



## **Summary of Selected Provisions of the Hospital Outpatient Prospective Payment System Final Rule for Calendar Year 2011**

On November 2, 2010, the Centers for Medicare & Medicaid Services (CMS) released the hospital outpatient prospective payment system (OPPS) final rule for calendar year (CY) 2011 (“Final Rule”).<sup>1</sup> The Final Rule will be published in the Federal Register on November 24, 2010. CMS will accept comments on certain portions of the Final Rule until January 3, 2011.

The final payment rates for 2011 reflect a 2.35 percent increase in the hospital operating market basket. This update includes a 0.25 percentage point reduction required by the Patient Protection and Affordable Care Act (PPACA). Hospitals that fail to meet the quality data reporting requirements will receive an update that is reduced by 2.0 percentage points. CMS projects that total Medicare payments to hospital outpatient departments (HOPDs) will be approximately \$39 billion and total payments to ambulatory surgical centers (ASCs) will be approximately \$4 billion in 2011.

### **OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**

In general, CMS will continue to use the same methodology and policies to establish payment for drugs, biologicals, and radiopharmaceuticals in 2011 as the agency used in 2010. The payment rate for separately payable drugs, biologicals, and radiopharmaceuticals without pass-through status will be average sales price (ASP)+5 percent in 2011, however, rather than ASP+4 percent as it has been in 2010. In the Proposed Rule, this approach produced a payment rate of average sales price (ASP)+6 percent, although CMS did caution stakeholders that the final payment rate could be lower than ASP+6 after CMS finalized its calculations using data later in the year. As proposed, the packaging threshold will be \$70.

### **Pass-Through Status for Drugs and Biologicals**

As proposed, CMS will continue pass-through status in CY 2011 for 31 drugs and biologicals. These products, 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 2011.

### **Drugs and Biologicals with Continuing Pass-Through Status in 2011**

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<sup>1</sup> CMS, Department of Health and Human Services, Final Rule with Comment Period, Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals (Display Copy posted Nov. 2, 2010), available at [http://www.ofr.gov/OFRUpload/OFRData/2010-27969\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2010-27969_PI.pdf).

CY 2010 HCPCS Code	CY 2011 HCPCS Code	CY 2010 Long Descriptor	CY 2011 SI	CY 2011 APC
A9582	A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	G	9247
A9583	A9583	Injection, gadofosvesettrisodium, 1 ml	G	1299
C9250	C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	G	9250
C9255	J2426	Injection, paliperidonepalmitate, 1 mg	G	9255
C9256	J7312	Injection, dexamethasone intravitreal implant, 0.1 mg	G	9256
C9258	J3095	Injection, telavancin, 10 mg	G	9258
C9259	J9307	Injection, pralatrexate, 1 mg	G	9259
C9260	J9302	Injection, ofatumumab, 10 mg	G	9260
C9261	J3357	Injection, ustekinumab, 1 mg	G	9261
C9263	J1290	Injection, ecallantide, 1 mg	G	9263
C9264	J3262	Injection, tocilizumab, 1 mg	G	9624
C9265	J9315	Injection, romidepsin, 1 mg	G	9625
C9266	J0775	Injection, collagenase clostridium histolyticum, 0.1 mg	G	9266
C9267	J7184	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	G	9267
C9268	J7335	Capsaicin, patch, 10cm2	G	9268
C9269	J0597	Injection, C-1 Esterase inhibitor (human), Berinert, 10 units	G	9269
C9270	C9270	Injection, immune globulin (Gammalex), intravenous, non-lyophilized (e.g., liquid), 500 mg	G	9270
C9271	J3385	Injection, velaglucerasealfa, 100 units	G	9271
C9272	C9272	Injection, denosumab, 1 mg	G	9272
C9273		Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAPGM-CSF in 250 mL of Lactated Ringer's, including leukapheresis and all other preparatory procedures, per infusion	G	9273
	C9274	Crotalidae polyvalent immune fab (ovine), 1 vial	G	9274
	C9275	Injection, hexaminolevulinat hydrochloride, 100 mg, per study dose	G	9275
	C9276	Injection, cabazitaxel, 1 mg	G	9276
	C9277	Injection, alglucosidasealfa (Lumizyme), 1 mg	G	9277
	C9278	Injection, incobotulinumtoxin A, 1 unit	G	9278
	C9279	Injection, ibuprofen, 100 mg	G	9279
C9360	C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	G	9360
C9361	C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	G	9361
C9362	C9362	Porous purified collagen matrix bone void filler (Integra MozaikOsteoconductive Scaffold Strip), per 0.5 cc	G	9362
C9363	C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	G	9363

C9364	C9364	Porcine implant, Permacol, per square centimeter	G	9364
C9367	C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
J0598	J0598	Injection, C1 esterase inhibitor (human), 10 units	G	9251
J0641	J0641	Injection, levoleucovorin calcium, 0.5 mg	G	1236
J0718	J0718	Injection, certolizumabpegol, 1 mg	G	9249
J1680	J1680	Injection, human fibrinogen concentrate, 100 mg	G	1290
J2562	J2562	Injection, plerixafor, 1 mg	G	9252
J8705	J8705	Topotecan, oral, 0.25 mg	G	1238
J9155	J9155	Injection, degarelix, 1 mg	G	1296
J9328	J9328	Injection, temozolomide, 1 mg	G	9253
Q0138	Q0138	Injection, Ferumoxytol, for treatment of iron deficiency anemia, 1 mg	G	1297
Q2025	J8562	Fludarabine phosphate, oral, 10 mg	G	9262

As proposed, the pass-through status of 18 drugs and biologicals will expire on December 31, 2010. These products are listed below.

