



Summary of Selected Provisions of the Hospital Outpatient Prospective Payment System Final Rule for Calendar Year 2012

On November 1, 2011, the Centers for Medicare & Medicaid Services (CMS) released the hospital outpatient prospective payment system (OPPS) final rule for calendar year (CY) 2012 (the "Final Rule").¹ The Final Rule will be published in the Federal Register on November 30, 2011, and CMS will accept comments on it until January 3, 2012.

CMS announced that the payment rates for 2012 will increase by 1.9 percent. This reflects a 3.0 percent increase in the hospital operating market basket, a -1.0 percent multifactor productivity (MFP) adjustment, and a 0.1 percentage point reduction required by the Affordable Care Act (ACA). Hospitals that fail to meet the quality data reporting requirements will receive an update that is reduced by 2.0 percentage points. CMS expects that total Medicare payments to hospital outpatient departments (HOPDs) will be approximately \$41.1 billion and total payments to ambulatory surgical centers (ASCs) will be \$3.5 billion in 2012.

The addenda containing relative weights, payment rates, wage indices and other payment information are no longer printed in the Federal Register. Instead, the addenda are available only on the CMS web site. Addenda relating to the OPPS are available at: <http://www.cms.hhs.gov/HospitalOutpatientPPS>, and addenda relating to the ASC payment system are available at: <http://www.cms.hhs.gov/ASC Payment/>.

1. OPPS Payment Changes for Drugs, Biologicals and Radiopharmaceuticals

In general, CMS uses the same methodology and policies to establish payment for drugs, biologicals, and radiopharmaceuticals in 2012 as it used in 2011, with adjustments for inflation as well as a new adjustment to minimize "intra-rulemaking fluctuation." In the Final Rule, this approach produces a payment rate of Average Sales Price (ASP) plus 4 percent for separately payable drugs, biologicals, and radiopharmaceuticals without pass-through status. Drugs, biologicals, and radiopharmaceuticals with pass-through status will continue to be reimbursed at ASP+6 percent, the rate applicable in physicians' offices, as required by statute. The packaging threshold will increase from \$70 to \$75.

a. Pass-Through Payment for Drugs and Biologicals

In 2012, 38 drugs and biologicals will have pass-through status. These therapies, listed below, will be reimbursed at ASP+6 percent, equivalent to the rate these drugs and biologicals will receive in the physician's office setting in CY 2012.

¹ CMS, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgery Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements, http://www.ofr.gov/OFRUpload/OFRData/2011-28612_PI.pdf.

Drugs and Biologicals with Continuing Pass-Through Status in CY 2012

CY 2011 HCPCS Code	CY 2012 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 SI	Final CY 2012 APC
C9406**	A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9275	C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	G	9275
C9279	C9279	Injection, ibuprofen, 100 mg	G	9279
C9285**	C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9286	C9286	Injection, belatacept, 1 mg	G	9286
N/A	C9287	Injection, brentuximab vedotin, 1 mg	G	9287
N/A	C9366	EpiFix, per square centimeter	G	9366
C9367	C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
C9283**	J0131	Injection, acetaminophen, 10 mg	G	9283
C9277	J0221	Injection, alglucosidase alfa (Lumizyme), 1 mg	G	1413
Q2044**	J0490	Injection, belimumab, 10 mg	G	1353
J0597	J0597	Injection, C-1 Esterase inhibitor (human), Berinert, 10 units	G	9269
J0638	J0638	Injection, canakinumab, 1 mg	G	1311
C9282	J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
J0775	J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	G	1340
C9274	J0840	Crotalidae polyvalent immune fab (ovine), 1 vial	G	9274
C9272	J0897	Injection, denosumab, 1 mg	G	9272
J1290	J1290	Injection, ecallantide, 1 mg	G	9263
C9270	J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	9270
J1572***	J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	947
C9281	J2507	Injection, pegloticase, 1 mg	G	9281

