FINAL RULE: MEDICARE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS FOR CY 2012

SUMMARY

On November 1, 2011, the Centers for Medicare & Medicaid Services (CMS) placed the CY 2012 final rule with comment period for Medicare's hospital outpatient prospective payment system (OPPS), CMS-1525-FC, hereinafter referred to simply as the final rule, on public display; it will be published in the November 30th *Federal Register*. The final rule, which generally takes effect on January 1, 2012, updates payment policies under the OPPS for 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 establishes payment policies for services furnished in Ambulatory Surgical Centers (ASCs).

The final rule revises requirements for the Hospital Outpatient Quality Reporting (OQR) Program, sets requirements for an ASC Quality Reporting System, and revises provisions of the Hospital Inpatient Value-Based Purchasing (VBP) Program. It suspends the effective dates of the Hospital-Acquired Condition (HAC), Agency for Healthcare Research and Quality (AHRQ), and Medicare spending per beneficiary measures. The rule allows eligible hospitals and CAHs participating in the Medicare Electronic Health Record (EHR) Incentive Program to meet the clinical quality measure reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

The rule finalizes, with changes, the proposal for additional payment to 11 designated cancer centers as required by the Affordable Care Act (ACA). The additional payments are budget neutral, resulting in a reduction of about 0.2 percent to all hospitals, compared to a reduction of 0.6 percent in the proposed rule.

CMS also changes the rules governing the whole hospital and rural provider exceptions to the physician self-referral prohibition for expansion of facility capacity as well as changes to provider agreement regulations on patient notification requirements.

As with the proposed rule, the Addenda containing relative weights, payment rates, wage indices and other payment information are not included in the regulation document and will not be printed in the *Federal Register*. They are available only on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS for the OPPS and http://www/cms.hhs.gov/ASC Payment/ for the ASC payment system.

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 January 3rd. Comments can be filed electronically. Details of the final rule are provided in the summary below.

TABLE OF CONTENTS

SUMMARY OF FINAL RULE: MEDICARE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS FOR 2012

I. Overview

A. Estimated Impact of the Final Rule on Hospitals

CMS projects that total payments for services furnished during CY 2012 under the OPPS will be approximately $41.1 billion, while total projected payments under the ASC payment system will be approximately $3.5 billion. It estimates the aggregate increase from changes in the final rule together with changes in enrollment, utilization, and case-mix in expenditures under the OPPS for 2012 compared to 2011 to be about $600 million.

Average payments per service are projected to increase about 1.9 percent based on an annual update factor of 1.9 percent, compared to 1.5 percent in the proposed rule, reflecting a market basket increase of 3.0 percent, a 1.0 percent offset for productivity as required by the ACA and an additional reduction of 0.1 percentage point also required by the ACA; the proposed rule had shown a market basket increase of 2.8 percent and a 1.2 percent offset for productivity. Hospitals that satisfactorily report quality data will qualify for the full update of 1.9 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 negative update of -0.1 percent.

The regulation's impact analysis, which is 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. The other changes include:

- pass-through payments, which represent a change of -0.07 percent in the pass-through estimate between CY 2011 and CY 2012;
- outlier payments, which represent a change of +0.07 percent for the difference in estimated outlier payments between 2011 (0.93 percent) and 2012 (1.0 percent);
- application of the frontier State wage adjustment, which is not budget neutral and increases average payments 0.10 percent; and
- expiration of the section 508 wage index adjustment on September 30, 2011, resulting in a change in average payments of -0.09 percent.

Changes to the APC weights and 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 would not affect aggregate OPPS payments because these changes are budget neutral, but they do affect the distribution of payments. Their effect on the conversion factor is discussed in section II.B. below.

CMS projects that the final rule will increase average payments per case by 1.9 percent for all hospitals and facilities, with an average increase also equal to 1.9 percent for all hospitals excluding cancer and children's hospitals and CMHCs; in the proposed rule, the increase for hospitals excluding the latter groups had been 0.8 percentage points lower than the overall increase due largely to the adjustment to cancer hospitals).

Impact of cancer adjustment. CMS estimates that the 11 cancer centers would see payments increase about 11.3 percent (approximately $71 million) due to the cancer adjustment, compared to estimated payments that would have been made to these hospitals under the OPPS, including hold harmless payments; the proposed rule had shown a net increase of about 9 percent to the cancer hospitals. The budget neutrality adjustment to offset the cost of additional payments to the cancer hospitals causes payments to all other hospitals to decrease about 0.2 percent, compared to -0.6 percent in the proposed rule. CMS mitigated the impact of the cancer adjustment in response to comments by providing that the payment adjustments will be in the form of an aggregate payment to a cancer hospital at cost report settlement. The final rule policy shift avoids the higher copayments for beneficiaries and budget neutrality adjustment to non-cancer hospitals associated with providing the adjustment on a claims basis as was proposed.

The macro impact of the final rule, as shown in the table below, shows only small variations by type of hospital but masks more substantial redistributions that occur primarily due to the wage index and reduction in the proposed decrease in payment for APC 0034 (Mental Health Services Composite).

	Proposed Rule	**Final Rule**
All Facilities	1.5%	1.9%
All Hospitals (except cancer and children's) and excluding CMHCs	1.1%	1.9%
Urban	1.2%	1.9%
Rural	0.9%	1.5%
Major Teaching	1.2%	1.9%
By type of ownership:		
Voluntary	1.3%	2.0%
Proprietary	0.8%	1.7%
Government	0.7%	1.6%

Hospitals expected to experience negative impacts include:

- Low volume urban hospitals (those billing fewer than 11,000 lines annually for OPPS services) would experience decreases ranging from 0.3 percent to 2.9 percent, with those billing fewer than 5,000 lines decreasing 2.9 percent; there are 594 such hospitals in the impact analysis. CMS attributes the reduction primarily to the decrease in payments for APC 0034 (Mental Health Services Composite) and APC 0176 (Level II Partial Hospitalization, 4 or more services, for Hospital-based PHPs).

- Hospitals for which DSH payments are not available would experience a decrease of 3.6 percent. Many hospitals in this category are not paid under the inpatient prospective payment system (IPPS), such as rehabilitation, psychiatric, and long-term care hospitals. They also provide a large number of psychiatric services and are affected by the decrease noted above.

Urban New England hospitals are expected to see an increase of 5.5 percent as a result of the implementation of the rural floor. Urban hospitals in other regions show increases ranging from 1.2 percent to 2.3 percent, while rural hospitals will see increases ranging regionally from 0.7 percent to 2.9 percent. In response to public comments, the final rule includes a table showing the payment impact of the rural floor and the imputed floor with budget neutrality at the State level in Table 60. CMS projects payment increases totaling about $92 million for hospitals in Massachusetts, with hospitals in five other states (Colorado, Alaska, New Hampshire, California, Connecticut, and New Jersey) in line for increases ranging from $1.5 to $14 million. Hospitals in the other 45 states, including the District of Columbia, will see state-level total payments fall from $0.2 to about $12 million.

B. Beneficiary Coinsurance

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 co-payment amount for a service to the inpatient hospital deductible for the applicable year, which is $1,156 in 2011. The inpatient hospital deductible limit is applied to the actual co-payment amount due for the service after adjusting for the wage index. For this reason, the co-insurance levels shown in the payment rate addenda of the final rule do not incorporate the hospital deductible limit.

For 2012 as in 2011, 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 chooses not to report the required quality measures, or that reports them unsatisfactorily.

CMS estimates that total beneficiary liability for copayments under the final rule would be 21.8 percent as a percentage of total payments to hospitals, down from 22.1 percent in the proposed rule and 22.0 percent in 2011.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Weights

1. Data development process and calculation of median costs

To recalibrate the relative Ambulatory Payment Classification (APC) weights for the 2012 final rule, CMS used hospital claims for services furnished from January 1, 2010 through December 31, 2010 (and processed before July 1, 2011). Cost data are from

the most recent cost reports, in most cases for cost reporting periods beginning in 2009. The rule continues the methodology that CMS has used for many years, including the calculation of median cost for each procedure only from single procedure claims or "pseudo" single claims created from bills containing multiple codes. In a separate document available on the CMS website, the agency provides a detailed description of the claims preparation process and an accounting of claims used in the development of the final payment rates, including the number of claims derived at each stage of the process: http://www.cms.gov/HospitalOutpatientPPS.

For each APC, CMS calculates an unscaled relative payment weight by comparing the median cost of the APC to the median cost of APC 0606 (Level III Clinic Visit), which is one of the most frequently performed services in the hospital outpatient setting and also is the APC for the middle level clinic visit. CMS assigns APC 0606 an unscaled relative payment weight of 1.00.

2. Pseudo single procedure claims and bypass codes for 2012

To create pseudo single procedure claims for the 2012 final rule, CMS bypasses all of the Healthcare Common Procedure Coding System (HCPCS) codes on an updated bypass list, unchanged from the proposed rule, of 460 HCPCS codes (listed in Addendum N of the final rule). It finalizes its proposal to remove 11 codes that are not separately paid under the OPPS (Table 1, page 67 of the display copy).

3. Calculation of median costs: cost-to-charge ratios (CCRs); packaged revenue codes; wage index standardization of costs; application of 2-times rule

To convert charges on the outpatient claims to estimated costs, CMS multiplies billed charges by the CCR associated with each revenue code using its established methodology, described in detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). CMS calculates CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database at the most detailed level possible, generally the hospital-specific, departmental level.

CMS 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 comment on the proposed rule) on the CMS Web site: http://www.cms.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage.

The rule finalizes the addition of one new CCR for 2012. For 2010, the National Uniform Billing Committee added revenue codes 860 (Magnetoencephalography (MEG); general classification) and 861 (Magnetoencephalography (MEG)). To apply a CCR to charges reported under revenue codes 860 and 861, CMS is using nonstandard Medicare cost report cost center 3280 (Electrocardiogram (EKG) and

Electroencephalography (EEG)) as the primary cost center and using standard cost center 5400 (Electroencephalography (EEG)) as the secondary cost center.

CMS finalizes the list of revenue codes for which costs derived from charges are packaged for purposes of calculating the 2012 median costs (Table 2 of the final rule, pages 108-110 of the display copy). It also finalizes its proposal to continue to use the pre-reclassified wage indices for standardization because they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices; wage index standardization continues to apply to 60 percent of the costs of the claims.

Having received no public comments, CMS finalizes its policies for calculating the median cost of each APC, including its long-standing policies for application of the 2 times rule to limit cost variation within an APC. In applying the 2 times rule, CMS considers only 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 median cost.

4. Charge compression and cost report changes

CMS rejects comments urging it to calculate CY 2012 relative payment weights using the new CCR for implantable devices charged to patients, which was made available for use for cost reporting periods beginning on or after May 1, 2009, because the high cost of items charged to this cost center likely would lead to very different final rule relative weights and cause payment redistributions without an opportunity for public comment. The agency reports that in the proposed rule cost report data, 363 hospitals reported approximately $4.9 billion in costs in the implantable medical device cost center, while in the final rule cost report data, 1,689 hospitals reported approximately $20.7 billion in that cost center.

Since May 1, 2010, hospitals have been required to report the costs and charges for computed tomography (CT) scans, magnetic resonance imaging (MRI) and cardiac catheterization using new standard cost centers. The preamble states that CMS will assess the availability of data for the “Implantable Devices Charged to Patients” cost center, and the “MRI, CT Scans, and Cardiac Catheterization” cost centers, for the CY 2013 OPPS rulemaking cycle. Finally, in January 2010, CMS created nonstandard cost centers for Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, and Lithotripsy, effective for cost reporting periods ending on or after October 1, 2009. In the final rule, CMS disagrees with a renewed request to create a new cost center exclusive to the costs of MEG, reiterating as it stated in the CY 2011 OPPS/ASC final rule that it does not believe a new cost center is needed to capture the costs of MEG.

5. Recalibration Budget Neutrality Adjustment

Medicare law requires that the APC reclassification and recalibration changes be budget neutral. As in past years, CMS compares the estimated aggregate weight

calculated using the final CY 2012 unscaled relative weights and service volume in the CY 2010 claims data to the aggregate weight using the final CY 2011 scaled relative weights and service volume in the CY 2010 claims data. Based on this comparison, the final rule unscaled APC payment weights were adjusted by a weight scaler of 1.3588, compared to a proposed weight scaler of 1.4647. The effect of the adjustment is to increase the unscaled weights by about 35.9 percent. CMS continues to include payments to CMHCs in the budget neutrality calculation for CY 2012 as well as payments for "specified covered outpatient drugs" (SCODs) and brachytherapy sources; these policies are the same as for CY 2011.

6. Payment for APC 0606, Level III Clinic Visit

The final rule provides a payment rate of $95.14 for a Level 3 clinic visit (APC 0606) in CY 2012, a decrease of $4.57 or 4.6 percent compared to the October 1, 2011 payment rate of $99.71, and a decrease of $6.54 compared to the proposed rule. The relative weight for APC 0606 decreases 6.1 percent in CY 2012 compared to CY 2011.

7. Calculation of single procedure APC criteria-based median costs

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

Device-dependent APCs.

CMS finalizes its proposal to continue to calculate median costs for device-dependent APCs using only the subset of single bills from 2010 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.

The final device-dependent APCs for 2012 are listed in Table 3, reprinted below. As reflected in the table, CMS also is finalizing five proposed device-dependent APC title changes and one proposed deletion for 2012. The restructuring behind APC 0083, APC 0229 and APC 0319 is discussed in section II.A.7 below; APC 0040 and APC 0061 are discussed in section II.A.7 below. The deletion of APC 0418 (Insertion of Left Ventricular Pacing Electrode) is discussed in section II.A.8.f below. CMS does not finalize its proposal to limit the payment for services that are assigned to APC 0108 to the IPPS standardized payment amount for MS-DRG 227, as discussed in section II.A.8.f below.

TABLE 3. — CY 2012 DEVICE-DEPENDENT APCs

CY 2012 APC	CY 2012 Status Indicator	CY 2012 APC Title
0039	S	Level I Implantation of Neurostimulator Generator
0040	S	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes
0061	S	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes
0082	T	Coronary or Non-Coronary Atherectomy
0083	T	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity
0084	S	Level I Electrophysiologic Procedures
0085	T	Level II Electrophysiologic Procedures
0086	T	Level III Electrophysiologic Procedures
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090	T	Insertion/Replacement of Pacemaker Pulse Generator
0104	T	Transcatheter Placement of Intracoronary Stents
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107	T	Insertion of Cardioverter-Defibrillator
*0108	T	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes
0115	T	Cannula/Access Device Procedures
0202	T	Level VII Female Reproductive Procedures
0227	T	Implantation of Drug Infusion Device
0229	T	Level II Endovascular Revascularization of the Lower Extremity
0259	T	Level VII ENT Procedures
0293	T	Level V Anterior Segment Eye Procedures
0315	S	Level II Implantation of Neurostimulator Generator
0318	S	Implantation of Cranial Neurostimulator Pulse Generator and Electrode
0319	T	Level III Endovascular Revascularization of the Lower Extremity
0384	T	GI Procedures with Stents

0385	S	Level I Prosthetic Urological Procedures
0386	S	Level II Prosthetic Urological Procedures
0425	T	Level II Arthroplasty or Implantation with Prosthesis
0427	T	Level II Tube or Catheter Changes or Repositioning
0622	T	Level II Vascular Access Procedures
0623	T	Level III Vascular Access Procedures
0648	T	Level IV Breast Surgery
0652	T	Insertion of Intraperitoneal and Pleural Catheters
0653	T	Vascular Reconstruction/Fistula Repair with Device
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker
*0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents
0674	T	Prostate Cryoablation
0680	S	Insertion of Patient Activated Event Recorders

Blood and blood products. The final rule continues, without change, to set payment rates for blood and blood products using the blood-specific CCR methodology. This methodology, which has been CMS' standard rate-setting methodology for blood and blood products since 2005, utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. CMS finalizes the policy despite some commenters' concern that there is a gap between the payments for blood and blood products and the costs incurred by hospitals for the acquisition, management, and processing of blood and blood products, including high volume products such as leukocyte reduced red blood cells, described by HCPCS codes P9016 (Red blood cells, leukocytes reduced, each unit), P9021 (Red blood cells unit), and P9040 (Red blood cells, leukoreduced irradiated).

Single allergy tests. CMS adopts its proposal to continue the current methodology of differentiating single allergy tests ("per test") from multiple allergy tests ("per visit") by assigning these services to two different APCs. Multiple allergy tests are assigned to APC 0370 (Allergy Tests), with a median cost calculated based on the standard OPPS methodology. CMS addresses data limitations affecting median costs of APC 0381 (Single Allergy Tests) by continuing the payment policy employed beginning in 2006 whereby a "per unit" median cost for APC 0381 is calculated using claims with multiple units or multiple occurrences of a single CPT code. The 2012 final median cost for APC 0381 using the "per unit" methodology is approximately $31, compared to the approximate $33 in the 2011 final rule. The 2012 final rule also revises the title of APC 0370 from "Allergy Tests" to "Multiple Allergy Tests" to more accurately describe all the services assigned to the APC. The final 2012 median cost of APC 0370 is approximately $80 based on 306 claims.

Hyperbaric oxygen therapy. For 2012, CMS continues to use the methodology employed since 2005 to estimate a "per unit" median cost for HCPCS code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval). The final 2012 median cost is approximately $105, compared to a median cost of $104 in 2011.

Payment for Ancillary Outpatient Services When Patient Expires (-CA Modifier).

The HCPCS-CA modifier addresses situations where a procedure on the OPPS inpatient list must be performed to resuscitate or stabilize a patient (whose status is that of an outpatient) with an emergent, life-threatening condition, and the patient dies before being admitted as an inpatient. For 2012, CMS continues to use its established rate-setting methodology for calculating the median cost of APC 0375 (Ancillary Outpatient Services When Patient Expires) and to make one payment under APC 0375 for the services that meet the specific conditions for using modifier –CA. The median cost for APC 0375 varies significantly from year to year (see Table 4 below) due to the small number of claims and because the specific cases are grouped by the presence of the HCPCS modifier "-CA" and not according to the standard APC criteria of clinical and resource homogeneity. CMS received no public comments.

TABLE 4.--CLAIMS FOR ANCILLARY OUTPATIENT SERVICESWHEN PATIENT EXPIRES (–CA MODIFIER) FOR CYs 2007 THROUGH 2012

Prospective Payment Year	Number of Claims	APC Median Cost
CY 2007	260	$3,549
CY 2008	183	$4,945
CY 2009	168	$5,545
CY 2010	182	$5,911
CY 2011	168	$6,304
CY 2012	208	$6,039

Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319). For 2011, the AMA's CPT Editorial Panel created 16 new CPT codes in the Endovascular Revascularization section of the 2011 CPT Code Book to describe endovascular revascularization procedures of the lower extremity performed for occlusive disease. In the 2011 final OPPS rule, CMS made APC assignments for the new codes to APCs 0229, 0319, and 0083 and used the "NI" comment indicator to identify the new APC assignments as interim and open to public comment. The CY 2011 OPPS/ASC final rule with comment period provides a detailed description of CMS' mapping process (75 FR 71841 through 71845). CMS accepts an APC Panel recommendation, made at its February 2011 meeting, that CMS provide data to allow the Panel to investigate and monitor the APC weights for the lower extremity revascularization procedures.

After analysis of claims data and consideration of public comments expressing both support and disagreement, CMS finalizes the policies of the CY 2011 interim final rule and also its proposals for CY 2012. The proposals for CY 2012 include using the CY 2011 methodology to simulate median costs for 12 of the 16 new separately payable endovascular revascularization codes based on claims and the most current cost report data. The 4 CPT codes for which CMS was unable to use current data to simulate a median cost are assigned to APC 0083. One of the procedures with significant claims data in APC 0083 violates the "2 times rule." Therefore, CMS reassigns CPT 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), with a median cost of $7,053, to APC 0229, which has a final 2012 median cost of approximately $8,088. The final rule APC assignments for the new endovascular revascularization codes are shown in Table 5 (pp. 146-147 of the display copy).

Non-Congenital Cardiac Catheterization (APC 0080). For 2011, the AMA CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes and replaced them with 20 new CPT codes in the Cardiac Catheterization and Injection-Related section: 14 new CPT codes in the 93400 series and 6 in the 93500 series. Of the 19 deleted codes, 10 CPT codes had been separately payable under the hospital OPPS, while the other 9 CPT codes that describe injection procedures and imaging supervision during cardiac catheterization were packaged. Many of the 20 new 2011 CPT codes had been described previously by multiple 2010 CPT codes. The CY 2011 OPPS/ASC final rule with comment period provides a detailed description of CMS' crosswalk and mapping process (75 FR 71846 through 71849) and assigns the "NI" comment indicator to identify them as interim and open to public comment. All of the separately payable services that describe cardiac catheterization procedures, which include both congenital and non-congenital cardiac catheterization, are assigned to APC 0080 (Diagnostic Cardiac Catheterization) in 2011.

In the CY 2012 final rule, CMS adopts its proposal to use the CY 2011 methodology to simulate median costs for the new separately payable codes. The final CY 2012 median cost for APC 0080 is approximately $2,721, which is slightly greater than the median cost of approximately $2,698 in the CY 2011 final rule.

Cranial Neurostimulator and Electrodes (APC 0318). For 2011, the AMA CPT Editorial Panel created a new CPT code 64568 (Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator) and indicated that it describes the services formerly included in the combinations of:

> (1) CPT code 64573 (Incision for implantation of neurostimulator electrodes; cranial nerve) and CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array); or

(2) CPT code 64573 and CPT code 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays).

CMS estimated the median costs of new CPT code 64568 for the CY 2011 OPPS final rule using the new descriptor, 2009 claims data and the most recent cost report data to simulate the new definition of the service.

CMS received no comments on its CY 2012 proposal to simulate a CY 2012 median cost using the CY 2011 methodology. The final rule calculates an estimated median cost for CPT code 64568 of approximately $24,262 from 455 single claims to set a payment rate for APC 0318 for CY 2012. The final rule maintains CPT code 64568 as the only code assigned to APC 0318 for 2012.

Brachytherapy Sources. For 2012, CMS continues its current policy of paying for brachytherapy sources at prospective payment rates based on source-specific median costs calculated using the general OPPS rate-setting methodology. The rule also continues the other payment policies for brachytherapy sources as finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). In maintaining these policies, CMS rejects comments requesting that it discard its prospective payment methodology for brachytherapy sources based on source-specific median costs and make payments based on brachytherapy charges adjusted to costs.

CMS also finalizes its proposal to pay for the "not otherwise specified" (NOS) codes for stranded and non-stranded sources (HCPCS codes C2698 and C2699, respectively) at the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed, for example, to per mCi). CMS continues the current policy concerning payment for new brachytherapy sources for which the agency lacks claims data. Under that policy, the agency can 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 eligible for outlier payments; their payment weights also will continue to be subject to scaling for budget neutrality. Brachytherapy sources are assigned status indicator "U"; their descriptions and payment rates are listed in Addendum B, published on the CMS website.

8. Calculation of composite APC criteria-based median 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 continues to believe that bundling payment for multiple independent services into a single OPPS payment enables hospitals to manage their resources with maximum flexibility and promotes greater efficiency. It also allows CMS to use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than

relying upon single procedure claims which typically have low volume and/or are incorrectly coded.

For 2012, CMS proposed to add four new composite APCs for cardiac resynchronization therapy services. It also proposed to continue its established composite APC policies for extended assessment and management, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services.

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

For 2012, after consideration of public comments, CMS adopts its proposal to continue 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. CMS also maintains its 2011 methodology for combining services into the composite APCs for calculating median costs. The final CY 2012 median cost resulting from this methodology for composite APC 8002 is approximately $393, which was calculated from 18,447 single and "pseudo" single bills that met the required criteria. The proposed CY 2012 median cost for composite APC 8003 is approximately $721, which was calculated from 247,334 single and "pseudo" single bills that met the required criteria.

At its February 2011 meeting, the APC Panel recommended that CMS study the feasibility of expanding the extended assessment and management composite APC methodology to include services commonly furnished in conjunction with visits and observation services, such as drug infusion, electrocardiogram, and chest X-ray. CMS previously accepted this recommendation and reports that it examined various options to expand the current extended assessment and management composite APCs to further limit the possibility that total beneficiary copayments would exceed the inpatient deductible during extended observation encounters. CMS decided not to pursue any of the alternatives it studied because they also had the effect of possibly increasing copayments by a small amount for the majority of beneficiaries undergoing extended observation. The final rule reaffirms that CMS will continue to model other composite structures for a possible new extended assessment and management composite structure for 2013.

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

For the 2012 final rule, CMS adopts its proposal to continue the composite APC policy that has been applied since 2008 for Low Dose Rate (LDR) Prostate Brachytherapy. Under this policy, the OPPS 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 median 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. The final CY 2012 median cost for composite APC 8001 is approximately $3,340, which is calculated from 595 single bills and is an increase over the 2011 final rule median cost of approximately $3,195 based on 849 claims.

c. Cardiac Electrophysiologic Evaluation and Ablation Composite APC

For the 2012 final rule, CMS, as proposed, maintains the APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) policies first established in 2008 to pay for a composite service made up of at least one specified electrophysiologic evaluation service and one electrophysiologic ablation service. To calculate the median cost for composite APC 8000, CMS uses multiple procedure claims that contain at least one CPT code from group A for evaluation services and at least one CPT code from group B for ablation services reported on the same date of service on an individual claim. Consistent with the agency's practice since 2008, the final rule does not use the claims that meet the composite payment criteria in the calculation of the individual median costs for APC 0085 and APC 0086, to which the CPT codes in both groups A and B for composite APC 8000 are otherwise assigned. Median costs for APCs 0085 and 0086 continue to be calculated using single procedure claims.

For the final rule, CMS uses 11,706 claims from CY 2010 containing a combination of group A and group B codes and calculates a final CY 2012 median cost of approximately $11,313 for composite APC 8000. Table 7 in the final rule and below lists the groups of procedures upon which composite APC 8000 for CY 2012 is based. For a full discussion of how the agency identifies the group A and B procedures and establishes the payment rate for the cardiac electrophysiologic evaluation and ablation composite APC, see the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659).

TABLE 7.— GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes Used in Combinations: At Least One in Group A and One in Group B	CY 2012 CPT Code	Single Code CY 2012 APC	CY 2012 SI (Composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	93619	0085	Q3

Codes Used in Combinations: At Least One in Group A and One in Group B	CY 2012 CPT Code	Single Code CY 2012 APC	CY 2012 SI (Composite)
Group A			
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	93652	0086	Q3

d. Mental Health Services Composite APC (APC 0034)

The final rule for 2012 continues CMS' 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. Through the claims processing software, when the total payment for the individual services for specified mental health services – based on the final rule 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, which has the same payment rate as proposed APC 0176.

As described in Section VIII below, the final rule continues the provider-specific two tiered payment approach finalized in 2011 for partial hospitalization services to distinguish payment made for services furnished in a CMHC from payment made for services furnished in a hospital. It also continues the long-standing two-tiered approach to distinguish between partial hospitalization involving 3 services and partial hospitalization involving 4 or more services. The most resource intensive partial hospitalization APC is APC 0176, which applies for partial hospitalization furnished in a hospital and involving 4 or more services. Because this is the most resource intensive of the four partial hospitalization APCs, CMS sets the payment rate for APC 0034 (Mental Health Services Composite) at the level of the payment rate for APC 0176. CMS received no public comments on these proposals.

