Oncology Reimbursement Update 2015

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Change is inevitable—except from a vending machine.

ROBERT C. GALLAGHER, BUSINESSMAN AND FORMER DIRECTOR OF THE GREEN BAY PACKERS

That quote is never more accurate than when final regulations, code updates, and other oncology reimbursement changes occur at the end of each year. And this year we have challenges with physicians and hospitals scrambling to update their respective chargemasters, fee schedules, and other reimbursement documents because in 2015 there are different procedure codes reported based on the radiation oncology setting.

New & Revised Procedure Codes

Each year the Centers for Medicare & Medicaid Services (CMS) releases new codes, revised codes, and updates to its coding guidelines. For 2015, there is only one change to the Evaluation and Management (E/M) Guidelines: "military history" has been added as one of the items included in social history. Many physicians already document this history element, so this may not be a significant change for oncologists. In addition, two new codes have been created for advance care planning, including completion of advance directive. This service is frequently provided by oncology physicians, but it must be completely documented in the medical record in order to report the following codes:

- **99497**: Advance care planning, including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified healthcare professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.
- **99498**: This code is for each additional 30 minutes and should be listed separately and in addition to the code for the primary procedure (**99497**, listed above).

CMS will not pay separately for this service in calendar year (CY) 2015, but it will consider separate payment in subsequent years.

There has also been an update to add a HCPCS Level II code for lung cancer screening, which was effective Oct. 1, 2014.

- **S0832**: Low dose computed tomography for lung cancer screening. (Note: CMS published the code as "S8032" in its Transmittal, but the HCPCS File for 2015 lists the code as **S0832**.)

CMS has indicated its intention to pay for this service, but with specific patient criteria, radiologist criteria, and facility criteria.

Teletherapy & Brachytherapy Isodose Planning

The three existing codes for simple, intermediate, and complex teletherapy isodose plans (**77305**, **77310**, and **77315**) have been deleted and been replaced with two new codes for simple and complex teletherapy isodose plans; these new codes include basic dosimetry, which means code **77300** will *not* be reported in addition to these computer plans. The two new codes are:

- **77306**: Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s).
- **77307**: Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s).

The three existing codes for brachytherapy isodose plans (**77326, 77327,** and **77328**) have also been deleted. They have been replaced by three new codes that define the levels for remote afterloading brachytherapy in terms of channels rather than sources; like the new teletherapy isodose plan codes, these plan codes also include basic dosimetry:

- **77316**: Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s).
- **77317**: Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s).
- **77318**: Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading

brachytherapy, over 12 channels), includes basic dosimetry calculation(s).

Treatment Delivery, Image Guidance & Motion Tracking

While the new CPT procedure codes for treatment planning will be used in all practice settings (hospitals, freestanding cancer treatment centers, and physician offices), there are different Medicare treatment delivery and image guidance codes for hospitals and freestanding radiation centers for calendar year 2015.

For hospital billing on the UB-04 claim form, the existing IMRT treatment delivery codes (**77418**, **0073T**) were deleted and replaced by two new codes for simple and complex treatment delivery, both of which include image guidance and motion tracking (when performed). This means that IGRT (e.g., cone-beam CT, CT on rails, stereoscopic imaging, US guidance) and intra-fraction motion tracking will no longer be separately coded by the hospital when IMRT treatment is performed. Instead hospitals will report these two new codes:

- **77385**: Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple (prostate, breast, compensator-based).
- **77386**: Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex (all other sites, non-compensator-based).

The existing Category III code for intra-fraction localization and tracking (**0197T**), code **77421** (Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy), and code **76950** (Ultrasonic guidance for placement of radiation fields) were deleted. Effective Jan. 1, 2015, hospitals will report this new code when patients receive standard external beam therapy (e.g., this code is *not* reported with IMRT treatment):

- **77387**: Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed.