J3095	J3095	Injection, telavancin, 10 mg	G	9258
J3262	J3262	Injection, tocilizumab, 1 mg	G	9624
J3357	J3357	Injection, ustekinumab, 1 mg	G	9261
J3385	J3385	Injection, velaglucerase alfa, 100 units	G	9271
N/A	J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u.	G	1416
Q2041**	J7183	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rho	G	1352
J7335	J7335	Capsaicin 8% patch, per 10 square centimeters	G	9268
J8562	J8562	Fludarabine phosphate, oral, 10 mg	G	1339
C9276	J9043	Injection, cabazitaxel, 1 mg	G	9276
C9280	J9179	Injection, eribulin mesylate, 1 mg	G	1426
C9284**	J9228	Injection, ipilimumab, 1 mg	G	9284
J9302	J9302	Injection, ofatumumab, 10 mg	G	9260
J9307	J9307	Injection, pralatrexate, 1 mg	G	9259
J9315	J9315	Injection, romidepsin, 1 mg	G	9625
Q2040****	J0588	Injection, incobotulinumtoxin A, 1 unit	G	9278
Q2043*	Q2043*	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion	G	9273
C9365**	Q4124	Oasis Ultra Tri-Layer Matrix, per square centimeter	G	9365

*HCPCS code C9273 was deleted June 30, 2011, and replaced with HCPCS code Q2043 effective July 1, 2011.

**These HCPCS codes were effective July 1, 2011, and are included in the Addenda to this final rule with comment period.

***HCPCS code J1572 has a status indicator of "G," effective July 1, 2011.

**** HCPCS code C9278 was deleted March 31, 2011, and replaced with HCPCS code Q2040 effective April 1, 2011.

As proposed, CMS the pass-through status of 19 drugs and biologicals will expire on December 31, 2011. These therapies are listed below.

Drugs and Biologicals with Expiring Pass-Through Status in CY 2011

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI	CY 2012 APC
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	N	N/A
A9583	Injection, gadofosveset trisodium, 1 ml	N	N/A
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	K	9250
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	K	9360
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	N	N/A
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	N	N/A
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	K	9363
C9364	Porcine implant, Permacol, per square centimeter	N	N/A
J0598	Injection, C-1 esterase inhibitor (human), Cinryze, 10 units	K	9251
J0641	Injection, levoleucovorin calcium, 0.5 mg	K	1236
J0718	Injection, certolizumab pegol, 1 mg	K	9249
J1680	Injection, human fibrinogen concentrate, 100 mg	K	1290
J2426	Injection, paliperidone palmitate, 1 mg	K	9255
J2562	Injection, plerixafor, 1 mg	K	9252
J7312	Injection, dexamethasone intravitreal implant, 0.1 mg	K	9256
J8705	Topotecan, oral, 0.25 mg	K	1238
J9155	Injection, degarelix, 1 mg	K	1296
J9328	Injection, temozolomide, 1 mg	K	9253
Q0138	Injection, Ferumoxylol, for treatment of iron deficiency anemia, 1 mg	K	1297

b. Pass-Through Payment for Radiopharmaceuticals

Consistent with its CY 2011 policy for diagnostic and therapeutic radiopharmaceuticals, CMS will provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. For purposes of pass-through payment, CMS considers radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2012, CMS will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive, resulting in a payment rate of ASP+6 percent for CY 2012. If ASP data are not available for a radiopharmaceutical, CMS will provide pass-through payment 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 will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP).

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

i. *Packaged Drugs, Biologicals, and Radiopharmaceuticals*

CMS finalized an increase in the packaging threshold for drugs and biologicals from \$70 per day to \$75 per day. This increase is smaller than what CMS initially proposed due to CMS's use of the most recent forecast of the quarterly Producer Price Index for Prescription Drugs. Payment for drugs and biologicals with a per day cost of less than or equal to \$75 will be packaged, and drugs and biologicals with a per day cost greater than \$75 will be separately payable.

CMS will continue to package payment for all contrast agents and diagnostic radiopharmaceuticals regardless of their per day costs. CMS also will continue to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices.

ii. *Separately Payable Drugs and Biologicals*

As proposed, CMS is implementing a payment rate of ASP+4 percent for separately payable drugs and biologicals. This rate is a change from the current payment rate of ASP+5 percent. CMS arrived at the final rate by modifying slightly the methodology it has used since CY 2010.