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

After consideration of the public comments, CMS adopts its CY 2012 proposal, without modification, to continue paying for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite payment methodology. 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. Since 2009, CMS has applied the following multiple imaging policy:

i. Create five multiple imaging composite APCs: APC 8004 (Ultrasound Composite); APC 8005 (CT and CTA without Contrast Composite); APC 8006 (CT and CTA with Contrast Composite); APC 8007 (MRI and MRA without Contrast Composite); and APC 8008 (MRI and MRA with Contrast Composite).
ii. Provide one composite APC payment when a hospital bills more than one procedure described by a HCPCS codes within an OPPS 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, make 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. Assign the status indicator "S" to the proposed composite APCs, thus signifying that payment for the APC would not be reduced when appearing on the same claim with other significant procedures.
v. Continue current billing practices whereby hospitals use the same HCPCS codes to report imaging services and the I/OCE determines when combinations of imaging procedures would qualify for composite APC payment or would map to standard APCs for payment.

Table 8 of the final rule (included in the appendix to this summary) lists the HCPCS codes that are subject to the policy, the final median costs for the imaging composite APCs, and their respective imaging families for 2012. These HCPCS codes are assigned status indicator "Q3"' in Addendum B to the final rule. Addendum B shows APC assignments when services are separately payable and Addendum M shows composite APC assignments when codes are paid through a composite APC. [Note: the composite APC assignment indicated in Addendum M corresponds to the assignment shown in Table 8.]

In calculating median costs for the multiple imaging composite APCs for the 2012 final rule, CMS uses approximately 1.1 million "single session'' claims out of an estimated 2.2

million potential composite cases from its ratesetting claims data, or approximately one-half of all eligible claims.

f. Cardiac Resynchronization Therapy Composite APC (APCs 0108, 0418, 0655, and 8009)

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. The service utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD); "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 prior years, both commenters and the APC panel have recommended that CMS establish new composite APCs for CRT-D due to significant fluctuations in the median cost of one of the CPT codes required as part of the procedure, CPT code 33225, causing fluctuations in the payment rate for APC 0418, which only includes one other CPT code. Because the definition of CPT code 33225 specifies that the pacing electrode is inserted at the same time as an ICD or pacemaker, CMS typically does not have many valid single or pseudo single claims upon which to calculate an accurate median cost of APC 0418 (Insertion of Left Ventricular Pacing Electrode).

For 2012, CMS proposed to create a new composite APC for CRT-D services, APC 8009 (Cardiac Resynchronization Therapy - ICD Pulse Generator and Leads), to be used when CPT 33249 and CPT 33225 are performed on the same day. Although other combinations of CRT procedures may also be performed together, CMS did not propose to implement composite APCs for them because the low frequency of these other combinations did not indicate that they are commonly performed together.

CMS also proposed to cap the payment rate for composite APC 8009 at the payment amount for the most comparable Medicare-severity diagnosis-related group (MS-DRG) established under the IPPS for payment when CRT-D services are furnished to hospital inpatients. Specifically, CMS proposed to pay APC 8009 at the lesser of the new composite APC 8009 median cost or the IPPS payment rate for MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity). CMS proposed to establish this MS-DRG cap by considering only the operating portion of the IPPS payment, thus excluding capital costs, which are included in the OPPS rates. The proposed rule stated that a cap was necessary to avoid an inappropriate payment incentive to provide CRT-D services in one setting of care over another by paying more for CRT-D in the outpatient setting compared to the inpatient setting.

Many commenters supported the creation of a composite APC for CRT-D services and the restructuring of APC 0108 in order to address the median cost fluctuations in APC 0418. Many commenters, however, objected to the proposal to cap payments for the composite APC 8009 and for APC 0108 at the IPPS payment rate for MS-DRG 227,

raising several different objections. Some commenters argued that the payment cap is unnecessary, projecting that average actual payment differences (after accounting for wage index adjustments, indirect medical education (IME) payments, and disproportionate share hospital (DSH) payments) under the CRT-D composite APC (with no payment cap applied) and MS-DRG 227 would be unsubstantial and unlikely to create inappropriate payment incentives. At its August 10-11 meeting, the APC Panel recommended that CMS establish the payment rates for APC 8009 (Cardiac Resynchronization Therapy with Defibrillator, Composite) and APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) using only outpatient claims data.

After consideration of the public comments and the APC Panel recommendation, CMS does not include a payment cap in the final rule. The final rule treats CPT codes 33225 and 33249 as a single, composite service when they are performed on the same day as proposed, but rather than assigning the procedures to composite APC 8009, CMS assigns them to existing APC 0108. In calculating the CY 2012 median costs for APC 0108, CMS includes 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. The final rule uses 11,055 single bills from the CY 2012 final rule claims data (3,145 composite CRT-D service claims and 7,910 claims for other services assigned to APC 0108) to calculate a median cost of approximately $29,839.

Hospitals will continue to use the same CPT codes to report CRT-D procedures, and the I/OCE will determine when combinations of procedures qualify for composite service payment or map to standard (sole service) APCs for payment. CMS makes a single payment for those procedures that qualify for composite service payment, as well as any packaged services furnished on the same date of service. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, CMS assigns them status indicator “Q3” (Codes that may be paid through a composite APC) in Addendum B. The assignment of CPT codes 33225 and 33249 to APC 0108 when treated as a composite service is reflected in Addendum M. CMS finalizes its proposal to change the title of APC 0108 to “Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes.”

Hospitals will continue to use the same CPT codes to report CRT-D procedures and ICD-only procedures, and the I/OCE will identify when the combination of CPT codes 33225 and 33249 on the same day qualify for composite service payment and will make 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 will continue to be 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 will be assigned to APC 0655 (rather than to APC 0108 as provided in the proposed rule when the service does not appear with CPT code 33249).

CMS also finalizes its proposals to reassign CPT code 33224 to APC 0655 for CY 2012; to change the title of APC 0655 from "Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker" to "Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode;" and to delete APC 0418. Finally, CMS adopts its proposed policy to implement claims processing edits that will return to providers incorrectly coded claims on which a pacing electrode insertion (the procedure described by CPT code 33225) is billed without a procedure to insert an ICD or pacemaker.

9. 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. The final rule for 2012 maintains the extended packaging with no significant changes.

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 because 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.

Response to APC Panel Recommendations. CMS' final rule responses to the packaging recommendations made by the APC Panel at its February 28-March 1, 2011 and August 10-11 meetings are summarized in the two tables below.

APC Panel Recommendation and Related Comments, February 28-March 1, 2011 Meeting	CMS Response
Recommendation 4: HCPCS code 31627 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])) should continue to be assigned a status indicator of "N." Also, CMS should	CMS accepts the recommendations to package HCPCS 31627 with status indicator "N" and to provide further claims information on HCPCS code 31627 to the APC Panel when it becomes available.

APC Panel Recommendation and Related Comments, February 28-March 1, 2011 Meeting	CMS Response
continue to collect claims data for HCPCS code 31627.	
Recommendation 5: CMS should consider a more appropriate APC assignment for HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers), the most common code with which HCPCS code 31627 was billed in 2010.	CMS accepts the recommendation and reassigns HCPCS code 31626 from APC 0076 to APC 0415 (Level II Endoscopy Lower Airway).
Recommendation 7: CMS should furnish the results of its investigation of claims that contain the following unconditionally packaged codes without separately paid procedures: ● HCPCS code G0177 (Training and educational services related to the care and treatment of patient's disabling mental health problems per session (45 minutes or more)); ● HCPCS code G0378 (Hospital observation service, per hour); ● HCPCS code 75940 (Percutaneous placement of IVC filter, radiological supervision and interpretation); ● HCPCS code 76937 (Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)).	CMS accepts the recommendation.
Recommendation 8: The work of the APC Groups and Status Indicator (SI) Assignments Subcommittee should continue.	CMS accepts the recommendation.

APC Panel Recommendation and Related Comments, August 10-11 Meeting	CMS Response
Recommendation 9: CMS should give HCPCS code 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) a status indicator of “T” and provide the Panel with correlating claims data when available.	CMS considers this service a type of specialized bandage that is typically placed on the surface of the eye immediately after a surgery that has resulted in a corneal epithelial defect and disagrees that the procedure described by CPT code 65778 is a significant procedure. CMS finalizes its proposal to assign status indicator “Q2” to CPT code 65778. When the service is furnished with a separately payable surgical procedure with status indicator “T” on the same day, payment for CPT code 65778 is packaged. Otherwise payment for CPT code 65778 is made separately through APC 0233, with a CY 2012 final median cost of approximately $1,164.

B. Conversion Factor Update

The OPPS conversion factor for CY 2011 is $68.876. To set the conversion factor for CY 2012, the CY 2011 conversion factor is adjusted by the fee schedule increase factor and further adjusted by various budget neutrality factors. The fee schedule increase factor equals the hospital inpatient market basket percentage increase, which equals 3.0 percent, reduced by a productivity adjustment as required by the ACA, and reduced an additional 0.1 percentage point as also required by the ACA. The law defines the productivity adjustment as equal to the Secretary's projection of the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP), which equals 1.0 percentage points in the CY 2012 final rule. [For a discussion of the calculation of the MFP adjustment, see the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949 through 25951).] Thus, the final rule provides a fee schedule increase factor of 1.9 percent for the CY 2012 OPPS (3.0 percent hospital market basket increase, less the proposed 1.0 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 XIV below, resulting in a fee schedule increase factor of -0.1 percent for such hospitals.

The final rule includes these additional adjustments for CY 2012: a wage index budget neutrality factor of 1.0005 and a cancer hospital budget neutrality adjustment factor of 0.9978 to offset the cancer hospital adjustment described in section F below. CMS estimates CY 2012 pass-through spending equal to 0.22 percent of total projected CY 2012 OPPS spending, an increase of 0.07 percentage points compared to CY 2011 pass-through spending of 0.15 percent of total CY 2011 OPPS spending. CMS adjusts the conversion factor to reflect the 0.07 percentage point increase in the level of drug and device pass-through payments estimated for CY 2012 compared to CY 2011. No other adjustments are required since CMS proposes the same level for the outlier offset (1.0 percent) and there is no change in the rural adjustment policy. The table below shows the calculation of the final CY 2012 conversion factor.

Calculation of CY 2012 Conversion Factor

2011 Final Rule Conversion Factor	Remove 2012 Pass-Through Adjustment	Apply 2012 Pass-Through Adjustment	Apply 2012 Wage Index Budget Neutrality Adjustment	Apply 2012 Cancer Hospital Budget Neutrality Adjustment	Fee Schedule Increase Factor	2012 Rule Conversion Factor
$68.876	0.9985	0.9978	1.0005	0.9978	1.019	
	$68.979	$68.828	$68.862	$68.711	$70.016	$70.016

The combined effect of these factors is a total increase in the conversion factor of $1.140, or 1.66 percent, yielding a final conversion factor for CY 2012 equal to $70.016

for hospitals satisfying the requirements of the quality reporting program. To calculate the CY 2012 reduced market basket conversion factor for those hospitals that fail to satisfy the requirements of the OQR, the final rule applies a reduced fee schedule increase factor of -0.1 percent, rather than the full update factor of 1.9 percent, keeping all other adjustments the same, resulting in a proposed reduced conversion factor for CY 2012 of $68.642.

C. Wage Index Changes

Area Wage Index. The Secretary is required to determine a wage adjustment factor to adjust a portion of the OPPS payment rate, which includes the copayment standardized amount, for geographic wage differences attributable to labor and labor-related costs. This adjustment must be made in a budget neutral manner. The CY 2012 OPPS labor-related share is 60 percent of the national OPPS payment.

CMS adopts the final hospital IPPS wage index in its entirety as the wage index for adjusting the OPPS standardized payment amounts for labor market differences. This means that the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS, including all adjustments, and will be used to adjust the 2012 OPPS payment and copayment amounts to recognize geographic differences in labor costs in the OPPS. The final wage index tables are available at the CMS Website at: http://www.cms.gov/HospitalOutpatientPPS/.

In the final rule, CMS reiterates its concern that hospitals that convert their status can significantly inflate wage indexes across a State, in a manner that was not intended by the Congress, as well as inflate other States' rural floors through reclassification under section 1886(d)(8)(E). In the proposed rule, CMS had sought comment on various policy options to address situations where IPPS wage index adjustments, such as the rural floor, are resulting in significant fluctuations in the wage index. The options were:

(1) To adopt the IPPS wage index for the OPPS in its entirety including the rural floor, geographic reclassifications and all other wage index adjustments;
(2) To adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor to the benefit of all other hospitals in the State;
(3) To adopt the IPPS wage index for the OPPS in its entirety but apply rural floor budget neutrality within each State instead of nationally; or
(4) To adopt another decision rule for when the rural floor should not be applied in the OPPS when the agency has concerns about disproportionate impact.

Many commenters recommended continuing the current policy (option (1) above) because of the inseparable nature of hospital inpatient and outpatient departments, the undue administrative complexity associated with the use of differing wage indexes, and the belief that only true, comprehensive wage index reform will address volatility of the wage index and remove incentives to game the system. Some commenters supported

option (2) but only if CMS could explicitly define a threshold for the “small number” test as well as what would constitute a benefit. There was a divergence of opinion on whether budget neutrality is best set at the national versus at the state level. CMS will continue to consider the policy options in future rulemaking, and in response to a recommendation provides a table (in section XX of the final rule) showing the impact by State of the rural floor and imputed floor policies with national budget neutrality on OPPS hospitals and their payments.

Comments were mixed in reaction to the CMS proposal to determine the applicable rural wage index floor for both the IPPS and the OPPS using only data from hospitals which are geographically rural under OMB and the Census Bureau’s MSA designations, and without including wage data associated with hospitals reclassified from urban to rural status under section 1886(d)(8)(E), with some supporting and others opposing it.

In response to another comment, CMS explains that the budget neutrality factors that applied to the standardized amount under IPPS as a result of the rural floor were not applied to the OPPS conversion factor and thus have no effect on OPPS budget neutrality.

Affordable Care Act (ACA) Provisions. The ACA contains provisions that affect the final FY 2012 IPPS wage index values, including revisions to the reclassification wage comparability criteria that were finalized in the FY 2009 IPPS final rule (73 FR 48568 through 48570), and the application of rural floor budget neutrality on a national, rather than State-specific, basis through a uniform, national adjustment to the area wage index (76 FR 26021).

Section 10324 of the ACA requires CMS to apply, beginning in 2011 and in a non-budget neutral manner, a wage index floor of 1.00 for hospitals located in frontier states which applies to the wage index for all HOPDs, including providers that are not paid under the IPPS. For 2012, CMS finalizes its proposal to adjust the FY 2012 IPPS wage index, as adopted on a calendar year basis for the OPPS, for all hospitals paid under the OPPS located in a frontier state to 1.00 where the assigned FY 2011 wage index for these hospitals (after accounting for Medicare Geographic Classification Review Board (MGCRB) reclassifications, application of the rural floor, and the rural floor budget neutrality adjustment) is less than 1.00. CMS confirms that similar to existing policy for HOPDs that are affiliated with multi-campus hospital systems, HOPDs will receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated; thus if the associated hospital is located in a frontier state, then the wage index adjustment applicable to the hospital will also apply for the affiliated HOPD.

The section 508 reclassifications and certain special exceptions expired on September 30, 2011, and are no longer applicable effective with FY 2012. As it did in a similar situation for 2010, CMS revised wage index values for certain special exception hospitals from January 1, 2011 through December 31, 2011, under the OPPS, in order to give these hospitals the special exception wage indices under the OPPS for the same

time period as under the IPPS. In addition, because the OPPS pays on a calendar year basis, the effective date under OPPS for all other non-section 508 and non-special exception providers is July 1, 2011, instead of April 1, 2011, so that these providers may also receive a full 6 months of payment under the revised wage index comparable to IPPS.

Out-Migration Adjustment. As proposed, CMS continues its policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county, noting that these hospitals qualify because they cannot reclassify. Addendum L to the OPPS final rule (available on the CMS Website) shows the non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2012 OPPS and also includes Table 4J in the FY 2012 IPPS/LTCH PPS final rule (available on the CMS Website at: http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp) which identifies counties eligible for the out-migration adjustment and providers that will receive the adjustment for FY 2012.

Beginning with FY 2012, under the IPPS an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH) payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. CMS also finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599) a procedural change permitting a Lugar hospital that qualifies for and accepts the out-migration adjustment to automatically waive its urban status for the 3-year period for which the out-migration adjustment is effective.

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

CMS will update the default CCRs for CY 2012 using the most recent cost report data. CMS also finalizes its proposal to apply its standardized methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that are used to adjust charges to costs on claims data for setting the CY 2012 OPPS relative weights. CMS notes that for this final rule, roughly 47 percent of submitted cost reports used in the default ratio calculations represented data from cost reporting periods ending in CY 2010, and 53 percent from cost reporting periods ending in CY 2009. For Maryland, CMS uses an overall weighted national average for all hospitals. CMS observed modest changes in statewide average default CCRs between CY 2011 and CY 2012. Table 11 in the final rule lists the final 2012 default urban and rural CCRs by state and compares them to the 2011 default CCRs.

E. OPPS Payment to Certain Rural and Other Hospitals

Hold Harmless Transitional Payments. Due to extensions included in many laws, most recently the ACA and the MMEA, the period of transitional outpatient payments (TOPs) to rural hospitals that are not SCHs with 100 beds or fewer extends to services provided before January 1, 2012. These Acts also extended the period of TOPs to SCHs

(including EACHs) for services provided before January 1, 2012 and removed the 100-bed limitation applicable to such SCHs for covered OPD services furnished on and after January 1, 2010, and before January 1, 2012. Thus, when the OPPS payment is less than the provider's pre-BBA amount, the amount of the OPPS payment is increased by 85 percent of the amount of the difference between the two payment amounts. However, effective for services provided on or after January 1, 2012, rural hospitals having 100 or fewer beds that are not SCHs and SCHs (including EACHs) will no longer be eligible for hold harmless TOPs. CMS received no comments on this issue.

Adjustment for Rural SCHs Implemented in 2006 Related to the MMA. For the 2012 OPPS, CMS finalizes its proposal without modification to continue the policy of a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, 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 applied before calculating outliers and copayment. CMS reiterates that it will 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 received no comments on its proposal.

F. OPPS Payments to Cancer Hospitals

The ACA directs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by 11 exempt cancer hospitals exceed the costs incurred by other hospitals. The provision applies to the 11 cancer hospitals that Medicare law exempts from payment under the IPPS. The ACA requires the Secretary to take into consideration the cost of drugs and biologicals when studying cancer hospital costliness. Finally, the ACA requires a budget neutral adjustment to the extent that the Secretary determines the cancer hospitals' OPPS costs to be greater than other OPPS hospitals' costs. Cancer hospitals remain eligible for transitional outpatient payments (TOPs), which are not budget neutral, and outlier payments, which are budget neutral.

CY 2012 Proposed Rule. The proposed rule reviewed CMS' study and findings completed in 2010 for the CY 2011 rulemaking and again concluded that the cancer hospitals' costs are higher and that an adjustment is required. As it had proposed, but not finalized for CY 2011, CMS proposed to make a hospital-specific payment adjustment determined as the percentage of additional payment needed to raise each cancer hospital's payment to cost ratio (PCR), excluding TOPs, to the weighted average PCR for all other hospitals paid under the OPPS. The adjustment would apply to all covered hospital outpatient services except devices with pass-through status. A cancer hospital with a PCR exceeding the weighted national average payment to cost ratio would receive a zero percent adjustment. CMS updated the level of adjustments in the CY 2011 proposal using the most recently available data, which are 2010 OPPS claims, cost report data for cost reporting periods ending primarily in FY 2009 or FY 2010, and the CY 2012 payment model.

CMS reconfirmed that TOPs could not be included when establishing the payment to cost ratio target given the current statutory language. It also revisited the issue of whether payments associated with the cancer hospital payment adjustment can be excluded from the amount of payment on which the copayment amount is determined and concluded that the statute requires these payments to be included in the amount of payment upon which the copayment amount is determined.

Commenters raised several concerns with the CMS proposal, especially the significant increase in beneficiary copayments, the proposal's disregard of TOPs payments, and the occurrence of Medicare savings from a provision that Congress directed to be budget neutral.

CY 2012 Final Rule. With significant changes from the proposed rule, CMS finalizes a policy to make additional payments to the 11 cancer hospitals sufficient to bring each hospital's 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 final rule makes the cancer hospital payment adjustment 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.

To address commenters' concerns about disregarding TOPs in calculating budget neutrality, which results in Medicare savings, the final rule calculates the budget neutral payment reduction that is associated with the cancer hospital payment adjustment as the difference in estimated CY 2012 total payments to cancer hospitals, including the cancer hospital payment adjustment, and estimated CY 2012 total payments to cancer hospitals without the cancer adjustment, including TOPs. Based on updated cost report data, the final rule estimates the budget neutrality adjustment to the OPPS conversion factor to be 0.9978, a reduction of 0.22 percent, compared to a reduction of 0.7 percent in the proposed rule.

Under the final rule , CMS will examine each cancer hospital's data at cost report settlement, determine the cancer hospital's PCR (before the cancer hospital payment adjustment), and determine 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, a cancer hospital payment adjustment of zero is given.

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 CY 2012, the target PCR for purposes of the cancer hospital payment adjustment is 0.91. To calculate the target PCR, CMS uses the same extract of cost report data available for the final rule from the set of hospitals used to calibrate the final rule. Using these cost report data and the CY 2010 claims data available for the final rule, CMS calculates a PCR of 0.674 for the cancer hospitals compared to a weighted average PCR of 0.91 for all other hospitals. Individual cancer hospital's PCRs range from approximately 0.63 to

approximately 0.78. CMS intends to recalculate the target PCR annually using the most recent claims and cost report data.

To show the impact of the final rule policy, CMS calculated estimates in percentage terms of the CY 2012 payment adjustment for each cancer hospital, as shown in Table 13 below. The actual amount of the CY 2012 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2012 payments and costs. The payment adjustments for cancer hospitals are estimated to result in an aggregate increase in OPPS payments to cancer hospitals of 34.5 percent for CY 2012 and a net increase in total payment, including TOPs, of 9.5 percent.

TABLE 13.—ESTIMATED CY 2012 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS (WITHOUT REGARD TOPS) TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Percentage increase without TOPs
050146	City of Hope Helford Clinical Research Hospital	15.8%
050660	USC Kenneth Norris Jr. Cancer Hospital	32.8%
100079	University of Miami Hospital & Clinic	28.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.4%
220162	Dana-Farber Cancer Institute	44.8%
330154	Memorial Hospital for Cancer and Allied Diseases	39.4%
330354	Roswell Park Cancer Institute	25.2%
360242	James Cancer Hospital & Solove Research Institute	30.9%
390196	Hospital of the Fox Chase Cancer Center	16.0%
450076	University of Texas M. D. Anderson Cancer Center	39.4%
500138	Seattle Cancer Care Alliance	44.7%
Total		**34.5%**

G. Hospital Outpatient Outlier Payments

For CY 2012, CMS continues to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It calculates the final rule fixed-dollar threshold using largely the same methodology as was used to set the threshold for CY 2011 and stipulates, as previously, that the outlier threshold is 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 $1,900 fixed-dollar threshold; the proposed rule had projected a fixed-dollar threshold of $2,100. The outlier payment equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar $1,900 threshold are met.

CMS continues to set aside 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 is determined as the amount of estimated outlier payments that would result from the final CMHC outlier threshold as a proportion of total estimated outlier payments. 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 is calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals that fail to satisfy the OQR 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.

CMS reports the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. The agency's current estimate of total outlier payments as a percent of total CY 2010 OPPS payment, using available CY 2010 claims and the revised OPPS expenditure estimate for the 2011 Trustee's Report, is approximately 1.13 percent of the total aggregated OPPS payments, or about 0.13 percentage points above the outlier target of 1.0 percent of total payments. Similarly, CMS currently estimates that aggregate outlier payments for CY 2011 will be approximately 1.06 percent of total 2011 OPPS payments.

Estimated 2012 outlier payments for hospitals and CMHCs can be found in the Hospital–Specific Impacts - Provider-Specific Data file on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS/.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT codes (Category I and Category III) and Level II HCPCS codes are used to report procedures, services, items and supplies under the hospital OPPS. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases these new codes and makes the codes effective (codes can be reported on Medicare claims) outside of the formal rulemaking process through the OPPS quarterly update CRs. CMS solicits comments on these new codes and finalizes the proposals related to these codes through the annual rulemaking process.

Table 14 in the final rule (copied below) summarizes the CMS process for updating codes.

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2011	Level II HCPCS Codes	April 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
July 1, 2011	Level II HCPCS Codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
October 1, 2011	Level II HCPCS Codes	October 1, 2011	CY 2012 OPPS/ASC final rule with comment	CY 2013 OPPS/ASC final rule with comment period
January 1, 2012	Level II HCPCS Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment	CY 2013 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period

Treatment of New Codes CMS Solicited Public Comments in the CY 2012 Proposed Rule

In this rule, CMS finalizes the status indicators, APC assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category III CPT codes that were newly recognized in either the April or July OPPS quarterly update CRs. Effective April 1 and July 1 of CY 2011, CMS made effective a total of 22 new Level II HCPCS codes and 14 Category III CPT codes. CMS recognized a total of 28 of these new HCPCS codes (16 Level II HCPCS codes and 12 Category III CPT codes) for separate payment for CY 2012.

CMS finalizes the proposed APC assignments, payment rates, and status indicators for the 5 new Level II HCPCS codes that were implemented in April 2011 OPPS quarterly update CR (see Table 16 of the final rule).
CMS finalizes the proposed APC assignments, payment rates, and status indicators for the 17 new Level II HCPCS codes that were implemented in the July 2011 OPPS quarterly update CR (see Table 17 of the final rule). Of the 17 HCPCS codes that were

made effective July 1, 2011, CMS did not recognize separate payment for 6 HCPCS codes that describe DME because they are paid under the DMEPOS Fee Schedule and not the OPPS.

For CY 2012, CMS continued its established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July. There were no new Category I vaccine CPT codes for the July 2011 update. Through the July OPPS quarterly update CR, CMS allowed separate payment for 12 of the 14 new Category III CPT codes effective July 1, 2011. Table 18 of the final rule lists these codes, their final status indicators, final APC assignments where applicable, and final payment rates for CY 2012.

Process for Soliciting Public Comments in CY 2012 OPPS/ASC Final Rule with Comment Period

CMS finalizes its proposal, without modification, to provide interim final status indicators and APC assignments and payment rates, if applicable, for all CPT codes newly implemented in January 2011 and all HCPCS codes newly implemented in October 2010 or January 2011 in Addendum B to this final rule. These codes are flagged with comment indicator "NI" in Addendum B of the final rule. Note Addendum B includes 315 codes with comment indicator "NI."

