

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

On July 1, 2011, the Centers for Medicare & Medicaid Services (CMS) released the hospital outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2012 (the "Proposed Rule"). The Proposed Rule was published in the Federal Register on July 18, 2011, and CMS will accept comments on it until August 30, 2011.<sup>1</sup>

CMS is proposing that the payment rates for 2012 will increase by 1.5 percent. This reflects a 2.8 percent increase in the hospital operating market basket, a -1.2 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 \$41.9 billion and total payments to ambulatory surgical centers (ASCs) will be \$3.61 billion in 2012.

Beginning with this rule, the addenda containing relative weights, payment rates, wage indices and other payment information no longer will be printed in the Federal Register. 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. Proposed OPPS Payment Changes for Drugs, Biologicals and Radiopharmaceuticals

In general, CMS proposes to use the same methodology and policies to establish payment for drugs, biologicals, and radiopharmaceuticals in 2012 as it used in 2011, with an adjustment for inflation. In the Proposed Rule, this approach produces a payment rate of Average Sales Price (ASP)+4 percent for separately payable drugs, biologicals, and radiopharmaceuticals without pass-through status. CMS cautions stakeholders that the final payment rate for nonpass-through drugs, biologicals, and radiopharmaceuticals could be lower than ASP+4 percent after CMS finalizes its calculations with updated data later this year. 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 proposed packaging threshold is proposed to increase from \$70 to \$80.

#### a. Pass-Through Payment for Drugs and Biologicals

CMS is proposing to continue pass-through status in CY 2012 for 33 drugs and biologicals. These therapies, listed below, would be reimbursed at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2012.

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<sup>1</sup> 76 Fed. Reg. 42170 (July 18, 2011).

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

<b>Proposed CY 2012 HCPCS Code</b>	<b>CY 2012 Long Descriptor</b>	<b>Proposed CY 2012 SI</b>	<b>Proposed CY 2012 APC</b>
C9270	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	9270
C9272	Injection, denosumab, 1 mg	G	9272
C9274	Crotalidae polyvalent immune fab (ovine), 1 vial	G	9274
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	G	9275
C9276	Injection, cabazitaxel, 1 mg	G	9276
C9277	Injection, alglucosidase alfa (Lumizyme), 1 mg	G	9277
C9279	Injection, ibuprofen, 100 mg	G	9279
C9280	Injection, eribulin mesylate, 1 mg	G	9280
C9281	Injection, pegloticase, 1 mg	G	9281
C9282	Injection, ceftaroline fosamil, 10 mg	G	9282
C9283**	Injection, acetaminophen, 10 mg	G	9283
C9284**	Injection, ipilimumab, 1 mg	G	9284
C9285**	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9365**	Oasis Ultra Tri-Layer Matrix, per square centimeter	G	9365
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
C9406**	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
J0597	Injection, C-1 Esterase inhibitor (human), Berinert, 10 units	G	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	G	1340
J1290	Injection, ecallantide, 1 mg	G	9263
J1572***	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	947
J3095	Injection, telavancin, 10 mg	G	9258
J3262	Injection, tocilizumab, 1 mg	G	9624
J3357	Injection, ustekinumab, 1 mg	G	9261
J3385	Injection, velaglucerase alfa, 100 units	G	9271
J7335	Capsaicin 8% patch, per 10 square centimeters	G	9268
J8562	Fludarabine phosphate, oral, 10 mg	G	1339
J9302	Injection, ofatumumab, 10 mg	G	9260
J9307	Injection, pralatrexate, 1 mg	G	9259
J9315	Injection, romidepsin, 1 mg	G	9625

Q2040	Injection, incobotulinumtoxin A, 1 unit	G	9278
Q2041**	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rc0	G	1352
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
Q2044**	Injection, belimumab, 10 mg	G	1353

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

\*\*These HCPCS codes are effective July 1, 2011, and are not included in the addenda to this Proposed Rule.