For CY 2012, CMS continues the overhead adjustment methodology in use since CY 2010 to establish the payment rate for separately payable drugs and biologicals. In CY 2010 and CY 2011, pursuant to this methodology, CMS redistributed \$200 million in cost from coded packaged drugs with an ASP and uncoded packaged drugs. For CY 2012, CMS adjusts this \$200 million reallocation to account for inflation and changes in the prices of pharmaceuticals in the overall economy, as well as changes in the total estimated cost of drugs between the proposed rule and the Final Rule. In the proposed rule, CMS proposed to increase the overhead reallocation from \$200 to \$215 million to account for inflation. The proposed reallocation of \$215 million in costs -- \$161 million from coded drugs and \$54 million from uncoded packaged drugs and biologicals -- to separately payable drugs and biologicals resulted in a proposed CY 2012 payment rate for separately payable drugs and biologicals of ASP+4 percent. Without this reallocation, the payment rate for separately payable drugs would have been ASP-2 percent and the total aggregate cost for packaged drugs would be ASP+188 percent. In the proposed rule, CMS noted that the payment rate could be lower in the final rule after the agency has taken more recent data into account.

In the Final Rule, CMS found that applying the proposed reallocation of \$215 million to updated cost data produced an estimated total cost for separately payable drugs of ASP+3 percent instead of ASP+4 percent. CMS concludes that the "intra-rulemaking fluctuation" in the calculated payment rate is due to the agency's practice of holding constant the amount of reallocated overhead costs despite increases in total estimated costs between the proposed and final rules each year. To address this fluctuation, CMS decides to hold constant the proportion of redistributed packaged drug costs, instead of the amount of costs from the proposed rule to the final rule. The proposed reallocated amounts were equal to 35 percent of coded packaged drug costs and 10.7 percent of uncoded packaged drug cost. Applying these proportions to the total costs in the Final Rule, CMS arrived at a final reallocation of \$240.3 million (\$169 million from coded packaged drugs and \$71.3 million from uncoded packaged drugs) and a final payment rate of ASP+4 percent. CMS also finalized its proposal to include the claims data from hospitals participating in the 340B program in its calculation

of the payment rate for separately payable drugs and biologicals. In addition, CMS continues to encourage hospitals to bill all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes, regardless of whether they are separately payable or packaged.

iii. Separately Payable Therapeutic Radiopharmaceuticals

CMS will continue to reimburse all nonpass-through, separately payable therapeutic radiopharmaceuticals under payment level established for separately payable drugs and biologicals (ASP+4 percent) based on ASP information, if available, for a “patient ready” dose and updated on a quarterly basis for products for which manufacturers report ASP data. CMS also will rely on CY 2010 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to its usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available.

iv. Payment for Blood Clotting Factors

CMS will pay for blood clotting factors at ASP+4 percent, consistent with its payment policy for other nonpass-through separately payable drugs and biologicals, and will continue its policy for payment of the furnishing fee using an updated amount. CMS will announce the final update to the furnishing fee, based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year, through applicable program instructions and posting on the CMS web site.

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

CMS will continue its payment policies for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals that have HCPCS codes that do not crosswalk to CY 2011 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data. CMS will provide payment at ASP+4 percent, consistent with the proposed CY 2012 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals.

In the absence of ASP data, CMS will continue its policy of using the WAC to establish the initial payment rate for new nonpass-through drugs and biologicals and therapeutic radiopharmaceuticals with HCPCS codes without OPPS claims data. If the WAC is also unavailable, CMS will make payment at 95 percent of the product’s most recent AWP.

CMS also will continue its policy of packaging payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data.

vi. Blood and Blood Products

CMS will continue to establish payment rates for blood and blood products using its blood-specific cost-to-charge (CCR) methodology that uses actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood

products to costs. This methodology has been CMS's standard rate-setting methodology for blood and blood products since CY 2005.

2. Payment for Drug Administration Services

A table of the 2011 and 2012 drug administration payment rates is attached at the end of this document.

3. Pass-Through Payments for Devices

When CMS released the proposed rule, there was one new device category eligible for pass-through payment, described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)), announced in the October 2010 OPSS Update. Since the proposed rule was published, CMS announced that two new categories are eligible for pass-through payment effective October 1, 2011: HCPCS codes C1830 (Powered bone marrow biopsy needle), and C1840 (Lens, intraocular (telescopic)). CMS established an expiration date for pass-through payment for device category C1749 of December 31, 2012. CMS will propose expiration dates for pass-through status for C1830 and C1840 in a future rulemaking.