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

<b>CY 2010 HCPCS Code</b>	<b>CY 2011 HCPCS Code</b>	<b>CY 2010 Long Descriptor</b>	<b>CY 2011 SI</b>	<b>CY 2011 APC</b>
A9581	A9581	Injection, gadoxetate disodium, 1 ml	N	N/A
C9248	C9248	Injection, clevidipien butyrate, 1 mg	K	9248
C9356	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter	N	N/A
C9358	C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	K	9358
C9359	C9359	Porous purified collagen matrix bone void filler (Integra MozaikOsteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc	N	N/A
J1267	J1267	Injection, doripenem, 10 mg	N	N/A
J1453	J1453	Injection, fosaprepitant, 1 mg	K	9242
J1459	J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	1214
J1571	J1571	Injection, hepatitis b immune globulin (hepagam b), intramuscular, 0.5 ml	K	0946
J1573	J1573	Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5ml	K	1138
J1953	J1953	Injection, levetiracetam, 10 mg	N	N/A
J2785	J2785	Injection, regadenoson, 0.1 mg	K	9244
J2796	J2796	Injection, romiplostim, 10 micrograms	K	9245
J9033	J9033	Injection, bendamustinehcl, 1 mg	K	9243
J9207	J9207	Injection, ixabepilone, 1 mg	K	9240

J9225	J9225	Histrelin implant (vantas), 50 mg	K	1711
J9226	J9226	Histrelin implant (supprelin la), 50 mg	K	1142
Q4114	Q4114	Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc	K	1251

Status indicator N = Packaged, K= separately paid without pass-through status

### Pass-Through Status for Radiopharmaceuticals

CMS finalized its proposal to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. If ASP data are not available for a radiopharmaceutical, CMS would 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 would provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent average wholesale price (AWP).

In both the Proposed and Final Rules, CMS reported that it has received questions from hospitals on how to bill for a nuclear medicine scan when they receive a diagnostic radiopharmaceutical free of charge or with full credit. CMS instructs hospitals to report the “FB” modifier in these situations “in order to ensure that the OPSS is making appropriate and equitable payments under such circumstances and that a hospital can comply with the required radiolabeled product edits.” The “FB” modifier would be reported on the line with the procedure code for the nuclear medicine scan in which the no cost/full credit diagnostic radiopharmaceutical is used. Modifier -FB is “Item Provided Without Cost to Provider, Supplier or Practitioner, or Credit Received for Replacement Device (Examples, but not Limited to: Covered Under Warranty, Replaced Due to Defect, Free Samples).” In cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit, the hospital should report a token charge of less than \$1.01.

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

#### Packaging Policies

In the Final Rule, CMS increased the packaging threshold for drugs and biologicals from \$65 per day to \$70 per day. CMS also will continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals regardless of their per day costs for CY 2011. ACCC submitted comments urging CMS to reinstate separate payment for these products. Nonetheless, CMS continued this policy because of the agency’s belief that these products function effectively as supplies and are “always ancillary and supportive to an independent service rather than serving themselves as the therapeutic modality.”

As proposed, 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 as devices. Two of the therapies with expiring pass-through status for CY 2011 are biologicals that are solely surgically implanted according to their FDA-

approved indications. These products are described by Healthcare Common Procedure Coding System (HCPCS) codes C9356 (Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter) and C9359 (Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc). CMS will package payment for these products in 2011.

#### Payment for Separately Payable Drugs

In the Final Rule for CY 2010, CMS redistributed \$200 million in pharmacy overhead from packaged drug cost to separately payable drugs. This \$200 million included the \$150 million redistributed from the pharmacy overhead cost of coded packaged drugs and biologicals for which an ASP is reported and an additional \$50 million dollars from the total uncoded drug and biological cost to separately payable drugs and biologicals as a “conservative estimate of the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals.” This redistribution of overhead cost resulted in a payment rate for separately payable drugs without pass-through status of ASP+4 percent. Without such a redistribution, the payment rate established under CMS’s standard methodology would have been ASP-3 percent. If a less conservative estimate of uncoded packaged drug cost had been used, CMS would have achieved a payment rate of ASP+7 percent. CMS acknowledged that, “to some unknown extent, there are pharmacy overhead costs being attributed to the items and services reported under the pharmacy revenue code without HCPCS codes that are likely pharmacy overhead for separately payable drugs,” but the agency “could not know the amount of overhead” associated with uncoded packaged drugs.

For 2011, CMS proposed to use the same methodology and redistribute \$200 million in pharmacy overhead cost from packaged drugs to separately payable drugs. In the Proposed Rule, this methodology and redistribution produced a proposed payment rate of ASP+6 percent, but CMS acknowledged that the rate could be lower in the final rule due to use of more recent data. Without the reallocation of \$200 million, the payment rate would have been ASP+0 percent. CMS estimates that the total aggregate cost for packaged drugs with a HCPCS code for which manufacturers report ASP data (status indicator “N”), including acquisition and pharmacy overhead costs, is equivalent to ASP+283 percent. The estimated total cost of both packaged drugs with a HCPCS code and separately payable drugs (status indicators “N”, “K” and “G”) for which CMS has ASP data, including acquisition and pharmacy overhead costs, is ASP+14 percent. CMS believes that ASP+0 percent may not be sufficient, and ASP+283 percent may “overstate the combined acquisition and pharmacy overhead cost of packaged drugs and biologicals.”