The radiation treatment delivery codes billed by the hospital were also restructured for CY 2015. There is still a single code for superficial and orthovoltage treatment, but there are now only three codes for treatment delivery at any dose greater than or equal to 1 MeV (previously there were 12 codes based on both the complexity and the MeV.) The following codes were deleted:

- **77403**, **77404**, and **77406** for simple treatment delivery
- **77408**, **77409**, and **77411** for intermediate treatment delivery
- **77413**, **77414**, and **77416** for complex treatment delivery.

Starting in CY 2015, hospitals will now bill these new codes:

- **77401**: Radiation treatment delivery, superficial and/or orthovoltage, per day.
- **77402**: Radiation treatment delivery, >1 MeV; simple.
- **77407**: Radiation treatment delivery, >1 MeV; intermediate
- **77412**: Radiation treatment delivery, >1 MeV; complex.

Starting in CY 2015, physician practices and freestanding centers (claims submitted on the CMS1500 form) will not report any of the new CPT treatment delivery or image guidance procedure codes for Medicare patients. Instead, these entities will report HCPCS Level II codes, which have the same definitions as the deleted CPT codes (see Table 1, page 3). Of importance, while Medicare requires the HCPCS Level II codes identified in Table 1, physician practices and freestanding cancer centers may be required to report the new CPT procedure codes (**77401**, **77402**, **77407**, and **77412**) for their other payers.

The physician will continue to report the professional charge for image guidance performed in conjunction with IMRT treatment, when all documentation requirements are met. While the technical component of IGRT is part of the new IMRT treatment delivery codes for hospital billing (and for freestanding centers that report codes **77385** and **77386** to non-Medicare payers), the professional component can be separately charged.

HCPCS Level II Codes & Modifiers

No modifiers were deleted or revised, but the following new HCPCS Level II modifiers were added for calendar year 2015:

- **PO**: Services, procedures, and/or surgeries provided at off-campus provider-based outpatient departments.
- **XE**: Separate encounter, a service that is

(*continued on page 4*)

Table 1. 2015 Treatment Delivery and Image Guidance Codes Reported by Physician Practices and Freestanding Cancer Centers

2014 CPT CODE	2015 HCPCS CODE	DESCRIPTION
76950	G6001	Ultrasonic guidance for placement of radiation therapy fields
77421	G6002	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
77402	G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; up to 5 MeV
77403	G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; 6 – 10 MeV
77404	G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; 11 – 19 MeV
77406	G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; 20 MeV or greater
77407	G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; up to 5 MeV
77408	G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 6 – 10 MeV
77409	G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 11 – 19 MeV
77411	G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 20 MeV or greater
77412	G6011	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 MeV
77413	G6012	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6 – 10 MeV
77414	G6013	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11 – 19 MeV
77416	G6014	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 MeV or greater
77418	G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
0073T	G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensators, convergent beam modulated fields, per treatment session
0197T	G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

Table 2. CY 2015 Q-codes for Epoetin Beta

2015 CODES	DESCRIPTION	DELETED 2014 CODES	DESCRIPTION
J0887	Injection, epoetin beta, 1 microgram (for ESRD on dialysis)	Q9972	Injection, epoetin beta, 1 microgram (for ESRD on dialysis)
J0888	Injection, epoetin beta, 1 microgram (non-ESRD use)	Q9973	Injection, epoetin beta, 1 microgram (non-ESRD use)

Table 3. CY 2015 Codes for Clotting Factors

2015 CODES	DESCRIPTION	DELETED 2014 CODES	DESCRIPTION
C9136	Injection, factor viii, fc fusion protein, (recombinant), per iu		
J7181	Injection, factor xiii a-subunit, (recombinant), per iu		
J7182	Injection, factor viii, (antihemophilic factor, recombinant), (Novoeight), per iu		
J7200	Injection, factor ix, (antihemophilic factor, recombinant), Rixubis, per iu	C9133	Factor ix (antihemophilic factor, recombinant), Rixubis, per iu
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu		
		C9134	Factor xiii (antihemophilic factor, recombinant), Tretten, per 10 iu
		C9135	Factor ix (antihemophilic factor, recombinant), Alprolix, per iu

(*continued from page 2*)

distinct because it occurred during a separate encounter.