4. Proposed Payment Changes for Single Procedure Ambulatory Payment Classifications (APCs), Composite APCs, and Packaged Supporting and Ancillary Services

a. Brachytherapy Sources

CMS finalized its proposal to use the median costs from CY 2010 claims data for setting the proposed CY 2012 payment rates for brachytherapy sources and to continue the other payment policies for brachytherapy sources it finalized and first implemented in the CY 2010 final rule. Under these policies, CMS pays for the stranded and non-stranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed, for example, to a per mCi). CMS also assigns new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on its consideration of external data and other relevant information regarding the expected costs of the sources to hospitals for new brachytherapy sources for which there are no claims data. Finally, CMS will subject brachytherapy sources to outlier payments and will subject brachytherapy source payment weights to scaling for purposes of budget neutrality. CMS will continue to add new brachytherapy source codes and descriptors to its systems for payment on a quarterly basis.

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

CMS finalizes, without modification, its proposal to continue to include the extended assessment and management composite APCs 8002 and 8003 in the OPSS, using the payment methodology and criteria that it finalized for CYs 2009, 2010, and 2011. At its February 28-March 1, 2011 meeting, the Advisory Panel on APC Groups (APC Panel) recommended that CMS consider expanding the extended assessment and management composite APCs for CY 2012. CMS accepted the Panel's recommendation; however, it decided based on its analysis of the issue not to pursue the expanded extended assessment and management composite APCs. CMS said that while the composites that it modeled would serve to further limit the number of beneficiaries with copayments that exceeded the

inpatient deductible, the modeled composites also had the effect of possibly increasing copayments by a small amount for the majority of beneficiaries undergoing extended observation. In addition, CMS stated that expanded assessment and management composite APCs do not address certain concerns about extended observation services raised by stakeholders at CMS’s observation listening session last year (that is, observation time not counting towards the three-day prior hospitalization requirement for the skilled nursing facility benefit).

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

CMS will continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. The final median cost for composite APC 8001 for CY 2012 is approximately \$3,340. This is an increase compared to the CY 2011 final median cost for this composite APC of approximately \$3,195.

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

CMS will 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. CMS used the same methodology to calculate the median costs of these composite APCs that it used to calculate the final CY 2011 median costs.

e. Bronchoscopy

CMS will continue to assign HCPCS code 31627, the code used with electromagnetic navigation bronchoscopy (ENB), to status indicator “N” for the CY 2012 OPPS and will package payment for the procedure into payment for the bronchoscopy to which CMS believes it is ancillary and supportive.

CMS also will reassign HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers), which is the most common code with which HCPCS code 31627 was billed in 2010, and which has a final CY 2012 median cost of \$2,674, from APC 0076 (final median cost of \$733) to APC 0415 (Level II Endoscopy Lower Airway), that has a final CY 2012 APC median cost of approximately \$2,024.

5. Final APC Group Policies

a. Treatment of New CPT and Level II HCPCS Codes

CMS finalized the following treatment for certain newly implemented Level II HCPCS codes:

CY 2011 HCPCS Code	CY 2012 CPT Code	CY 2011 Long Descriptor	CY 2012 Status Indicator	CY 2012 APC	CY 2012 Payment Rate
C9730	0276T	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe	T	415	\$2023.82
C9731	0277T	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency	T	415	\$2023.82

		ablation of airway smooth muscle, 2 or more lobes			
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CMS finalized following treatment for certain newly implemented Category III CPT codes:

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2012 Status Indicator	CY 2012 APC	CY 2012 Payment Rate
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	S	0112	\$2,494.33
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	S	0112	\$2,494.33
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	S	0112	\$2,494.33

b. New Technology APCs

CMS finalizes its proposal, without modification, to continue New Technology payments for another year for the three procedures currently receiving payment through a New Technology APC. These are: HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens); and HCPCS code G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens). As proposed, CMS will assign these codes to lower paying New Technology APCs for CY 2012.

c. Computed Tomography of Abdomen and Pelvis (APCs 0331 and 0334)

The American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel created three new codes for computed tomography (CT) of the abdomen and pelvis that were effective January 1, 2011: CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); CPT code 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions). CMS made an interim APC assignment for each new code for CY 2011 based on its understanding of the resources required to furnish the service as the service was defined in the new code.