One commenter recommended that CMS request public input on codes through a web posting and was concerned that lack of stakeholder input on the interim APC assignments may negatively impact Medicare beneficiaries. CMS acknowledges challenges and time constraints that make obtaining public comment not feasible while still meeting systems deadlines for claims processing and payment files for the upcoming quarter. CMS also notes that with all new codes it assigns the service to an APC based on input from a variety of sources, including information provided by the public. Some commenters requested CMS implement a 1 to 2 year dampening period to minimize significant fluctuations in payments from year to year for newly bundled or packed procedure codes. One commenter stated that limiting the payment reduction to 10 percent would prevent hospitals from experiencing substantial payment reductions and allow hospitals time to update their charge masters to reflect the newly packaged codes. CMS does not believe it is necessary or appropriate to limit payment reductions for any service in order to prevent hospitals from experiencing substantial payment reductions and notes that while payment rates for individual services may vary, the total estimated payments made to hospitals remain the same because the OPPS is, by statute, a budget neutral payment system. Further, CMS expects hospitals to carefully review each new HCPCS code when setting charges for the forthcoming year.

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, changes in 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

As required, 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. For purposes of identifying significant HCPCS for examination in the 2 times rule, CMS considers 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 median cost to be significant. Addendum B of the final rule identifies with comment indicator "CH" those the final CY 2012 changes.

Proposed 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 used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs: resource homogeneity, clinical homogeneity, hospital outpatient setting, frequency of service (volume), and opportunity for upcoding and code fragments.

CMS is finalizing a list of 23 APCs exempted from the 2 times rule for CY 2012 (Table 19 in the final rule). Based on the final CY 2010 claims data, CMS identified 23 APCs with 2 times rule violations, a cumulative increase of APCs from the proposed rule. CMS removed 5 APCs from the proposed exemption list because they no longer violated the 2 times rule and added 10 APCs to the exemption list because based on the complete CY 2010 data, they violated the 2 times rule and met the above criteria. The median costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule can be found on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/01_overvoew.asp.

C. New Technology APCs

CMS retains services within New Technology APC groups until it gathers sufficient claims data to enable CMS to assign the service to an appropriate clinical APC. This policy allows CMS to move a service from a New Technology APC in less than 2 years or to retain a service in a New Technology APC for more than 2 years based on sufficiency of claims data.

CMS notes that each year it receives many requests for higher payment amounts under the New Technology APCs for specific procedures under the OPPS 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-efficient settings. These payment rates are based on Medicare beneficiary projected utilization and payment rates are not based on initial projections of low utilization for services in a transitional period.

Proposed Movement of Procedures

For CY 2012, CMS finalizes its proposal to reassign three prostate saturation biopsy procedures to different New Technology APC groups (Table 20 in the final rule). Although analysis of hospital outpatient claims data indicates that these procedures are low volume, CMS believes that it should continue the New Technology payments for another year. CMS believes the finalized APC assignments would more appropriately reflect the procedures described, based on clinical and resource considerations.

D. OPPS APC-Specific Policies

Cardiovascular Services

Cardiovascular Computed Tomography (CCT) (APC 0340 and 0383)

CMS finalizes the continued assignment of CPT code 75571 to APC 0340, with a final CY2012 median cost of approximately $46. It is also maintaining the assignment of CPT codes 75572, 75573, and 75574 to APC 0383, with a final CY 2012 median cost of approximately $262.

In response to comments about the calculation of CY 2012 median costs, CMS compared the median costs and single procedure claims based on CY 2009 and CY 2010 data. Based on the analysis of the data, CMS believes that the median costs calculated reflect valid estimates of the costs of CPT codes 75572, 75573, and 75574. A commenter also requested reassignment of CPT code 75571 from APC 0340 to APC 0282. CMS believes that CPT code 75571 is a minor ancillary procedure and is appropriately assigned to APC 0340, in terms of resources and clinical similarity. CPT code 75571 has a median cost of approximately $31, and APC 0340 has a final median cost of approximately $46. In contrast, APC 0282 has a median cost of approximately $107, driven largely be a single major procedure CPT code for CT (CPT code 76380). Therefore, CMS does not consider CPT code 75571 to have resource similarity for APC 0282.

Cardiac Imaging (APC 0377)

CMS finalizes the continued assignment of CPT codes 78451, 78451, 78453, and 78454 to APC 0377, with a final CY 2012 median cost of approximately $672.

Several commenters expressed concern over the proposed 11 percent payment reduction to APC 0377. Commenters believed there were irregularities in the hospital cost data that suggested inaccurate reporting of costs associated with procedures in APC 0377, rather than an actual decline in resource use. Commenters pointed out that according to CMS data CPT code 78453 (single study) has a higher mean and median cost than CPT code 78454 (multiple studies), but it was illogical for hospitals to use

fewer resources for furnishing multiple studies than for furnishing a single study. Commenters made several recommendations for how CMS could reevaluate the data and recalculate the median costs for these procedures. CMS notes that the final CY 2012 median cost represents a slight decline from the median cost of approximately $701, which the CY 2012 proposed payment rate was based and the median cost of approximately $752, which the final CY 2011 payment rate was based. CMS also notes that it already engages in a standard review process for all APCs that experience significant changes in median costs. CMS examined the claims data for APC 0377 for the CY 2011 OPPS final rule, the CY 2012 proposed rule, and this final rule (Table 21 in final rule provides selected data for APC 0377). Based on the data, CMS believes that the reduction in the payment rate for APC 0377 is attributable to the slight decrease in the CCRs and the significant decline in the packaged cost. CMS acknowledges that it appears peculiar that the estimated cost for a single study, CPT code 78453, would be greater than the estimated cost for a multiple study, CPT code 78454. CMS states it is not unusual for hospitals to establish charges that do not comport with their expectations based on the definition of the code for the service. Based on the review of the claims data and cost report data, CMS maintains the estimated median cost for APC 0377 is a valid estimate of the relative costs of the services under the APC and does not see any reason to adopt an alternative methodology to calculate median costs.

Implantable Loop Recorder Monitoring (APC 0690)
CMS finalizes the reassignment of CPT code 93299 to APC 0690, with a final CY 2012 median cost of approximately $38.

Some commenters objected to the reassignment of CPT code 93299 from APC 0691 to 0690 because this would result in inadequate payment to hospitals for the resources required to provide the service. CMS maintains this proposal because almost all the claims used for ratesetting were single claims. Further, CMS states the calculated median cost of approximately $38 for CPT code 93299 is similar to that of most of the other CPT codes in APC 0690, and very close to the overall APC median cost of approximately $35. In contrast, the overall median cost for APC 0691 is approximately $168, more than four times the median cost of CPT code 93299.

Echocardiography (APCs 0128, 0269, 0270, and 0697)
CMS finalizes its CY 2012 proposal to continue to calculate the median costs for the non-contrast echocardiography procedures based on APCs 0697, 0269, 0270, and to calculate the median costs for the contrast-echocardiography procedures based on APC 0128. CMS believes that continuing its methodology used to make these determinations in CY 2012 results in payment rates for the contrast and non-contrast cardiac echo procedures that appropriately reflect the costs for these services (Table 22 in the final rule).

In response to commenters concerns that the proposed 5 percent decrease in payment rate for CPT code 93006 (approximately $394) could be the result of miscoding, CMS examined the CY 2010 hospital outpatient claims, which showed a significant volume of data for CPT code 93306, and a median cost of approximately $394. CMS notes that it

will again reevaluate the status indicator and APC assignment for CPT code 93306 for the CY 2013 OPPS rulemaking cycle. Several commenters stated that fetal echocardiography is just as resource intensive as adult procedures; others state that the low median cost for these services is the result of low frequency for these services and suggested that this contributes to miscoding. CMS acknowledges that these codes have been in existence for almost 20 years and believes that the low frequency of these services is the result of infrequent use of this procedure on Medicare patients. Based on claims data from the past 3 years, CMS believes these codes are appropriately placed in APC 0697 based on their clinical homogeneity and resource costs compared with the other procedures in this APC.

Several commenters expressed concern that the proposed payment rate of approximately $567 for the non-contrast echocardiograms assigned to APC 0270 is higher that the proposed payment rate of approximately $564 for the contrast echocardiograms assigned to APC 0128. The commenters indicated it is not appropriate for a contrast enhanced procedure to have a lower median cost and lower payment rate that a non-contrast procedure. The commenters requested that CMS develop a more consistent and stable payment methodology for echocardiograms that utilize contrast agents because the cost of contrast agents is approximately $117 and requires more work when compared to non-contrast echocardiograms. Commenters made several suggestions including the development of three APCs for contrast-enhanced echocardiograms and separate payment for the cost and administration of the contrast agents. CMS agrees with the commenters that, in general, contrast based procedures would involve more resources but it also believes that some non-contrast echocardiograms are more complex than contrast-based echocardiograms and would expect their costs to be higher. CMS claims data demonstrates that the costs involved with the non-contrast echocardiograms assigned to APC 0270 are significantly higher than the contrast –based echocardiograms assigned to APC 0128. CMS also finds no evidence that the median costs calculated for these APCs is incorrect, and since the current APC composition does not result in a 2 times rule violation it has no reason to reconfigure the current APCs. CMS will again review the claims data for these services for the CY 2013 OPPS rulemaking cycle.

Gastrointestinal Services

Upper Gastrointestinal Services (APCs 0141, 0419, 0422)

CMS finalizes its proposals to create new APC 0419 (Level II Upper GI Procedures), to rename APC 0422 as “Level III Upper GI Procedures, and to reassign the HCPCS codes for upper GI procedures to the three APC configuration (APCs 0141, 0419 and 0422) for CY 2012 OPPS (Table 23 in the final rule). CMS is also finalizing the APC recommendation that CPT code 43830 is reassigned to APC 0422 for the CY 2012 OPPS but CMS is not accepting the APC Panel’s recommendation to reassign CPT code 43227 to APC 0422 because it is a very low volume service with unstable median costs.

Commenters requested the creation of a new level IV upper GI procedure APC for CPT codes 43257 and C9724 because these services are clinically different from most other

services in APC 0422 and their resources are much greater. CMS disagrees that the codes are clinically different from the other services assigned to APC 0422. Further, the final median cost for CPT code 43257 of approximately $1,535 falls below the final median cost for APC 0422 of approximately $1,819. CMS acknowledges that to the extent that the costs for the catheter used in this procedure increases after CY 2010, these costs will be used to establish payment rates for the years in which the claims are used. CMS notes that HCPCS code C9724 is a low volume service with median costs that have varied widely over the past few years making it unsuitable for establishment of a single APC. CMS is not creating a level IV upper GI procedure APC because it believes HCPCS codes 43257 and C9724 are appropriately assigned.

Gastrointestinal Transit and Pressure Measurement (APC 0361)
CMS finalizes the continued assignment of CPT code 0242T to APC 0361, with a final CY 2012 median cost of approximately $286. CMS will review this assignment for CY 2013 when some claims data should be available for this procedure.

Several commenters requested reassignment of CPT code 0242T from APC 0361 to New Technology APC 1510 (New Technology APC- Level X), which has a payment rate of $850. Commenters believed that CPT code 0242T is significantly different than the other procedures in APC 0361 and that the disposable capsule and special meal required to capture the multiple pressure and transit measurements throughout the GI tract cost $600 per procedure. CMS disagrees that assignment to a clinical APC necessarily implies that there are clinical and cost data for a new service and that it routinely makes assignments of new CPT codes to clinical APC's before having claims data. CMS reviews claims data once it is available and make reassignments accordingly based on those data. CMS does not believe a New Technology APC is warranted for this procedure; it believes the clinical attributes and CY median costs of the services found in APC 0361 support the assignment of CPT code 0242T to APC 0361 as an initial assignment.

Genitourinary System
Laser Lithotripsy (APC 0163)
CMS finalizes the continued assignments of CPT code 52353 to APC 0163, with a final CY 2012 median cost of approximately $2,596, and CPT code 50590 to APC 0169, which has a final CY 2012 median cost of approximately $3,647.

In response to comments, CMS states that based on the analysis of the final CY 2012 claims data, it believes that these codes are in the appropriate APCs. CMS will continue to review on an annual basis the APC assignment for these codes and determine whether a reassignment is necessary.

Percutaneous Renal Cryoablation (APC 0423)
CMS finalizes the continued assignment of CPT code 50593 to APC 0423, with a final CY 2012 APC median cost of approximately $4,096.

In response to comments, CMS states that based on the analysis of the final CY 2012 claims data, it believes that this code is in the appropriate APC and that the grouping of the four CPT codes assigned to APC 0423 does not violate the 2 times rule. CMS reiterates that the final APC relative weights and payment rates are based on median hospital costs, not mean costs, for APC groups and it does not believe it would be appropriate to use a combination of these measures to establish payment weights for different APCs under the OPPS. In response to designating procedure-to-device edits for the all the CPT codes assigned to APC 0423, CMS comments that it is not possible to develop edits because there are no Level II HCPCS codes that describe all of the technologies that may be used in the procedures.

Nervous System

Revision/Removal of Neurostimulator Electrodes (APC 0040 and 0687)

CMS finalizes the proposal to assign CPT codes 63663 and 63664 to APC 0040 and to assign CPT codes 63661, 63662 and 64569 to APC 0687. CMS also finalizes the title change of APC 0040 to Level Implantation/Revision/Replacement of Neurostimulator Electrodes" and the title of APC 0061 to "Level II Implantation/Revision/Replacement of Neurostimulator Electrodes."

Several commenters supported the reassignment of CPT codes 63663 and 63664 from APC 0687 to APC 0040. In response to a comment recommending the creation of two HCPCS codes to allow hospitals to differentiate between revision and replacement procedures, CMS describes that for the proposed rule it examined the CY 2010 claims data to determine if CPT codes 63663 or 63664 were billed with and without HCPCS code C1778 (Lead, neurostimulator (implantable)) or HCPCS code C1897 (Lead, neurostimulator test kit (implantable)). Because the majority of claims did not contain HCPCS code C1778 or C1897, CMS concluded that these CPT codes are being used by hospitals to describe mainly device revision procedures, although there were a significant number of cases with device replacement procedures in the claims data.

Magnetoencephalography (MEG) (APCs 0065, 0066, and 0067)

CMS is finalizing the APC Panel's recommendation to reassign CPT code 95965 to APC 0066, with a final CY 2012 median cost of approximately $2,521.

At the August 2011 meeting, the APC Panel also recommended that CMS implement edits requiring hospitals to use the new MEG revenue code, 086X, with the CPT codes for MEG (CPT codes 95965, 95966 and 95967). CMS is not accepting this recommendation because it does not believe is it necessary or appropriate. According to CMS, Medicare pays for a low volume of MEG services and there are no special requirements that would justify creation of edits that force hospitals to report particular revenue codes for particular CPT codes. CMS does not believe that it is reasonable to implement national CPT-to-revenue code edits to enforce the use of MEG-specific revenue codes when a small number of hospitals reported only 144 lines of MEG in total for the 3 MEG codes.

Transcranial Magnetic Stimulation Therapy (TMS) (APC 0218)
CMS finalizes the reassignment of CPT codes 90867 and 90868 from APC 0216 to APC 0218, with a final CY 2012 median cost of approximately $84.

In response to comments, CMS states that based on analysis of hospital outpatient claims data for the predecessor codes 0160T (CPT code 90867) and 0161T (CPT code 90868) from CY 2006 through CY 2010, CMS believes that both CPT code 90867 and 90868 are more appropriately placed in APC 0218 instead of APC 0216.

Ocular and Ophthalmic Services
Placement of Amniotic Membrane (APCs 0233 and 0244)
CMS is finalizing its proposal to assign status indicator "Q2" to CPT code 65778. When the service is furnished with a separately payable surgical procedure with status indicator "T" on the same day, payment for CPT code 65778 is packaged. Otherwise payment for CPT code 65778 is made separately through APC 0233, with a CY 2012 final median cost of approximately $1,164. CMS is finalizing its proposal to reassign CPT code 65779 from APC 0255 to APC 0233, with a final CY 2012 median cost of approximately $1,164. It is also finalizing the continued assignment of CPT code 65780 to APC 0244, with a final CY 2012 median cost of approximately $2,654. (Table 24 summarizes the amniotic membrane procedures and their CY 2012 final APC assignments).

Several commenters urged CMS not to conditionally package CPT code 65778 and assign it to status indicator "T", a recommendation also made by the APC Panel. Based on the manufacturer's description, CMS considers this service a type of specialized bandage that is typically placed on the surface of the eye immediately after a surgery that has resulted in a corneal epithelial defect and disagrees that the procedure described by CPT code 65778 is a significant procedure. In CY 2012, CMS will again reevaluate these CPT codes for the CY 2013 OPPS rulemaking cycle.

Insertion of Anterior Segment Aqueous Drainage Device (APC 0673)
CMS finalizes the reassignment of CPT code 0253T from APC 0234 to APC 0673, with a final median cost of approximately $2,911 for CY 2012.

In response to comments, CMS reexamined the clinical and resource characteristics of CPT code 0253T and agrees with commenter's suggestions to reassign the code to APC 0673. CMS will monitor claims for cost report data related to CPT code 0253T as the data becomes available for future updates.

Scanning Ophthalmic Diagnostic Imaging (APC 0230)
CMS finalizes the assignment of CPT codes 92132, 92133, and 92134 to APC 0230, with a final CY 2012 median cost of approximately $45.

In response to a comment that the new CPT codes for scanning ophthalmic diagnostic imaging were not assigned to the correct APC groups, CMS states it assigned these new codes to the same APC and status indicators as their predecessor CPT codes

0187T and 92135. Given the significant information in the CY 2012 final rule claims data for predecessor CPT codes 92135 (CPT codes 92133 and 932134) and 0187T (CPT code 92132), CMS believes the claims data are sufficient to continue to assign these services to APC 0230. CMS will reevaluate the APC assignments for CPT codes 92132, 92133 and 92134 in future OPPS updates as claims data becomes available.

Intraocular Laser Endoscopy (APC 0233)
CMS finalizes the reassignment of CPT code 66711 from APC 0233 to APC 0234, with a final median cost of approximately $1,631 for CY 2012.

In response to comments, CMS reexamined the various procedures in APC 0233 and APC 0234 and decided that CPT code 66711 is more clinically similar to the range of procedures in APC 0234. From a resource perspective, CPT code 66711 fits in either APC 0233 or APC 0234.

Orthopedic and Musculoskeletal Services
Percutaneous Laminotomy/Laminectomy (APC 0208)
CMS finalizes the assignment of CPT code 0275T to APC 0208, with a final CY 2012 median cost of approximately $3,553.

For CY 2012, CMS proposed to maintain assignment of percutaneous laminotomy/laminectomy (HCPCS code C9729 is used in the CY 2012 proposed rule, while CPT code 0275T is used in the final rule) to APC 0208. Comments raised concerns about CPT code 0275T, because the phrase “unilateral or bilateral” in the CPT code descriptor suggests that the code must be reported unmodified when performed either unilaterally or bilaterally and precluded the use of modifiers 50 or 51, and requested that CMS either allow the modifiers or create a HCPCS G-code. The commenter anticipates that the CPT Editorial Panel will address the issue of bilateral or multiple levels in the CPT code 0275T descriptor for CY 2013. CMS will not create a HCPCS G-code for CY 2012 and will wait to see what actions the CPT Editorial Panel takes. For CY 2013, CMS will reevaluate the APC placement of CPT code 0275T.

Level II Arthroscopy (APC 0042)
CMS finalizes the current HCPCS code configuration for CY 2012, and will review the APC 0042 and component GCPCS code median costs again next year for clinical and resource similarity.

A commenter believed that the procedures currently assigned to APC 0042 have widely varying median costs and claimed that the APC currently violated the 2 times rule and that additional APCs were needed. Using the CY 2012 final rule claims data, CMS does not agree with the comments about widely varying median costs and does not identify any 2 times rule violations in APC 0042.

Closed Treatment Fracture of Finger, Toe and Trunk (APCs 0129, 0138, and 0139)
CMS removes the words “Finger/Toe/Trunk vises, in response to comments, from the group title for APCs 0129, 0138, and 0139. A commenter recommended that CMS

remove the words “Finger/Toe/Trunk” because there is no need to make this distinction since there is no other APC that describes closed treatment fractures. (See Table 25 in the final rule for final APC group titles).

Level I and II Strapping and Cast Application (APCs 0058 and 0426)
CMS finalizes the title of APC 0058 to read “Level I Strapping and Cast Application” and APC 0426 to read “Level II Strapping and Cast Application.”

Radiology Services
Proton Beam Therapy (APC 0664 and 0667)
CMS finalizes the assignment of CPT codes 77520 and 77522 to APC 0664, with a final CY 2012 APC median cost of approximately $1,184 and CPT codes 77523 and 77525 to APC 0667, with a final CY 2012 APC median cost of approximately $1,549.

In response to comments, CMS believes that based on the analysis of the data from claims submitted during CY 2010, these placements are appropriate in light of the resource cost and clinical intensity of the services describe by these CPT codes.

Sterotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067, and 0127)
CMS finalizes the existing CY 2011 APC assignments for the SRS HCPCS codes for CY 2012. Specifically:

- HCPCS G-codes G0173 and G0339 are assigned to APC 0067, which has a final CY 2012 APC median cost of approximately $3,374;
- HCPCS G-code G0251 to APC 0065, which has a final CY 2012 APC median cost of approximately $903;
- HCPCS G-code G0340 to APC 0066, which has a final CT 2012 APC median cost of approximately $2,521; and
- CPT code 77371 to APC 0127,which has a final CY 2012 APC median cost of approximately $7,461.

CMS also finalizes its proposal to continue to assign CPT codes 77372 and 77373 to status indicator “B” (these CPT codes are not payable under the OPPS).

In response to comments, CMS states that these HCPCS G-codes for SRS have been in effect for several years and it has no reason to believe that hospitals are confused about the reporting of these codes. Based on the analysis of the hospital outpatient claims data, CMS believes these placements are appropriate in light of the resource cost and clinical intensity of the services described by these CPT codes.

Adrenal Imaging (APC 0408)
CMS finalizes the continued assignment of CPT code 78075 to APC 0408, with a final CY 2012 median cost of approximately $958.

Commenters questioned CMS’ rational for the proposal to reassign CPT code 78075 from APC 0408 to APC 0414, citing a lack of clinical and cost similarity to APC 0414.

After analyzing the final CY 2012 median cost for CPT code 78075, CMS agrees with the commenters' assertion.

Positron Emission Tomography (PET) Imaging (APC 0308) (Created from Myocardial PET Imaging (APC 0307) and Non-Myocardial PET Imaging (APC 0308))
CMS finalizes the reassignment of CPT codes 78459, 78491, and 78492 to APC 0308, with a final CY 2012 median cost of approximately $1,038. CMS has made no other reassignments to APC 0308 nor has it removed codes that are assigned to APC 0308 for CY 2011 from APC 0308 for CY2012. CMS finalizes the deletion of APC 0307.

In response to commenters, CMS agrees that myocardial PET and non-myocardial PET have similar clinical characteristics and similar resource requirements. Therefore, for CY 2012 it reassigned the CPT codes 78459, 78491 and 78492 to APC 0308 which it renamed PET Imaging. CMS' decision was influenced by a significant unexpected and unusual decrease in the median cost for 78492 between the proposed rule and the final rule data for the CY 2012 OPPS. CPT code 78492 comprises approximately 98 percent of the volume of the three myocardial PET services that were assigned to APC 0307 and therefore largely would control the median cost for APC 0307 if it had been retained for CY 2012 OPPS. CMS examined the claims and cost report data for single procedure claims for CPT code 78492 and believes there are multiple reasons for the median cost for APC 0307 to decline from CY 2011 to CY 2012. (See Table 26 in the final rule for select data for CPT code 78492.) One important observation is that the number of hospitals that furnished the service increased and that the volume of services increased significantly, a total increase from CY 2009 to CY 2010 of 33.3 percent. Based on the data, CMS believes there is a transition in CCRs underway that should stabilize once the numbers of hospitals that furnish the service is stable and once the volume of services being furnished each year is stable. CMS believes that the CCR changes are increasing the instability in the median costs for CY 2012 and that combining the two APCs is a reasonable response. CMS will reevaluate the relative resource utilization of the services after the cost center transitions are complete.

In response to comments, CMS notes that it does not discuss all services paid under the OPPS at the APC Panel meetings. According to CMS the APC Panel meetings offer the opportunity for the public to make presentations within the scope of the Panel's charter and for CMS to seek Panel comment and advice on issues for which CMS believes that would be useful. CMS also notes that the proposed rule does not include service-specific discussions of the calculation of median costs for each separately paid HCPCS code or for each APC. Rather, CMS discusses the general methodology and specific APCs or services in the proposed rule only when it has a specific reason to do so. CMS will reassess whether it continues to be appropriate to assign both the non-myocardial PET and the myocardial PET services to the same APC for CY 2013 based on the CY 2013 OPPS cost data. CMS notes that any necessary reassignments would be made through the standard annual notice-and-comment rulemaking process.

Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)
CMS finalizes the assignment of CPT code 77338, with a final median cost of approximately $188 to APC 0305, with a final CY 2012 median cost of $264.

Commenters objected to CMS' proposal to move CPT code 77338 from APC 0310 to APC 0305. Commenters believed that even if assigned to APC 0310, the code is being underpaid because the predecessor CPT code 77334 would have been charged 3 to 9 units for the initial IMRT treatment and that additional units would be charged 3 to 9 units for the successive IMRT treatments. Therefore, if the CPT codes had not been replaced, commenters stated they would have charged and been paid approximately $4,625 for 18 total units of CPT code 77334. CMS acknowledges it is peculiar the estimated cost for CPT code 77334, which represents the cost of a single device, would be greater than the estimated cost for CPT code 77338, which represents the cost of all devices in a single IMRT plan of treatment, but CMS estimated costs are based on the amounts of the charges established by hospitals for the service and the hospitals' CCRs, which are calculated from their Medicare cost reports. CMS cites reasons why this apparent anomaly could exist and states it is not unusual for hospitals to establish charges that do not comport with CMS' expectation of the charges they would establish based on the definition of the code for the service. Based on a robust set of single procedure bills containing actual charges for CPT code 77338 by 965 hospitals, CMS does not see any irregularities in the calculation of the median cost for CPT code 77338.

CT of Abdomen and Pelvis (APCs 0331 and 0334)
CMS is finalizing its proposal to create two new APCs to assign the combined abdominal and pelvis CT services. CMS is assigning CPT code 74176 to APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) and CMS is assigning CPT codes 74177 and 74178 to APC 0334 (Combined Abdominal and Pelvis CT With Contrast). For CY 2012, CMS calculates a simulated median cost of approximately $406 for APC 0331 and a simulated median cost of approximately $508 for APC 0334. CMS will reassess whether there is a continued need for these APCs for the CY 2013 OPPS once it has actual charges for these services.

CMS is also finalizing its proposal to assign CPT codes 74176 to APC 8005 where CPT code 74176 is reported with CT codes that describe CT services for regions of the body other than the abdomen and pelvis in which contrast is not used. CMS assigns CPT codes 774177 and 74178 to APC 8006 when either of them is reported with CT codes that describe CT services for regions of the body other than abdomen and pelvis in which contrast is used. For CY 2012, APC 8005 has a median cost of approximately $432 and APC 8006 has a median cost of approximately $722.

