not later than 3 business days (which is different from the 72 hours CMS had proposed) after completion of the review, or where applicable after the discussion with, or receipt of written statements from, the provider or practitioner. The QIO must notify by phone all parties both of its final initial determination and the right of all parties (including beneficiaries) to request reconsideration of the determination. Absent a request for reconsideration, the QIO must forward within 5 calendar days (an increase from the 72 hours CMS had proposed) written notice of the determination. Any such determination shall include all of the following information:

- A statement for each concern whether the care met the applicable standard of care.
- The standard of care identified by the QIO for each concern.
- A summary of facts pertinent to the determination (including medical information and any discussion with the provider or practitioner involved).

For complaints filed after July 31, 2014, all parties have the right to seek reconsideration of a QIO final initial determination, including beneficiaries who heretofore had no right to request from a QIO any form of appeal, redetermination, or reconsideration. The deadline to file a request is 3 calendar days following notice (by phone or in writing) of the final initial determination. If the third calendar day falls on a day when the QIO cannot accept a request, the deadline is delayed to noon of the next day the QIO is able to receive the request. This deadline represents an increase from the very short proposed deadline of no later than noon of the following calendar (not business) day. Parties must be available to respond to QIO queries or requests for information, and QIOs must afford the parties the opportunity to provide further information, including evidence, for the QIO's consideration.

CMS finalizes numerous technical changes to the regulations to facilitate this information exchange, including doing away with rights of attending practitioners to direct the withholding of information based on a "harm" determination, and clarifying that a provider's or practitioner's consent is not required before releasing information to a beneficiary in connection with an initial denial determination or providing a beneficiary results of QIO findings related to a beneficiary complaint review. CMS finalizes proposed changes to rules for the designation and identification of beneficiary representatives, focusing QIO representative identification efforts on state and local law requirements and procedures in lieu of difficult searches through medical records.

A QIO reconsideration is a final determination for which there is no further right of appeal. A QIO must complete its review and notify all parties of the decision no later than 5 calendar days (an increased from CMS's proposed 72 hours) after the later of 1) the receipt of a request for reconsideration, or 2) the receipt of any medical evidence or other records needed for the reconsideration. The notice may be initially done by phone and followed up in writing and mailed by noon of the following day. The notice must include the type of information included in the final initial determination described above as well as a statement indicating there are no further appeal rights. Additionally, a QIO may include in its final decision specific suggestions for areas of improvement, such as in the provider's or practitioner's delivery of care.

When a beneficiary fails to comply with requirements of the beneficiary complaint review process, a QIO may determine the complaint is abandoned; the QIO informs the parties that the complaint is discontinued and includes notice of the beneficiary's right to resubmit a written complaint. To reopen a complaint, a QIO will use procedures under §476.96 (procedures to reopen cases involving initial denial determinations and changes resulting from DRG validation).

### **C. General Quality of Care Review**

A QIO may initiate a general quality of care review itself, based on concerns identified through other review activities, referrals from other sources (such as federal or state agencies, contractors or individuals), or analysis of data available to it. The scope of this type of QIO review is not limited to an episode of care analysis; the QIO may focus on all concerns raised. Similar to other forms of QIO quality of care reviews, a QIO uses evidence-based standards of care to the maximum extent practicable, and the standard used in the review is not be subject to appeal.

Similar to medical information requests pursuant to beneficiary complaint reviews, providers and practitioners must deliver all requested information within 14 days (an increase from the 10 days CMS had proposed), or sooner in potential cases of gross and flagrant, or substantial, quality of care concerns. Providers and practitioners may face denial of claims for failure to comply with requests for information. The QIO must complete the initial determination within 10 days (an increase from the 7 days CMS had proposed) of receipt of all requested medical information.

Consistent with reconsideration rights in the case of beneficiary complaint reviews, for complaints filed after July 31, 2014, providers and practitioners may seek reconsideration of a QIO initial determination under a general quality of care review. The applicable deadlines are identical to those under a beneficiary complaint review. Providers and practitioners must be available to respond to QIO queries or requests for information, and QIOs must afford them the opportunity to provide further information, including evidence for the QIO's consideration. Consistent with the process for beneficiary complaint review, not later than 5 calendar days (an increase from the proposed 72 hours) after the later of 1) the receipt of a request for reconsideration, or 2) the receipt of any medical evidence or other records needed for the reconsideration, the QIO must complete its review and notify the provider or practitioner of its decision, which may initially be done by phone and followed up in writing and mailed by noon of the following day. The notice must include the type of information included in the initial determination described above as well as a statement indicating there are no further appeal rights. Additionally, the QIO may include in its final decision specific suggestions to improve the care furnished to patients.