In the Final Rule, of the total estimated overhead for packaged drugs of \$438 million, CMS again will reallocate \$200 million to separately payable drugs, which it believes is a reasonable amount to transfer. Without this transfer, CMS would have achieved a payment rate of ASP-1 for separately payable drugs and an estimated total aggregate cost for coded packaged drugs of ASP+296. In February 2010, the Advisory Panel on Ambulatory Payment Classification (APC) Groups (APC Panel) recommended that CMS redistribute a larger portion of pharmacy overhead costs from packaged drugs to separately payable drugs. Although ACCC

and other commenters urged CMS to adopt the APC Panel's recommendation, CMS did not do so because CMS believes it needs more information to determine the amount of pharmacy overhead cost attached to packaged drugs. Due to variations in hospitals' methods of setting charges for drugs and overhead, CMS states it cannot be certain of the amount of overhead attached to packaged drugs. CMS also believes that uncoded drugs may have different overhead costs than coded drugs because most uncoded drugs appear on claims with surgical services and most coded drugs appear on claims with medical services. As in the Proposed Rule, CMS concluded that it has "no compelling reason to redistribute a greater amount of drug cost." Nonetheless, as recommended by the APC Panel, CMS will evaluate the impact of changes in its drug payment policy on hospitals (categorized by type and size) of such a reallocation and present this analysis to the APC Panel at its next meeting.

In the Final Rule, CMS continues to encourage hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged. The agency stops short of requiring hospitals to do so, however. In addition, CMS encourages hospitals to consider reporting all drugs in revenue code 0636 (Pharmacy-Extension of 025X; Drugs Requiring Detailed Coding) to improve HCPCS coding for packaged drugs and biologicals in the claims data to improve the accuracy of CMS's ASP+X calculation.

#### Payment for Therapeutic Radiopharmaceuticals

CMS finalized its proposal to continue to reimburse all nonpass-through, separately payable therapeutic radiopharmaceuticals at the same rate as nonpass-through drugs and biologicals 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. If ASP data are not available, CMS will use CY 2009 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals. Thus, where ASP data is available, "patient-ready" doses of nonpass-through, separately payable therapeutic radiopharmaceuticals will be paid at ASP+5 percent.

#### Payment for Blood Clotting Factors

CMS finalized its proposal to reimburse blood clotting factors under the same payment policy for other nonpass-through separately payable drugs and biologicals (ASP+5 percent). CMS also adopted its proposal to continue to provide a furnishing fee updated by 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 applicable CPI data is released after the Medicare Physician Fee Schedule (PFS) and OPPS/ASC Proposed Rules are published, CMS was not able to include the actual updated furnishing fee in the Final Rule. CMS 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 its Website.

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

CMS finalized its proposals to continue the CY 2010 payment methodology for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), non-implantable biologicals, and therapeutic radiopharmaceuticals that meet the following conditions: (1) those drugs, biologicals and therapeutic radiopharmaceuticals that have HCPCS codes that do not crosswalk to CY 2010 HCPCS codes, (2) those that do not have pass-through status, and (3) those that are without OPPS claims data. These products will be reimbursed at the same rate as other separately-payable pass-through drugs (ASP+5 percent where ASP data are available). New nonpass-through drugs and biologicals with HCPCS codes but without OPPS claims data will continue to be reimbursed initially using the product's WAC, and if the WAC is also unavailable, CMS will reimburse the product at 95 percent of its most recent AWP.

CMS also finalized its proposal to establish payment for new therapeutic radiopharmaceuticals with HCPCS codes, but that do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, CMS proposes to make payment for a new therapeutic radiopharmaceutical at 95 percent of the product's most recent AWP.

CMS also finalized its proposal to continue to package payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data (those new CY 2011 diagnostic radiopharmaceutical, contrast agent, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes), consistent with the proposed packaging of all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents and implantable biologicals.

#### Blood and Blood Products

CMS finalized its proposal to continue to use blood-specific cost-to-charge ratios to establish payment for blood and blood products. CMS has used this methodology since CY 2005.

#### OPPS Payment for Drug Administration Services

For CY 2011, CMS will continue to use the full set of Current Procedural Terminology (CPT) codes for reporting drug administration services and continue to pay separately for the same set of drug administration codes under the CY 2011 OPPS as were paid separately in the CY 2010 OPPS. Also, as proposed, CMS did not accept the APC Panel's recommendation to make CPT code 96368 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure) and CPT code 93676 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary, separately payable procedure) separately payable. CMS believes that these two codes each describe services that, by definition, always are provided in conjunction with an initial drug administration code and therefore are appropriately packaged into the payment for the separately payable services that they usually accompany. These services have been packaged since the inception of the OPPS,

and CMS continues to believe they are appropriately packaged into the payment for the separately payable services without which, under CPT guidelines and definitions, they cannot be appropriately reported.

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

## Payment for Devices and Related Procedures

### Pass-Through Categories for Devices

For the Final Rule, one new device category, C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)) became effective October 1, 2010, and is eligible for pass-through payments through CY 2011. Other device pass-through applications are pending. In the Final Rule, CMS estimated that pass-through spending for devices would be \$42.3 million. For CY 2011, CMS will use the device pass-through evaluation process and payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice).

### Device-Dependent APCs

CMS will continue to use its standard methodology for calculating median costs for device-dependent APCs without modification. Under this methodology, CMS uses claims data that generally represent the full cost of the required device and include only claims that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than \$1.01) for devices; do not contain the “FB” modifier signifying that the device was furnished without cost to the provider, supplier, or practitioner, or where a full credit was received; and do not contain the “FC” modifier signifying that the hospital received partial credit for the device. The “FC” modifier became effective January 1, 2008, and was present for the first time on claims that were used in OPPS ratesetting for CY 2010.