In response to comments, CMS notes that it believes it is appropriate to base payments for CPT codes 74176, 74177 and 74178 on simulated median costs established using the cost data for predecessor codes. Because these codes were created effective January 1, 2011, CMS will have claims data containing actual charges for use in calculating the median cost of these services for the CY 2013 OPPS.

Complex Interstitial Radiation Source Application (APC 0651)
CMS finalizes the final CY 2012 median cost for APC 0651of approximately $835, based on 96 claims. CMS also finalizes that when CPT code 77778 is billed alone it will be paid at the APC 0651 payment rate.

Several commenters believed the 96 claims used to set the proposed rate for APC 0651 are inadequate and recommended that CMS continue to explore additional methodologies to increase the number of multiple procedure claims used for brachytherapy ratesetting. CMS agrees that 96 single claims are not optimal for APC 0651 ratesetting but it believes that a low volume of single claims for this code is not unexpected due to the clinical nature of the procedure. CMS states that the application of brachytherapy sources described by CPT code 77778 and the placement of needles or catheters into the prostate described by CPT code 55875 are generally provided in the same operative session in the same hospital on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer. In this situation, CMS continues to pay for these procedures when performed together through composite APC 8001. CMS acknowledges there are a few occasions when a physician places the needles or catheters outside the hospital, in which case CPT code 77778 would be reported alone in the hospital outpatient setting. CMS believes that the variation in the median costs for CPT code 77778 between the CY 2011 and CY 2012 final rule appears to be normal variation that is expected with a low-volume service. CMS will continue to evaluate additional refinements and improvements to its ratesetting methodologies to maximize use of claims data to establish the payment rate for APC 0651.

Radioelement Applications (APC 0312)
CMS finalizes a CY 2012 median cost for APC 0312 of approximately $378, based on 183 single claims.

In response to comments, CMS believes that the variation in the median costs between the CY 2011 and the CY 2012 final rule appears to be normal variation that it would expect to see for low-volume services. CMS agrees that it would be preferable to have more single bills on which to base the payment for APC 0312 and will continue to evaluate additional refinements and improvements in the methodologies to maximize the use of claims data to establish the payment rate for APC 0312.

<u>Respiratory Services</u>
Pulmonary Rehabilitation (APC 0102)
CMS finalizes that HCPCSs code G0424 is the only assigned code to APC 0102 with a final CY 2012 median cost of approximately $37.

Commenters objected to the proposed CY 2012 payment because it proposed a significant reduction in payment from the payment that resulted from the simulated median cost for pulmonary rehabilitation for CY 2010 and CY 2011 (the CY 2011 OPPS final rule median cost of approximately $62). They stated that CMS data supports that

hospitals are not reporting charges associated with the corollary services that are part of HCPCS code G0424. They urged CMS to freeze the payment for pulmonary rehabilitation for CY 2012 at the CY 2011 rate and to shift from the use of a standard cost center to the use of a nonstandard cost center for determining the relative cost of pulmonary rehabilitation services. They indicated that the proposed payment would reduce access to care.

In response to these comments, CMS expanded the data analysis to look at the charges and CCRs for HCPCS code G0424 and for HCPCS code G0237 through G0239, the codes commenters indicated are similar services. Analysis of this data supported the methodology CMS used to calculate the median cost for APC 0102. CMS does not agree with commenters that the payment will result in reduced access to care for Medicare patients. CMS notes that in CY 2010, when the payment rate for HCPCS code G0239 was $27.39 hospitals reported a total frequency of 146,616 which indicates no access to care problems for a payment rate significantly less than the median cost for HCPCS code G0424 in CY 2012. CMS is not establishing a special purpose cost center for pulmonary rehabilitation because the service is largely furnished by respiratory therapists which have a standard cost center (4900, Respiratory Therapy), and which is already used to reduce most charges for HCPCS code G0424 to costs. CMS does not believe that creating a pulmonary rehabilitation cost center in addition to the standard respiratory therapy cost center is necessary to the calculation of the median cost of HCPCS code G0424.

Bronchial Thermoplasty (APC 0415)
CMS finalizes the proposal to maintain the assignment of bronchial thermoplasty procedures (CPT codes 0276T and 0277T beginning January 1, 2012) to APC 0415, with a final CY 2012 median cost of approximately $2,024.

In response to comments, CMS believes that that bronchial thermoplasty service is clinically similar to the procedures in APC 0423 and does not belong in a New Technology APC. CMS also states there is no evidence that APC 0415 needs to be split into 2 APCs and will reevaluate the APC assignment when adequate actual hospital reported cost data is available.

Insertion of Bronchial Valve (APC 0415)
CMS finalizes the assignment of CPT code 0250T to APC 0415, with a final CY 2012 median cost of approximately $2,024. CMS will review this assignment for CY 2013, when there should be some claims data for the code to determine the cost of the procedure.

In response to commenters, CMS believes the services described by CPT code 0250T are clinically similar to the services in APC 0415.

<u>Other Services</u>
Skin Repair (APCs 0133, 0134, and 0135)

For CY 2012, The AMA's CPT Editorial Panel deleted 24-skin replacement and skin-substitute-related CPT codes and replaced them with 8 new CPT codes to describe more accurately the services associated with skin replacement procedures. CMS' standard process for dealing with new CPT codes is to assign the code to the APC that it believes contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. In the case of the new skin replacement and skin substitute-related CPT codes, CMS crosswalked the existing CY 2011 CPT codes to the new CY 2012 CPT codes. In assigning the new codes to their appropriate APCs, CMS took into consideration the size of the wound described in the code. Table 29 in the final rule lists the CPT code changes and their APCs. The new CPT codes are given a comment indicator of "NI" (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) to identify them as new interim APC assignments open to public comment.

Nasal Sinus Endoscopy (APC 0075)
CMS finalizes the assignment of CPT codes 31295, 31296, and 31297 to APC 0075.

In response to comments, CMS states that these CPT codes should not be assigned to a new device-dependent APC. CMS believes that the most clinically appropriate APC is APC 0075, which includes other nasal and sinus endoscopy procedures. Further, even the non-claims data-based cost estimates for these procedures offered by the commenters is within the approximate range of median costs for procedures assigned to APC 0075. Once OPPS data claims data are available for these procedures, CMS will reevaluate the APC assignments.

Bioimpedance Spectroscopy (APC 0097)
CMS finalizes the reassignment of CPT code 0239T from APC 0099 to APC 0097, with a final CY 2012 median cost of approximately $65.

In response to commenters, CMS states that it has no CY 2010 claims data for the service reported by CPT code 0239T because the CPT code is new for CY 2011. Therefore, CMS assigned the new code to the APC that it believes to be most similar clinically and with regard to homogeneity of hospital resources. After examination of information provided by a commenter, CMS agrees with the comment that CPT code 0239T appears to be somewhat dissimilar in resource utilization to the services assigned to APC 0099 but CMS does not agree with the commenters that the code rises to the same level of complexity as codes that are assigned to APC 0096. CMS does believe, however, that CPT code 0239T would be more appropriately placed in APC 0097, based on its clinical homogeneity and resource similarity to other procedures in the APC. CMS will reassess the APC placement when it has claims data for services furnished on and after January 1, 2011, the effective date for CPT code 0239T.

Autologous Blood Salvage (APC 0345)
CMS finalizes the assignment of CPT code 86891 to APC 0345, with a final CY2012 median cost of approximately $15.

In response to comments that this service should be further analyzed and a more appropriate payment level established based upon analysis using external data, CMS states that it has no reason to believe that the claims and cost report data does not accurately reflect hospitals' costs of the services assigned to APC 0345, including the service described by CPT code 86891.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

When the proposed rule was issued, one device category was eligible for pass-through payment:

> HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable), which CMS announced in the October 2010 OPPS Update (Transmittal 2050, Change Request 7117, dated September 17, 2010).

Pass-through payment status for this device category continues in CY 2012 and expires on December 31, 2012; beginning January 1, 2013, device category C1749 will no longer be eligible for pass-through payments.

Two new device categories became eligible for pass-through payment status on October 1, 2011:

> HCPCS code C1830 (Powered bone marrow biopsy needle), and
> HCPCS code C1840 (Lens, intraocular (telescopic)).

These were announced in Transmittal 2296, Change Request 7545, dated September 2, 2011.

The final rule does not terminate pass-through payment status for any device categories in CY 2012 and it does not propose pass-through payments for any new devices. If CMS creates new device categories for pass-through payment status during 2012, it will propose expiration dates following the statutory requirement that they be eligible for pass-through payments for at least 2, but not more than 3, years from the date on which pass-through payment for any medical device described by the category can be made.

The final rule continues the following policies related to pass-through payment for devices, without modification from CY 2011 or the proposed rule:

1) treat 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 OPPS pass-through evaluation process and pass-through payment methodology;
2) include implantable biologicals in calculating the device APC offset amounts;
3) use the device APC offset amounts to evaluate whether the cost of a device

(including 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) reduce 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.

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

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 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 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.

Since 2008, OPPS payment for the implantation procedure has been reduced by 100 percent of the device offset amount for full credit/no cost cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Payment for the implantation procedure is reduced by 50 percent of the device offset amount for partial credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. 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 applies three criteria when determining the APCs to which the policy applies:

- 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.

The final rule continues current policies, including application of the three criteria above. The no cost/full credit adjustment for each APC to which the policy applies is the device offset percentage for the APC (the estimated percentage of the APC cost that is attributable to the device costs that are packaged into the APC). Similarly, the partial credit device adjustment for each APC would continue to be 50 percent of the no cost/full credit adjustment for the APC.

The proposed and final rules for CY 2012 make no changes to the APCs and devices to which the offset policy applies other than deletion of APC 0418 (Insertion of Left Ventricular Pacing Electrode) from the list of APCs to which the no cost/full credit and partial credit device adjustment policy applies because this APC is deleted in CY 2012, as discussed in section II.A.8.f above.

Table 30 of the final rule lists the APCs to which the payment adjustment policy for no cost/full credit and partial credit devices applies in CY 2012 and indicates the payment adjustment percentages for both no cost/full credit and partial credit circumstances. Table 31 lists the devices to which the payment adjustment policy applies in CY 2012 (pp. 565-568 of the display copy).

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

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

1. Drugs and Biologicals with Expiring Pass-Through Status in CY 2012

The pass-through status of 19 drugs and biologicals expires on December 31, 2011 (Table 32, pp. 576-577 of display copy). All of these drugs and biologicals were approved for pass-through status on or before January 1, 2010 and will have had pass-through payment status for at least 2 years and no more than 3 years by December 31, 2011. The costs of 14 of the 19 drugs and biologicals exceed the $75 OPPS packaging threshold for CY 2012 and will be paid separately at ASP+4 percent. The other 5 products will be packaged in CY 2012; one of these is a diagnostic radiopharmaceutical falling into the always-packaged category.

2. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2012

The proposed rule listed 33 drugs, which were approved for pass-through status between April 1, 2010 and July 1, 2011 and given payment status indicator “G,” with pass-through status continuing in CY 2012. Five additional drugs were granted pass-through status effective October 1, 2011 or January 1, 2012. The final rule continues pass-through status in CY 2012 for these 38 drugs and biologicals because none of them will have had OPPS pass-through status for at least 2 years and no more than 3 years by December 31, 2011 (Table 33, pp. 588-590).

Payment for drugs and biologicals with pass-through status continues to be made at the physician’s office payment rate of ASP+6 percent. The pass-through payment portion of the Medicare payment is the difference between ASP+4 percent, the CY 2012 payment rate for nonpass-through, separately payable drugs, and ASP+6 percent. Determining the pass-through portion of a drug’s payment is important, in part, because this is the amount that is counted in calculating total pass-through payments for the purpose of the conversion factor offset.

For CY 2012, CMS continues its CY 2011 policy of paying for both diagnostic and therapeutic pass-through radiopharmaceuticals based on the ASP methodology. If ASP data are not available for a radiopharmaceutical, CMS sets the payment rate at wholesale acquisition cost (WAC) plus 6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, CMS pays for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. 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 (as described in the next subsection) because, if not on pass-through status, payment for these products would be packaged into the associated procedures.

The final rule continues to set the copayment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals to zero for CY 2012. If these items did not have pass-through status they would be packaged and no separate payment would be made for their use.

The final rule notes that, for CY 2010 and the first two quarters of CY 2011, HCPCS code J1572 (Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg) had a status indicator of "K" and was paid separately as a nonpass-through, separately payable drug. Beginning on July 1, 2011, HCPCS code J1572 was assigned a status indicator of "G" and will be given pass-through status for at least 2, but not more than 3, years.

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: The final rule continues current policies for the "policy-packaged" drug offset to ensure that no duplicate radiopharmaceutical payment is made. CMS deducts from the payment for pass-through radiopharmaceuticals an amount that reflects the portion of the APC payment associated with predecessor radiopharmaceuticals. CMS estimates the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment. CMS utilizes a "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, CMS 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, accordingly, reduces the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Table 34 (pp. 598-599) displays the APCs to which nuclear medicine procedures are assigned in CY 2012 and for which an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status. Currently there is one radiopharmaceutical with pass-through status: HCPCS code C9406 (Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries), which was granted pass-through status beginning July 1, 2011 and will continue to have pass-through status in CY 2012. CMS applies the radiopharmaceutical payment offset policy to pass-through payment for this product.

The radiolabeled product edits in the Outpatient Code Editor require a hospital to report a diagnostic radiopharmaceutical with a nuclear medicine scan in order to receive payment for the nuclear medicine scan. CMS finalizes its proposal, without modification, to continue requiring hospitals to append modifier "FB" to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit in CY 2012. The agency also will continue to reduce the payment amount for procedures in the APCs listed in Table 34 by the full "policy-packaged" offset amount appropriate for diagnostic radiopharmaceuticals. Finally, it continues to require hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit. When a hospital bills an -FB with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table 34 would be reduced by the full "policy-packaged" offset amount appropriate for diagnostic radiopharmaceuticals.

Payment Offset Policy for Contrast Agents: There is currently one contrast agent with pass-through status under the OPPS: HCPCS code A9583 (Injection, gadoxetate disodium, per ml), which was granted pass-through status beginning January 1, 2010, and will continue with pass-through status in CY 2012. CMS deducts from the 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 for pass-through contrast agents, CMS applies the same methodology that is used for radiopharmaceuticals, as described above.

CMS identifies procedural APCs for which a pass-through contrast agent offset could be applicable as any procedural APC with a "policy-packaged" drug amount greater than $20 that is not a nuclear medicine APC identified in Table 34 of the final rule. The APCs that meet these criteria are displayed in Table 35 (pp. 603-604).

CMS will continue to post a file annually at http://www.cms.gov/HospitalOutpatientPPS containing the APC offset amounts, including diagnostic radiopharmaceuticals and contrast agents.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status

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

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

Cost Threshold for Packaging of "Threshold-Packaged Drugs": "Threshold-packaged drugs" under OPPS 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. The final rule updates the packaging threshold for drugs, biologicals, and radiopharmaceuticals from the current $70 to $75 for CY 2012. Using the most recent forecast of the quarterly Producer Price Index (PPI) index levels, the trended dollar amount changed from $77.63 in the proposed rule to $77.44 in the final rule; rounding to the nearest $5 increment, the slight decrease in the trended dollar amount results in a packaging threshold of $75, reduced from $80 in the proposed rule.

To calculate the per day costs for the CY 2012 final rule, CMS used a payment rate of ASP+4 percent for each drug and non-implantable biological HCPCS code based on manufacturer submitted ASP data from the first quarter of 2011. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS used their mean unit cost derived from the CY 2010 hospital claims data to determine their per day cost.

Use of quarterly ASP data: CMS continues to use quarterly ASP updates as follows:

- 4th quarter of 2010: budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B for the OPPS 2012 proposed rule;
- 1st quarter of 2011: budget neutrality estimates, packaging determinations, and impact analyses for the OPPS 2012 final rule;
- 2nd quarter of 2011: payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the final rule;
- 3rd quarter of 2011: payment rates effective January 1, 2012 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, 2012 for drugs and biologicals 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. In the final rule. CMS continues its policy to make an annual packaging determination for a HCPCS code for the final rule. Only HCPCS codes that are identified as separately payable in the final rule will be subject to quarterly updates; codes that are identified as packaged in the final rule will have packaged status for the entire year.

The final rule packaging status of several threshold-packaged drugs is different in the final rule than in the proposed rule due to the use of more data for the packaging determination. For its CY 2012 final rule determinations, CMS applied these rules, which are unchanged from past years:

i. HCPCS codes that were separately payable in CY 2011 and were proposed for separate payment in CY 2012 will continue to be separately payable in CY 2012 even if the updated data used for the CY 2012 final rule indicate per day costs equal to or less than $75.
ii. HCPCS codes that were packaged in CY 2011, proposed for separate payment in CY 2012, and then have per day costs equal to or less than $75 based on the updated data used for the CY 2012 final rule will remain packaged in CY 2012.
iii. HCPCS codes for which CMS proposed packaged payment in 2012 but then have per day costs greater than $75 based on the updated data used for the 2012 final rule are separately payable in CY 2012.

For CY 2012:

- 3 HCPCS codes will continue to be paid separately based on rule i despite having final rule costs per day lower than $75: J2513, J3310, and J9351;
- 1 HCPCS code will packaged based on rule ii even though its proposed rule per day cost exceeded $75: J2597; and
- 13 HCPCS codes will be paid separately based on rule iii because their final rule costs per day are at least $75: 90378, J0364, J1324, J1642, J1644, J1756, J2700, J3030, J9070, J9185, J9206, J9390, and Q4103.

For 2012, CMS continues its policy of not exempting 5-HT3 antiemetic products from the standard packaging methodology, resulting in packaging payment for all of the 5-HT3 antiemetics except palonosetron hydrochloride (J2469).

Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages: For CY 2012, CMS continues 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 applies are listed in Table 36 of the final rule (pp. 625-628). Using updated data and the lower $75 threshold, the final rule designates two HCPCS codes, J1642 and J1644, packaged in the proposed rule, as separately payable and assigns status indicator “K” to them.

Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals ("Policy-Packaged" Drugs and Devices): For CY 2012, CMS continues these policies:

- 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 OPPS 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.

The final rule includes an extensive discussion of commenters' concerns with the CMS decision, which it reaffirms in the final rule, to policy-package all contrast agents and diagnostic radiopharmaceuticals. CMS disagrees and provides a lengthy rationale for its decisions.

Three of the products with expiring pass-through status for CY 2012 are biologicals that are only surgically implanted according to their FDA-approved indications. These products are described by HCPCS codes C9361 (Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length), C9362 (Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc), and C9364 (Porcine implant, Permacol, per square centimeter). CMS finalizes its proposal to package payment for these products in CY 2012 and assigns them status indicator "N."

For nonpass-through biologicals that may sometimes be used as implantable devices, CMS continues to instruct hospitals to not bill separately for the HCPCS codes for these 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: CMS estimates the aggregate cost of drugs and biologicals from the charges on hospital claims in a calculation that the agency believes captures both the average hospital acquisition cost of the drugs and biologicals, which the statute requires for payment of SCODs, and the associated pharmacy overhead cost. CMS compares these estimated costs to manufacturer-reported ASP data to establish an equivalency between the two data sources – for example, that average cost from claims data equals ASP + X percent. The final rule continues to use this methodology with an adjustment for pharmacy overhead that was first applied to set ASP-based payment rates in CY 2010.

Beginning with CY 2010 and including the proposed rule for CY 2012, CMS acknowledges that its method of converting billed charges to costs attributes, to an unknown extent, some portion of pharmacy overhead costs to packaged drugs and biologicals that more appropriately should be attributed to separately payable drugs. CMS concludes that without an adjustment, its cost estimation methodology may understate the cost of pharmacy overhead costs associated with separately payable drugs and biologicals and may overstate the pharmacy overhead cost associated with packaged drugs and biologicals. Therefore, beginning with CY 2010, CMS redistributes a portion of pharmacy overhead costs from packaged drugs to separately payable drugs.

For the CY 2011 final rule, CMS redistributed $150 million from the total pharmacy overhead costs of packaged drugs and biologicals with HCPCS codes and reported ASP data; and it redistributed $50 million from total pharmacy overhead costs of uncoded packaged drugs and biologicals without an ASP, for a total redistribution of $200 million in pharmacy overhead costs from coded and uncoded packaged drugs to separately payable drugs. CMS states that these redistributions of pharmacy overhead costs occur only among drugs and biologicals and that no redistribution of costs occurs from other services to drugs and biologicals or vice versa. The CY 2011 redistribution resulted in a final payment rate for separately payable drugs and biologicals of ASP+5 percent, compared to ASP-1 percent before the redistribution. The table below, from the CY 2012 final rule, summarizes the redistributions for CYs 2010, 2011 and 2012; for CY 2012, the final rule columns show the ASP-equivalent payment using the proposed rule redistributions.

TABLE 38.—INTRA-RULEMAKING CHANGES IN THE ASP+X CALCULATION USING FIXED-AMOUNT

	Packaged Drug Redistribution Amount (in millions)		Total Drug Costs (in millions)		ASP+X Percent	
	Proposed	**Final**	**Proposed**	**Final**	**Proposed**	**Final**
CY 2010	$200	$200	$3,671	$4,136	ASP+4	ASP+4
CY 2011	$200	$200	$4,155	$4,604	ASP+6	ASP+5
CY 2012	$215	$215	$4,680	$5,443	ASP+4	ASP+3*

* ASP+3 is displayed here for illustrative purposes only, and would have only occurred had CMS finalized its proposed drug distribution methodology in CY 2012 without modification.

b. Payment Policy for CY 2012: CMS determined the amounts to be reallocated for the CY 2012 proposed rule by updating the CY 2011 reallocation levels to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. CMS applied the PPI for Prescription Drugs, the same index the agency has used for the past 5 years to update the drug packaging threshold. With the inflation data available at the time of the proposed rule, the $150 million previously

redistributed from coded packaged drugs and biologicals with reported ASP data would be $161 million, and the $50 million previously redistributed from the cost of uncoded packaged drugs and biologicals without an ASP would be $54 million. Thus, CMS proposed to reallocate a total of $215 million from the costs of coded and uncoded packaged drugs and biologicals to separately payable drugs and biologicals; this is equivalent to the $200 million redistributed in 2011 adjusted for inflation. With the pharmacy overhead adjustment, the proposed rule provided a CY 2012 payment rate for separately payable drugs and biologicals of ASP+4 percent. Without the redistributions, the payment rate for these drugs and biologicals would have been ASP-2 percent.

The final rule notes a consensus among commenters concerning the necessity of a redistribution methodology to correct for relatively high and low ASP values for packaged and separately payable drugs using CMS' standard methodology. Commenters expressed concern over the intra-rulemaking fluctuation that can occur with the proposed methodology and requested that CMS consider addressing it. Using an unaltered proposed rule methodology in the final rule would result in a payment rate for separately payable drugs of ASP+3 percent in the final rule, as shown in Table 38 above. CMS had warned in the proposed rule that, in past years, the proposed ASP+X amount decreased by at least 1 percentage point with updated data used for the final rule.

The final rule observes that a significant cause of the fluctuation is the use of additional cost and claims data between the proposed rule and final rules in order to include a full year of data. Table 38 shows that total drug costs used to set payment rates increased from $4.7 billion to $5.4 billion between the proposed and final rules. Applied to the calculation of the ASP+X percent, using the higher level of total drug costs but fixing the dollar amount to be redistributed at the proposed rule level ($215 million) results in the ASP-equivalent payment rate falling from ASP+4 in the proposed rule to ASP+3 in the final rule.

Thus, CMS finalizes the proposed rule methodology with a modification. Rather than holding the redistribution amounts constant between the proposed and final rules – a redistribution of $161 million from coded packaged drugs and $54 million from uncoded packaged drugs – the final rule holds constant the proportions of overhead costs that are redistributed from the two categories; the proportions are 35 percent and 10.7 percent, respectively. In summary, the final rule updates the CY 2011 redistribution amounts by the PPI for Prescription Drugs (yielding $215 million), calculates the resulting proportions, and then holds the proportions constant between the proposed and final rules resulting in redistributions of $169 million (or 35 percent) from coded packaged drug overhead cost and $71.3 million (or 10.7 percent) of uncoded packaged drug overhead cost. The final rule redistributes a total amount of $240.3 million and maintains the payment rate for separately payable drugs at ASP + 4 percent. Table 39, copied below from the final rule, shows the ASP equivalents after application of the pharmacy overhead adjustment.

TABLE 39.—CY 2012 PHARMACY OVERHEAD ADJUSTMENT PAYMENT METHODOLOGY: ASP+X CALCULATION

	Total ASP Dollars for Drugs and Biologicals in Claims Data (in millions)*	Total Cost of Drugs and Biologicals in Claims Data *after adjustment* (in millions)**	Ratio of Cost to ASP (column 3/column 2)	ASP+X Percent
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	$595***	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	$251	$565	2.25	ASP+125
Separately Payable Drugs and Biologicals with a reported ASP	$4,137	$4,284	1.04	ASP+4
All Coded Drugs and Biologicals with a reported ASP	$4,388	$4,777	1.09	ASP+9

*Total July 2011 ASP dollars (ASP multiplied by drug or biological units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.
**Total cost in the CY 2010 claims data for drugs and biologicals
***Pharmacy revenue code costs without HCPCS codes.

The final rule 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.

The final rule continues to include claims data from 340B hospitals in the ASP + X calculations and also continues to pay 340B hospitals using the same payment rates for separately payable drugs and biologicals as are paid to hospitals that do not participate in the 340B program. Commenters continue to oppose differential payment for hospitals based on their 340B participation status but many believe that data from 340B hospitals should be excluded in making the ASP + X calculation.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2012, CMS continues its policy, first established in 2010, to pay for all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+4 percent when manufacturers submit the necessary ASP data, consistent with the final payment rate for separately payable drugs and biologicals described above. CMS allows manufacturers to submit the ASP data in a patient-specific dose or patient-ready form in order to calculate the ASP amount for a given HCPCS code. CMS will use 2010 mean

unit cost data derived from hospital claims data to set the payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable.

4. Payment for Blood Clotting Factors

For 2012, CMS finalizes its proposal to continue to pay for blood clotting factors using the same methodology as for other nonpass-through separately payable drugs and biologicals under the OPPS, at the payment rate of ASP+4 percent. It also will update the furnishing fee based on the percentage increase in the CPI following the same methodology it has used since 2008. The updated amount will be based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending in June 2011. CMS will announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through program instructions and postings on the CMS Web site.

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

For 2012, CMS continues to pay for new 2012 drugs and biologicals (excluding contrast agents, diagnostic radiopharmaceuticals and implantable biologicals) and therapeutic radiopharmaceuticals using the same methodology (ASP+4 percent) as for other nonpass-through separately payable drugs and biologicals.

For 2012, CMS is continuing the 2011 policy of packaging payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data (those new 2012 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.

In the absence of ASP data, for 2012, CMS continues the policy first implemented in 2005 of using wholesale acquisition costs (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 OPPS will be adjusted based on the ASP methodology using the ASP+4 payment amount.

New 2012 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 2012 OPPS final rule. They are assigned comment indicator "NI" in Addendum B to reflect that their interim final OPPS treatment is open to public comment.