General quality of care reviews differ from beneficiary complaint reviews in two significant aspects. First, beneficiaries are not provided any information regarding these reviews. Second, providers and practitioners do not have the opportunity to discuss the QIO initial determination before it becomes final which means they have only one opportunity to respond to review findings. The rationale for omitting this opportunity for discussion is that past experience shows that no actual discussion occurs; rather, CMS asserts that practitioners and providers use this

period as an opportunity to submit further medical evidence. CMS believes its changes to QIO requests for medical information will ensure the timely provision of all relevant information.

#### **D. Other Matters**

CMS adopts without modification its proposals for QIO use of confidential information that explicitly or implicitly identifies patients. Thus, a QIO may not use confidential information unless the beneficiary executes a valid authorization document that sets forth the manner in which such information may be used or disclosed as well as all of the following:

1. A meaningful description of the confidential information in question.
2. The names and other identification of —
  - a. the QIO and the QIO points of contact making the request, and
  - b. the persons to whom information is to be disclosed.
3. A description of each purpose for the use or disclosure.
4. The expiration date of the authorization.
5. A signature and date.

Additionally, the authorization must be in plain English and must inform the beneficiary of the right to revoke the authorization in writing, and any related exceptions to that revocation right (such as when the QIO has already acted in reliance on the authorization). Additionally, the authorization must state that the QIO may not condition its review activities on an authorization as well as the consequences of such an authorization, such as potentially impeding a QIO from carrying out an activity or, the inability of the QIO to protect information from redisclosure. CMS declines to create model authorization forms and instead relies on QIOs to develop them.

QIOs may now send and receive secure transmissions of electronic versions of health information (such as the use of secure electronic faxes). CMS believes this reflects the current mode of conducting business which will reduce the laborious and costly process of mailing copies of all requested medical records and related information to QIOs. The efficiency afforded by electronic transmissions also permits shorter compliance times for transmission of medical information. The deadline is 14 days from the date of a QIO request (in lieu of the 10 days CMS had proposed).

CMS removes the requirement that QIOs use peer reviewers with active staff privileges in one or more hospitals to increase the number of available peer reviewers. CMS notes that there is a decline in the number of family practice physicians who provide any care in hospitals as well as a trend of generalist physicians who only provide care in the inpatient or outpatient hospital setting. CMS also believes that removal of this requirement will enable QIOs to use physicians with expertise in the actual settings in which the care in question is provided. CMS does retain the requirement that reviewing physicians be from the QIO area.

#### **E. Regulatory Impact**

CMS revises the table for its estimated annual savings to show an aggregate annual savings of \$3,000,422 by reason of its changes to the QIO regulations. (The row in that table in the final



rule for copying costs for QIO activities that are not related to quality reporting includes estimated savings related to PPS providers of approximately \$306,250 that appears to have been omitted from the similar table in the proposed rule.) The transmission of electronic versions of health information reduces costs associated with QIO program requests from hospitals of approximately 62,400 medical records each year for the Hospital IQR and Hospital OQR Programs (copying, shipping and labor costs). It also reduces costs for compliance with other QIO review activities, such as requests for roughly 100,000 medical records necessary to complete other review activities, including general quality of care reviews, written beneficiary complaint reviews, medical necessity reviews, and expedited discharge appeal reviews.

Immediate advocacy is expected to not only expedite resolution of complaints (CMS estimates a normal completion time of two days), but also to reduce cost per case from \$960 for cases processed using the traditional peer review process to roughly \$87. One commenter questioned this \$87 figure wondering how that amount could compensate for staff time involved but did not include any documentation or other information to challenge the estimate; thus CMS does not revise it in the final rule. The following table is modified from the final rule (it corrects the subtotal for the item "I. Authority to transmit information electronically"):

<b>Provision</b>	<b>Savings per year</b>
I. Authority to transmit information electronically	\$2,694,872 (total per year)
Quality Reporting Information (Copying)	\$901,152
Quality Reporting Information (Mailing)	\$142,220
Other QIO Activities (Copying)	\$1,487,500
Other QIO Activities (Mailing)	\$164,000
II. Immediate Advocacy	\$305,550 (total per year)
<b>Total Savings</b>	<b>\$3,000,422 (per year)</b>