### Composite APCs

As proposed, CMS will continue to use the existing composite APCs for extended assessment and management, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services. In addition, as recommended by the APC Panel, CMS will consider creating a composite APC or custom APC that captures the costs of stem cell acquisition performed in conjunction with recipient transplantation and preparation of tissue. The agency will report the results of its assessment to the APC Panel at a future meeting.

CMS increased the payment for composite APC 8001 for LDR prostate brachytherapy from the rate in effect in 2010 due to increased median costs for the procedure. ACCC submitted comments in support of CMS’s proposal with respect to these services as brachytherapy is an important treatment option for prostate cancer and thus should be reimbursed appropriately.

As proposed, 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 also accepts the APC Panel's recommendation to provide information to the APC Panel on the impact of the creation of the imaging composite APCs on services to beneficiaries.

#### Packaged Supporting and Ancillary Services

In CY 2008, CMS implemented expanded packaging of supporting and ancillary services under the OPSS. Several stakeholders have been concerned that expanded packaging would hurt access to packaged services and could result in inappropriate payment reductions over time if hospitals are discouraged from reporting packaged services on each claim because the code would not affect payment at the time reported. In the Final Rule, CMS discussed the analysis of payment for packaged services that it presented to the APC Panel in February 2010. CMS reviewed claims data from early CY 2009 and generally observed increases in the billing and reporting of packaged services described by these categories, although it could not explain declines in reporting of codes in the image processing category. CMS believes the data indicate "steady beneficiary access to these categories of supporting and ancillary services." CMS also found that hospitals do not appear to have significantly changed their reporting patterns as a result of the expanded packaging policy, and hospitals do not appear to have stopped offering packaged supporting and ancillary services. Although ACCC submitted comments urging CMS to reinstate separate payment for radiation oncology procedures, CMS will continue to unconditionally package these services in CY 2011.

#### Electromagnetic Navigational Bronchoscopy

The APC Panel asked CMS to consider whether CPT code 31627, describing Electromagnetic Navigational Bronchoscopy (ENB), should be packaged or paid separately, and if it should be paid separately, to investigate the appropriate APC assignment. CMS packaged payment for this code in 2010, and CMS explained in both the Proposed Rule and the Final Rule that it continues to believe this service should be packaged because it describes a procedure that is supportive of and ancillary to the primary diagnostic or therapeutic modality, in this case, bronchoscopy procedures. CMS will continue to package payment for CPT code 31627 in 2011.

#### Guidance for Breast Needle Placement

The APC Panel recommended that CMS conditionally package payment for the guidance procedures that would accompany breast needle placement using the following codes:

- 19290 Preoperative placement of needle localization wire, breast
- 19291 Preoperative placement of needle localization wire, breast; each additional lesion (List separately in addition to code for primary procedure)
- 19295 Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration (List separately in addition to code for primary procedure)
- 77031 Stereotactic localization guidance for breast biopsy or needle placement (e.g., for wire localization or for injection)), each lesion, radiological supervision and interpretation

- 77032 Mammographic guidance for needle placement, breast (e.g., for wire localization or for injection), each lesion, radiological supervision and interpretation
- 76942 Ultrasonic guidance for needle placement (e.g. , biopsy, aspiration, injection, localization device), imaging supervision and interpretation)) when these guidance services are performed separately

In general, CMS did not accept the APC Panel's recommendation to conditionally package these codes in the Final Rule, and the agency will maintain the unconditional packaged payment status for these procedures in 2011. However, CMS has decided to pay separately for CPT code 19295 when it is not reported on a claim with any other separately paid procedure with a status indicator of "S," "T," "V," or "X," making it an "STVX-packaged code."

### Cancer Hospitals

CMS discusses its implementation of section 3138 of PPACA that requires the Secretary of Health and Human Services to study whether the 11 PPS-exempt cancer hospitals incur greater outpatient costs than other hospitals. If the cancer hospitals' costs are determined to be greater than the costs of other hospitals paid under the OPSS, the Secretary shall provide an appropriate adjustment to reflect these higher costs. Section 3138 of PPACA also requires that this adjustment be budget neutral, and it would be effective for outpatient services provided at cancer hospitals on or after January 1, 2011.

CMS conducted a study and found that the PPS-exempt cancer hospitals had higher costs than other hospitals. CMS estimates that on average, the OPSS payments to the 11 cancer hospitals, not including transitional outpatient payments (TOPs, or hold harmless payments), are approximately 62 percent of reasonable cost (a payment-to-cost ratio (PCR) of 0.615) compared to average OPSS payments to other hospitals of approximately 87 percent of reasonable cost (PCR of 0.868). Individual cancer hospitals' OPSS PCRs range from approximately 48 percent to approximately 82 percent. When TOPs are included in the calculation of the PCR, cancer hospitals, as a group, receive payments that are approximately 83 percent of reasonable cost, which is still lower than the average PCR of other OPSS hospitals of approximately 87 percent of reasonable cost. CMS concluded that the cancer hospitals are more costly than other hospitals paid under the OPSS.

CMS proposed to make hospital-specific adjustments for the 11 cancer hospitals, which would have been applied to the wage adjusted payments for all items, except for items and services paid at charges adjusted to cost or devices receiving pass-through status. ACCC submitted comments expressing concern that the proposed adjustments were not budget-neutral. After consideration of the comments received, CMS determined that further study and deliberation of this issue was required, and declined to implement the agency's proposed adjustments.