For CY 2012, CMS finalized its proposal to assign CPT code 74176 to new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) with a median cost of \$406. CMS

also assigned CPT codes 74177 and 74178 to new APC 0334 (Combined Abdominal and Pelvis CT With Contrast) with a median cost of \$581. CMS will reassess whether there is a continued need for these APCs for the CY 2013 OPSS once it has actual charges for these services. In cases where CPT code 74176 is reported with CT codes that describe CT services for other regions of the body other than the abdomen and pelvis in which contrast is not used, it will be assigned to imaging composite APC 8005 (CT and CTA Without Contrast), with a median cost of \$435. In cases where CPT code 74177 or 74178 is reported with CT codes that describe CT services for regions of the body other than abdomen and pelvis in which contrast is used, the code will be assigned to APC 8006 (CT and CTA With Contrast), with a median cost of \$722.

6. Proposed OPSS Payments to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

Section 3138 of the ACA instructs the Secretary to conduct a study to determine if, under the OPSS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Social Security Act with respect to APC groups exceed the costs incurred by other hospitals furnishing services under section 1833(t) of the Act. If the Secretary determines that cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary is required to provide an appropriate adjustment to reflect these higher costs. Cancer hospitals described in section 1886(d)(1)(B)(v) of the Act remain eligible for transitional outpatient payments (TOPs) (which are not budget neutral) and outlier payments (which are budget neutral). For CY 2011, CMS proposed an adjustment for cancer hospitals to reflect the higher costs of those hospitals, but because the many public comments CMS received identified a broad range of issues and concerns associated with the proposed cancer hospital payment adjustment, CMS determined that further study and deliberation was necessary and, therefore, did not finalize the CY 2011 proposed payment adjustment for certain cancer hospitals.

CMS continues to believe a straightforward method to adjust payments of cancer hospitals described in section 1886(d)(1)(B)(v) of the Act in order to reflect their higher costs with respect to APC groups is most appropriate. Therefore, for services furnished on and after January 1, 2012, CMS will make a hospital-specific payment adjustment for a cancer hospital with an individual payment-to-cost ratio (PCR) (as determined by the Secretary) below the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary) (Target PCR).

CMS estimates that, on average, the OPSS payments to the 11 cancer hospitals, not including TOPs, are approximately 67 percent of reasonable cost (that is, CMS calculated a PCR of 0.674 for the cancer hospitals), whereas, CMS estimates that, on average, the OPSS payments to other hospitals furnishing services under the OPSS are approximately 91 percent of reasonable cost (resulting in a PCR of 0.91).

Based on comments from stakeholders, CMS revised several aspects of its methodology for calculating these adjustments. In particular, CMS agreed to consider, for purposes of determining the budget neutrality adjustment for payments to non-cancer hospitals, the TOPs that would have been made if there were no cancer hospital adjustment. Including the TOPs in the baseline expenditures significantly reduces the offset in payments to other hospitals. The proposed offset was 0.7 percent, and the final offset is 0.2 percent.



CMS also agreed to make the cancer hospital adjustment through an aggregate payment determined at the time of cost report settlement, instead of an adjustment at the APC level, to avoid increasing beneficiaries' copayments.

After making these adjustments to its methodology, CMS estimates that the payment adjustments for cancer hospitals will be as follows:

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%

CMS will recalculate the PCR of each cancer hospital and the weighted average PCR of the other hospitals furnishing services under 1833(t) on an annual basis in order to determine an appropriate hospital specific payment adjustment to cancer hospitals each year. This is because, under section 7101 of ACA, cancer hospitals are eligible to participate in the 340B drug program, potentially causing significant changes in each cancer hospital's PCR compared to the previous year's calculation.

7. Hospital Outpatient Outlier Payments

CMS will continue its policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. To ensure that the estimated CY 2012 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, CMS set the hospital outlier threshold so that outlier payments will be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$1,900 fixed-dollar threshold.