**APPENDIX: TABLES REPRODUCED FROM THE FINAL RULE**

**TABLE 57.—ESTIMATED IMPACT OF THE CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM**

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Median) (%)	Impact of Basing Weights Using Geo Mean (%)	APC Recalibration (Geo Mean) (%)	New Wage Index and Provider Adjustments (%)	Combination of Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier Wage Index Adjustment (%)	All Changes (%)
ALL FACILITIES *	4,127	0.0	0.0	0.0	0.0	1.8	1.9	1.9
ALL HOSPITALS	3,905	0.0	0.0	0.0	0.0	1.8	1.9	1.9
(excludes hospitals permanently held harmless and CMHCs)								
URBAN HOSPITALS	2,957	-0.1	0.0	-0.1	0.0	1.8	1.8	1.9
LARGE URBAN (GT 1 MILL.)	1,611	-0.1	0.0	-0.1	0.2	1.9	1.9	2.0
OTHER URBAN (LE 1 MILL.)	1,346	-0.1	0.0	-0.1	-0.1	1.6	1.8	1.7
RURAL HOSPITALS	948	0.3	0.1	0.5	-0.2	2.1	2.3	2.2
SOLE COMMUNITY	385	0.4	0.1	0.5	0.0	2.3	2.8	2.4
OTHER RURAL	563	0.3	0.1	0.4	-0.4	1.9	1.9	2.0
BEDS (URBAN)								
0 - 99 BEDS	1,047	0.4	0.2	0.6	0.0	2.5	2.6	2.7
100-199 BEDS	833	0.1	0.1	0.2	0.2	2.2	2.3	2.3
200-299 BEDS	458	-0.1	0.0	-0.1	0.1	1.7	1.9	1.9
300-499 BEDS	415	-0.2	0.0	-0.2	0.1	1.7	1.8	1.9
500 + BEDS	204	-0.2	-0.1	-0.3	-0.2	1.3	1.3	1.5
BEDS (RURAL)								
0 - 49 BEDS	356	0.8	0.4	1.2	-0.3	2.8	3.0	2.8
50- 100 BEDS	352	0.5	0.1	0.7	0.0	2.4	2.7	2.6
101- 149 BEDS	137	0.2	0.1	0.2	-0.6	1.5	1.7	1.6
150- 199 BEDS	55	0.3	0.1	0.4	-0.3	1.8	2.4	2.0
200 + BEDS	48	-0.2	0.0	-0.2	0.1	1.7	1.7	1.8