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

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

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

Proposed CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2012 SI	Proposed 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 is proposing to 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 is proposing to 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 is proposing to provide pass-through payment at Wholesale Acquisition Cost (WAC)+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, CMS is proposing to 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 proposes an increase in the packaging threshold for drugs and biologicals from \$70 per day to \$80 per day. Payment for drugs and biologicals with a per day cost of less than or equal to \$80 would be packaged, and drugs and biologicals with a per day cost greater than \$80 would be separately payable.

CMS proposes to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals regardless of their per day costs. CMS also proposes to 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*

Using the methodology described below, which generally is unchanged from prior years with the exception of an adjustment for inflation, CMS is proposing a payment rate of ASP+4 percent for separately payable drugs and biologicals. CMS acknowledges that the rate could be lower in the final rule due to use of more recent data.

For CY 2012, CMS is proposing to continue the CY 2010 and CY 2011 overhead adjustment methodology 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 is proposing to apply an adjust the \$200 million reallocation to account for inflation and changes in the prices of pharmaceuticals in the overall economy. Therefore CMS is proposing to redistribute a total overhead redistribution amount, adjusted for inflation, of \$215 million from coded and uncoded packaged drugs and biologicals to separately payable drugs and biologicals. This results 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 rugs would be ASP+188 percent.

*iii. Separately Payable Therapeutic Radiopharmaceuticals*

CMS is proposing to continue to reimburse all nonpass-through, separately payable therapeutic radiopharmaceuticals under payment level established for separately payable drugs and biologicals (proposed at 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 is proposing to 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 is proposing to pay for blood clotting factors at ASP+4 percent, consistent with its proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue its policy for payment of the furnishing fee using an updated amount. The proposed furnishing fee update is 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. Because the Bureau of Labor Statistics releases the applicable CPI data after the physician fee schedule and OPPS/ASC proposed rules are published, CMS is not able to include the actual updated furnishing fee in the proposed rules but will announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure 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 is proposing to 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 is proposing to 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 is proposing to 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 would make payment at 95 percent of the product’s most recent AWP.

CMS also is proposing to 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 consistent with the proposed packaging of all existing

nonpass-through diagnostic radiopharmaceuticals, contrast agents and implantable biologicals.

*vi. Blood and Blood Products*

CMS is proposing to 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**

CMS does not specifically discuss drug administration services in the preamble to the Proposed Rule. In a review of the addenda, it appears that CMS is proposing to pay separately for the same set of drug administration codes under the CY 2012 OPSS as were paid separately in the CY 2012 OPSS.

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

**3. Pass-Through Payments for Devices**

There currently is one new device category eligible for pass-through payment, described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable), which was announced in the October 2010 OPSS Update. CMS is proposing an expiration date for pass-through payment for device category C1749 of December 31, 2012. Therefore, beginning January 1, 2013, device category C1749 no longer will be eligible for pass-through payments.

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

a. Brachytherapy Sources

CMS is proposing 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 is proposing to pay 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); to assign 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 is no claims data; to subject brachytherapy sources to outlier payments; and to 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)

At its February 28-March 1, 2011 meeting, the 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 says 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 states 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). CMS indicates that it will continue its efforts to model other composite structures for a possible new extended assessment and management composite structure for CY 2013. Accordingly, CMS is proposing to continue the extended assessment and management composite APC payment methodology and criteria that it finalized for CYs 2009, 2010, and 2011.

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

CMS is proposing to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. The proposed median cost for composite APC 8001 for CY 2012 is approximately \$3,364. This is an increase compared to the CY 2011 final median cost for this composite APC of approximately \$3,195. The proposed CY 2012 median cost for this composite APC is slightly less than \$3,555, which is the sum of the proposed median costs for APCs 0163 and 0651 (\$2,658 + \$897), the APCs to which Current Procedural Terminology (CPT)<sup>2</sup> codes 55875 and 77778 map if one service is billed on a claim without the other. CMS believes the proposed CY 2012 median cost for composite APC 8001 of approximately \$3,364, calculated from claims it believes to be correctly coded, would result in a reasonable and appropriate payment rate for this service in CY 2012.