8. Hospital Visits

As proposed, CMS is not issuing national guidelines for coding for hospital visits. CMS encourages hospitals to continue to report visits during CY 2012 according to their own internal hospital guidelines.

9. Physician Supervision

CMS proposed to create an independent advisory review process for consideration of stakeholder requests for assignment of supervision levels other than direct supervision for specific outpatient hospital therapeutic services. CMS finalized several major elements of this proposal, including the following:

- The existing APC Panel will serve as the independent review entity. CMS will make some modifications to the APC Panel scope and composition in order to create a body that is prepared to address supervision standards and that reflects the full range of parties subject to the standards.
- Decisions based on APC Panel recommendations will be issued through sub-regulatory guidance. CMS's decisions will be posted on the OPSS web site for public review and comment, and would be effective either in July or January following the most recent APC Panel meeting.
- To begin evaluating services in CY 2012, CMS will use the same APC Panel process that is used to solicit services or categories of services from stakeholders to construct the agenda to solicit potential services for consideration of a change in supervision level. CMS also will have the ability independently to ask the Panel to review the supervision level for one or more services as necessary.
- If CMS receives an unmanageable number of requests, it will prioritize requests by service volume, total expenditures, and/or frequency of requests. CMS also will prioritize services requested for review through public comment on the CY 2010 and CY 2011 proposed rules and services that have not previously been evaluated by the Panel.
- Requests must include justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. CMS also will consider these justifications in deciding which services to forward to the APC Panel for evaluation.
- CMS will charge the APC Panel with recommending a supervision level (general, direct, or personal) to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a HCPCS or CPT code.
- In recommending a supervision level to CMS, the Panel will assess whether there is a significant likelihood that the supervisory practitioner would need to reassess the patient and modify treatment during or immediately following the therapeutic intervention, or provide guidance or advice to the individual who provides the service. In answering that question, the Panel will consider: (1) Complexity of the service; (2) Acuity of the patients receiving the service; (3) Probability of unexpected or adverse patient event; and (4) Expectation of rapid clinical changes during the

therapeutic service or procedure, and (5) Recent changes in technology or practice patterns that affect a procedure’s safety. As CMS states, these criteria include, but extend well beyond, the likelihood of the need to manage medical emergencies during or after the provision of the service.

- For requests for review of a service that has already been considered, CMS will require the requestor to submit new evidence to support a change in policy, for example, evidence of a change in clinical practice patterns due to new techniques or new technology. If sufficient new information was provided with the request, CMS will send the request to the APC Panel, and the Panel will reconsider the service and make another recommendation to CMS, which could be the same or a different level of supervision than the current level for the service.

CMS also extended the notice of nonenforcement of the requirement for direct supervision in Critical Access Hospitals (CAHs) and small rural hospitals another year, through CY 2012.

CMS finalized its proposal to define the terms “personal supervision” and “general supervision” for the hospital outpatient setting using the definitions established for purposes of the Physician Fee Schedule.

Finally, CMS finalized its proposal to clarify that the requirements under 42 C.F.R. § 410.27 (relating to conditions for “incident to” services) apply to all outpatient therapeutic services and supplies furnished in hospitals and in CAHs, including those services and supplies described by Medicare benefit categories other than the “incident to” benefit category.

10. Quality Reporting and Incentive Programs

a. Hospital Outpatient Quality Reporting Program Updates

In the CY 2011 final rule, CMS added new measures over a three year period for the CY 2012, CY 2013, and CY 2014 payment determinations to assist hospitals in planning, meeting future reporting requirements, and implementing quality improvement efforts. These measures are as follows:

Hospital OQR Program Measures Previously Adopted for the CY 2011, CY 2012, CY 2013, and CY 2014*** Payment Determinations
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery*
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic

Headache*
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**
OP-17: Tracking Clinical Results between Visits**
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients**
OP-19: Transition Record with Specified Elements Received by Discharged Patients**
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional**
OP-21: ED- Median Time to Pain Management for Long Bone Fracture **
OP-22: ED- Left Without Being Seen**
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 **

* New measure adopted beginning with the CY 2012 payment determination.