### Outlier Payments

For CY 2011, 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 2011 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPTS, CMS would set the hospital outlier threshold 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 \$2,025 fixed-dollar threshold.

#### New Technology APCs for Surgical Pathology, Gross and Microscopic Examination for Prostate Needle Biopsy Sampling

Currently, HCPCS code G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens), is assigned to New Technology APC 1505 (New Technology - Level V (\$300 - \$400)); and HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens), is assigned to New Technology APC 1507 (New Technology - Level VII (\$500 - \$600)). Beginning in 2011, CMS will reassign code G0416 from New Technology APC 1505 to clinical APC 0661 (Level V Pathology), which has an APC median cost of approximately \$165, and HCPCS code G0417 from New Technology APC 1507 (New Technology - Level VII (\$500 to \$600)) to New Technology APC 1506 (New Technology - Level VI (\$400 - \$500)).

#### Payment for Brachytherapy Sources

CMS uses the median costs from CY 2009 claims data for setting the proposed CY 2011 payment rates for brachytherapy sources, using the same methodology it proposed and that is used for most other items and services that will be paid under the CY 2011 OPPTS. ACCC had submitted comments in support of this proposal. CMS also will continue the other payment policies for brachytherapy sources that were finalized in the CY 2010 OPPTS final rule. Under these policies, CMS will continue 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).

#### Hospital Visits

CMS did not propose any new national guidelines for coding for hospital visits. Until national guidelines are established, CMS advises hospitals to continue using their own internal guidelines to determine the appropriate reporting of different levels of clinic and emergency department visits. In the Final Rule, CMS promised to provide hospitals with 6 to 12 months notice prior to implementation of national guidelines, and therefore will not implement any national guidelines prior to CY 2012.

#### Physician Supervision

In the final rule for CY 2010, CMS issued new regulations on supervision of outpatient therapeutic services. In the Proposed Rule for 2011, CMS proposes “modest changes” to the supervision policy for therapeutic services. As proposed, in the Final Rule, the agency identified

a set of services with a significant monitoring component that can extend for a sizable period of time, that are not surgical, and that typically have a low risk of complication after assessment at the beginning of the service, as “nonsurgical extended duration therapeutic services.” CMS will require direct supervision for the initiation of these services followed by general supervision for the remainder of the service. “Initiation of the service” is defined as the beginning portion of a service ending when the patient is stable and the supervising physician or appropriate nonphysician practitioner believes the remainder of the service can be delivered safely under their general direction and control without needing his or her immediate availability. CMS considered four criteria when identifying the list of services would apply: (1) the service must be of extended duration, frequently extending beyond normal business hours; (2) the service must have a substantial monitoring component typically conducted by auxiliary staff; (3) the service must have a low risk of requiring the physician’s or appropriate non-physician practitioner’s immediate availability after initiation of the procedure; and (4) the service is not primarily surgical in nature. The proposed list of nonsurgical extended duration therapeutic services includes several drug administration services, but CMS did not include chemotherapy or blood transfusions in the list because, as articulated in the Proposed Rule, the agency believes that these services require the physician’s or nonphysician practitioner’s recurrent physical presence in order to evaluate the patient’s condition in the event it is necessary to redirect the service.

The list of nonsurgical extended duration therapeutic services appears below.

#### **List of Nonsurgical Extended Duration Therapeutic Services**

<b>HCPCS Code</b>	<b>Long Description</b>
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump
G0378	Hospital observation service, per hour
G0379	Direct admission of patient for hospital observation care
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug);

	intravenous push, single or initial substance/drug
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)

CMS also discusses comments it received on the supervision level for particular services. In the CY 2012 OPSS rulemaking cycle, CMS will propose to establish an independent review process that will allow for an assessment of the appropriate supervision levels for individual hospital outpatient therapeutic services. CMS is considering using the APC Panel to review requests for changes in supervision levels from the usual requirement for direct supervision and to make recommendations to CMS. CMS requests comments on an independent review process for reviewing these requests, criteria to apply, and other technical panels that could consider these requests.

For 2011, CMS extends its decision to not enforce the requirement for direct supervision of therapeutic services provided to outpatients in Critical Access Hospitals.

CMS reiterates its requirement that the supervising practitioners have authority under hospital privileges and state licensure to perform the services they supervise. The agency explains that this does not require the physician or non-physician practitioner to be in the same specialty as the services they supervise, but should be knowledgeable enough about the service to service to be able to furnish assistance and direction, and not merely manage an emergency. CMS expects that hospitals can adjust their bylaws and privileging standards sufficiently to cover practitioners whom they wish to act in a supervisory capacity.

In response to comments seeking a clearer definition of “immediately available,” CMS revised the definition of direct supervision for hospital outpatient therapeutic and diagnostic services to remove the reference to “on the same campus” or “in the off-campus provider-based department of the hospital” and it removed the definition of “in the hospital or CAH” from the regulation entirely. The definition of direct supervision is revised simply to require immediate availability, meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary. The new definition states:

For services furnished in the hospital or CAH or in an outpatient department of the hospital or CAH, both on- and off-campus, as defined in section 413.65 of this subchapter, ‘direct supervision’ means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor or medicine or osteopathy as specified in §§410.47 and 410.49, respectively.

For diagnostic services furnished under arrangement in non-hospital locations, direct supervision will continue to mean physical presence in the office suite.

