Hospital Regulatory Update

The Hospital Outpatient Prospective Payment System (OPPS) is not intended to be a fee schedule, in which separate payment is made for each coded line item. Instead, the OPPS is currently a prospective payment system that packages some items and services, but not others. CMS' overarching goal is to make payments for all services covered under OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. For CY 2015, CMS will continue base payments on geometric mean costs. Under this methodology, claims are selected for services paid under the OPPS and matched to the most recent cost report filed by the individual hospitals represented in the claims data.

CMS estimates that total payments, including the beneficiary cost share, to the approximately 400 facilities paid under OPPS will be approximately $56.1 billion in CY 2015, an increase of just over $5.1 billion compared to CY 2014 payments. Outpatient hospital payment rates will increase by 2.2 percent and CMS will continue the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements. The CY 2014 conversion factor of $72.672 rises to $74.144 with the 2.2 percent increase, but for hospitals that fail to meet the OQR (Outpatient Quality Reporting) requirements, the conversion factor will drop to $72.661 in 2015.

CMS will also continue the policy of providing additional payments to the 11 designated cancer hospitals so that the hospitals' payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals. And last, CMS will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC (ambulatory payment classification) payment amount when both the 1.75 multiple threshold and the final fixed-dollar threshold of $2,775.00 are met.

Packaged Services

For CY 2015, CMS will continue to unconditionally or conditionally package the following five categories of items and services:

- Drugs, biologicals, and radiopharmaceuticals used in a diagnostic test or procedure
- Drugs and biologicals when used as supplies in a surgical procedure
- Certain clinical diagnostic laboratory tests
- Procedures described by add-on codes
- Device removal procedures.

In CY 2014 CMS proposed the packaging of ancillary services, but decided further study was needed. The agency finalized this proposal for CY 2015, and included the following provisions:

- Ancillary service APCs with a geometric mean cost of $100 or less will be conditionally packaged.
- Status indicator X (ancillary service) will be deleted; services formerly assigned status indicator X will be converted to status Q1 (STV-packaged) or S (Procedure or service, not discounted when multiple).
- Status Q1 services will continue to be paid separately when not performed with status S, T, or V services.
- Preventive services (including bone density studies, glaucoma screening, AAA screening, EKG for IPPE, and obtaining Pap smear) will be excluded from this policy even though they are under the $100 cutoff.
- Certain psychiatry and counseling services are also excluded.
- Low-cost drug administration services are excluded as CMS is current looking at alternative ways to pay for drug administration.

CMS continues to state that given the frequency of drug administration services in the hospital outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals, further study of the payment methodology for these services is warranted. According to CMS, the agency is "examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes." Last, CMS continues to emphasize that "hospitals should report all HCPCS codes for all services, including those for packaged services, according to correct coding principles."

Comprehensive APCs

To improve the accuracy and transparency of payment for certain device-dependent services, CMS finalized the policy to establish 28 comprehensive APCs (ambula-

tory payment classifications) to prospectively pay for the most costly hospital outpatient device-dependent services, and will implement this policy in CY 2015. A comprehensive APC, by definition, will provide a single payment that includes the primary service and all adjunct services performed to support the delivery of the primary service. For services that trigger a comprehensive APC payment, the comprehensive APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment for the comprehensive service. This means that hospitals will continue to report procedure codes for all services performed, but will receive a single payment for the total service. According to the 2015 OPPS final rule:[1]

For CY 2015, we [will] convert the following existing APCs into C-APCs: APC 0067 (Single Session Cranial Stereotactic Radiosurgery) and APC 0351 (Level V Intraocular Surgery). C-APC 0351 only contains one procedure – CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens). We also proposed to assign the CPT codes for IORT (CPT codes 77424 and 77425) to C-APC 0648 (Level IV Breast and Skin Surgery) because IORT is a single session comprehensive service that includes breast surgery combined with a special type of radiation therapy that is delivered inside the surgical cavity but is not technically brachytherapy. The HCPCS codes that we proposed to assign to these C-APCs in CY 2015 would be assigned to status indicator "J1."

This means that single-fraction stereotactic radiosurgery will be reimbursed through a single payment and intraoperative radiation therapy will be included in the payment for the surgical procedure beginning in CY 2015.

Off-Campus Provider-Based Departments

In the CY 2014 proposed rule, CMS solicited comments regarding a potential new claims modifier or other data element that would designate services furnished in an off-campus provider-based department (PBD). According to CMS, research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resulting increase in the delivery of physician services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office.

For physician and/or practitioner professional claims, CMS has decided to implement new place of service (POS) codes rather than a modifier. For hospital claims, CMS will proceed with the modifier requirement. The new modifier is PO (Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments). Reporting of the modifier will be voluntary until CY 2016, at which point it will become mandatory.