** New measure adopted beginning with the CY 2013 payment determination.

*** All 23 measures were adopted for the CY 2014 payment determination.

CMS did not revise any of the CY 2012 measures. For CY 2013, CMS changed the reporting requirements for measure OP-22 (ED-Left Without Being Seen) is collected. Instead of having to submit patient-level information for the measure, hospitals will submit aggregate data on the number of patients who left without being evaluated and number of patients who signed to be evaluated. Hospitals will submit these data between July 1 and August 15, 2012 for the period January 1, 2012 through June 30, 2012, and will be required to submit the data using a Web-based form for this measure available on the QualityNet Web site.

CMS added three new measures to the existing measure set for the CY 2014 payment determination:

- Cardiac Patient Referral from an Outpatient Setting
- Safe Surgery Checklist Use
- Hospital Outpatient Volume for Selected Outpatient Surgical Procedures

CMS did not finalize its proposal to add a measure on Surgical Site Infections because procedures included in the proposed surgical site infection measure do not represent a large number of procedures that are performed in hospital outpatient departments or in ASCs. CMS intends to propose the measure again in future rulemaking after measurement and operational issues for HOPDs are resolved. CMS also did not finalize its proposed chart-abstracted diabetes care measures due to public comments regarding the burden and the need to further specify these measures for the hospital outpatient setting.

CMS did not finalize a proposed new measure for the CY 2015 payment determination, Influenza Vaccination Coverage among Healthcare Personnel. The National Quality Forum is reviewing this measure, and CMS intends to propose it for inclusion in the CY 2016 payment determination.

Measures that are under consideration for future use (beginning CY 2015) that may be of particular interest include the following:

- Measures for future development:
 - Colonoscopy and other Endoscopy measures
 - 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
 - Hospital Transfer/Admission

- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
- CAHPS Surgical Care Survey
- 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

b. ASC Quality Reporting Program

By statute, CMS is permitted, but not required, to require ASCs to submit quality data and to reduce the annual update by two percentage points for ASCs that fail to submit data. CMS will implement the ASC Quality Reporting Program beginning CY 2014, with data collection beginning in CY 2012 for most of the measures to be used for the CY 2014 payment determination. The ASC Program Measurement Set for the CY 2014 payment determination (with data submission to occur in 2012 and 2013) includes the following measures:

- ASC-1: Patient Burn
- ASC-2: Patient Fall
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4: Hospital Transfer/Admission
- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing

CMS did not finalize three proposed measures:

- ASC-6: Ambulatory Surgery Patients with Appropriate Method of Hair Removal
- ASC-7: Selection of Prophylactic Antibiotic First OR Second Generation Cephalosporin
- ASC-8: Surgical Site Infection Rate

For CY 2015, CMS will add two structural measures:

- Safe Surgery Checklist Use
- ASC Facility Volume Data on Selected ASC Surgical Procedures

For CY 2016, CMS will add the Influenza Vaccination among Healthcare Personnel measure to the ASC measure set.

c. Hospital Value Based Purchasing (VBP) Program

In ACA, Congress required the Secretary to create an inpatient hospital VBP program. CMS issued a final rule implementing that program earlier this year. Although it applies to hospital inpatient services, CMS discusses the program and measures for it in this year's Proposed Rule. It does not appear that any of the adopted measures are directly related to cancer care.

11. Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition

In last year's rulemaking, CMS implemented the changes made by ACA to the whole hospital and rural provider exception to the physician self-referral prohibition that imposed additional restrictions on physician ownership or investment in hospitals. Pursuant to those changes, in



order to meet the whole hospital and rural provider exception, a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010.

Under the Act, CMS is required to establish and implement an exception process to the prohibition on expansion of facility capacity. In the Final Rule, CMS implements that exception process. Under this process, a hospital or high Medicaid facility can seek an exception from the prohibition on expansion up to once every two years and will have to meet criteria relating to population increase, Medicaid inpatient admissions, non-discrimination, average bed capacity, and average bed occupancy. CMS will publish requests and provide an opportunity for community input. Decisions will be made within 60 days of receipt of a complete request.