This revised definition allows physicians or other practitioners in locations that are close to the hospital but not in actual hospital space to directly supervise services that are within their State scope of practice and hospital granted privileges, so long as these individuals remain immediately available. This policy also allows supervision from any location within a building off-campus that houses multiple provider-based departments (PBDs) of a hospital as long as the supervising practitioner is immediately available, rather than requiring a supervising practitioner to be located within each PBD in that building. CMS did not revise the definition to allow supervision via telecommunication, but it notes that the independent panel that is proposed to review supervision levels could consider this issue.

In addition, in response to comments about supervision of radiation oncology services, CMS quotes the guidance from the Benefit Policy Manual, ch. 6, sec. 20.5.24, that a technician may operate the equipment, but the supervising practitioner must be knowledgeable about the service and clinically appropriate to furnish the service.

Preventive Services

PPACA requires Medicare to waive the coinsurance and deductible for the initial preventive physical examination and for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. CMS identifies the following services and indicates whether coinsurance or deductible would apply.

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating	CY 2010 Coinsurance/ Deductible	CY 2011 Coinsurance/ Deductible
Initial Preventive Physical Examination (IPPE)	G0402	Initial preventive physical examination; face to face visits, services limited to new beneficiary during the first 12 months of Medicare enrollment	*Not Rated	Coinsurance applies and deductible is waived	Waived
	G0404	Electrocardiogram, routine ECG with 12 leads; tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination		Not Waived	Not Waived
Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)	G0389	Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) ultrasound screening	B	Coinsurance applies and deductible is waived	Waived

Screening Pap Test (Specimen Collection)	Q0091	Screening papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory	A	Coinsurance applies and deductible is waived	Waived
Screening Pelvic Exam	G0101	Cervical or vaginal cancer screening; pelvic and clinical breast examination	A	Coinsurance applies and deductible is waived	Waived
Bone Mass Measurement	G0130	Single energy x-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	B	Not Waived	Waived
	77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		Not Waived	Waived
	77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		Not Waived	Waived
	77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		Not Waived	Waived
	77081	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		Not Waived	Waived
	77083	Radiographic absorptiometry (eg, photodensitometry, radiogrammetry), 1 or more sites		Not Waived	Waived
	76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method		Not Waived	Waived
Colorectal Cancer Screening	G0104	Colorectal cancer screening; flexible	A	Coinsurance applies and	Waived

		sigmoidoscopy		deductible is waived	
	G0105	Colorectal cancer screening; colonoscopy on individual at high risk		Coinsurance applies and deductible is waived	Waived
	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk		Coinsurance applies and deductible is waived	Waived
	G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema	*Not Rated	Coinsurance applies and deductible is waived	Coinsurance applies and deductible is waived
	G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema.		Coinsurance applies and deductible is waived	Coinsurance applies and deductible is waived
Prostate Cancer Screening	G0102	Prostate cancer screening; digital rectal examination	D	Not Waived	Not Waived
Glaucoma Screening	G0117	Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist	I	Not Waived	Not Waived
	G0118	Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist		Not Waived	Not Waived
Influenza Virus Vaccine	90655	Influenza virus vaccine, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use	B	Waived	Waived
	90656	Influenza virus vaccine, split virus, preservative free, when administered to individuals 3 years and older, for intramuscular use		Waived	Waived
	90657	Influenza virus vaccine, split virus, when administered to children 6-35 months of age, for intramuscular use		Waived	Waived

	Q2035	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (afluria)		N/A	Waived
	Q2036	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (flulaval)		N/A	Waived
	Q2037	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (fluvirin)		N/A	Waived
	Q2038	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (fluzone)		N/A	Waived
	Q2039	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (not otherwise specified)		N/A	Waived
	90660	Influenza virus vaccine, live, for intranasal use		Waived	Waived
	90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use		Waived	Waived
	G0008	Administration of influenza virus vaccine		Waived	Waived
	G9141	Influenza a (h1n1) immunization administration (includes the physician counseling the patient/family)		Waived	Waived
	G9142	Influenza a (h1n1)		Waived	Waived

		vaccine, any route of administration			
Pneumococcal Vaccine	90669	Pneumococcal conjugate vaccine, polyvalent, when administered to children younger than 5 years, for intramuscular use	B	Waived	Waived
	90670	Pneumococcal vacc, 13 valim		Waived	Waived
	90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use		Waived	Waived
	G0009	Administration of pneumococcal vaccine		Waived	Waived
Hepatitis B Vaccine	90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use	A	Not Waived	Waived
	90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use		Not Waived	Waived
	90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use		Not Waived	Waived
	90746	Hepatitis B vaccine, adult dosage, for intramuscular use		Not Waived	Waived
	90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use		Not Waived	Waived

\*This table lists only the preventive services, as defined by PPACA, that are paid under the OPSS or at reasonable cost, and excludes preventive services such as screening mammography and cardiovascular screening blood tests that are paid under another fee schedule such as the Medicare PFS or the Clinical Laboratory Fee Schedule.

## Extension of Waiver of Deductible to Services Furnished in Connection with or in Relation to a Colorectal Cancer Screening Test That Becomes Diagnostic or Therapeutic

PPACA waives the deductible with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. As proposed, all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema will be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test. CMS will implement this provision by creating a HCPCS modifier that providers would append to the diagnostic procedure code that is reported instead of the screening colonoscopy or screening flexible sigmoidoscopy HCPCS code or as a result of the barium enema when the screening test becomes a diagnostic service.