Providers will append the modifier to every code for all outpatient hospital services furnished in an off-campus provider-based department of a hospital. CMS defines the campus as "the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."

The modifier should not be used on services performed at remote locations of the hospital, satellite facilities of the hospital, or emergency departments. A remote location is defined as "a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider." CMS states that questions about whether a particular location requires the modifier should be referred to the CMS regional offices.

Quality Measures & EHRs

CMS continues to align measures across the Hospital OQR and ASCQR (Ambulatory Surgical Center Quality Reporting) Programs, and is finalizing the addition of one outcome-based measure for the CY 2018 payment determination and subsequent years for both programs. In addition, CMS is excluding one previously adopted measure from the measure set for the CY 2016 payment determination and changing this measure from required to voluntary for the CY 2017 payment determination and subsequent years for both the Hospital OQR and ASCQR Programs. Facilities will not be subject to payment reductions while the measure is voluntary. Additionally, for the Hospital OQR Program, CMS is:

1. Removing two "topped-out" prophylactic antibiotic surgery measures
2. Clarifying data submission requirements for one measure
3. Noting a delayed data collection for two colonoscopy measures.

Also, for the Hospital OQR Program, CMS is formalizing a review and corrections period for chart-abstracted measures, and updating validation procedures. Specifically, hospitals will only be eligible for random selection for validation if they submit at least 12 cases to the Hospital OQR Program Clinical Data Warehouse during the quarter with the most recently available data. Hospitals will also have the option to submit validation data using electronic methods and must identify the medical record staff responsible for submission of records to the designated CMS contractor.

New Code Process Changes

In the 2015 proposed OPPS rule, CMS outlined plans for changing the way it handles new procedure codes and this plan was adopted as proposed. Beginning with the 2016 rulemaking process, CMS will

publish APC assignments for new codes as part of the proposed rule, as long as the codes are received in time. Otherwise, CMS will establish HCPCS Level II G-codes equivalent to the prior year's CPT codes and require providers to use those G-codes, rather than the new CPT codes, until the following year's rulemaking. CMS states:[1]

Therefore, beginning with the CY 2016 OPPS update, we will publish proposed APC and status indicator assignments for any new and revised CPT codes for January 1, 2016, that are publicly released by the AMA in time for us to consider them for inclusion in the OPPS/ASC proposed rule. After review of the public comments received on the proposed rule, we will finalize the status indicator and APC assignments for those new and revised CPT codes in the CY 2016 OPPS/ASC final rule. Because the APC assignments would be final, we would no longer request comments in the OPPS/ASC final rules for these new and revised CPT codes that are included in the proposed rule. For any new and revised codes released too late for us to consider them for inclusion in the CY 2016 OPPS/ASC proposed rule, we will create HCPCS G-codes that reflect the same description(s), and APC and status indicator assignments, as their predecessor codes. These HCPCS G-codes will be used during CY 2016, and then we will include proposals for the corresponding new and revised codes and APC and status indicator assignments in the CY 2017 OPPS/ASC proposed rule.

CMS states that it anticipates the use of the G-codes "will be largely a temporary solution or may not be necessary in the OPPS." With the Medicare Physician Fee Schedule (PFS) CMS has to wait for RUC recommendations in order to determine the RVUs for the code. Under OPPS this is not necessary, so CMS states that even if G-codes are created for the PFS, they may not need to be used for OPPS billing.

Radiation Oncology Services

CMS also included a discussion of APC assignments and valuation issues for specific services in this final rule.

- Stereotactic body radiation therapy (code **77373**) will continue to be assigned to APC 0066, which will be renamed to "Level V Radiation Therapy."
- C-APC 0067 for stereotactic radiosurgery (codes **77371** and **77372**) will be renamed to "Single Session Cranial Stereotactic Radiosurgery."
- Radiosurgery HCPCS codes **G0173** and **G0251** were deleted effective Dec. 31, 2014.
- HCPCS Level II codes **G0339** and **G0340** are not used for hospital billing, but will not be deleted since these codes will continue to be used under PFS.
- Hospitals will continue to report codes **77371-77373** for radiosurgery and stereotactic body radiotherapy.
- Last, CMS plans to re-evaluate the APC assignments for all of the radiosurgery codes as part of the 2016 rulemaking.

Beginning in CY 2008, CMS began providing a single payment allowance under a Composite APC for low-dose rate (LDR) prostate brachytherapy. At least two procedure codes are used to report the composite treatment service because there are separate codes that describe placement of the needles (code **55875**, transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and the application of the brachytherapy (code **77778**, interstitial radiation source application, complex). These codes are generally present together on claims for the same date of service and the same operative session. For CY 2015, CMS will continue to pay for LDR prostate brachytherapy using APC 8001.