- **XP**: Separate practitioner, a service that is distinct because it was performed by a different practitioner.
- **XS**: Separate structure, a service that is distinct because it was performed on a separate organ/structure.
- **XU**: Unusual non-overlapping service, the use of a service that is distinct because it does not overlap usual components of the main service.

Modifiers XE, XP, XS, and XU are intended to replace modifier 59 for Medicare patients. Each Medicare contractor will post information on when and how these modifiers are to be applied.

New, Revised & Deleted Drug Codes

Here are the new, revised, and deleted codes for drugs, biologicals, radiation sources, and radiopharmaceuticals.

Two new codes for CY 2015 include:

- **A9606**: Radium Ra-223 dichloride, therapeutic, per microcurie.
- **C2644**: Brachytherapy source, Cesium-131 chloride solution, per millicurie.

Table 4. CY 2015 Drug Code Changes for Testosterone

2015 CODES	DESCRIPTION	DELETED 2014 CODES	DESCRIPTION
J1071	Injection, testosterone cypionate, 1mg	J1070	Injection, testosterone cypionate, up to 100 mg
		J1080	Injection, testosterone cypionate, 1 cc, 200 mg
		J1060	Injection, testosterone cypionate and estradiol cypionate, up to 1 ml
J3121	Injection, testosterone enanthate, 1mg	J3120	Injection, testosterone enanthate, up to 100 mg
		J3130	Injection, testosterone enanthate, up to 200 mg
		J0900	Injection, testosterone enanthate and estradiol valerate, up to 1 cc
J3145	Injection, testosterone undecanoate, 1 mg	C9023	Injection, testosterone undecanoate, 1 mg
		J3140	Injection, testosterone suspension, up to 50 mg
		J3150	Injection, testosterone propionate, up to 100 mg

For CY 2015, the Q-codes for epoetin beta have been replaced with J-codes (Table 2, above).

Starting in CY 2015, there are five new codes, one revised code, and three deleted codes for clotting factors (Table 3, page 4. There is one clotting factor code with a revised description for 2015:

- **J7195**: Injection, factor ix (antihemophilic factor, recombinant) per iu, not otherwise specified.

Replacement codes were created for two chemotherapy drugs. For CY 2015, CMS deleted code **J9265** (Injection, paclitaxel, 30 mg) and replaced it with code **J9267** (Injection, paclitaxel, 1 mg). Similarly, CMS deleted code **C9021** (Injection, obinutuzumab, 10 mg) and replaced it with code **J9301** (Injection, obinutuzumab, 10 mg). In addition to these chemotherapy drugs, CMS deleted codes **Q9970** (Injection, ferric carboxymaltose, 1 mg) and **C9022** (Injection, elosulfase alfa, 1 mg), replacing them with codes **J1439** (Injection, ferric carboxymaltose, 1 mg) and **J1322** (Injection, elosulfase alfa, 1 mg), respectively.

For CY 2015 CMS created two new codes for chemotherapy drugs:

- **C9027**: Injection, pembrolizumab, 1 mg
- **C9442**: Injection, belinostat, 10 mg.

Other new drug HCPCS codes effective Jan. 1, 2015, include:

- **C9443**: Injection, dalbavancin, 10 mg.
- **C9444**: Injection, oritavancin, 10 mg.
- **C9446**: Injection, tedizolid phosphate, 1 mg.
- **C9447**: Injection, phenylephrine and ketorolac, 4 ml vial.
- **J7327**: Hyaluronan or derivative, monovisc, for intra-articular injection, per dose.

Table 4 (above) shows CY 2015 drug code changes for various forms of testosterone.

In addition to the codes listed in this article, there are a number of changes to HCPCS quality measure codes, diagnostic imaging agents, and other medical supplies. Finally, remember that the existence of a procedure or supply code does not guarantee reimbursement; payment for a service depends on the patient's insurance policy, medical necessity, and other determining factors. OI

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 long-standing 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 will expire 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 10) 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.