## Reporting Quality Data for Annual Payment Rate Updates

### Expansion of Hospital Outpatient Quality Data Reporting Program (HOP QDRP) Quality Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

As proposed, for the CY 2012 payment determination, CMS will retain the existing 11 HOP QDRP measures. These measures continue to address areas of topical importance regarding the quality of care provided in HOPDs and reflect consensus among affected parties. CMS will also add one structural measure for the CY 2012 payment determination: “Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data” (NQF # 0489).

CMS will also add three new claims based imaging efficiency measures to the HOP QDRP measurement set, all of which were listed as under consideration for CY 2012 and subsequent years in the CY 2010 OPSS final rule.

1. Pre-operative Evaluation for Low-Risk Non-Cardiac Surgery Risk Assessment
2. Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
3. Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

Similar to the current imaging efficiency measures in the HOP QDRP measurement set, these three measures are based on Medicare claims and will not require additional data submission on the part of hospitals. CMS had also proposed to add an additional claims-based measure, “Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG” as a quality measure for these purposes, but declined to finalize this measure for the CY 2012 payment determination based on a National Quality Forum (NQF) recommendation that CMS further refine the measure.

CMS also declined to add one new chart-abstracted measure to the HOP QDRP measurement set for the CY 2012 payment determination: “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” because the proposed collection start date may not have allowed sufficient time for hospitals to submit data to CMS. Instead, CMS is adopting this measure for the CY 2013 annual payment update.

As proposed, for the CY 2013 payment determination, CMS will retain all of the measures adopted for the CY 2012 payment determination and will add one structural measure to the HOP QDRP measurement and six new chart-abstracted measures. The structural measure is: Tracking Clinical Results between Visits. The chart-abstracted measures are:

1. Median Time from ED Arrival to ED Departure for Discharged ED Patients
2. Transition Record with Specified Elements Received by Discharged Patients
3. Door to Diagnostic Evaluation by a Qualified Medical Professional
4. ED - Median Time to Pain Management for Long Bone Fracture
5. ED -Patient Left Before Being Seen
6. ED - Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Who Received Head CT Scan Interpretation Within 45 minutes of Arrival.

For the CY 2014 payment determination, CMS proposed to adopt six new chart-abstracted measures, including five diabetes care and one additional imaging efficiency measure. However, in response to public comments, CMS has declined to adopt these measures and instead will retain only the 23 measures discussed above for purposes of the CY 2014 payment determination. The chart-abstracted measures that had been proposed include:

1. Hemoglobin A1c Poor Control in Diabetic Patients
2. Low Density Lipoprotein (LDL-C) Control in Diabetic Patients
3. High Blood Pressure Control in Diabetic Patients
4. Dilated Eye Exam in Diabetic Patients
5. Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
6. Exposure Time Reported for Procedures Using Fluoroscopy

CMS also provided a list of quality measures that are under consideration for future adoption into the HOP QRDP measurement set. In the Proposed Rule, CMS requested comments in response to these proposed measures and measurement topics to enable CMS to consider proposing them beginning with the CY 2013 payment determination. The comments received are summarized in the Final Rule. The measures and measurement topics under consideration are listed below.

### **Measures and Measurement Topics under Consideration for Future Payment Determinations Beginning with CY 2013**

#### **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.

Pneumococcal Vaccination Status

Influenza Vaccination Status  
Cardiac Rehabilitation Referral  
Medication Reconciliation  
Appropriate surgical site hair removal  
Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)  
Heart Failure: Left Ventricular Ejection Fraction Assessment  
Heart Failure: Combination Medical Therapy for Left Ventricular Systolic Dysfunction  
Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction  
Heart Failure: Counseling regarding Implantable Cardioverter-Defibrillator (ICD) Implantation for Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy  
Heart Failure: Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy  
Heart Failure: Symptom Management  
Heart Failure: Symptom and Activity Assessment  
Heart Failure: Patient Education  
Heart Failure: End of Life Care Plan  
Heart Failure: Overuse of Echocardiography  
Heart Failure: Post-Discharge Appointment for Heart Failure Patients

**Measures and Measurement Topics under Consideration for Future Payment Determinations Beginning with CY 2013**

Emergency Department Transfer Communication: Administrative Communications  
Emergency Department Transfer Communication: Medication Information  
Emergency Department Transfer Communication: Nursing Information  
Emergency Department Transfer Communication: Patient Information  
Emergency Department Transfer Communication: Physician Information  
Emergency Department Transfer Communication: Procedures and Tests  
Emergency Department Transfer Communication: Vital Signs

**Measurement Topics for future development:**

Chemotherapy  
Unplanned Reintubation  
Unplanned Inpatient Transfer  
Post-discharge follow up  
Post-discharge ED visit within 72 hours  
Safe Surgery Checklist  
Immunization Refusal rate  
Breast Cancer Detection rate

Reporting of Quality Data in ASCs

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. In the Proposed Rule, CMS invited public comment on: (1) the deferral of quality data reporting for ASCs; (2) suggestions for quality measures geared toward the services provided by ASCs; and

(3) potential reporting mechanisms for ASC quality data, including electronic submission of these data. In addition, CMS invited public comment on the following measures under future consideration for ASC quality data reporting:

- Patient Fall in the ASC;
- Patient Burn;
- Hospital Transfer/Admission;
- Wrong Site, Side, Patient, Procedure, Implant;
- Prophylactic IV Antibiotic Timing;
- Appropriate Surgical Site Hair Removal;
- Surgical site infection (SSI);
- Medication administration variance (MAV);
- Medication reconciliation; and
- VTE measures: outcome/assessment/prophylaxis.

The comments received are summarized in the Final Rule.