CMS continues its existing methodology for determining the 2012 packaging status of nonpass-through drugs and biologicals that were payable in 2010 and/or 2011 but for which CMS does not have 2010 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+4 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. The final rule packages items with an estimated per administration cost of less than or equal to $75. These products, their estimated units per day, status indicators and final APCs/packaging status in 2012 are listed in Table 40 of the final rule (pp. 732-733 of the display copy).

CMS continues to assign status indicator "E" to drugs and biologicals that were payable in 2010 but for which CMS lacks both 2010 claims data and pricing information for the ASP methodology. The 11 products that fall into this category are listed in Table 41 of the final rule (pp. 735-736 of the display copy). If pricing information becomes available for these products in 2012, CMS will assign the products status indicator "K" and pay for them separately for the remainder of 2012.

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

The CMS final estimate of total spending for drug and device pass-through payments during CY 2012 is $89.1 million, or 0.22 percent of total OPPS projected payments for CY 2012.

A. Devices

CMS projects $57 million total pass-through spending attributable to device categories in CY 2012, of which $47 million is projected for the first group of device categories, and $10 million for the second group. The final estimate for the first group is $12 million higher than the estimate in the proposed rule due in part to the identification of two additional new device categories receiving pass-through payments as of October 2011 that will continue for payment in CY 2012. The three device categories in this group are C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)), C1830 (Powered bone marrow biopsy needle), and C1840 (Lens, intraocular (telescopic)).

CMS will continue to use the general methodology described in the CY 2008 OPPS/ASC final rule while taking into account recent experience in approving new pass-through devices, and will also include implantable biologicals newly eligible for pass-through payment in the estimate for the second group.

B. Drugs and Biologicals

CMS projects $32.1 million in total pass-through spending attributable to drugs and nonimplantable biologicals in both groups in CY 2012, of which $21.5 million is

projected for the first group of drugs and nonimplantable biologicals, and $10.6 million for the second group. CMS considers radiopharmaceuticals as drugs for pass-through purposes and includes them in its estimates for drugs and biologicals.

CMS finalizes methodologies used to project spending for each group. For the first group, the agency projects utilization based on physician office data, information in pass-through applications, historical hospital claims data, as well as other data sources, and for the second it uses utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity, as well recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals.

VII. OPPS Payment for Hospital Outpatient Visits

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 CY 2012. The list of HCPCS codes for hospital reporting is presented in Table 42 of the final rule. CMS notes that it accepts APC panel recommendations to continue to report claims data for clinic and emergency department visits and observation services, to report changes in utilization patterns or cost to the Visits and Observation Subcommittee, and to continue work of the Subcommittee.

A. Clinic Visits: New and Established Patient Visits

CMS will continue to distinguish between new and established patient status by considering a patient visit to be established if the patient was registered as an inpatient or outpatient of the hospital, including its off-campus provider-based clinic or emergency department, within the past 3 years of the patient's visit to the hospital. CMS cites as support for its policy continued significant cost differences from hospital claims data and its belief that treatment of a patient who was recently treated at the hospital requires significantly fewer resources than a patient not treated at the hospital for several years, and declines to accept commenters' suggestions to only recognize established visits and calculate rates based on a blend of median costs for established and new visits.

CMS will continue to calculate median costs for clinic visit APCs (0604 through 0608) under the OPPS using historical hospital claims data, and to exclude claims for visits eligible for payment through extended assessment and management composite APC 8002. CMS will also continue to assign HCPCS code G0379 (Direct Admission of Patient for Hospital Observation Care) to APC 0604 and composite APC 8002, disagreeing with a commenter's suggestion and rationale to assign it to APC 0616 (Level 5 Type A Emergency Visit) and to composite APC 8003 (Level II Extended Assessment and Management).

B. Emergency Department Visits

CMS will continue to pay for Type B emergency department visits in CY 2012 based on median costs through five levels of APCs (0626, 0627, 0628, 0629 and 0630) and assigns HCPCS codes G0380, G0381, G0382, G0383, G0384, respectively, to those APCs. CMS believes this pays appropriately for each level of Type B emergency department visit based on estimated resource costs from the most recent claims data. In calculating median costs for the emergency department visit and critical care APCs (0609 through 0617 and 0626 through 0630), CMS excludes claims for visits eligible for payment through extended assessment and management composite APC 8002.

The final median costs (unchanged from the proposed rule) for Clinic Visit APCs, Type B Emergency Department Visit APCs, and Type A Emergency Department Visit APCs are contained in Table 43 of the final rule and are reproduced below:

Visit Level	CY 2012 Clinic Visit Approximate APC Median Cost	CY 2012 Type B Emergency Department Approximate APC Median Cost	CY 2012 Type A Emergency Department Approximate APC Median Cost
Level 1	$50	$41	$52
Level 2	$75	$59	$89
Level 3	$105	$94	$142
Level 4	$138	$141	$229
Level 5	$178	$271	$340

In CY 2012, CMS will continue the methodology it implemented in CY 2011 to 1) calculate a payment rate for critical care services based on historical data which includes costs of ancillary services and 2) implement claims processing edits that conditionally package payment for ancillary services previously included in CPT's definition of critical care services before CY 2011 with critical care services furnished on the same date. CMS rejects a recommendation for a modifier to identify ancillary services provided outside the critical care period, believing that all services furnished in conjunction with critical care as part of a single encounter are included in the critical care period, and noting that hospitals may use HCPCS modifier "-59" to indicate when an ancillary procedure or service is distinct or independent from critical care when performed on the same day but during a different encounter. In response to a suggestion that it review multiple cost centers, CMS notes that it bases its cost estimate of each packaged ancillary service on the most specific cost center to which the revenue code reported with the service maps and then packages the cost into the median critical care cost calculation.

C. Visit Reporting Guidelines

As it has consistently for the past few years, CMS again declines to establish national guidelines to report visits for CY 2012 believing hospitals are billing in an appropriate

manner and should continue to report visits according to their own internal hospital coding guidelines. CMS sought comment on the slight shift over time to higher numbers of level 4 and level 5 visits for Type A emergency department visit levels. Commenters suggested an analysis of the impact of the revised definition of "established patient visit" on this trend, including an evaluation of secondary diagnoses on these visit claims. CMS indicates it will continue to examine its data and examine any changes or trends correlating to this slight shift, but CMS generally believes hospitals are billing in an appropriate manner. CMS continues to expect that internal hospital coding guidelines will comport with principals listed in the CY 2008 OPPS/ASC final rule and in response to a suggestion notes that if the AMA developed facility-specific CPT codes for reporting visits provided in HOPDs, it would consider them.

VIII. Payment for Partial Hospitalization Services

A. Partial Hospitalization Program (PHP) APC Update for CY 2012

For CY 2012, CMS will continue to compute four separate PHP APC per diem rates, two each for community mental health center (CMHC) PHPs and for hospital-based PHPs, and will update those rates based on the median cost levels calculated using the most recent claims data from CY 2010 for each provider type. The final median per diem costs are contained in Tables 44 and 45 of the final rule and are reproduced below:

Category	CMHC PHPs	Hospital-based PHPs
Days with 3 services	$97.64	$160.74
Days with 4 or more services	$113.83	$191.16

Commenters reacted with concern about the decrease in rates for PHPs generally and expressed concern about the ability of providers to maintain programs as well as the impact on access for beneficiaries, especially vulnerable populations. CMS relies on its claims data and also infers that a portion of the decrease for CMHCs is attributable to fraud and abuse efforts, and for hospitals, the absence of data from one provider from the claims data in CY 2010. Hospital commenters seem incredulous that the removal of a single provider could have such dramatic results, and CMHCs point out that fraud and abuse efforts do not decrease operating costs of providers and instead result in the elimination of fraudulent providers from the program. CMS rejects arguments that reduced rates will occasion the shuttering of programs and instead posits program closures are more likely attributable to poor business management or marketing decisions, and it also notes that should PHP programs close, there are other outpatient mental health benefits under Medicare. CMS also rejects a request to freeze rates at the CY 2011 level or to mitigate the rate reductions.

B. Paladin Community Mental Health Center v. Sebelius

A CMHC and one of its outpatients challenged the CMS change in payment calculation methodology, especially the use of non-hospital data. The district court that heard *Paladin Community Mental Health Center v. Sebelius* dismissed the complaint, and

associated request for a preliminary injunction, and accepted the government's arguments that CMS has broad authority to establish payment rates under section 1833(t) of the Act and that the statutory term "based on" does not mean "based exclusively on". Thus CMS believes it has ample authority to base relative payment rates for CMHC PHP services solely on CMHC data. CMS further believes that the statutory mandate to establish rates under section 1833(t)(2)(C) of the Act applies to APCs established at the beginning of the OPPS (in 2000) as well as to newly added APCs. CMS finds support for this position in section 1833(t)(9)A) of the Act which requires review and revision of groups, relative payment rates, and wage and other adjustments under section 1883(t)(2) of the Act to take into account "..., the addition of new services, new cost data and other relevant information and factors.". Thus CMS finds it may stop using hospital data after the original establishment of the relative payment weights for a given APC, which may well impact updates to OPPS services other than PHP services.

C. Separate Threshold for Outlier Payments to CMHCs

For CY 2012, CMS allocates 0.12 percent of outlier payments to CMHCs for PHP outliers and sets the outlier threshold of CMHCs for CY 2012 at 3.40 times the APC payment amount and the CY 2012 outlier percentage applicable to costs in excess of the threshold at 50 percent. As proposed, CMS does not set a dollar threshold for CHMC outlier payments.

D. Regulatory Impact

CMS estimates that the combined impact on CMHCs for CY 2012 will be a 30.8 percent decrease in payments as a result of the full transition in CY 2012 to payment rates for partial hospitalization services at CMHCs, the continuation of the four separate APC method of payment calculation (based on cost report and claims data submitted by CMHCs), and other adjustments (including the 1.9 percent OPD fee schedule increase factor).

IX. Procedures That Would Be Paid Only as Inpatient Procedures

Based on additional input from the August 2011 APC Panel meeting and from stakeholders, CMS removes 10 procedures (7 more than proposed) from the inpatient list: CPT code 0184T, 20930, 20931, 21346, 22551, 22554, 35045, 43281, 43770, and 54650. These procedures and their CPT codes, long descriptors, APC assignments and status indicators are displayed in Table 46 of the final rule.

CMS did not accept a number of APC Panel recommendations to remove procedures from the inpatient list due principally either to the clinical intensity of services or the low volume in the hospital outpatient setting, including procedures described by CPT codes 22552, 22585, 54411, 61107, 61210, and 63267. CMS reevaluated data on CPT code 54411 (and also 54417) and suggestions from commenters, but the agency remains

convinced that the procedures may only be safely performed in the inpatient setting due to their invasive and complicated nature.

Commenters made a range of suggestions, including elimination of the inpatient list altogether, establishment of an appeals process, and sufficiency of Joint Commission accreditation or Medicare conditions of participation as evidence of safety. Commenters also complained that neither CMS nor hospital education efforts are effective. CMS rejects each of the suggestions noting that the inpatient list serves as a mechanism not only to ensure safety for Medicare beneficiaries (which is more effective than accreditation and conditions of participation afford) but also as a manner to protect beneficiaries from excessive cost-sharing or other liabilities. CMS declines to establish an appeals mechanism asserting that notice and comment rulemaking affords stakeholders sufficient voice and representation, and reminds stakeholders that ultimately they are responsible for knowing which procedures are on the inpatient list and that hospitals should be aware which services are being provided in their outpatient settings.

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

A. Background

CMS restates its position and actions with respect to requirements for physician supervision for hospital outpatient diagnostic and therapeutic services before and after its CY 2009 “restatement and clarification” of the requirements. With respect to hospital outpatient therapeutic services, CMS reminds readers of its definition of direct supervision[1]. In CY 2010, CMS further clarified that the direct supervision requirements applied to services furnished at CAHs, considering it a technical correction. CAHs and small rural hospitals requested an exemption from the policy noting that it was at odds with longstanding and prevailing practice in rural communities where they generally function with reduced levels of supervision of therapeutic services and stating the many difficulties for them to meet the requirements; in response, CMS issued a notice of nonenforcement of the direct supervision requirement for CY 2010 and extended it through CY 2011.

In CY 2011, CMS identified a limited set of nonsurgical extended duration therapeutic services for which a two-phase supervision requirement applies under which direct supervision is required for the initiation of the service followed by general supervision for the remainder of the service. These are services that frequently extend beyond normal business hours and largely consist of a significant monitoring component typically

[1] Direct supervision generally means that the physician or appropriate NPP is immediately available to furnish assistance and direction throughout the performance of a therapeutic service or procedure but is not required to be in the room where the service is performed. CMS removed previous physical boundary requirements and permits the supervising physician or NPP to be immediately available which is defined as physically present, interruptible, and able to furnish assistance and direction thought the performance of the procedure.

conducted by nursing or other auxiliary staff and that are of sufficiently low risk so as not to require direct supervision often during the furnishing of the service.

CMS also notes that it received very few comments on CY 2010 final rule revisions to outpatient hospital diagnostic services requiring physician supervision of nonphysician practitioners performing diagnostic tests unless the NPP is specifically exempted and neither proposed nor makes any changes to those revisions in the final rule.

CMS finalizes, with some modifications described below, all its proposals in the CY 2012 OPPS/ASC proposed rule with comment period. CMS:

- Establishes the Federal Advisory APC Panel as the independent review body to evaluate potential assignment of supervision requirements for outpatient hospital therapeutic services;
- Uses for purposes of outpatient hospital therapeutic services the definitions of personal and general supervision established for purposes of the MPFS, and clarifies that NPPs authorized in section 410.27(a)(1)(iv)(C) to provide direct supervision may furnish general or personal supervision as required by CMS;
- Extends its nonenforcement policy for direct supervision of outpatient therapeutic services in CAHs and small rural hospitals through CY 2012 to afford time to the facilities to meet the appropriate supervision standards; and
- Clarifies that supervision requirements apply with respect to all services and supplies furnished to hospital or CAH outpatients, not just "incident to" services under section 1861(s)(2)(B) of the Act.

B. Issues Regarding the Physician Supervision of Hospital Outpatient Therapeutic Services Raised by Hospitals and Other Stakeholders

1. Independent Review Process

CMS will use the Federal Advisory APC Panel as the independent review body to evaluate potential assignment of lower or higher supervision requirements for outpatient hospital therapeutic services due in part to its status as a FACA committee (thereby requiring balance of viewpoints and inclusion of representatives from affected stakeholders), the weight its recommendations carry, and its clinical and nonclinical perspectives. To make the APC Panel more suitable for this duty, CMS adds four members to the composition of the panel, two each to represent CAHs and small rural PPS hospitals (the same hospitals protected under the notice of nonenforcement of direct supervision). CAHs may not, but small rural PPS hospital will, participate in APC Panel deliberations about APC groups and weights under the OPPS. Commenters had asked that 8 additional members be appointed to the APC Panel and also suggested that those representatives be limited to clinicians; CMS rejects both those suggestions. CMS instead urges stakeholder groups, such as specialty associations, to nominate qualified candidates who CMS believes should represent the types of practitioners who furnish the services. CMS notes that the Panel's scope of review is limited to evaluating supervision standards and presenting recommendations to the full panel; it will not evaluate or recommend the types of practitioners that should be permitted to supervise.

Despite strong commenter opposition, CMS finalizes its proposal to issue its decisions through subregulatory guidance rather than following notice and comment rulemaking procedures. CMS believes it will afford interested parties more opportunity (at least twice a year) to submit requests and greater flexibility for CMS to respond more nimbly to access or practice of care concerns. CMS will post its decisions on the OPPS Web site for a 30-day period of public review and comment (rather than the 45- or 60-day review sought by commenters), and will finalize decisions within 60 days which will take effect either in July or January following the most recent APC Panel meeting. CMS notes that this is similar to the process used to set supervision levels for diagnostic services under the MPFS.

The APC Panel will recommend the appropriate supervision level (general, direct, or personal) that ensures an appropriate level of quality and safety delivery of a given service (defined by a HCPCS or CPT code). Recommendations are based on clinical and evaluation criteria, especially an assessment of the likelihood that a supervisory practitioner would need to reassess the patient and modify treatment during or immediately after the therapeutic intervention, or provide guidance or advice to the individual providing the service. CMS establishes six criteria the APC Panel must consider in making recommendations: the complexity of the service, the acuity of patients receiving the service, the probability of unexpected or adverse patient outcomes, the expectation of rapid clinical changes during the service, recent changes in technology or practice patterns that affect the safety of a procedure, and the clinical context in which the service is delivered. CMS emphasizes that supervision means more than the mere capacity to respond to an emergency; it includes availability to reassess the patient and modify treatment as needed on a nonemergency basis, to redirect or take over performance of the service, and to issue additional orders.

CMS rejects commenters' requests to set general supervision as the default supervision level and reiterates that direct supervision is the appropriate level for "incident to" hospital outpatient services. CMS also notes the APC Panel may recommend personal supervision as the appropriate level for some services, including for purposes of ensuring adequate supervision of auxiliary personnel or personnel in training. CMS further notes that in the case of supervisory practitioners who are unavailable in person, the Panel shall apply definitions of general, direct, and personal supervision under regulations which distinguish between direct and general supervision based on the physical presence of the practitioner; the Panel's scope will not include changes to the definitions or recommending another type of supervision based on the supervisory practitioner's location. CMS also rejects a commenter recommendation to set supervision levels for services no higher than those that apply under the MPFS.

CMS will use standard APC Panel protocols for meetings (twice a year) and will set the agenda for requests of supervision level changes by assigning priority for consideration by service volume, total expenditures, and frequency of requests, including those requested through public comments on the CY 2010 and CY 2011 OPPS/ASC proposed rules. Requests must be justified and supported by clinical evidence if

available. CMS may independently seek APC Panel review for supervision level for services. CMS will forward to the APC Panel a request for reconsideration of a previously evaluated service supervision level if the requester shows new evidence to support a policy change such as a change in clinical practice due to new technology or techniques; the Panel will review the service using the process for evaluating a new request.

2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

Citing longstanding policy and manual guidance, CMS clarifies that supervision requirements apply with respect to all services and supplies furnished to hospital or CAH outpatients maintaining that it has long considered "incident to" services to mean all hospital outpatient services, including services listed in sections of the Act other than section 1861(s)(2)(B). CMS modifies the regulation text in §410.27 to define the services to mean "all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or practitioner in the treatment of the patients" which parallels the definition under the Medicare Benefit Policy Manual. CMS believes that there is a similar clinical level of risk in therapeutic services not described in section 1861(s)(2)(B) as apply to services specifically defined as "incident to" services, and does not believe that large classes of services were ever intended to be omitted from the supervision requirement. In response to a comment seeking clarification on the applicability of the modification to services not paid under the OPPS, such as physical therapy services or services paid under other fee schedules, CMS notes that §410.27 requirements are facility component requirements of hospital outpatient therapeutic services and do not apply to the professional component of the services or to services paid under other fee schedules.

CMS also makes technical changes to the regulation text to correct outdated cross-references, and inserts "CAH" in the definition of nonsurgical extended duration therapy services clarifying that CAHs are subject to all aspects of §410.27. CMS rejects the argument that it should apply the CAH CoP governing standards for emergency personnel as the applicable supervision standards for payment purposes; the agency distinguishes between general condition of participations for a facility and specific supervision levels required for a service and finds no need to reconcile the two.

XI. Final CY 2012 OPPS Payment Status and Comment Indicators

CMS did not receive any comments on its proposed OPPS Payment Status Indicator definitions for CY 2012, and finalizes them, without modification. The final status indicators and definitions are listed in the tables under sections XI.A.1., 2., 3., and 4. of the final rule.

CMS did not receive any comments on its proposed Comment Indicator definitions for CY 2012, and finalizes them without modification. CMS will continue to use comment indicators “CH” and “NI” for CY 2012. The final comment indicators and definitions are

listed in Addendum D2 found on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS.

XII. OPPS Policy and Payment Recommendations

CMS reiterates that it looks forward to reviewing the results of MedPAC's examination of what it sees as a trend of physician practices and ambulatory surgical centers to reorganize as hospital outpatient entities to maximize program payments.

CMS notes that it took the findings of the OIG report, "Payment for Drugs under the Hospital Outpatient Prospective Payment System" (OIG-03-09-00420), when developing the final OPPS drug payment policies for CY 2012.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

The CY 2012 OPPS/ASC final rule updates the Medicare ASC payment system to implement statutory requirements and changes arising from continuing experience with the payment system. CMS indicates the relative payment weights and amounts for services furnished in ASCs, specified Healthcare Common Procedure Coding System (HCPCS) codes to which these changes apply and other important rate-setting information for the CY 2012 ASC payment system. As described in section XIV.K of this summary, the final rule also establishes a quality reporting program for ASCs.

It is important to note that the ASC payment system is closely patterned after the OPPS payment system. Thus, the reader is strongly encouraged to review the policy changes to the CY 2012 OPPS payment system described elsewhere in this summary.

The ASC payment system was revised beginning CY 2008 and was given a four-year transition period from that date, with the exception of HCPCS codes newly payable in the ASC setting. Thus, beginning January 1, 2011, ASCs are being paid using 100 percent of the new payment amounts.

A. Estimated CY 2012 Impact

According to CMS, the final rule increases payment rates to ASCs by 1.6 percent in CY 2012. CMS estimates it will pay about 5,000 ASCs a total of approximately $3.5 billion for CY 2012.

For the second year of the fully implemented payment system in CY 2012, CMS estimates that the cardiovascular system procedures specialty group will receive a 3.0 percent decrease and auditory system procedures a 2.0 percent decrease in the aggregate payment amount. Aggregate Medicare payments for the eye and ocular adnexa specialty and respiratory system groups are estimated to increase 1 percent over their CY 2011 payment levels. Also displayed is an estimate of Medicare ASC payments for a group of separately payable covered ancillary items and services which are estimated to decrease about 26 percent. CMS attributes most of this decrease to

the expiration of the active class of New Technology Intraocular Lenses (NTIOLs) for reduced spherical aberration. All the remaining groups are estimated to receive an increase. CMS notes that aggregate payments for these items and services are estimated to increase about 2.0 percent for CY 2012 compared to CY 2011. Table 61 of the final rule, reproduced below, shows the estimated impact by surgical specialty group.

TABLE 61. ESTIMATED IMPACT OF THE FINAL CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2012 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group	Estimated CY 2011 ASC Payments (Millions)	Estimated CY 2012 Percent Change
Total	$3,369	2%
Eye and ocular adnexa	$1,440	1%
Digestive system	$685	4%
Nervous system	$431	0%
Musculoskeletal system	$415	2%
Genitourinary system	$149	5%
Integumentary system	$130	1%
Respiratory system	$43	2%
Cardiovascular system	$31	-3%
Ancillary items and services	$29	-26%
Auditory system	$10	-2%
Hematologic & lymphatic systems	$4	5%

Table 62 (see below) shows the estimated impact of the CY 2012 payment system on aggregate ASC payments for selected procedures during CY 2012. The table displays 30 procedures receiving the most estimated CY 2012 ASC payments. The procedures are sorted in descending order by estimated program payment.

TABLE 62. ESTIMATED IMPACT OF THE FINAL CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code	Short Descriptor	Estimated CY 2011 ASC Payments (millions)	Estimated CY 2012 Percent Change
66984	Cataract surg w/iol, 1 stage	$1,080	1%
43239	Upper GI endoscopy, biopsy	$155	-1%
45380	Colonoscopy and biopsy	$133	4%
45378	Diagnostic colonoscopy	$100	4%
45385	Lesion removal colonoscopy	$85	4%

CPT/HCPCS Code	Short Descriptor	Estimated CY 2011 ASC Payments (millions)	Estimated CY 2012 Percent Change
66982	Cataract surgery, complex	$79	1%
62311	Inject spine l/s (cd)	$67	2%
64483	Inj foramen epidural l/s	$66	2%
66821	After cataract laser surgery	$56	0%
29826	Shoulder arthroscopy/surgery	$42	-37%
15823	Revision of upper eyelid	$39	0%
63650	Implant neuroelectrodes	$38	-3%
64493	Inj paravert f jnt l/s 1 lev	$32	2%
G0105	Colorectal scrn; hi risk ind	$32	5%
29881	Knee arthroscopy/surgery	$30	3%
64721	Carpal tunnel surgery	$30	3%
63685	Insrt/redo spine n generator	$26	3%
29880	Knee arthroscopy/surgery	$25	3%
G0121	Colon ca sren not hi rsk ind	$25	5%
43235	Upper gi endoscopy, diagnosis	$24	-1%
45384	Lesion remove colonoscopy	$24	4%
52000	Cystoscopy	$20	-5%
28285	Repair of hammertoe	$19	2%
64590	Insrt/redo pn/gastr stimul	$16	0%
62310	Inject spin c/t	$16	2%
67904	Repair eyelid defect	$16	3%
26055	Incise finger tendon sheath	$16	4%
29827	Arthroscop rotator cuf repr	$15	23%
67042	Vit for macular hole	$15	4%
50590	Fragmenting of kidney stone	$15	29%

B. Treatment of New Codes

Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes. CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, CMS recognizes the following codes on CMS claims: (1) Category I CPT codes, which describe medical services and procedures; (2) Category III CPT codes, which describe new and emerging technologies, services and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes. CPT codes are established by the

American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. CMS will continue its policy, finalized in the CY 2008 OPPS/ASC final rule, to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations in the annual OPPS/ASC final rule regarding whether they meet the criteria for payment in the ASC setting and, if so, whether they are office-based procedures. In addition, CMS will identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. New HCPCS codes that were released in April and July 2011 were included in the CY 2012 OPPS/ASC proposed rule.

In addition, CMS will continue the policy of implementing through the ASC quarterly update process new mid-year CPT codes, generally Category III CPT codes, that the AMA releases in January to become effective the following July, and releases in July to become effective the following January.

Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2011 for Which CMS Solicited Public Comments in the CY 2012 OPPS/ASC Proposed Rule. CMS made effective for April 1 or July 1, 2011 a total of 13 new level II HCPCS codes that covered ancillary services (see Tables 48 and 49 in the final rule) and 6 new Category III CPT codes (see Table 50 in the final rule) that were not addressed in the CY 2011 OPPS/ASC final rule with comment period. CMS is finalizes these codes in the CY 2012 OPPS/ASC final rule with comment period.

Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which CMS Is Soliciting Public Comments in the CY 2012 OPPS/ASC Final Rule. For CY 2012 CMS is including in Addenda AA and BB to this final rule with comment period the new Category I and III CPT codes effective January 1, 2012 that are incorporated in the January 2012 ASC quarterly update and the new Level II HCPCS codes, effective October 1, 2011 or January 1, 2012, released by CMS in its October 2011 and January 2012 ASC quarterly update. The new codes are flagged with the comment indicator “NI” to indicate that CMS has assigned them an interim payment status.

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

Covered Surgical Procedures

- Additions to the List of ASC Covered Surgical Procedures

  CMS did not propose additions to the list of ASC covered surgical procedures for CY 2012 in the CY 2012 OPPS/ASC proposed rule. However, in response to public comments to add 232 CPT codes (see Table 51 in the final rule for a listing of these CPT codes) as well as several CPT unlisted codes, CMS adds six of these codes to the CY 2012 ASC list of covered surgical procedures (see Table 52 in the final rule).