CMS also finalized the proposals affecting the proton beam therapy services for CY 2015 as follows:

- CPT code **77520** is reassigned from APC 0664 to APC 0412
- CPT code **77522** is reassigned from APC 0664 to APC 0667
- CPT codes **77523** and **77525** are reassigned to APC 0667
- APC 0664 is deleted
- APC 0667 is re-named to "Level IV Radiation Therapy."

According to the final rule[1]:

The three CPT codes, 77522, 77523, and 77525, are similar clinically. All three of these CPT codes describe procedures that involve proton beam therapy delivery services with a continuum of complexity. The procedure described by CPT code 77520 is the least complex. The procedure described by CPT code 77522 is more complex than the procedure described by CPT code 77520, and the procedure described by CPT code 77523 is more complex than the procedure described by CPT code 77522. The procedure described by CPT code 77525 is the most complex procedure of the series proposed to be reassigned to APC 0667. We proposed to reassign CPT code 77520 from APC 0664 to APC 0412 because of the resource comparability with respect to the other procedures involving proton beam therapy delivery services assigned to APC 0412, not based on the clinical dissimilarity with respect to the procedures assigned to APC 0664. In regard to the remaining three procedures involving proton beam therapy delivery services (the procedures described by CPT codes 77522, 77523, and 77525), we believe that these procedures are clinically similar, but each has a slightly varying level of complexity relative to the others. The proposed configuration of APC 0667 only contains the three proton beam therapy delivery services described by CPT codes 77522, 77523, and 77525, and does not include any other service codes. APC 0667 is the most clinically homogeneous APC under the OPPS to assign these services that would ensure adequate payment, with the exception of single service APCs. With regard to the resource comparability of the procedures described by CPT codes 77522, 77523 and 77525, the lowest geometric mean cost among these procedures is associated with the procedure.

CMS continues to package all image guidance under the OPPS, and made minor APC changes to low-dose rate intracavitary and interstitial code placement, as well as hyperthermia codes.

Medical Oncology & Hematology Services

Based on the final rule, for CY 2015, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status continue to be set at the statutory default of average sales price (ASP)+6 percent. In addition, CMS finalized the proposed policy to continue to establish payment rates for blood and blood products using a blood-specific cost-to-charge methodology.

Section 1833 of the Social Security Act permits CMS to make pass-through payments for a period of at least two, but not more than three years after the product's first payment as a hospital outpatient service under Medicare Part B. The longstanding practice has been to provide pass-through payment for a period of two to three years, with expiration of pass-through status proposed and

finalized through the annual rulemaking process. Table 5 (below) lists the drugs for which pass-through status expired on Dec. 31, 2014.

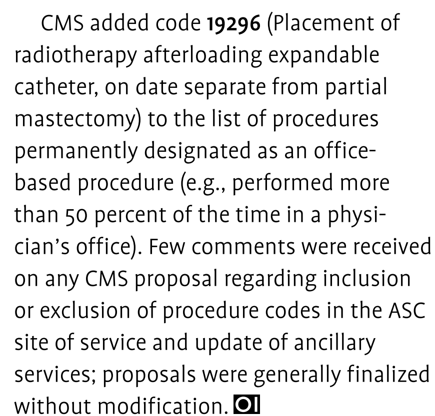
In addition to drugs and biologicals with expired pass-through status, other medications and substances were approved for pass-through during CY 2015. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. If ASP data are not available for a radiopharmaceutical, CMS will provide pass-through payment at Wholesale Acquisition Cost (WAC)+6 percent. And, if WAC information is also not available, CMS will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP). Table 6 (page 18) lists the drugs and biologicals that continued or were granted pass-through status as of January 2015.

CMS estimates that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2015, including those devices, drugs, and biologicals that first become eligible for pass-through during CY 2015 will be approximately $82.8 million (approximately $61.0 million for device categories and approximately $21.8 million for drugs and biologicals), which represents 0.15 percent of total projected OPPS payments for CY 2015.

Ambulatory Surgical Center (ASC) Update

There are approximately 5,300 Medicare-participating ASCs paid under the ASC payment system. For CY 2015, CMS is increasing payment rates under the ASC payment system by 1.4 percent. Based on this update, CMS estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2015 will be approximately $4.147 billion, an increase of approximately $236 million compared to estimated CY 2014 Medicare payments. The 2015 ASC conversion factor is $44.071 for centers that meet the quality reporting requirements and $43.202 for those facilities that do not meet quality reporting requirements.

In the CY 2013 OPPS/ASC final rule with comment period, CMS finalized the proposal to establish the ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes **55875** and **77778** are performed on the same date of service in an ASC. For CY 2015, the ASC will continue to report HCPCS Level II code G0458 instead of the CPT codes to describe this service. Last, ASC payment for brachytherapy sources mirrors the payment policy under the OPPS. Both hospitals and ASCs are paid for brachytherapy sources provided integral to covered surgical procedures at prospective rates adopted under the OPPS.