#### Changes Relating to Payments to Hospitals for Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs

Section 5504(a) of PPACA amended the Medicare statute to significantly reduce the costs that hospitals must incur for residents training in nonhospital sites in order to count the full time equivalent (FTE) residents for purposes of Medicare direct GME payments. The statute, as amended, allows a hospital to count all the time that a resident trains in a nonhospital site so long as the hospital incurs the costs of the residents' salaries and fringe benefits for the time that the resident spends training in the nonhospital site. In the Final Rule, CMS amends the regulations to implement this change, and clarifies that this change is fully prospective, with an effective date of July 1, 2010.

#### Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition and Related Changes to Provider Agreement Regulations

Section 6001(a) of PPACA amended the whole hospital and rural provider exceptions to impose additional restrictions on physician ownership or investment in hospitals to qualify for such exceptions. In order to satisfy the whole hospital exception, a physician-owned hospital must meet the requirements described in a new section 1877(i)(1) of the Act no later than September 23, 2011.

1. Have physician owners or investors and a provider agreement in effect no later than December 31, 2010;
2. Not expand facility capacity beyond the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010, unless an exception is granted by the Secretary;
3. Comply with certain reporting and disclosure requirements and not condition any physician ownership or investment interests directly or indirectly on a physician making or influencing referrals to or generating other business for the hospital;
4. Comply with certain requirements designed to ensure that all ownership and investment interests in the hospital are *bona fide*;

5. Inform patients before admission if the hospital does not have a physician available on the premises during all hours and receive a signed acknowledgment that the patient understands this fact; and
6. Not have been converted from an ASC on or after March 23, 2010.

## Outpatient PPS Drug Administration Rates – Current 2010 Rates and 2011 Rates

Code	Description	2010			2011			Difference 2010-2011	% Change 2010-2011
		SI	APC	Rate	SI	APC	Rate		
90471	Immunization admin	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
90472	Immunization admin, each add	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
90473	Immune admin oral/nasal	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
90474	Immune admin oral/nasal addl	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
96360	Hydration iv infusion, init	S	0438	\$75.50	S	0438	\$75.58	\$0.08	0.11%
96361	Hydrate iv infusion, add-on	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
96365	Ther/proph/diag iv inf, init	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96366	Ther/proph/dg iv inf, add-on	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
96367	Tx/proph/dg addlseq iv inf	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96368	Ther/diag concurrent inf	N			N			NA	NA
96369	Scther infusion, up to 1 hr	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96370	Scther infusion, addlhr	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96371	Scther infusion, reset pump	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
96372	Ther/proph/diaginj, sc/im	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
96373	Ther/proph/diaginj, ia	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96374	Ther/proph/diaginj, iv push	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96375	Ther/proph/diaginj add-on	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96376	Tx/pro/dx inj new drug adon	N			N			NA	NA
96379	Ther/prop/diaginj/infproc	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
96401	Chemo, anti-neopl, sq/im	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96402	Chemo hormonantineoplsq/im	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96405	Chemo intralesional, up to 7	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96406	Chemo intralesional over 7	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96409	Chemo, iv push, snl drug	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96411	Chemo, iv push, addl drug	S	0438	\$75.50	S	0438	\$75.58	\$0.08	0.11%
96413	Chemo, iv infusion, 1 hr	S	0440	\$219.42	S	0440	\$205.86	-\$13.56	-6.18%
96415	Chemo, iv infusion, addlhr	S	0437	\$37.35	S	0437	\$36.88	-\$0.47	-1.26%
96416	Chemo prolong infuse w/pump	S	0440	\$219.42	S	0440	\$205.86	-\$13.56	-6.18%
96417	Chemo iv infus each addlseq	S	0438	\$75.50	S	0438	\$75.58	\$0.08	0.11%
96420	Chemo, ia, push technique	S	0438	\$75.50	S	0438	\$75.58	\$0.08	0.11%
96422	Chemo ia infusion up to 1 hr	S	0440	\$219.42	S	0440	\$205.86	-\$13.56	-6.18%
96423	Chemo ia infuse each addlhr	S	0438	\$75.50	S	0438	\$75.58	\$0.08	0.11%
96425	Chemotherapy,infusion method	S	0440	\$219.42	S	0440	\$205.86	-\$13.56	-6.18%
96440	Chemotherapy, intracavitary	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96445	Chemotherapy, intracavitary	S	0440	\$219.42	D			-\$219.42	-100.00%
96446*	Chemotxadmnrptl cavity	S			S	0439	\$128.44		
96450	Chemotherapy, into CNS	S	0440	\$219.42	S	0440	\$205.86	-\$13.56	-6.18%
96521	Refill/maint, portable pump	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96522	Refill/maint pump/resvrsyst	S	0439	\$126.47	S	0439	\$128.44	\$1.97	1.56%
96523	Irrig drug delivery device	Q1	0624	\$41.23	Q1	0624	\$43.58	\$2.35	5.70%
96542	Chemotherapy injection	S	0438	\$75.50	S	0438	\$75.58	\$0.08	0.11%
96549	Chemotherapy, unspecified	S	0436	\$25.61	S	0436	\$26.35	\$0.74	2.89%
C8957	Prolonged IV inf, req pump	S	0440	\$219.42	S	0440	\$205.86	-\$13.56	-6.18%
G0008	Admin influenza virus vac	S	0350	\$25.61	S	0350	\$26.35	\$0.74	2.89%
G0009	Admin pneumococcal vaccine	S	0350	\$25.61	S	0350	\$26.35	\$0.74	2.89%

SI = Status indicator

\*New code for 2011