- Changes for CY 2012 to Covered Surgical Procedures Designated as Office-Based

  Physician office-based procedures are those surgical procedures that are performed at least 50 percent of the time in the physician's office. For office-based procedures that are performed in an ASC, the aggregate payment cannot exceed what the physician is paid if the surgical procedure was performed in the physician's office.

  Based on its review of the CY 2010 volume and utilization data, in this final rule with comment period, CMS designates ten surgical procedures that the agency believes meet the criteria for designation as permanently office-based for CY 2012 (see Table 53 in the final rule).

  CMS also reviewed CY 2010 data for the 23 procedures finalized for temporary office based status in the CY 2011 OPPS/ASC final rule with comment period. There were eight procedures with very few claims data, so CMS will maintain their temporary office-based designation for CY 2012. For the remaining 15 procedures, CMS finalizes its proposal that they not be designated as office-based in CY 2012. CMS found that the volume and utilization data for these latter CPT codes were sufficient to indicate that these procedures are not performed predominantly in physicians' offices. See Table 54 for a listing of these 23 procedures.

- Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2012

  In the CY 2008 OPPS/ASC final rule with comment period, CMS adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedures is adequate to provide packaged payment for the high-cost implantable devices used in those procedures.

  CMS adds 64 procedures to the ASC list of covered surgical procures that are eligible for payment according the device intensive procedure payment methodology for CY 2012; see Table 55 in the final for a list of these 64 procedures.

- ASC Treatment of Surgical Procedures Removed from the OPPS Inpatient list for CY 2012

  CMS will continue the removal of three surgical procedures from the OPPS inpatient list for CY 2012 using the criteria for exclusion from the list of covered ASC surgical procedures. These are the same surgical procedures that were removed from the covered ASC surgical procedures in CY 2011. See Table 56 in the final rule for a listing of these three procedures.

Covered Ancillary Services

CMS is updating the ASC list of covered ancillary services as proposed to reflect the payment status for the services under the OPPS. All CY 2012 ASC covered ancillary services and their payment indicators are included in Addendum BB to this final rule.

D. Update to ASC Covered Surgical Procedures and Covered Ancillary Services

Payment for Covered Surgical Procedures and Covered Ancillary Services

CMS will continue the same payment update policies adopted for CY 2008; that is the final CY 2012 payment rates will be calculated according to the standard methodology of multiplying the final CY 2012 ASC relative payment weight for the procedure by the final CY 2012 conversion factor. For device-intensive procedures, the final ASC payment will be updated based on the updated OPPS claims data.

CMS will update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system.

Most covered ancillary services and their CY 2012 payment indicators are listed in Addendum BB to this final rule.

Adjustment to ASC Payments for Partial or Full Device Credit

CMS is not adopting any policy changes as regards ASC payment for partial or full device credits. Current ASC policies for ASC payments for partial or full device credits are the same as OPPS policies. Under these policies, when the necessary device is furnished to an ASC without cost or with full credit, Medicare's payment to an ASC is reduced by the device offset amount that CMS estimates represents the cost of the device. When the necessary device is furnished to an ASC with partial credit, payment is reduced by one half of the device offset amount that would be applied if a device were provided at no cost or with full credit. Table 57 in the final rule lists the ASC covered device-intensive procedures that will be subject to the no cost/full credit and partial credit device adjustment policy for CY 2012.

Waiver of Coinsurance and Deductible for Certain Preventive Services

The Affordable Care Act waived the deductible and coinsurance for those preventive services under section 1861(ddd)(3)(A) that are recommended by the U.S. Preventive Services Task Force with a grade A or B for any indication or population and that are appropriate for the individual. CMS implemented these provisions in the CY 2011 OPPS/ASC final rule.

In addition, the Affordable Care Act waived the Part B deductible for colorectal cancer screening tests that become diagnostic. Accordingly, CMS adopted, in the CY 2011 OPPS/ASC final rule with comment period, the provision that all surgical services

furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy will be considered as being "furnished in connection with, as a result of, and in the same clinical encounter as the screening test."

Payment for the Cardiac Resynchronization Therapy Composite

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CMS will apply the same conditions for ASC payment for such a service as the agency will pay in the OPPS setting. That is, the payment policy, which CMS adopts, is intended to ensure appropriate and equitable payment to hospitals and ASCs to preclude inappropriate payment incentives to provide this service in one setting of care over another by paying more in the outpatient setting compared to the inpatient setting.

Payment for Covered Ancillary Services for CY 2012

CMS states that it will pay for covered ancillary services in CY 2012 in accordance with the policies finalized in the CY 2011 OPPS/ASC final rule with comment period with one modification. CMS is setting the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent.

E. New Technology Intraocular Lenses (NTIOL)

CMS says that the agency received by the March 5, 2011 due date four requests for review to establish a new NTIOL class[2] for CY 2012. These requests came from Alcon Laboratories, Inc., Bausch & Lomb, Inc., Hoya Surgical Optics, Inc., and Lenstec, Inc. In the CY 2012 OPPS/ASC final rule, CMS denied all four requests.

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50. As it did for CY 2011, CMS will continue the $50 payment adjustment for CY 2012.

F. ASC Conversion Factor and ASC Payment Rates

The Medicare law specifies that annual ASC payment updates are to be updated by the consumer price index for all urban consumers (CPI-U) and, beginning on or after January 1, 2011, reduced by a productivity adjustment factor. The CMS latest estimate of the CPI-U is a 2.7 percent increase for the 12-month period ending with the mid-point of CY 2012. The productivity adjustment is required to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The latest

[2] In the CY 2007 OPPS/ASC final rule, CMS adopted a process to establish new active classes of NTIOLs and for recognizing new candidate IOLs inserted during or subsequent to cataract extraction as belonging to a NTIOL class that is qualified for a payment adjustment.

MFP is projected to be 1.1 percent. CMS calculates the final CY 2012 ASC conversion factor by adjusting the CY 2011 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2011 and CY 2012 and by applying the CY 2012 MFP-adjusted CPI-U of 1.6 percent (2.7 percent CPI-U minus 1.1 percent MFP). The final CY 2012 ASC conversion factor is $42.627; the CY 2011 ASC conversion factor is $41.939.

It should be noted that the final CY 2012 OPPS conversion factor is $70.016. Thus, ASCs will be paid about 60.9 percent of the amount paid hospital outpatient departments for corresponding outpatient procedures. This is approximately the same percentage as in CY 2011.

Addenda AA and BB to the final rule display the final ASC payment rates for CY 2012 for covered surgical procedures and covered ancillary services, respectively.

XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting Program

A. Background

CMS makes changes to the Hospital Outpatient Quality Reporting (OQR) Program, formerly called the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), including a change to one measure for the CY 2013 payment determination and the addition of three measures beginning with the CY 2014 payment determination. Under this rule, a total of 26 measures will be required for both the CY 2014 and CY 2015 OQR Program payment determinations.

In responding to comments on the general principles used by CMS for development and use of measures, CMS states support for retaining process measures when there is evidence that supports a direct link between the process being measured and patient outcome. CMS also notes that it considers The Joint Commission's criteria for accountability measures in selecting measures for the OQR Program. CMS directs readers to http://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp on the consensus-based measure development process used by CMS for some measures.

Readers are referred to the QualityNet.org website for technical specifications for the Hospital OQR Program measures, which are included in the Hospital OQR Specifications Manual, published every 6 months with addenda issued as necessary. CMS states that the release schedule provides at least 3 months advance notice for substantial changes such as those to ICD-9, CPT, NUBC, and HCPCS codes and at least 6 months notice for changes to data elements requiring significant system changes.

CMS discusses comments it received on its policy of publicly posting Hospital OQR Program data. With respect to concerns about confusion over the interpretation of data

on imaging measures posted on *Hospital Compare*, CMS plans to evaluate whether alternatives such as categorical displays may be more informative to consumers.

In general, CMS indicates that data are posted on the *Hospital Compare* website as soon as possible after a provider preview period, and prior to that may be made temporarily available on other, non-interactive, CMS Web sites such as cms.hhs.gov/HospitalQualityInits/ if there are pending display design and other unresolved issues. CMS will consider ways of making information on the data sources for the various measures more transparent to the public.

B. Revision to Measures Previously Adopted for the Hospital OQR Program for the CY 2012, CY 2013 and CY 2014 Payment Determinations

In the 2011 OPPS/ASC final rule, CMS finalized measures for CYs 2012 through 2014 and emphasized that this multi-year approach does not preclude future measure additions or modifications for these years. Fifteen measures were finalized for the 2012 payment determination and 23 measures for the 2013 and 2014 payment determinations. (A table at the end of this section displays Hospital OQR Program measures for 2011-2015, including measures finalized in this rule and earlier rules.)

In this rule, CMS finalizes with a modification the proposed change in the data submission for the chart-abstracted measure OP-22, ED-Left Without Being Seen, which was adopted for the OQR in last year's rulemaking to begin with the 2013 payment determination. Rather than quarterly reporting of patient level data on this measure, aggregate numerator and denominator counts will be submitted once a year using a web-based form to be made available for this purpose through the QualityNet.org website. The numerator is the total number of patients who left without being evaluated by a physician/advance practice nurse/physician's assistant and the denominator is total number of patients who signed in to be evaluated for emergency services.

The modification from the proposed rule relates to the period for which data will be submitted on this measure. Data submission will occur as proposed between July 1, 2012 and August 15, 2012 and will cover the period January 1, 2012 through June 30, 2012 rather than the proposed time frame of calendar year 2011. This change responds to comments expressing concern about the burden of retroactive retrieval of aggregate data.

In this section of the preamble, CMS also responds to numerous comments received on other previously finalized OQR measures, a few of which are summarized here.

- *OP-15, Use of Brain CT in the ED for Atraumatic Headache*, CMS indicates that it expects that its technical expert panel review of this measure will result in refinements, such as additional exclusion criteria, before public reporting begins. The panel will review suggestions received during a dry

run of the measure earlier this year, the comment period on the proposed rule and the measure maintenance process.

- *OP-19, Transition Record with Specified Elements Received by Discharged Patient.* Several commenters suggested delaying implementation of this measure, which relates to outpatient emergency department (ED) encounters. CMS responds by stating that many EDs are already keeping track of patient encounters and related tests and does not believe the required data reporting is burdensome, noting that it can be generated using certified electronic health record (EHR) technology. Additionally, as part of maintenance for this measure, CMS intends to revisit with its technical expert panel how to capture all observation patients under this measure.

- *OP-21, ED Median time to pain management for long bone fracture.* CMS will consider including ibuprofen as a recommended medication in the list of analgesics during the next update of the Specifications Manual, while noting that the list of medications are suggestions and the purpose of the measure is to assess the timing of analgesic administration, not the type. CMS will also revisit how to address patients who do not receive pain medication.

C. New Quality Measures for the 2014 and 2015 Payment Determinations

CMS finalizes some but not all of the measures it had proposed for addition to the OQR Program for the CY 2014 and CY 2015 payment determinations. Three measures are added for 2014, and no new measures are finalized for 2015.

Additions for 2014. For the CY 2014 payment determination, three of the proposed nine new measures are finalized. They are 1) Cardiac Rehabilitation Patient Referral from an Outpatient Setting, 2) Safe Surgery Checklist Use and 3) Outpatient Volume for Selected Surgeries. The proposed measures that are not adopted are a surgical site infection measure and five diabetes care measures.

Cardiac Rehabilitation Patient Referral from an Outpatient Setting. This NQF-endorsed measure is the percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced an acute myocardial infarction or chronic stable angina or who have undergone coronary artery bypass (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery (CVS), or cardiac transplantation, who have not already participated in an early outpatient cardiac rehabilitation/secondary prevention program for the qualifying event and who are referred to an early outpatient cardiac rehabilitation/secondary prevention program, unless there is a documented medical or patient-oriented reason why a referral was not made. Specifications for this measure are available at: http://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx

In response to comments, CMS indicates that the measure will encourage HOPDs to coordinate the care their patients receive, and clarifies that this measure focuses on the process of referring a patient to a cardiac rehabilitation or secondary prevention program, not whether the patient actually enrolls in such a program.

Safe Surgery Checklist Use. This structural measure will indicate whether or not the hospital outpatient department uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during three perioperative periods: 1) prior to administration of anesthesia, 2) prior to skin incision, and 3) closure of incision prior to patient leaving the operating room. The measure will be reported for the calendar year 2012 time period via a web-based tool to be made available on the QualityNet website, with reporting occurring between July 1, 2013 and August 15, 2013.

In responding to comments received on this measure CMS indicates that the measure is also finalized for the ASC Quality Reporting Program and will be considered for inclusion in the IQR Program in the future. With respect to the lack of NQF endorsement, CMS believes the measure reflects significant consensus among affected parties. While the measure does not require use of a specific checklist, in response to comments CMS is considering providing links to specific examples of surgical safety checklists as an Appendix in the Specifications Manual.

Outpatient Volume for Selected Outpatient Surgical Procedures. This measure requires hospitals to submit all-patient volume data for eight categories of surgical procedures which CMS says account for 99 percent of all outpatient procedures (cardiovascular, eye, gastrointestinal, genitourinary, musculoskeletal, nervous system, respiratory, and skin). The HCPCS codes for which volume must be reported are included in the table at the end of this section which lists all the existing and proposed Hospital OQR Program measures.

In response to comments that the eight categories are too broad to provide meaningful information to consumers, CMS indicates that it will further identify groupings of key procedure types within the eight categories. These refinements will be included in an upcoming release of the Specifications Manual. CMS further indicates that it will consider for future rulemaking a suggestion that a facility's volume of procedures be related to the number of physicians performing the procedure at the facility.

CMS expresses disagreement with comments that the measure is not evidence-based, stating its belief that the literature cited in the proposed rule linking quality and volume is relevant to HOPDs. Further, CMS indicates that high-risk procedures are performed in HOPDs, noting that in 2010 more than 25,000 arterial transposition procedures and more than 31,000 endovascular repairs of the aorta and its branches were performed in HOPDs.

Surgical Site Infection (NQF#0299). In response to comments, CMS is not finalizing adoption of the proposed Surgical Site Infection measure to the OQR at this time, although it intends to propose a measure once one better suited for the HOPD setting is

fully developed. The measure that was proposed is among those collected by the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) and assesses the percentage of surgical site infections (SSIs) occurring within 20 days after an NHSN-defined operative procedure if no implant is left in place or within one year if an implant is left in place and the infection appears to be related to the procedure. This measure has been adopted for the Hospital IQR Program for the fiscal year 2014 hospital inpatient prospective payment system payment determination. In response to a comment, CMS reports that as of September 2011, 26 states have adopted NHSN as the operational system for state healthcare associated infection (HAI) reporting mandates, and that CDC is adding personnel and technical capacity to support additional use of NHSN.

Commenters objected to the addition of this measure for various reasons involving measurement and operational issues for HOPDs. Some noted that the surgeries for which this measure will apply in the inpatient setting (colon surgery and abdominal hysterectomy) are infrequently performed in the outpatient setting. Others raised concerns that surgery-related infections may not occur until after discharge. CMS indicates that a commenter is correct in noting that the CDC is working with the American College of Surgeons to develop a harmonized surgical site infection measure consistent with the approaches of both organizations.

Diabetes Care Measures. CMS does not finalize the adoption of five measures related to diabetes care to the Hospital OQR Program, citing comments regarding the burden of chart-abstracted measures, particularly in light of the transition to the ICD-10 classification system, and the need to further specify the diabetes measures for hospital outpatient setting. CMS intends to further refine the measures and re-propose them at a future date, taking into account suggestions made by commenters.

The five proposed diabetes care measures that are not adopted are:

(1) NQF # 0059 - percentage of adult patients with diabetes (ages 18-75) with most recent HgA1c level greater than 9 percent (poor control);
(2) Measure Pair NQF # 0064 - A. percentage of adult patients with diabetes (18-75) whose most recent LDL-C test was <130 mg/dl and B. percentage of adult patients with diabetes (18-75) whose most recent LDL-C test was <100 mg/dl;
(3) NQF # 0061 - percentage of patient visits by adults with diabetes (age >18) with diagnosed hypertension;
(4) NQF # 0055 - percentage of adult patients with diabetes (18-75) who received a dilated eye exam or seven standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist or imaging to verify diagnosis during the reporting year, or, for patients at low risk of retinopathy, in the prior year; and
(5) NQF # 0062 - percentage of adult diabetic patients (18-75) with at least 1 test for microalbumin during the measurement year or who had evidence of medical attention for existing nephropathy.

Measures for CY 2015. This rule finalizes for the CY 2015 payment determination continuation of the 26 measures adopted for CY 2014. The proposed addition of one additional measure, Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) is not finalized. This measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. CDC has submitted a revised measure proposal to the NQF based on results of field testing, and CMS expects to propose an influenza vaccination measure for the CY 2016 payment determination. CDC's revised measure narrows the denominator for data collection to include staff on facility payroll, licensed independent practitioners, student trainees and adult volunteers.

The following table summarizes the Hospital OQR Program measures over time, including those previously adopted and those added under this final rule.

Hospital OQR Measurement Sets					
	Payment Determination Year				
	CY2011	**CY2012**	**CY2013**	**CY2014**	**CY2015**
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		X	X	X	X

Hospital OQR Measurement Sets					
	Payment Determination Year				
	CY2011	CY2012	CY2013	CY2014	CY2015
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			X	X	X
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
OP-19: Transition Record with Specified Elements Received by Discharged Patients			X	X	X
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 Before 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	X
OP-25: Safe Surgery Checklist Use				X	X
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures				X	X
OP 26- Procedure Category	*OP 26 - Corresponding HCPCS Codes*				
Gastrointestinal	*40000 through 49999, G0104, 0105,G0121,C9716, C9724, C9725, 0170T*				
Eye	*65000 through 68999, G0186, 0124T, 0099T, 0017T,0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T,0191T, 0192T, 76510, 0099T*				
Nervous System	*61000 through 64999, G0260, 0027T, 0213T, 0214T,0215T, 0216T, 0217T, 0218T, 0062T*				
Musculoskeletal	*20000 through 29999, 0101T, 0102T, 0062T, 0200T,0201T*				
Skin	*10000 through 19999, G0247, 0046T, 0268T, G0127,C9726, C9727*				
Genitourinary	*50000 through 58999, 0193T, 58805*				
Cardiovascular	*33000 through 37999*				
Respiratory	*30000 through 32999*				

D. Possible Quality Measures under Consideration for Future Inclusion in the Hospital OQR Program

CMS reports having received many comments on measures and measure topics considered for future adoption into the Hospital OQR program beginning with CY 2015, which will be considered during future measure selection activity. The table below lists the potential measurement areas that CMS is considering. (This table appeared in both the proposed and final rules.)

Measures and Measurement Topics under Consideration for Future Hospital OQR Program Payment Determinations Beginning with CY 2015
Measures for future development:
Procedure Specific Measures
Colonoscopy and other Endoscopy measures
Cataract Surgery measures
Cancer Care
Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer
Adjuvant Hormonal Therapy for Patients with Breast Cancer
Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection.
Heart Failure
Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Heart Failure: Left Ventricular Ejection Fraction Assessment
Heart Failure: Combination Medical Therapy for Left Ventricular Systolic Dysfunction
Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction
Heart Failure: Counseling regarding Implantable Cardioverter-Defibrillator (ICD) Implantation for Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy
Heart Failure: Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy
Heart Failure: Symptom Management
Heart Failure: Symptom and Activity Assessment
Heart Failure: Patient Education
Heart Failure: Overuse of Echocardiography
Heart Failure: Post-Discharge Appointment for Heart Failure Patients
Surgical Safety
Patient Fall
Patient Burn
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

Measures and Measurement Topics under Consideration for Future Hospital OQR Program Payment Determinations Beginning with CY 2015
Hospital Transfer/Admission
Patient Experience-of-Care
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
CAHPS Surgical Care Survey
Anesthesia Related Complications
Death
Cardiac Arrest
Perioperative Myocardial Infarction
Anaphylaxis
Hyperthermia
Transfusion Reaction
Stroke, Cerebral Vascular Accident, or Coma following anesthesia
Visual Loss
Medication Error
Unplanned ICU admission
Patient intraoperative awareness
Unrecognized difficult airway
Reintubation
Dental Trauma
Perioperative aspiration
Vascular access complication, including vascular injury or pneumothorax
Pneumothorax following attempted vascular access or regional anesthesia
Infection following epidural or spinal anesthesia
Epidural hematoma following spinal or epidural anesthesia
High Spinal
Postdural puncture headache
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia
Infection following peripheral nerve block
Additional Measurement Topics
NQF Serious Reportable Events in Healthcare
Medication Reconciliation
Chemotherapy
Post-discharge follow up
Post-discharge ED visit within 72 hours
Breast cancer detection rate

E. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the 2012 Payment Update

CMS finalizes its proposal to continue for the 2012 update the existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements. No comments were received on these

policies. The reporting ratio is 0.98, calculated by dividing the reduced conversion factor of $68.616 by the full conversion factor of $70.016. The reporting ratio will be applied to all services calculated using the OPPS conversion factor. The ratio, when applicable, 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. For hospitals failing to meet the reporting requirements, 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 OPPS national unadjusted payment rates would be applied, and OPPS outlier eligibility and outlier payment are based on the reduced payment rates.

In the regulatory impact analysis of this rule, CMS reports that 107 hospitals failed to meet the Hospital OQR Program requirements for the full 2011 update. Most of these hospitals (more than 90 of the 107) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program.

F. Extraordinary Circumstances Extension or Waiver for 2012 and Subsequent Years

CMS finalizes as proposed the procedures under which a hospital facing extraordinary circumstances beyond its control may request and CMS may grant an extension or waiver of the Hospital OQR program reporting requirements. The only change made from previous years extends the procedures to include submission of medical record documentation under the data validation requirement of the Hospital OQR Program.

G. Requirements for Reporting of Hospital OQR Program Data for 2013 and Subsequent Years

CMS adopts as proposed the administrative, data collection and submission and data validation requirements for participation in the Hospital OQR Program for CY 2013 and subsequent years. Most of the requirements are unchanged from those that CMS adopted for the 2012 determination. Significant changes from previous years are made with respect to data validation requirements, although proposed requirements regarding reporting of population and sample size data are not finalized.

Data Validation Requirements. CMS finalizes, with one modification from the proposed rule, several significant changes to the Hospital OQR Program data validation requirements. First, the number of randomly selected hospitals will be reduced from 800 to 450. All hospitals that have submitted at least 10 encounters to the OPPS Clinical Warehouse during the data collection period will be eligible for random selection for validation.

Second, up to 50 additional hospitals will be selected for validation based on targeting criteria. For 2013, the criteria will include hospitals that either fail the validation requirement for the 2012 payment determination or have an outlier value based on the data it submits. An outlier value is defined as a measure value that appears to deviate

markedly from those of other hospitals, specifically those with a measure value that is more than 5 standard deviations from the mean. If more than 50 hospitals meet one or the other of these criteria, 50 hospitals would be selected randomly from among them for validation.

The modification that CMS does not finalize is its proposal to reduce the time period given to hospitals to submit medical record documentation to the CMS contractor from 45 days to 30 days. Numerous commenters raised concerns about the burden of the proposed shortened time frame and inconsistency with other CMS programs, such as the Recovery Audit Contractor.

For the 2013 payment determination, CMS will validate data for April 1, 2011 to March 31, 2012 encounters. Other features of the current validation procedures are continued, including validation of up to 48 randomly selected encounters (12 per quarter) and the method for calculating the validation score.

CMS sought comment on three additional targeting criteria that may be used to select hospitals for validation in 2014 and subsequent years. These are 1) whether a hospital was open under its current CMS Certification Number and had not been chosen for validation in the previous three years, 2) whether a hospital submitted a low number of encounters relative to population sizes, or 3) whether a hospital reported significant numbers of “unable to determine” data elements. In responding to comments, CMS indicates that extending the first option from those not selected for the previous three years to the previous four years would increase to five years the maximum number of years a hospital could avoid selection for validation, which CMS considers to be too long.

Population and Sampling Data Requirements. In response to comments, CMS does not finalize its proposal to require quarterly reporting of population and sample size data on each measure. Instead, for the CY 2013 payment determination the existing policy of accepting voluntary submission of the data will continue. CMS indicates that 17.3 percent of hospitals have issues meeting sampling minimums, and due to accuracy concerns regarding these hospitals raised by commenters, the proposal is not finalized.

Hospital OQR Program Participation and Withdrawal. As proposed, administrative requirements will remain unchanged, but deadlines for submitting the participation form are updated. Any hospital that has a Medicare acceptance date on or after January 1 of the year prior to the payment determination year (e.g., 2012 for the 2013 payment determination) must submit a participation form no later than 180 days from the date identified as the Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. CMS will consider a hospital’s request to allow additional time in the case of a Medicare acceptance date that has been back-dated.

Any hospital that has a Medicare acceptance date before January 1 of the year prior to the payment determination year that is not currently participating in the Hospital OQR

Program but wishes to participate must submit a participation form by March 31 of the year prior to the payment determination year (e.g., March 31, 2012 for the 2013 payment determination). This requirement applies to all hospitals, whether or not they bill for payment under the OPPS.

For 2013 and subsequent payment determination years, a hospital may withdraw from the Hospital OQR Program at any time from January 1 to November 1 of the year prior to the payment determination year. A hospital that withdraws may not later sign up for that payment determination, receives a 2.0 percentage point reduction in the OPD fee schedule increase factor for that year, and must submit a new participation form for any future year in which it elected to participate.

Data Submission Requirements. For chart-abstracted measures submitted directly to CMS for the 2013 payment determination, data are to be submitted for the 3rd and 4th quarters of 2011 and the 1st and 2nd quarters of 2012. Hospitals with a Medicare acceptance date on or after January 1, 2012 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, 2012 that did not participate in the 2012 Hospital OQR Program will begin data submission with the 1st quarter 2012 encounters.

Similarly, for the 2014 payment determination, the applicable quarters for data submission are the 3rd and 4th quarters of 2012 and the 1st and 2nd quarters of 2013, except that for the new cardiac rehabilitation measure, reporting will only be required for the 1st and 2nd quarters of 2013.

Hospitals are required to comply with the data submission schedule on the QualityNet.org website. Data are reported using the specified CMS abstraction and reporting tool or through a third party vendor that meets the specification requirements for data transmission to QualityNet. Submission deadlines are, in general, 4 months after the last day of the calendar quarter.

CMS continues the policy that hospitals with five or fewer all-patient encounters for a particular measure are not required to submit patient-level data for the entire measure topic for that quarter. Hospitals may voluntarily submit these data, however.

Claims-based measures will be calculated for the CYs 2013 and 2014 payment determinations using paid Medicare FFS claims for services furnished during calendar years 2010 and 2011, respectively.

CMS modifies its proposal regarding data submission for the structural measures. For the 2013 payment determination, data submission will occur as proposed between July 1st and August 15th, 2012 but instead of submitting data for CY 2011, the data time period will be January 1, 2012 through June 30, 2012.

As noted earlier, for the measure OP-22, (ED-Patient Left Without Being Seen), CMS finalizes with modification its proposed reporting schedule. Like the structural measures,

reporting on this measure will occur using a web-based tool on the QualityNet website and the same time frames apply. For the 2013 payment determination, data will be reported between July 1st and August 15th, 2012, for the period from January 1, 2012 through June 30, 2012.