CMS added code **19296** (Placement of radiotherapy afterloading expandable catheter, on date separate from partial mastectomy) to the list of procedures permanently designated as an office-based procedure (e.g., performed more than 50 percent of the time in a physician's office). Few comments were received on any CMS proposal regarding inclusion or exclusion of procedure codes in the ASC site of service and update of ancillary services; proposals were generally finalized without modification. OI

Table 5. Drugs & Biologicals for Which Pass-Through Status Expired Dec. 31, 2014

CY 2015 HCPCS CODE	CY 2015 LONG DESCRIPTOR	FINAL CY 2015 SI	FINAL CY 2015 APC
C9290	Injection, bupivicaine liposome, 1 mg	N	N/A
C9293	Injection glucarpidase, 10 units	K	**9293**
J0178	Injection, aflibercept, 1 mg vial	K	**1420**
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 mg	K	**1431**
J9019	Injection, asparaginase (erwinaze), 1000 iu	K	**9289**
J9306	Injection, pertuzumab, 1 mg	K	**1471**
Q4131	EpiFix, per square centimeter	N	N/A
Q4132	Grafix core, per square centimeter	N	N/A
Q4133	Grafix prime, per square centimeter	N	N/A

Table 6. Drugs & Biologicals with Pass-Through Status in CY 2015

CY 2014 HCPCS CODE	CY 2015 HCPCS CODE	CY 2015 LONG DESCRIPTOR	FINAL CY 2015 SI	FINAL CY 2015 APC
A9520	**A9520**	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	**1463**
N/A	**A9586**	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	**1664**
C9021	**J9301**	Injection, obinutuzumab, 10 mg	G	**1476**
C9022	**J1322**	Injection, elosulfase alfa, 1 mg	G	**1480**
C9023	**J3145**	Injection, testosterone undecanoate, 1 mg	G	**1487**
C9025	**C9025**	Injection, ramucirumab, 5 mg	G	**1488**
C9026	**C9026**	Injection, vendolizumab, 1 mg	G	**1489**
N/A	**C9027**	Injection, pembrolizumab, 1 mg	G	**1490**
C9132	**C9132**	Prothrombin complex concentrate (human), Kcentra, per iu of Facto IX activity	G	**9132**
C9133	**J7200**	Factor IX (antihemophilic factor, recombinant), Rixubus, per iu	G	**1467**
C9134	**J7181**	Injection, Factor XIII A-subunit, (recombinant), per iu	G	**1746**
C9135	**J7201**	Injection, Factor IX, fc fusion protein, (recombinant), per iu	G	**1486**
N/A	**C9136**	Injection, Factor VIII, fc fusion protein, (recombinant), per iu	G	**1656**
C9441	**J1439**	Injection, ferric carboxymaltose, 1 mg	G	**9441**
N/A	**C9349**	FortaDerm, and FortaDerm Antimicrobial, any type, per square centimeter	G	**1657**
N/A	**C9442**	Injection, belinostat, 10 mg	G	**1658**
N/A	**C9443**	Injection, dalbavancin, 10 mg	G	**1659**
N/A	**C9444**	Injection, oritavancin, 10 mg	G	**1660**
N/A	**C9446**	Injection, tedizolid phosphate, 1 mg	G	**1662**
N/A	**C9447**	Injection, phenylephrine and ketorolac, 4 ml vial	G	**1663**
C9497	**C9497**	Loxapine, inhalation powder, 10 mg	G	**9497**
J1446	**J1446**	Injection, tbo-filgrastim, 5 micrograms	G	**1477**
J1556	**J1556**	Injection, immune globulin (Bivigam), 500 mg	G	**9130**
J3060	**J3060**	Injection, taliglucerase alfa, 10 units	G	**9294**
J7315	**J7315**	Mitomycin, ophthalmic, 0.2 mg	G	**1448**
J7316	**J7316**	Injection, Ocriplasmin, 0.125 mg	G	**9298**
J7508	**J7508**	Tacrolimus, extended release, oral, 0.1 mg	G	**1465**
J9047	**J9047**	Injection, carfilzomib, 1 mg	G	**9295**
J9262	**J9262**	Injection, omacetaxine mepesuccinate, 0.01	G	**9297**
J9354	**J9354**	Injection, ado-trastuzumab emtansine, 1 mg	G	**9131**
J9371	**J9371**	Injection, vincristine sulfate liposome, 1 mg	G	**1466**
J9400	**J9400**	Injection, Ziv-Aflibercept, 1 mg	G	**9296**
Q4121	**Q4121**	Theraskin, per square centimeter	G	**1479**
Q4122	**Q4122**	Dermacell, per square centimeter	G	**1419**
Q4127	**Q4127**	Talymed, per square centimeter	G	**1449**