Outpatient PPS Drug Administration Rates – 2011 – 2012

Code	Description	2011			2012			Difference 2011-2012	% Change 2011- 2012
		SI	APC	Rate	SI	APC	Rate		
90471	Immunization admin	S	0436	\$26.35	S	0437	\$34.81	\$8.46	32.11%
90472	Immunization admin, each add	S	0436	\$26.35	S	0436	\$24.82	-\$1.53	-5.81%
90473	Immune admin oral/nasal	S	0436	\$26.35	S	0436	\$24.82	-\$1.53	-5.81%
90474	Immune admin oral/nasal addl	S	0436	\$26.35	S	0436	\$24.82	-\$1.53	-5.81%
96360	Hydration iv infusion, init	S	0438	\$75.58	S	0438	\$72.73	-\$2.85	-3.77%
96361	Hydrate iv infusion, add-on	S	0436	\$26.35	S	0436	\$24.82	-\$1.53	-5.81%
96365	Ther/proph/diag iv inf, init	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96366	Ther/proph/dg iv inf, add-on	S	0436	\$26.35	S	0437	\$34.81	\$8.46	32.11%
96367	Tx/proph/dg addl seq iv inf	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96368	Ther/diag concurrent inf	N			N			NA	NA
96369	Sc ther infusion, up to 1 hr	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96370	Sc ther infusion, addl hr	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96371	Sc ther infusion, reset pump	S	0436	\$26.35	S	0437	\$34.81	\$8.46	32.11%
96372	Ther/proph/diag inj, sc/im	S	0436	\$26.35	S	0437	\$34.81	\$8.46	32.11%
96373	Ther/proph/diag inj, ia	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96374	Ther/proph/diag inj, iv push	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96375	Ther/proph/diag inj add-on	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96376	Tx/pro/dx inj new drug adon	N			N			NA	NA
96379	Ther/prop/diag inj/inf proc	S	0436	\$26.35	S	0436	\$24.82	-\$1.53	-5.81%
96401	Chemo, anti-neopl, sq/im	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96402	Chemo hormon antineopl sq/im	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96405	Chemo intralesional, up to 7	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96406	Chemo intralesional over 7	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96409	Chemo, iv push, sngl drug	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96411	Chemo, iv push, addl drug	S	0438	\$75.58	S	0438	\$72.73	-\$2.85	-3.77%
96413	Chemo, iv infusion, 1 hr	S	0440	\$205.86	S	0440	\$207.80	\$1.94	0.94%
96415	Chemo, iv infusion, addl hr	S	0437	\$36.88	S	0437	\$34.81	-\$2.07	-5.61%
96416	Chemo prolong infuse w/pump	S	0440	\$205.86	S	0440	\$207.80	\$1.94	0.94%
96417	Chemo iv infus each addl seq	S	0438	\$75.58	S	0438	\$72.73	-\$2.85	-3.77%
96420	Chemo, ia, push technique	S	0438	\$75.58	S	0438	\$72.73	-\$2.85	-3.77%
96422	Chemo ia infusion up to 1 hr	S	0440	\$205.86	S	0440	\$207.80	\$1.94	0.94%
96423	Chemo ia infuse each addl hr	S	0438	\$75.58	S	0438	\$72.73	-\$2.85	-3.77%
96425	Chemotherapy, infusion method	S	0440	\$205.86	S	0440	\$207.80	\$1.94	0.94%
96440	Chemotherapy, intracavitary	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96446	Chemotx admn prtl cavity	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96450	Chemotherapy, into CNS	S	0440	\$205.86	S	0440	\$207.80	\$1.94	0.94%
96521	Refill/maint, portable pump	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96522	Refill/maint pump/resvr syst	S	0439	\$128.44	S	0439	\$126.71	-\$1.73	-1.35%
96523	Irrig drug delivery device	Q1	0624	\$43.58	Q1	0624	\$42.49	-\$1.09	-2.50%



96542	Chemotherapy injection	S	0438	\$75.58	S	0438	\$72.73	-\$2.85	-3.77%
96549	Chemotherapy, unspecified	S	0436	\$26.35	S	0436	\$24.82	-\$1.53	-5.81%
C8957	Prolonged IV inf, req pump	S	0440	\$205.86	S	0440	\$207.80	\$1.94	0.94%
G0008	Admin influenza virus vac	S	0350	\$26.35	S	0350	\$24.82	-\$1.53	-5.81%
G0009	Admin pneumococcal vaccine	S	0350	\$26.35	S	0350	\$24.82	-\$1.53	-5.81%

SI = Status Indicator