H. Reconsideration and Appeals Procedures

CMS proposes to continue for the 2013 payment determination the reconsideration and appeals procedures that were finalized in last year's rulemaking for the 2012 payment determination.

I. Electronic Health Records

As it has in prior rules, CMS again states 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. While CMS 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, it expects the transition for reporting on Hospital OQR Program measures to be somewhat later. This is 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.

Responding to comments regarding the transition to EHR technology for quality data submission, CMS reports that 1) it is in the process of developing a validation strategy for quality measures submitted through certified EHR technology after manual chart-abstraction is phased out, 2) it is collaborating with the NQF, measure stewards, and the Office of the National Coordinator for Health Information Technology to develop accurate, easy to understand, and medical-record compatible electronic specifications for measures while maintaining the integrity of the measures as endorsed, and 3) it is working with various stakeholders to define a process for field-testing EHR-specified measures.

J. 2012 Measure EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

Under the American Recovery and Reinvestment Act of 2009, eligible hospitals and CAHs may quality for incentive payments if they demonstrate meaningful use of certified EHR technology. Implementing regulations established requirements for meaningful use, including the electronic reporting of clinical quality measures (CQMs). However, CMS has acknowledged that it does not yet have the capacity to receive the CQM data electronically. Reporting in 2011 has been required through attestation.

In this rule, CMS finalizes as proposed establishment of an electronic reporting pilot for eligible hospitals and CAHs. Specific changes are made to the EHR Incentive Program regulations at §495.8(b)(2)(ii) and §495.8(b)(2)(vi). For 2012 and subsequent years,

eligible hospitals may continue to report CQMs as calculated by EHRs through attestation. Alternatively, for the 2012 payment year, they can participate in a FY 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs.

Eligible hospitals and CAHs may voluntarily register to participate in the Pilot as part of the attestation process for the Medicare EHR Incentive Program. Hospitals that participate in the Pilot will satisfy requirements of the Incentive Program and do not need to attest to the results of CQMs as calculated by certified EHR technology.

Under the Pilot, eligible hospitals and CAHs are required to submit to CMS data on all 15 CQMs listed in Table 10 of the Medicare EHR Incentive Program final rule (75 FR 44418 through 44420) via a secure portal based on data obtained from the eligible hospital or CAH's certified EHR technology. Rather than aggregate-level CQM data, patient-level data would be required for Medicare patients only. Specifically, participating hospitals and CAHs must: (1) submit CQM data on Medicare patients only; (2) submit Medicare patient-level data from which CMS may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the eligible hospital or CAH's certified EHR technology; (3) submit CQM data for the full Federal fiscal year 2012, regardless of the eligible hospital or CAH's year of participation in the Medicare and Medicaid EHR Incentive Programs; and (4) use electronic specifications for transmission as specified by CMS, which CMS expects would be Quality Data Reporting Architecture (QRDA) Category 1.

Data for the Pilot are to be submitted during the period from October 1st through November 30th, 2012 (60 days following the close of the measurement period).

In response to comments, CMS indicates that a test period will be provided before and during the submission period, and additional education and outreach will be provided to assist 2012 Electronic Reporting Pilot participants with transmitting electronic quality measure data.

K. ASC Quality Reporting Program

CMS finalizes its proposal to initiate an ASC Quality Reporting Program with the 2014 payment determination. The statute authorizes, but does not require, the Secretary to implement such a system. [See 1833(i)(2)(D)(iv).] In previous rulemaking, CMS has stated its intent to implement a quality reporting system once ASCs acquired some experience with the new payment system that was put in place beginning in 2008. CMS cites statutory authority applying the Hospital OQR Program to ASC services in a similar manner to which they apply to hospitals, except as the Secretary may otherwise provide. [See section 1833(i)(7)(B)]

Data submission for the 2014 payment determination will begin on October 1, 2012, not January 1, 2012 as proposed. CMS makes this change in response to concerns of

commenters urging that ASCs will need more time to adapt data elements and operation systems.

This rule does not address the payment reduction to be applied for ASCs that do not participate in the quality reporting program. In response to comments, CMS states that under the statute these ASCs will incur a 2.0 percentage point reduction to any annual increase provided under the ASC payment system for a year. CMS will propose a method for calculating these penalties in the CY 2013 OPPS/ASC proposed rule.

As required under the ACA, CMS has submitted to Congress a report entitled "Medicare Ambulatory Care Surgical Center Value-Based Purchasing Implementation Plan." No statutory authority currently permits implementation of an ASC VBP program, but CMS indicates that it would develop a program and implement it though rulemaking if authorizing legislation were enacted. The report is available at http://www.cms.gov/ASCPayment/Downloads/C_ASC_RTC%202011.pdf.

Measure Selection. As it has done for the hospital IQR and OQR programs, CMS will use a multiyear approach to adopting measures for the ASC Quality Reporting Program. In this rule CMS finalizes measures for CYs 2014, 2015 and 2016, but as for these other programs, notes that it may revise or add measures in future rulemaking cycles to address program needs arising from new legislation or changes in HHS or CMS priorities.

In selecting measures for the ASC Quality Reporting Program, CMS states that it has focused on measures that have a high impact on and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency and patient satisfaction. For the future CMS intends to expand the measure set adopted for ASC quality reporting to address these priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate (i.e., hospital IQR and OQR programs, Physician Quality Reporting System, and reporting under the HITECH Act). As CMS has stated with respect to other quality reporting programs, it prefers to adopt measures that have been NQF-endorsed, but believes that the statutory requirement that measures reflect consensus among affected parties can be achieved in other ways.

CMS identifies four principles that it applied in developing the ASC Quality Reporting Program and other quality reporting programs. The principles involve 1) use of a mix of standards, processes, outcomes and patient experience of care measures, with a goal of moving toward greater use of outcomes and patient experience of care measures, 2) alignment of measures across public reporting and payment systems under Medicare and Medicaid, 3) minimizing collection of information burden on providers, and 4) endorsement of measures by a national, multi-stakeholder organization, to the extent practicable and feasible and recognizing differences in statutory authorities.

A table at the end of this section shows the final ASC Quality Reporting measures for CYs 2014, 2015 and 2016.

In response to comments, CMS states that the majority of measures selected apply regardless of the types of procedures performed at a particular ASC, but CMS will consider for the future the usefulness of specialty-specific measures and exemptions based on case mix or low volume. Further, in seeking to align measures across settings, CMS notes that not all procedures performed in HOPDs are performed in ASCs, and therefore some HOPD measures may not be as relevant for ASCs.

Measures for 2014. CMS finalizes an initial measure set for the ASC Quality Reporting Program consisting of five claims-based measures. These are 1) Patient Burns; 2) Patient Falls; 3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; 4) Hospital Transfer/Admission; and 5) Timing of Prophylactic IV Antibiotics. Specifications for these measures are available at http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.

CMS reports that all comments on the first four measures were in support of the measures. Regarding the measure on timing of prophylactic IV antibiotics, CMS acknowledges that in one place the proposed rule included an error in the description of the denominator for this measure. The denominator is ASC admissions with a pre-operative order for a prophylactic IV antibiotic for the prevention of surgical site infection. CMS states that the specifications for the measures will be detailed in the forthcoming Specifications Manual that CMS will issue for this program.

Because the five finalized measures are all claims-based, reporting will not apply to all patients but instead will be limited to ASC services furnished to Medicare fee-for-service beneficiaries. CMS states that NQF has indicated that use of Medicare Part B claims submitted by ASCs to calculate the measures is an appropriate application of the NQF-endorsed measures to a subset of the broader population to which the endorsed measures apply.

CMS does not adopt three other measures it had proposed for the initial measure set. These are Surgical Site Infection, and two additional claims-based measures: Ambulatory Surgery Patients with Appropriate Hair Removal and Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin.

In deciding not to proceed with these measures as proposed, CMS generally agrees with concerns raised by commenters. The NHSN Surgical Site Infection measure that was proposed for both the ASC Quality Reporting Program and the OQR Program is not being adopted for either program. CMS agrees with commenters that commonly performed outpatient procedures are not addressed in the measure as it has been adopted for the IQR Program, and that a follow up and collection protocol that is better suited for outpatient surgical settings should be developed. Regarding the Appropriate Hair Removal measure, CMS agrees with commenters questioning the clinical evidence for the measure and notes a recently published systematic review indicating that not removing hair is associated with the least probability of infection. CMS also agrees with commenters that the Selection of Prophylactic Antibiotic measure may not address the

most prevalent area of services provided by ASCs. CMS will examine how the measure may be modified to capture procedures commonly performed in ASCs.

Reporting Process. All the finalized measures for 2014 are claims-based measures and CMS adopts its proposal to collect data on these measures via quality data codes (QDCs) that ASCs will be required to report on any claims involving one of the measures.

CMS indicates that it intends to provide education and outreach on data submission for the reporting program and will publish details about the QDCs in the ASC Quality Reporting Program Specifications Manual, which it anticipates releasing in the second quarter of 2012. In the proposed rule, CMS indicated that it is developing QDCs for the ASC Quality Reporting Program measures, which will be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. In addition, CMS planned to create a new ASC payment indicator, "M5", (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim.

In response to comments asking why CMS cannot adopt the same data collection process for ASCs that is used for the OQR Program claims-based measures, CMS indicates that the information needed to assess whether numerator events occurred in the ASC quality measures are not captured by the ICD-9 codes and CPT-1 codes used for OQR claims-based measures. In addition, CMS agrees with some commenters that in the early years of the PQRS there were instances where QDCs were incorrectly reported but this has diminished over time and CMS expects ASCs over time will have success with QDC-based measures.

Measures for 2015. CMS finalizes its proposal that, in general, unless a measure is retired from use in the ASC Quality Reporting Program, it will be retained from one payment determination year to another. Thus, for the FY 2015 payment determination, CMS finalizes continuation of all the measures adopted above for the FY 2014 payment determination.

In addition, CMS adopts as proposed two additional measures for the FY 2015 payment determination: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures. Both these measures are also adopted in this rule for use in the Hospital OQR Program, and CMS states this is in keeping with its goal of aligning measures across settings.

The Safe Surgery Checklist measure requires ASCs to report whether their facility employed during calendar year 2012 a safe surgery checklist that covered each of three perioperative periods: prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. ASC reporting would occur during a 45-day window from July 1st through August 15th, 2013 via an online web-based tool made available to ASCs via the QualityNet website. In response to comments CMS acknowledges that the measure cannot be validated because it does not use charts or

claims, but believes that it will heighten ASCs' awareness of patient safety and provide a safeguard against preventable human errors.

For the ASC Volume Data on Selected ASC Surgical Procedures measure, ASCs must report calendar year 2012 all-patient volume data for specific HCPCS codes within six categories of procedures. CMS states that analysis of 2009 ASC claims for Medicare beneficiaries shows that these six categories account for 98.5 percent of the total volume of procedures performed in ASCs.

Just as for the surgery checklist measure, reporting on the volume data measure will occur between July 1st and August 15th, 2013 via an online web-based tool made available to ASCs via the QualityNet website. The table at the end of this section summarizing the proposed measures shows the specific HCPCS codes to which the volume reporting measure would apply. CMS notes in response to a comment that these are different procedures than those that apply to the OQR Program volume reporting because the type and frequency of procedures vary between the settings.

Some commenters suggested that the measure needs to be modified to provide meaningful information to consumers, and CMS indicates that it will further refine the specification by grouping the codes into procedure types commonly performed in ASCs within the six broad categories. This does not change the codes that are to be reported, but they will be reported by the subcategories that will be specified in the ASC Specifications Manual.

Measures for 2016. The seven measures adopted for the 2015 payment determination are finalized for continuation in 2016, and the proposed addition of the Influenza Vaccination Coverage Among Healthcare Personnel measure is also adopted for 2016, with a change to the initial reporting period. Collection of data on this measure will begin for immunizations from October 1, 2014 through March 31, 2015. Details on the data submission process will be proposed in future rulemaking. (The initial reporting period was proposed to be October 1, 2013 through March 31, 2014.)

ASC Program Measurement Sets for the CY2014-CY2016 Payment Determinations			
	Payment Determination Year		
	CY2014	CY2015	CY2016
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
ASC-7 Procedure Category	*ASC-7Corresponding HCPCS Codes*		

ASC Program Measurement Sets for the CY2014-CY2016 Payment Determinations			
Gastrointestinal	*40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T*		
Eye	*65000 through 68999, G0186, 0124T, 0099T, 0017T,0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T,0191T, 0192T, 76510, 0099T*		
Nervous System	*61000 through 64999, G0260, 0027T, 0213T, 0214T,0215T, 0216T, 0217T, 0218T, 0062T*		
Musculoskeletal	*20000 through 29999, 0101T, 0102T, 0062T, 0200T,0201T*		
Skin	*10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727*		
Genitourinary	*50000 through 58999, 0193T, 58805*		
ASC-8: Influenza Vaccination Coverage among Healthcare Personnel***			X

*Claims-based data submission begins October 1, 2012.
**Data submission on calendar year 2012 data begins in 2013.
***Data submission begins with October 1, 2014 vaccinations.

ASC Measure Topics for Future Consideration. CMS will consider comments received on the list of possible future measures and measurement topics that was published in the proposed rule. (It is reproduced below.)

Measures and Measurement Topics under Consideration for Future ASC Payment Determinations
Patient Experience of Care:
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
CAHPS Surgical Care Survey
Procedure Specific Measures
Colonoscopy and other Endoscopy measures
Cataract Surgery measures
Anesthesia Related Complications:
Death
Cardiac Arrest
Perioperative Myocardial Infarction
Anaphylaxis
Hyperthermia
Transfusion Reaction
Stroke, Cerebral Vascular Accident, or Coma following anesthesia
Visual Loss
Medication Error
Unplanned ICU admission
Patient intraoperative awareness

Measures and Measurement Topics under Consideration for Future ASC Payment Determinations
Unrecognized difficult airway
Reintubation
Dental Trauma
Perioperative aspiration
Vascular access complication, including vascular injury or pneumothorax
Pneumothorax following attempted vascular access or regional anesthesia
Infection following epidural or spinal anesthesia
Epidural hematoma following spinal or epidural anesthesia
High Spinal
Postdural puncture headache
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia
Infection following peripheral nerve block
Additional Future Measurement Topics:
NQF Serious Reportable Events in Healthcare
Medication administration variance
Medication reconciliation
Venous thromboembolism measures: outcome/assessment/prophylaxis
Presence of Physician during Entire Recovery Period
Post-discharge follow up
Post-discharge ED visit within 72 hours

Technical Specification Updates and Data Publication

CMS finalizes its proposal to provide technical specifications for quality measures in a Specifications Manual to be posted after publication of the CY 2012 OPPS/ASC final rule with comment period on the CMS QualityNet website at www.QualityNet.org. In addition, CMS will post the information on the CMS website to increase ASC awareness of the technical and measure specifications.

CMS also adopts its proposal to use for the ASC Quality Reporting Program the same subregulatory process it has adopted for updates to the technical specifications for calculating the Hospital OQR Program. Under that process, CMS can change measure specifications outside the normal regulatory process in response to changes in scientific evidence or other substantive changes. 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.

CMS will make data submitted by ASCs under the quality reporting program available on a CMS website after providing ASCs an opportunity to preview the data to be made public. Data will be displayed at the CMS Certification Number level. CMS intends to propose more detail on the publication of data in later rulemaking.

Requirements for Reporting ASC Quality Data for the 2014 Payment Determination

For 2014 payment determination, CMS will consider an ASC as participating in the ASC Quality Reporting Program if it includes QDCs specified for the program on their 2012 claims related to the finalized measures.

Data completeness for the 2014 measures, all of which are claims-based measures, will be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications but did not have the appropriate QDC on the claim. CMS intends to provide additional details regarding participation notification and other administrative requirements and assessment of data completeness in 2013 rulemaking.

In response to comments expressing concern about deferring rulemaking on administrative requirements, data validation and data completeness requirements and reconsideration and appeals process requirements until the CY 2013 OPPS/ASC proposed rule, CMS revises its plan and indicates that these proposals will instead be included in the FY 2013 IPPS/LTCH PPS proposed rule, which will be finalized earlier.

As noted earlier, CMS is delaying the beginning of data collection for the CY 2014 payment determination from January 1, 2012 until October 1, 2012. As a result, the claims-based QDC data collection mechanism will be used for ASC services furnished for Medicare patients from October 1, 2012 through December 31, 2012.

CMS indicates agreement with commenters that for the initial year of the program a low threshold should be used for determining data completeness, noting that 50 percent was used in the PQRS. Additionally, CMS indicates that waiving data submission requirements for low case loads is reasonable and will be considered with other comments as proposals are developed. Proposals on data completeness will be included with other ASC Quality Reporting Program features in the FY 2013 IPPS/LTCH proposed rule.

Collection of Information Requirements

In the section of the rule that discusses Collection of Information Requirements, CMS presents estimates of the reporting burden on ASCs associated with the new ASC Quality Reporting Program. Based on data from the 71 percent of ASCs that participate in Medical Event Reporting, CMS estimates that reporting on the first four claims-based measures (burns, falls, surgical errors, and hospital transfer) will be nominal due to the small number of cases for which these measures apply (less than 1 case per month per ASC). For the measure on prophylactic IV antibiotic timing CMS estimates the aggregate burden associated with submitting QDCs for this measure to be 231,851 hours (2,788,640 claims per year x 50 percent of claims requiring QDC information x 0.167 hours per claim). For the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures to begin for the 2015 payment determination, CMS estimates that each participating ASC will spend 10 minutes per year to collect and submit the required data for each of the two measures.

XV. Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition: Exception for Expansion of Facility Capacity; and Changes to Provider Agreement Regulations Relating to Patient Notification Requirements

A. Changes Made by the Affordable Care Act Relating to Whole Hospital and Rural Provider Exceptions to Ownership and Investment Prohibition

Section 6001 of the ACA imposed additional requirements on physician ownership and investment interests in hospitals to qualify for the whole hospital or rural provider exceptions, all of which must be met by applicable deadlines. The hospital must:

- Have physician owners or investors and a provider agreement in effect no later than December 31, 2010;
- Not expand facility capacity above its baseline number of operating rooms, procedure rooms, and beds, unless the Secretary grants an exception;
- Comply with reporting and disclosure requirements and not condition physician ownership or investment interests directly or indirectly on a physician making or influencing referrals to or generating business for the hospital;
- Comply with requirements designed to ensure all ownership or investment interests in the hospital are *bone fide*;
- Inform patients before admission if the hospital does not have a physician available on premises during all hours and receive a signed acknowledgement that the patient understands this fact; and
- Not have been converted from an ASC on or after March 23, 2010.

B. Process for Requesting an Exception to the Prohibition on Expansion of Facility Capacity

Most commenters were supportive of the proposed exception process to the prohibition on expansion of facility capacity; thus, with few modifications, CMS finalizes its proposal. The principal modification is the reduction from three fiscal years of data required to satisfy criteria relating to inpatient admissions, bed capacity, and bed occupancy rates to the most recent fiscal year for which data are available. CMS now believes that this data on each criteria combined with the 5-year population growth criterion described below is sufficient for hospitals to demonstrate need for expansion. The exception process applies to requests from "applicable hospitals" and "high Medicaid facilities", and CMS imposes similar requirements and limitations to high Medicaid facilities as apply to applicable hospitals. The process sets forth relevant data sources and elements required for a complete exception request. CMS reiterates that the exception process protects only those referrals made after an exception is granted.

CMS codifies the statutory definition of applicable hospital. Hospitals seeking to qualify for an exception must use data from the CMS Healthcare Cost Report Information System (HCRIS) for the inpatient admission, bed capacity, and bed occupancy criteria,

and may only use HCRIS for a year if there is data from at least 6,100 hospitals for that year; failing that, CMS will look to most recent prior years for data from 6,100 hospitals. CMS will post average percent of total Medicaid admissions per county, average bed capacity per State, national average bed capacity, and average bed occupancy per State at: http://www.cms.gov/physicianselfreferral/85_physician_owned_hospital.asp. CMS is not persuaded by a commenter's suggestion to use State agency-maintained data due to concerns over lack of uniformity and potential inconsistent application of eligibility criteria; CMS notes it will make reasonable efforts to ensure HCRIS data are correct and complete at time of disclosure. A hospital must use the most current available population estimates from the Bureau of the Census to determine population percentage increases during the most recent 5-year period (as of the application date) with population estimates for both the county and State where the hospital is located. Hospitals will calculate Medicaid inpatient admission data, using filed hospital cost report discharge data, by dividing the number of discharges paid under Medicaid for a year by the total number of discharges paid by any governmental agency or private payer for that year.

But for the modification of reducing the requisite fiscal years of data described earlier, CMS finalizes its proposals for the calculation of bed capacity and bed occupancy as proposed. Thus, the State average bed capacity must be less than the national average bed capacity for the most recent fiscal year using filed cost report data to determine the State and national average bed capacities, and hospitals will calculate their own hospital bed occupancy rates (which must be greater than the State average bed occupancy rate for the most recent fiscal year) using filed hospital cost report data.

CMS codifies the statutory requirements for high Medicaid facilities seeking an expansion, and finalizes its proposals for these facilities without modification, other than the modification described above. CMS rejects a suggestion to permit hospitals to estimate their annual percentage of total Medicaid inpatient admissions considering Medicaid as a whole rather than broken down into primary and secondary payers. CMS also incorporates in regulations the statutory prohibition on nondiscrimination against beneficiaries by applicable hospitals, high Medicaid facilities, or physicians.

CMS finalizes its proposal for hospitals to submit requests (in lieu of a formal application) that contain the requisite information and data and that demonstrate how the criteria are met, state the nondiscrimination policy, clearly label documentation, include documentation supporting the calculation of the hospital's baseline number of operating rooms, procedure rooms, and beds, and include a certification by a hospital authorized representative of the truth and accuracy of the information in the request. In response to concerns that the requirements are burdensome, CMS notes that the documentation requirements have been substantially lessened because CMS will now only require data for the most recent fiscal year.

CMS received many comments on its proposal for community input, which, comments notwithstanding, it finalizes without modification. Interested individuals and entities in the community have 30 days to submit written comments beginning on the date of

publication of the request in the Federal Register. CMS does not adopt a suggested 60-day deadline for Federal Register publication of requests for expansion. Other commenters objected to the requirement to sign up for the CMS Hospital Listserv and suggested other forms of broader notification, including through newspapers or individual notice to other hospitals within a 50-mile radius. CMS instead will require hospitals to disclose any request on a hospital Web site accessible to the public for the period beginning on the date of the request and ending on the CMS decision date. A request that receives no comment during the 30-day comment period will be treated as complete at the end of that period. If a request generates comments, CMS will notify the hospital and afford it 30 days to rebut. Any request receiving comments during the comment period will be treated as complete at the end of the 30-day rebuttal period.

With respect to permitted increase, CMS finalizes with commenter support its policy to apply the limit to requests from both applicable hospitals and high Medicaid facilities. CMS finds it necessary to refine its proposed regulatory language to more closely track the wording and policy intent of the statute so that the limit clearly applies to the total number of operating rooms, procedure rooms, and beds for which the hospital is licensed after a permitted increase, rather than to the number of such rooms and beds by which the hospital seeks to expand. CMS also includes in regulations that approved expansions of capacity are limited to facilities on the main campus of the applicable hospital or the campus of a high Medicaid facility.

CMS will finalize decisions on requests within 60 days of receipt of a complete application and will post decisions on the CMS Web site which will include the number of operating rooms, procedure rooms, and beds by which the hospital may expand under the exception. CMS rejects a suggestion under which requests would be deemed approved if the agency failed to publish its final decision in the Federal Register within 60 days. The statute waives administrative or judicial review of the process to request a capacity expansion; CMS interprets this to mean that an agency decision on whether a hospital qualifies for an exception is not reviewable. Applicable hospitals and high Medicaid facilities may only make one request every two years from the date of the CMS decision letter for the most recent prior request.

C. Changes to Provider Agreement Regulations Relating to Patient Notification Requirements

CMS finalizes without modification all of its proposed revisions to the patient notification requirements on the presence, or lack thereof, of a physician (MD or DO, which CMS notes includes any resident who is an MD or DO) in the hospital 24 hours a day, 7 days a week. Though some comments indicated concern with additional costs or unnecessary patient alarm, CMS believes costs will actually be reduced because it requires fewer notices than under current regulations and it has no evidence of patient concern over these notices. These revisions apply to all hospitals and CAHs under §489.20(w) and essentially constitute minimum requirements. For example, CMS notes that physician-owned hospitals are also subject to requirements at §411.362(b)(5)(i) (which requires furnishing written notice to all inpatients and all outpatients) whereas for

non-physician-owned hospitals and CAHs, CMS requires written notice for inpatients and only certain outpatients: those receiving observation services, surgery, or any other procedure requiring anesthesia. Hospitals with dedicated emergency departments (ED) need only conspicuously post signage for hospital outpatients entering the ED indicating how the hospital will meet the needs of patients with emergency medical conditions when no physician is present. Main providers with remote locations or satellite facilities must determine whether notice is required separately at each location that provides inpatient services.

Written notice must be furnished at the beginning of a planned or unplanned inpatient stay or outpatient visit, which begins at the earliest point at which the patient presents at the hospital, and requires signed acknowledgement from the patient. Should a patient be admitted from the ED as an inpatient, individualized written disclosure and acknowledgement must be made at the time of the inpatient admission though CMS notes that the emergent condition of a patient's condition and immediate treatment needs may occasion some delay; CMS will apply the same standard when an outpatient encounter that does not require a notice requires immediate surgery or inpatient admission.

D. Regulatory Impact

CMS believes its proposals for an exception process would affect a relatively small number of physician-owned hospitals but bases its estimate on all 256 such hospitals. Because CMS eases regulatory requirements for applicable hospitals to satisfy criteria only for the most recent fiscal year for which data are available, it now estimates it will take a hospital 6 hours and 45 minutes to complete the request process at the cost of approximately $365.65 for each hospital which represents an annual burden of roughly 1,789 hours, at the cost of $96,897.25. CMS does not estimate the time or cost burden for hospitals to read and provide rebuttal statements in response to community input comments, and the associated time and costs for the hospital to send them to CMS, finding it difficult to anticipate due to the voluntary nature of this criterion.

CMS continues to believe its changes to the provider agreement regulations on patient notification will result in only a minor change in the number of hospitals that are subject to the disclosure requirements, specifically those multicampus hospitals that currently have 24/7 physician presence on one, but not all of their campuses with inpatient services which CMS believes are very few. The primary impact is the change in the number of annual written disclosures given by hospitals to patients, the cost of which CMS believes is a one-time cost for minor revisions to portions of hospital policies and procedures related to patient admission and registration, as well as providing written notification to patients and affected staff. Thus CMS does not believe that the proposed changes will have any significant economic impact on hospitals, physicians, other health care providers and suppliers, or the Medicare or Medicaid programs and their beneficiaries. Overall, CMS believes beneficiaries will be positively impacted by these provisions by reason of better information from which to make informed decisions about where to receive care.