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

CMS is proposing 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. To calculate the proposed median costs, CMS used the same methodology that it used to calculate the final CY 2011 median costs for these composite APCs.

e. Bronchoscopy

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

CMS also is proposing to reassign HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers), which

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<sup>2</sup> CPT is a registered trademark of the AMA.

is the most common code with which HCPCS code 31627 was billed in 2010, and which has a proposed CY 2012 median cost of approximately \$2,708, from APC 0076 (that has a proposed CY 2012 APC median cost of approximately \$751) to APC 0415 (Level II Endoscopy Lower Airway), that has a proposed CY 2012 APC median cost of approximately \$2,007.

## 5. Proposed APC Group Policies

### a. Proposed Treatment of New CPT and Level II HCPCS Codes

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

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC	Proposed CY 2012 Payment Rate
C9730	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe	T	415	\$1,971.77
C9731	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes	T	415	\$1,971.77

CMS is proposing the following treatment for certain newly implemented Category III CPT codes:

CY 2011 CPT Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC	Proposed 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	\$2,166.33
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	\$2,166.33
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	\$2,166.33

b. New Technology APCs

In its discussion of new technology APCs, CMS addresses requests for new technology APCs for specific procedures on the basis that they require the use of expensive equipment. In that regard, CMS states that:

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under our New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on Medicare beneficiary projected utilization and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPSS, we rely on hospitals to make informed business decisions regarding the acquisition of high cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings.<sup>3</sup>

This statement provides some insight into CMS's thinking regarding the establishment of a payment rate for new technologies.

Although noting their low volume, CMS is proposing 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). CMS is, however, proposing to assign them to lower paying New Technology APCs for CY 2012.

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<sup>3</sup> Id. at 42232.

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

The AMA CPT Editorial Panel created three new codes for computed tomography (CT) of abdominal 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. CMS now believes, however, that it is more appropriate to establish payment rates for these services based on historic claims data for the combinations of predecessor codes that are now reported by CPT codes 74176, 74177, and 74178.

CMS is proposing to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which it is proposing to assign CPT code 74176 and for which it is proposing to base the CY 2012 OPPS payment rate on a median cost of approximately \$417. CMS also is proposing to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which it is proposing to assign CPT codes 74177 and 74178 for the CY 2012 OPPS and for which it is proposing to base the CY 2012 OPPS payment rate on a median cost of approximately \$592. CMS also is proposing that, 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 would be assigned to imaging composite APC 8005 (CT and CTA Without Contrast), for which CMS is proposing a median cost of approximately \$445 for the CY 2012 OPPS. 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, CMS is proposing that the code would be assigned to APC 8006 (CT and CTA With Contrast), for which CMS is proposing a median cost of approximately \$744 for the CY 2012 OPPS.

**6. Proposed OPPS 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 OPPS, 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 is proposing that, 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 would make a hospital-specific payment adjustment by adjusting the wage-adjusted OPSS payment for covered outpatient services by the percent difference between the hospital's individual PCR and the Target PCR.

CMS estimates that, on average, the OPSS payments to the 11 cancer hospitals, not including TOPs, are approximately 65 percent of reasonable cost (that is, CMS calculated a PCR of 0.647 for the cancer hospitals), whereas, CMS estimates that, on average, the OPSS payments to other hospitals furnishing services under the OPSS are approximately 90 percent of reasonable cost (resulting in a PCR of 0.901). Based on these estimates, the proposed payment adjustments for cancer hospitals are as follows:

<b>Provider Number</b>	<b>Hospital Name</b>	<b>Percent Increase Without TOPs or Outlier Payment</b>
050146	City of Hope Helford Clinical Research Hospital	10.1%
050660	USC Kenneth Norris Jr. Cancer Hospital	15.7%
100079	University of Miami Hospital & Clinic	27.6%
100271	H. Lee Moffitt Cancer Center & Research Institute	21.6%
220162	Dana-Farber Cancer Institute	54.4%
330154	Memorial Hospital for Cancer and Allied Diseases	39.4%
330354	Roswell Park Cancer Institute	24.3%
360242	James Cancer Hospital & Solove Research Institute	30.1%
390196	Hospital of the Fox Chase Cancer Center	15.3%
450076	University of Texas M. D. Anderson Cancer Center	61.8%
500138	Seattle Cancer Care Alliance	43.7%
<b>Proposed Aggregate Payment Adjustment</b>		<b>39.3%</b>

The aggregate effect of this proposal is a 9 percent increase in payments to the 11 cancer hospitals and a 0.6 percent reduction in payments to all other hospitals.

CMS also is proposing to 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 because, under section 7101 of ACA, cancer hospitals are eligible to participate in the 340B drug program, which may cause significant changes in each cancer hospital's PCR compared to the previous year's calculation.

## **7. Proposed Hospital Outpatient Outlier Payments**

CMS is proposing to 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 is proposing that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure

by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$2,100 fixed-dollar threshold.

## **8. Hospital Visits**

CMS is not proposing to issue national guidelines for coding for hospital visits and encourages hospitals to continue to report visits during CY 2012 according to their own internal hospital guidelines.

## **9. Physician Supervision**

CMS includes in the Proposed Rule its proposal for 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. The major elements of this proposal include the following:

- CMS is proposing that the existing APC Panel would serve as the independent review entity. CMS would make some modifications to the APC Panel scope and composition in order to create a body that is prepared to address supervision standards and reflects the full range of parties subject to the standards.
- CMS is proposing that decisions based on APC Panel recommendations will be issued through sub-regulatory guidance. CMS' decisions would 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, or only in January of the upcoming payment year.
- To begin evaluating services in CY 2012, CMS is proposing to 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 would 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 is proposing to prioritize requests by service volume, total expenditures and/or frequency of requests. CMS also is proposing to prioritize services requested for review through public comment on the CY 2010 and CY 2011 proposed rules.
- CMS is proposing to require requests to include justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. CMS also would consider these justifications in deciding which services to forward to the APC Panel for evaluation.
- CMS is proposing to charge the 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 CPT code.
- In recommending a supervision level to CMS, CMS is proposing that the Panel 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 would 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. 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 is proposing to 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 would send the request to the APC Panel, and the Panel would 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.

In the interim period while CMS works toward establishing the independent review process, it anticipates extending 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 also is proposing 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 is proposing 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:

<b>Hospital OQR Program Measures Previously Adopted for the CY 2011, CY 2012, CY 2013, and CY 2014*** Payment Determinations</b>
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.

Although CMS finalized measures for a three year period of time, the agency states that it is not precluded from adopting additional measures or changing the list of measures for those payment determinations. Nonetheless in the Proposed Rule, CMS is not proposing to make any changes to the CY 2012 measures, and for CY 2013 is proposing only to change the method by which measure OP-22 (ED-Left Without Being Seen) is collected. Instead of having to submit patient-level information for the measure, CMS is proposing that for the CY 2013 payment determination, hospitals would submit aggregate data on the number of patients who left without being evaluated and number of patients who signed to be evaluated.

CMS is proposing to add new measures to the existing measure set for the CY 2014 payment determination. The measures it is proposing to include are the following:

- Surgical Site Infection
- Five chart abstracted diabetes care measures
- Cardiac Patient Referral from an Outpatient Setting
- Safe Surgery Checklist Use
- Hospital Outpatient Volume for Selected Outpatient Surgical Procedures

In addition to the existing measures and those proposed for CY 2014, CMS also is proposing to add the following new measure for the CY 2015 payment determination:

- Influenza Vaccination Coverage among Healthcare Personnel

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

- Measures for future development:
  - 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
  - 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 is

proposing to 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 proposed 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
- 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 is proposing also to add two structural measures:

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

For CY 2106, CMS is proposing to 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 or proposed 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. CMS describes its proposal to implement that exception process in the Proposed Rule. Under the proposal, a hospital or high Medicaid facility could seek an exception from the prohibition on expansion up to once every two years and would 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 Proposed			Difference 2011-2012	% Change 2011-2012
		SI	APC	Rate	SI	APC	Rate		
90471	Immunization admin	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
90472	Immunization admin, each add	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
90473	Immune admin oral/nasal	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
90474	Immune admin oral/nasal addl	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
96360	Hydration iv infusion, init	S	0438	\$75.58	S	0438	\$73.22	-\$2.36	-3.12%
96361	Hydrate iv infusion, add-on	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
96365	Ther/proph/diag iv inf, init	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96366	Ther/proph/dg iv inf, add-on	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
96367	Tx/proph/dg addl seq iv inf	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96368	Ther/diag concurrent inf	N			N			NA	NA
96369	Sc ther infusion, up to 1 hr	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96370	Sc ther infusion, addl hr	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96371	Sc ther infusion, reset pump	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
96372	Ther/proph/diag inj, sc/im	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
96373	Ther/proph/diag inj, ia	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96374	Ther/proph/diag inj, iv push	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96375	Ther/proph/diag inj add-on	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
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	\$26.24	-\$0.11	-0.42%
96401	Chemo, anti-neopl, sq/im	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96402	Chemo hormon antineopl sq/im	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96405	Chemo intralesional, up to 7	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96406	Chemo intralesional over 7	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96409	Chemo, iv push, snl drug	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96411	Chemo, iv push, addl drug	S	0438	\$75.58	S	0438	\$73.22	-\$2.36	-3.12%
96413	Chemo, iv infusion, 1 hr	S	0440	\$205.86	S	0440	\$211.00	\$5.14	2.50%
96415	Chemo, iv infusion, addl hr	S	0437	\$36.88	S	0437	\$36.65	-\$0.23	-0.62%
96416	Chemo prolong infuse w/pump	S	0440	\$205.86	S	0440	\$211.00	\$5.14	2.50%
96417	Chemo iv infus each addl seq	S	0438	\$75.58	S	0438	\$73.22	-\$2.36	-3.12%
96420	Chemo, ia, push technique	S	0438	\$75.58	S	0438	\$73.22	-\$2.36	-3.12%
96422	Chemo ia infusion up to 1 hr	S	0440	\$205.86	S	0440	\$211.00	\$5.14	2.50%
96423	Chemo ia infuse each addl hr	S	0438	\$75.58	S	0438	\$73.22	-\$2.36	-3.12%
96425	Chemotherapy,infusion method	S	0440	\$205.86	S	0440	\$211.00	\$5.14	2.50%
96440	Chemotherapy, intracavitary	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96446	Chemotx admn prtl cavity	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96450	Chemotherapy, into CNS	S	0440	\$205.86	S	0440	\$211.00	\$5.14	2.50%
96521	Refill/maint, portable pump	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%
96522	Refill/maint pump/resvr syst	S	0439	\$128.44	S	0439	\$132.71	\$4.27	3.32%

96523	Irrig drug delivery device	Q1	0624	\$43.58	Q1	0624	\$43.28	-\$0.30	-0.69%
96542	Chemotherapy injection	S	0438	\$75.58	S	0438	\$73.22	-\$2.36	-3.12%
96549	Chemotherapy, unspecified	S	0436	\$26.35	S	0436	\$26.24	-\$0.11	-0.42%
C8957	Prolonged IV inf, req pump	S	0440	\$205.86	S	0440	\$211.00	\$5.14	2.50%
G0008	Admin influenza virus vac	S	0350	\$26.35	S	0350	\$26.24	-\$0.11	-0.42%
G0009	Admin pneumococcal vaccine	S	0350	\$26.35	S	0350	\$26.24	-\$0.11	-0.42%

SI = Status indicator