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Median) (%)	Impact of Basing Weights Using Geo Mean (%)	APC Recalibration (Geo Mean) (%)	New Wage Index and Provider Adjustments (%)	Combination of Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier Wage Index Adjustment (%)	All Changes (%)
<b>VOLUME (URBAN)</b>								
LT 5,000 Lines	597	2.4	2.5	4.9	-0.1	6.7	6.8	6.8
5,000 - 10,999 Lines	126	1.3	1.3	2.6	-0.3	4.1	4.5	4.4
11,000 - 20,999 Lines	197	0.7	0.3	1.0	0.1	2.9	3.0	3.1
21,000 - 42,999 Lines	429	0.3	0.1	0.4	0.1	2.3	2.4	2.5
42,999 - 89,999 Lines	688	0.0	0.0	0.0	0.1	1.9	1.9	2.0
GT 89,999 Lines	920	-0.2	0.0	-0.2	0.0	1.6	1.7	1.8
<b>VOLUME (RURAL)</b>								
LT 5,000 Lines	59	1.8	1.3	3.1	-0.3	4.5	7.6	4.6
5,000 - 10,999 Lines	61	0.5	0.9	1.5	-0.9	2.3	2.3	2.5
11,000 - 20,999 Lines	146	0.6	0.6	1.2	-0.3	2.7	3.1	2.8
21,000 - 42,999 Lines	282	0.7	0.2	0.9	-0.3	2.4	2.7	2.5
GT 42,999 Lines	400	0.2	0.1	0.3	-0.2	1.9	2.2	2.1
<b>REGION (URBAN)</b>								
NEW ENGLAND	149	0.3	0.0	0.3	-0.6	1.5	1.5	1.5
MIDDLE ATLANTIC	349	-0.1	-0.1	-0.1	-0.3	1.4	1.4	1.5
SOUTH ATLANTIC	453	-0.1	-0.1	-0.2	-0.5	1.1	1.1	1.3
EAST NORTH CENT.	474	-0.2	0.0	-0.2	0.3	1.9	1.9	1.9
EAST SOUTH CENT.	179	-0.3	-0.1	-0.4	-0.7	0.7	0.7	0.8
WEST NORTH CENT.	188	0.0	0.0	0.0	0.3	2.1	3.1	2.5
WEST SOUTH CENT.	515	-0.1	0.1	-0.1	-0.4	1.4	1.4	1.6
MOUNTAIN	208	0.2	0.0	0.2	0.6	2.7	3.1	2.8
PACIFIC	395	-0.1	0.1	0.0	1.4	3.3	3.3	3.4
PUERTO RICO	47	-0.1	0.0	-0.1	0.1	1.8	1.8	2.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Median) (%)	Impact of Basing Weights Using Geo Mean (%)	APC Recalibration (Geo Mean) (%)	New Wage Index and Provider Adjustments (%)	Combination of Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier Wage Index Adjustment (%)	All Changes (%)
REGION (RURAL)								
NEW ENGLAND	25	0.7	0.0	0.7	0.4	3.0	3.0	3.1
MIDDLE ATLANTIC	67	0.4	0.0	0.4	0.0	2.2	2.2	2.3
SOUTH ATLANTIC	161	0.2	0.1	0.3	-0.4	1.6	1.6	1.7
EAST NORTH CENT.	127	0.2	0.1	0.3	0.4	2.5	2.5	2.5
EAST SOUTH CENT.	175	0.0	0.1	0.1	-0.5	1.4	1.4	1.5
WEST NORTH CENT.	98	0.5	0.1	0.7	-0.5	2.0	3.2	2.1
WEST SOUTH CENT.	201	0.5	0.4	0.9	-0.4	2.3	2.3	2.4
MOUNTAIN	65	0.6	0.0	0.6	0.7	3.1	5.2	3.5
PACIFIC	29	0.7	0.1	0.8	-0.9	1.7	1.7	1.8
TEACHING STATUS								
NON-TEACHING	2,930	0.1	0.1	0.2	0.0	2.0	2.1	2.1
MINOR	687	-0.1	0.0	-0.2	-0.1	1.5	1.8	1.7
MAJOR	288	-0.1	-0.1	-0.1	0.1	1.7	1.7	1.8
DSH PATIENT PERCENT								
0	14	1.4	0.0	1.4	-0.1	3.1	3.1	3.2
GT 0 - 0.10	343	0.1	-0.1	0.0	0.0	1.8	1.9	2.0
0.10 - 0.16	327	0.1	0.0	0.0	0.1	1.9	2.0	2.0
0.16 - 0.23	686	0.0	0.0	0.0	0.0	1.7	1.9	1.8
0.23 - 0.35	1,064	0.0	0.0	0.0	-0.1	1.7	1.9	1.9
GE 0.35	832	-0.2	0.0	-0.1	0.1	1.8	1.8	2.0
DSH NOT AVAILABLE **	639	2.1	4.3	6.5	-0.1	8.2	8.2	8.3
URBAN TEACHING/DSH								
TEACHING & DSH	885	-0.1	-0.1	-0.2	0.0	1.6	1.7	1.7
NO	1,458	0.0	0.0	0.0	0.1	1.9	2.0	2.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Median) (%)	Impact of Basing Weights Using Geo Mean (%)	APC Recalibration (Geo Mean) (%)	New Wage Index and Provider Adjustments (%)	Combination of Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier Wage Index Adjustment (%)	All Changes (%)
TEACHING/DSH								
NO TEACHING/NO DSH	14	1.4	0.0	1.4	-0.1	3.1	3.1	3.2
DSH NOT AVAILABLE**	600	2.1	4.1	6.2	0.0	8.0	8.0	8.0
<b>TYPE OF OWNERSHIP</b>								
VOLUNTARY	2,053	-0.1	0.0	-0.1	0.0	1.8	1.9	1.9
PROPRIETARY	1,294	0.1	0.2	0.3	-0.1	2.0	2.1	2.2
GOVERNMENT	558	0.1	0.0	0.1	-0.1	1.8	1.8	1.9
<b>CMHCs</b>								
CMHCs	159	-1.8	-3.9	-5.7	-0.6	-4.5	-4.5	-4.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of median costs in developing relative payment weights, and the final recalibration of APC weights based on CY 2011 hospital claims data.

Column (3) shows the estimated impact of basing the CY 2013 OPPS final payments on geometric mean costs, by comparing estimated CY 2013 payments under the policy for a geometric mean cost based system to those under a median based OPPS.

Column (4) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of geometric mean costs in developing the CY 2013 final OPPS relative payment weights, and the recalibration of APC weights based on CY 2011 hospital claims data.

Column (5) shows the budget neutral impact of updating the wage index by applying the FY 2013 hospital inpatient wage index. The rural adjustment is 7.1 percent in both years so its budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the final adjustment is minimal and thus results in a budget neutrality factor of 1.

Column (6) shows the impact of all budget neutrality adjustments and the final addition of the 1.8 percent OPD fee schedule increase factor (2.6 percent reduced by 0.7 percentage points for the multifactor productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (7) shows the non-budget neutral impact of applying the frontier State wage adjustment in CY 2013, after application of the CY 2013 final OPD fee schedule increase factor.

Column (8) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds estimated outlier payments. This column also shows the expiration of section 508 wages on March 30, 2012, and the application of the frontier State wage adjustment for CY 2012 and 2013.

\*These 4,127 facilities include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

\*\* Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.