XVI. Additional Proposals for the Hospital Value-Based Purchasing Program

In response to comments, CMS makes substantial changes from the proposed rule regarding modifications to the Hospital Value-Based Purchasing (VBP) Program for FY 2014. The VBP Program was established under section 3001(a) of the ACA, and will begin in FY 2013. Implementation has been addressed in two regulations prior to this one. Initial implementing regulations for the VBP were finalized in the May 6, 2011 *Federal Register,* setting forth the VBP Program for FY 2013 and modifying some elements for FY 2014*.* Additional rules for FY 2014 were finalized as part of the FY 2012 inpatient hospital prospective payment system (IPPS) rule for FY 2012, published on August 18, 2011. CMS indicates that multiple rulemaking vehicles were used due to VBP Program implementation deadlines and a desire to maximize public comment, and will be reduced in the future where possible.

Measures for 2014. In a major change from the proposed rule, CMS is suspending the effective date for addition of outcome and efficiency measures that were previously finalized for addition to the VBP Program in FY 2014. The final FY 2014 measure set now includes the 13 clinical process of care and patient experience of care measures finalized for FY 2013, the three mortality measures previously finalized for FY 2014, and one new clinical process of care measure: SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2. A chart showing the final measures for FY 2014 with baseline and performance periods and standards appears at the end of this section.

The previously finalized measures for which this rule suspends implementation are: 8 Hospital Acquired Condition (HAC) measures and 2 composite measures developed by the Agency for Health Care Research and Quality (AHRQ) which would have been included in the outcome domain, and a measure of Medicare spending per beneficiary, the only measure adopted under the efficiency domain. In suspending the effective date for these measures, CMS is also not finalizing at this time other proposals related to them, such as performance periods and scoring methodologies, and will take comments made on these proposals into account in future rulemaking.

CMS bases its decision to suspend implementation of these measures on comments questioning the statutory authority to include them without first publicly releasing the specifications and displaying hospital performance data on the *Hospital Compare* website for at least one year. CMS indicates that in proposing the addition of the measures for FY 2014 it was interpreting the statute in a way that enabled swift action to improve patient safety and efficiency. However, CMS acknowledges that hospitals would benefit from seeing performance data on measures before they are included in the VBP Program, and therefore announces it will publicly post hospital performance data on VBP Program candidate measures for at least one year prior to the start of the performance period.

The addition of the HAC, AHRQ and Medicare spending per beneficiary measures are therefore suspended because none of these measures have been posted on Hospital Compare in time to be added for the FY 2014 Hospital VBP Program. CMS concludes that in order to implement a program that responds to the concerns of commenters and enjoys wide public support, it has good cause to waive the Administrative Procedure Act (APA) requirements for notice and opportunity to comment on the decision to suspend the effective dates for adding these measures to the VBP Program. **CMS seeks public comment on its decision to waive the APA requirements for this purpose.**

Several important items are noted in CMS's discussion of its decision to suspend the addition of these measures to the VBP Program. First, performance data on the HAC and AHRQ measures were posted on Hospital Compare on October 13, 2011, and CMS is "working expeditiously to appropriately post Medicare spending per beneficiary data on Hospital Compare." Second, CMS intends to release specifications for the Medicare spending per beneficiary measure, and will "ensure that interested parties have an opportunity to comment on them." Finally, the suspension of these measures from addition to the VBP Program has no effect on their status under the Hospital Inpatient Quality Reporting Program.

Responding to additional comments on other VBP Program measures, CMS: 1) rejects suggestions to modify the HF-1 measure on discharge instructions, 2) notes that the three mortality measures adopted for FY 2014 are currently undergoing maintenance at the National Quality Forum and if recommendations for change are made these will be taken under advisement for future measure proposals for the VBP Program and 3) reiterates that as a general rule topped out measures will not be adopted for the VBP Program, noting that it made an exception in the case of the now-suspended HACs, which CMS believes capture critical patient safety data.

Minimum Numbers of Cases and Measures for the Outcome Domain for FY 2014. CMS finalizes that for FY 2014, hospitals must report a minimum of 10 cases in order to receive a VBP Program score on a mortality measure, and must report on at least two of the three mortality measures in order to receive a score on the outcome domain. This is a change from the proposed rule that is made in light of the decision to suspend the addition of the HACs and AHRQ measures to the outcome domain. As previously adopted in the VBP final rule, hospitals must have at least 10 cases for a clinical process of care measure to be included in its VBP score and must have scores for at least 4 clinical process of care measures in order to receive a score on the clinical process of care domain. For HCAHPS, at least 100 surveys are required for a domain score.

Further, CMS adopts its proposal that in order for a hospital to receive a total performance score under the VBP Program for FY 2014, the hospital must have enough cases and measures to report on all finalized domains (i.e., clinical process of care, patient experience of care and outcome).

In discussing its decision to require hospitals to report on at least two of the three mortality measures for an outcome domain score, CMS cites analysis by Brandeis University indicating that the vast majority of hospitals meet the 10-case minimum with respect to the pneumonia and congestive heart failure mortality measures, but smaller hospitals typically do not treat a sufficient number of heart attack cases to meet the 10-case minimum for a mortality measure score. CMS therefore concludes that a two-measure minimum would include as many hospitals as possible in the program while ensuring reliability of the domain score.

Not adopted in this final rule are proposals for minimums related to the measures for which CMS has suspended the effective date. CMS had proposed that in order to receive an outcome domain score, a hospital would need to report on 10 outcome measures, comprised of 7 of the 8 HAC measures along with 3 of the other outcome measures (e.g., 2 AHRQ measures and 1 mortality measure or 3 mortality measures). Because the HAC measure Foreign Object Retained After Surgery does not apply to the very small subset of hospitals that do not perform surgeries, this measure would not be required to be reported in order to achieve an outcome score. CMS also proposed that for the AHRQ composite measures, a 3-case minimum would be required for a hospital to receive a VBP Program score. With respect to the HAC measures, CMS had proposed that a hospital would receive a score as long as it submits at least 1 Medicare claim during the reporting period. CMS indicates that comments received on these proposals will be considered in future rulemaking.

In response to commenters requesting that CMS make public the Brandeis analysis of minimum cases and measures that were discussed in the proposed rule, CMS indicates that information will be made public to the extent the analyses “are not subject to privilege.” Specifically, within 30 to 45 days of this final rule, study methods and results will be posted on CMS’s VBP website: www.cms.gov/hospital-value-based-purchasing.

Performance Periods and Baseline Periods for FY 2014 Measures. CMS finalizes as proposed the FY 2014 VBP Program performance periods and baseline periods for the clinical process of care and patient experience of care (HCAHPS) measures. They are shown in the table below, with FY 2013 information included for reference. (FY 2014 baseline and performance periods for the mortality measures were finalized in the VBP Program final rule.)

Not finalized in this rule are the proposed performance periods for the suspended measures. CMS had proposed that for the FY 2014 VBP Program, the performance period for the HAC and AHRQ measures would be March 3rd to September 30th, 2012, with the baseline being the comparable period in 2010. (Baseline and performance periods for the other suspended measure, Medicare spending per beneficiary, were previously finalized in the FY 2012 IPPS/LTCH rule as May 15, 2010 through February 14, 2011 and May 15, 2012 through February 14, 2013, respectively.)

In discussing its decision to suspend the effective date for the outcome measures, CMS indicates that having a single performance period for all measures for a payment year is

a desirable goal for future years if possible. In addition, some commenters objected to the proposed 7-month period as too short to fairly assess hospital performance on the HAC and AHRQ measures. CMS indicates that it does not believe that the low incidence of HACs results in an unstable measure or that the AHRQ measures would be unreliable with the proposed performance period, but recognizes that a longer period would provide more data.

Hospital VBP Program Baseline and Performance Periods for FY 2013 and FY 2014		
Domain	**Baseline Period – FY 2013**	**Performance Period – FY 2013**
Clinical Process	July 1, 2009 – March 31, 2010	July 1, 2011 – March 31, 2012
Patient Experience	July 1, 2009 – March 31, 2010	July 1, 2011 – March 31, 2012
Domain	**Baseline Period – FY 2014**	**Performance Period – FY 2014**
Clinical Process	April 1, 2010 – December 31, 2010	April 1, 2012 – December 31, 2012
Patient Experience	April 1, 2010 – December 31, 2010	April 1, 2012 – December 31, 2012
Outcome		
• *Mortality*	July 1, 2009 – June 30, 2010	July 1, 2011 – June 30, 2012

Performance Standards for FY 2014. CMS finalizes as proposed the FY 2014 VBP Program performance standards for the clinical process of care and patient experience of care measures, and also reviews and displays the performance standards for mortality outcome measures as finalized in the VBP Program final rule. These are all shown in the table below.

FY 2014 VBP Program Performance Standards			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
Process of Care Measures			
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.8066	0.9630
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.9344	1.0000
HF-1	Discharge Instructions	0.9266	1.0000
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	0.9730	1.0000
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.9446	1.0000
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.9807	1.0000
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.9813	1.0000
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.9663	0.9996

FY 2014 VBP Program Performance Standards			
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.9634	1.0000
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2	0.9286	0.9989
SCIP–Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period	0.9565	1.0000
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	0.9462	1.0000
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	0.9492	0.9983
Patient Experience of Care Measures			
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)			
	Floor	**Performance Standard (Achievement Threshold)**	**Benchmark**
Communication with Nurses	42.84%	75.79%	84.99%
Communication with Doctors	55.49%	79.57%	88.45%
Responsiveness of Hospital Staff	32.15%	62.21%	78.08%
Pain Management	40.79%	68.99%	77.92%
Communication About Medicines	36.01%	59.85%	71.54%
Cleanliness and Quietness of Hospital Environment	38.52%	63.54%	78.10%
Discharge Information	54.73%	82.72%	89.24%
Overall Rating of Hospital	30.91%	67.33%	82.55%
Mortality Outcome Measures			
		Performance Standard (Achievement Threshold)	**Benchmark**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.8477	0.8673
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021

CMS does not finalize the proposed performance standards for the suspended AHRQ and HAC measures. CMS indicates that no comments were received regarding the performance standards for the AHRQ measures, and comments received regarding the methodology for calculating performance standard for the HACs, which differs from that used for the other measures, will be considered in future rulemaking.

Responding to other comments, CMS indicates that it is considering how best to conduct the transition from ICD-9 to ICD-10 for purposes of performance scoring and will provide more details in future rulemaking.

Scoring methodology. CMS adopts the proposal to continue for FY 2014 the domain scoring methodology finalized for FY 2013 with respect to the clinical process of care and patient experience of care domains, and also adopts with modifications the outcome domain scoring methodology. Specifically, CMS does not adopt the proposed scoring methodologies for the HAC and AHRQ measures, as the effective date of these measures for adoption in the VBP Program has been suspended under this final rule. Therefore, the final rule includes the outcome domain scoring methodology as proposed with respect to the mortality measures only. This method is the same as that used for the other domains. CMS indicates that comments received regarding the aggregate scoring methodology that it had proposed for scoring the HAC measures will be considered in future rulemaking.

In response to comments, CMS clarifies that in calculating an outcome domain score, the points earned for each of the mortality measures will be converted to a percentage of total points. That way, hospitals that do not have sufficient cases to report the 30-day heart attack mortality measure will not be disadvantaged. This is the same process used in calculating a score for the clinical process of care domain. All measures that apply to a hospital within a domain are given equal weight.

Ensuring HAC reporting accuracy. In the proposed rule, CMS indicated that it is considering proposing in the future adoption of a validation process for HACs, and in this rule indicates that comments received will be considered as policies in this area are further developed. Comments had been requested specifically regarding a process that would target a subset of hospitals that report zero or an aberrantly low percentage of HACs on Medicare fee-for-service IPPS claims relative to the national average of HACs. Suggestions from commenters included targeting hospitals with aberrantly high HAC rates and use of data sources other than claims. CMS would appreciate input on alternative data sources and methodologies.

Domain Weighting. CMS modifies its proposal regarding the domain weights for the FY 2014 VBP Program, which are finalized to be 45% for clinical process of care, 30% for patient experience of care (HCAHPS) and 25% for the outcome domain, which for FY 2014 will consist of the three mortality measures. The proposed rule would have weighted the clinical process of care domain at 20%, the patient experience of care and outcome domains each at 30%, and the efficiency domain at 20%. Because the proposed addition of the Medicare spending per beneficiary measure has been suspended, there are no measures in the efficiency domain for FY 2014.

As finalized in previous rulemaking, for the FY 2013 Hospital VBP Program, CMS will weight a hospital's score for the clinical process of care domain at 70% of the total performance score, with the remaining 30% weight given to the patient experience of

care domain. (The outcome measure domain does not apply for scoring in the FY 2013 Hospital VBP Program, the first year of implementation.)

In response to comments suggesting that weighting the patient experience domain at 30% is too high, CMS acknowledges that hospitals have less direct control over patient experience than clinical process of care, but states its belief that this does not diminish the importance of a patient's experience of care and the need for hospitals to make improvements in this area as well as other domains.

Regarding the weighting of the outcome domain, CMS reports having received comments that the proposed weight of 30% was too high and also that it was too low. Because the HAC and AHRQ measures have been suspended and three mortality measures will be in the outcome domain for FY 2104, CMS lowered the domain weight to 25% from the proposed 30%.

Review and Correction Process. CMS adopts, as proposed, processes that provide hospitals an opportunity to review and correct chart-abstracted data and patient experience data for the Hospital VBP Program. Different procedures are used for the chart-abstracted measures and the HCAHPS.

For chart-abstracted measures, CMS will rely on the process already in place for review and correction under the Hospital IQR Program. Specifically, once a hospital has an opportunity to review and correct data related to chart-abstracted measures submitted for the Hospital IQR Program, CMS will consider that the hospital has been given an opportunity for review and correction of these data for purposes of the VBP Program. Under the IQR process, hospitals have an opportunity to submit, review and correct chart-abstracted information submitted to the Quality Improvement Organization (QIO) Clinical Warehouse during the 4 ½ month period following the last discharge in a calendar quarter. (Under the FY 2012 IPPS/LTCH PPS proposed rule, CMS had proposed to change that period to 104 days, but this proposed change was not adopted in the final rule.)

For HCAHPS data, a two-phase process for data review and correction will be used. The first phase permits review and correction of HCAHPS data submitted for the Hospital IQR Program, and the second phase allows for review of the patient-mix and mode adjusted HCAHPS scores on those dimensions that are used to score hospitals under the VBP Program.

For the phase one review, which was finalized in the FY 2012 IPPS/LTCH PPS final rule, the HCAHPS submission deadline under the Hospital IQR Program is reduced from 14 weeks to 13 weeks providing a 1-week period for hospitals to review and correct their HCAHPS data. During the 1-week review and correction period, hospitals may provide any missing data or replace incorrect data for records that they submitted to the QIO Clinical Warehouse. They may also review frequency distributions of all their submitted data items, including hospital summary information, patient administrative data and patient survey responses. Hospitals may not submit new data records during

this period, and once the 1-week period has concluded, hospitals may not review, correct or submit additional HCAHPS data for the applicable quarter.

For phase two, hospitals will have 1 week to examine the HCAHPS dimension scores for the applicable VBP Program performance period. These scores are calculated after the data submitted by hospitals are analyzed to identify and remove incomplete surveys and after adjustments are made for effects of patient mix and survey mode. If a hospital believed its scores were miscalculated, CMS will check the calculation and recalculate the scores if necessary. Hospitals will not be able to modify HCAHPS data previously submitted or submit new data. CMS intends to propose detailed procedures for the phase 2 review and correction period in future rulemaking.

In response to comments, CMS indicates that in future rulemaking, details will be provided on review and corrections for claims-based measures, and an appeals process will be proposed.

APPENDIX: TABLES REPRODUCED FROM THE FINAL RULE

TABLE 8.— OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
CY 2012 APC 8004 (Ultrasound Composite)	**CY 2012 Approximate APC Median Cost = $192**
76604	Us exam, chest
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited
Family 2 - CT and CTA with and without Contrast	
CY 2012 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2012 Approximate APC Median Cost = $432**
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74261	Ct colonography, w/o dye
74176	Ct angio abd & pelvis

CY 2012 APC 8006 (CT and CTA with Contrast Composite)	CY 2012 Approximate APC Median Cost = $722
70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o&w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o&w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o&w/dye
73206	Ct angio upr extrm w/o&w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
73706	Ct angio lwr extr w/o&w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd&pelv w/contrast

74178	Ct angio abd & pelv 1+ regns
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE will assign APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2012 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2012 Approximate APC Median Cost = $700**
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
C8901	MRA w/o cont, abd
C8904	MRI w/o cont, breast, uni
C8907	MRI w/o cont, breast, bi
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr

CY 2012 APC 8008 (MRI and MRA with Contrast Composite)	CY 2012 Approximate APC Median Cost = $1,001
70549	Mr angiograph neck w/o&w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o&w/dye
70548	Mr angiography neck w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o&w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o&w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o&w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o&w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un

C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE will assign APC 8008 rather than APC 8007.	

TABLE 59.— ESTIMATED IMPACT OF THE FINAL CY 2012 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

		Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
ALL FACILITIES *		4,161	0	0	0	1.9	2	1.9
ALL HOSPITALS		3,895	0.2	0	-0.2	1.9	2	1.9
(excludes hospitals permanently held harmless and CMHCs)								
URBAN HOSPITALS		2,946	0.2	0	-0.2	1.9	2	1.9
	LARGE URBAN	1,607	0.2	0.1	-0.2	2	2	2
	(GT 1 MILL.)							
	OTHER URBAN	1,339	0.2	0	-0.2	1.9	2.1	1.9
	(LE 1 MILL.)							
RURAL HOSPITALS		949	0.1	-0.3	-0.2	1.5	1.7	1.5
	SOLE COMMUNITY	384	0	-0.2	-0.2	1.5	2	1.5
	OTHER RURAL	565	0.2	-0.4	-0.2	1.5	1.5	1.6
BEDS (URBAN)								
	0 - 99 BEDS	1,029	-0.5	0.1	-0.2	1.2	1.4	1.3
	100-199 BEDS	841	0.3	0.2	-0.2	2.1	2.2	2.1
	200-299 BEDS	454	0.4	0.1	-0.2	2.2	2.4	2.2
	300-499 BEDS	419	0.3	-0.2	-0.2	1.8	1.9	1.8
	500 + BEDS	203	0.1	0.1	-0.2	1.9	1.9	1.9
BEDS (RURAL)								
	0 - 49 BEDS	349	0	-0.1	-0.2	1.5	1.8	1.6
	50- 100 BEDS	355	0	-0.3	-0.2	1.5	1.7	1.5
	101- 149 BEDS	140	0.3	-0.2	-0.2	1.7	1.9	1.8
	150- 199 BEDS	57	0.1	-0.5	-0.2	1.3	1.8	1.3
	200 + BEDS	48	0.1	-0.3	-0.2	1.5	1.5	1.5

		Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
VOLUME (URBAN)								
	LT 5,000 Lines	594	-5.5	0.4	-0.2	-3.4	-3.3	-2.9
	5,000 - 10,999 Lines	148	-2	0.1	-0.2	-0.3	0	-0.3
	11,000 - 20,999 Lines	229	-0.6	0	-0.2	1	1	1
	21,000 - 42,999 Lines	476	0.3	-0.1	-0.2	1.9	1.9	1.8
	42,999 - 89,999 Lines	713	0.5	0.2	-0.2	2.3	2.4	2.3
	GT 89,999 Lines	786	0.2	0	-0.2	1.9	2	1.9
VOLUME (RURAL)								
	LT 5,000 Lines	66	-0.7	-0.7	-0.2	0.3	2.9	0.6
	5,000 - 10,999 Lines	70	0.7	0.3	-0.2	2.7	2.8	2.7
	11,000 - 20,999 Lines	167	0.3	-0.2	-0.2	1.8	2	1.7
	21,000 - 42,999 Lines	285	0.3	-0.2	-0.2	1.8	2	1.8
	GT 42,999 Lines	361	0	-0.3	-0.2	1.4	1.6	1.5
REGION (URBAN)								
	NEW ENGLAND	150	-0.2	4.2	-0.2	5.7	5.7	5.5
	MIDDLE ATLANTIC	355	0.1	0	-0.2	1.8	1.8	1.6
	SOUTH ATLANTIC	449	0.3	-0.5	-0.2	1.5	1.5	1.6
	EAST NORTH CENT.	473	0.3	-0.7	-0.2	1.3	1.3	1.2
	EAST SOUTH CENT.	183	0.6	-0.8	-0.2	1.5	1.5	1.6
	WEST NORTH CENT.	190	0.1	-0.1	-0.2	1.7	2.5	1.8
	WEST SOUTH CENT.	498	0.3	0.1	-0.2	2.1	2.1	2.1
	MOUNTAIN	208	0.1	-0.2	-0.2	1.6	2	1.7
	PACIFIC	394	0.1	0.2	-0.2	2	2	2.1

		Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
	PUERTO RICO	46	0.2	0.4	-0.2	2.3	2.3	2.3
REGION (RURAL)								
	NEW ENGLAND	25	-0.9	-0.3	-0.2	0.5	0.5	0.7
	MIDDLE ATLANTIC	67	-0.2	0.1	-0.2	1.6	1.6	1.7
	SOUTH ATLANTIC	162	0.3	-0.2	-0.2	1.7	1.7	1.8
	EAST NORTH CENT.	128	0	-0.8	-0.2	0.9	0.9	0.7
	EAST SOUTH CENT.	170	0.6	-0.6	-0.2	1.7	1.7	1.7
	WEST NORTH CENT.	101	-0.3	0.1	-0.2	1.5	2.7	1.7
	WEST SOUTH CENT.	200	0.5	-0.1	-0.2	2.1	2.1	2.1
	MOUNTAIN	67	0.1	-0.7	-0.2	1	2.8	1.1
	PACIFIC	29	0.1	1	-0.2	2.7	2.7	2.9
TEACHING STATUS								
	NON-TEACHING	2,896	0.2	-0.1	-0.2	1.9	2	1.9
	MINOR	708	0.3	-0.1	-0.2	1.9	2.1	1.8
	MAJOR	291	-0.1	0.3	-0.2	1.9	1.9	1.9
DSH PATIENT PERCENT								
	0	11	-1.6	-0.2	-0.2	-0.1	-0.1	0.5
	GT 0 - 0.10	353	0	0.2	-0.2	1.9	2	1.9
	0.10 - 0.16	357	0.3	-0.3	-0.2	1.6	1.7	1.6
	0.16 - 0.23	734	0.3	-0.1	-0.2	1.9	2.1	1.9
	0.23 - 0.35	1,040	0.3	0	-0.2	2	2.1	2
	GE 0.35	785	0.1	0.1	-0.2	1.9	1.9	2
	DSH NOT AVAILABLE **	615	-6	0.6	-0.2	-3.8	-3.7	-3.6
URBAN TEACHING/DSH								
	TEACHING & DSH	903	0.2	0.1	-0.2	1.9	2	1.9
	NO TEACHING/DSH	1,456	0.4	0	-0.2	2.1	2.1	2.1

		Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
	NO TEACHING/NO DSH	10	-1.6	-0.2	-0.2	-0.1	-0.1	0.5
	DSH NOT AVAILABLE**	577	-6.3	0.7	-0.2	-4	-3.9	-3.8
TYPE OF OWNERSHIP								
	VOLUNTARY	2,061	0.2	0.1	-0.2	2	2.1	2
	PROPRIETARY	1,273	0.1	-0.1	-0.2	1.7	1.7	1.7
	GOVERNMENT	561	0.1	-0.3	-0.2	1.5	1.5	1.6
CMHCs		204	-32.4	-0.3	-0.2	-30.8	-30.8	-30.8
Cancer Hospitals		11	0.6	0.3	11.3	14.1	14.1	13.7

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 and the final recalibration of APC weights based on CY 2010 hospital claims data.
Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2012 hospital inpatient wage index.
Column (4) shows the budget neutral impact of the cancer hospital payment adjustment which is estimated to result in an aggregate increase in OPPS payments to cancer hospitals of $71 million when TOPs are included..
Column (5) shows the impact of all budget neutrality adjustments and the addition of the 1.9 percent OPD fee schedule increase factor (3.0 percent reduced by 1.0 percentage point for the productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).
Column (6) shows the non-budget neutral impact of applying the frontier State wage adjustment, after application of the CY 2012 final OPD fee schedule increase factor.
Column (7) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds final outlier payments. This column also shows the expiration of section 508 wages on September 30, 2011 and the application of the frontier State wage adjustment for CY 2012.

*These 4,161 providers 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.

TABLE 60.—ESTIMATED PAYMENTS DUE TO RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals	Number of hospitals receiving rural floor or imputed floor	Percentage change in payments due to application of rural floor and imputed floor with budget neutrality	Difference (in millions)
Alabama	104	0	-0.5	-3.0
Alaska	6	4	3.3	1.7
Arizona	71	0	-0.5	-2.6
Arkansas	56	0	-0.5	-2.0
California	316	114	0.2	6.6
Colorado	55	10	0.3	1.5
Connecticut	35	15	1.6	8.3
Delaware	8	1	-0.5	-0.7
Florida	192	6	-0.4	-7.7
Georgia	125	0	-0.5	-4.9
Hawaii	14	0	-0.5	-0.5
Idaho	19	0	-0.4	-0.7
Illinois	139	0	-0.5	-8.4
Indiana	114	2	-0.4	-4.4
Iowa	35	5	-0.3	-1.4
Kansas	58	1	-0.5	-1.8
Kentucky	73	1	-0.4	-3.3
Louisiana	140	0	-0.4	-2.6
Maine	24	0	-0.4	-1.3
Massachusetts	82	83	7.6	92.1
Michigan	119	0	-0.5	-7.8
Minnesota	54	0	-0.5	-3.2
Mississippi	67	0	-0.4	-2.1
Missouri	92	3	-0.4	-4.2
Montana	14	1	-0.4	-0.6
Nebraska	24	0	-0.5	-1.2
Nevada	33	0	-0.5	-0.9
New Hampshire	14	9	1.3	3.7
New Jersey	79	53	1.4	14.0

State	Number of hospitals	Number of hospitals receiving rural floor or imputed floor	Percentage change in payments due to application of rural floor and imputed floor with budget neutrality	Difference (in millions)
New Mexico	34	0	-0.5	-0.9
New York	157	2	-0.5	-8.6
North Carolina	95	6	-0.4	-6.3
North Dakota	9	0	-0.4	-0.6
Ohio	157	13	-0.3	-5.1
Oklahoma	98	2	-0.5	-2.3
Oregon	34	3	-0.4	-1.4
Pennsylvania	186	24	-0.3	-4.5
Puerto Rico	46	12	0.0	0.0
Rhode Island	13	0	-0.5	-0.6
South Carolina	63	0	-0.5	-3.0
South Dakota	19	0	-0.4	-0.6
Tennessee	109	11	-0.3	-2.5
Texas	404	7	-0.5	-11.8
Utah	37	2	-0.4	-1.0
Vermont	7	0	-0.4	-0.5
Virginia	78	2	-0.4	-4.2
Washington	53	3	-0.3	-2.5
Washington, D.C.	11	0	-0.5	-0.7
West Virginia	39	4	-0.3	-0.9
Wisconsin	72	3	-0.4	-3.0
Wyoming	12	0	-0.4	-0.2