Table 5. Drugs & Biologicals for Which Pass-Through Status Expires 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**

Physician & Freestanding Center Regulatory Update

Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other providers under the Medicare Physician Fee Schedule (PFS). For reimbursement purposes, relative values are assigned to each of more than 7,000 services to reflect the amount of work, the direct and indirect (overhead) practice expenses, and the malpractice expenses typically involved in furnishing that specific service. After applying a geographic practice cost indicator, the resulting relative value units (RVUs) are summed for each service and multiplied by a fixed-dollar conversion factor to establish the payment amount for each visit or procedure.

The Sustainable Growth Rate (SGR) is a formula adopted by the Balanced Budget Act of 1997 to determine the conversion factor that may result in steep across-the-board reductions in fee schedule reimbursement. The CY 2015 conversion factor (CF) will remain at $35.80 from January 1 through March 31 as mandated by the Protecting Access to Medicare Act. Without a change in the law, effective April 1, 2015, the conversion factor will be $28.22 representing a 21.2 percent decrease. The President's budget calls for averting these cuts and finding a permanent solution to this annual problem. Table 7 (below) shows estimated CY 2015 payment increases or decreases by specialty (without considering the potential conversion factor change).

Radiation Vault

CMS did not finalize its proposal to remove the radiation treatment vault from the direct Practice Expense (PE) input and treat it as part of the infrastructure. The 2015 Final Rule states:[2]

Table 7. Estimated CY 2015 Payment Increases or Decreases by Specialty*

SPECIALTY	ALLOWED CHARGES (MILLIONS)	IMPACT OF WORK RVU CHANGES	IMPACT OF PE RVU CHANGES	IMPACT OF MP RVU CHANGES	COMBINED IMPACT
Hematology and Oncology	$1,811.00	0%	1%	0%	1%
Radiation Oncology	$1,794.00	0%	0%	0%	0%
Radiation Therapy Centers	$57.00	0%	0%	0%	1%

1. Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.
2. Allowed Charges: The aggregate estimated PFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates.
3. Impact of Work RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.
4. Impact of Practice Expense (PE) RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.
5. Impact of Malpractice (MP) RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.
6. Combined Impact: The estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns.

* Does not consider the potential conversion factor change.

In previous rulemaking, we indicated that we included the radiation treatment vault as a direct PE input for several recently reviewed radiation treatment codes for the sake of consistency with its previous inclusion as a direct PE input for some other radiation treatment services, but that we intended to review the radiation treatment vault input and address whether or not it should be included in the direct PE input database for all services in future rulemaking. Specifically, we questioned whether it was consistent with the principles underlying the PE methodology to include the radiation treatment vault as a direct cost given that it appears to be more similar to building infrastructure costs than to medical equipment costs.

CMS stated that it understands the essential nature of the vault in the provision of radiation therapy services and its uniqueness to a particular piece of medical equipment, but the agency is not convinced that either of these factors leads to the conclusion that the vault should be considered medical equipment for purposes of the PE methodology under the PFS. Although, CMS did not finalize the proposal at this time, the agency "intends to further study the issues raised by the vault and how it relates to our PE methodology."[2]

Off-Campus Provider-Based Departments

CMS had proposed creating a new modifier to be reported on all services performed in an off-campus provider based department (PBD), but based on comments received, it has decided to use a new place of service (POS) code for physician claims and a new modifier for hospital claims. This means that CMS will delete POS code 22 (outpatient hospital department) and request two new POS codes from the POS Workgroup. One will be for outpatient services furnished in on-campus, remote, or satellite locations of a hospital. The other will be for services in an off-campus hospital PBD setting that is not a remote location of a hospital, a satellite location of a hospital, or a hospital emergency department. The new POS codes must be used as soon as they are available, but CMS does not expect this to be until July 1, 2015. Providers will be notified prior to the implementation date.

Potentially Misvalued Codes

Consistent with amendments made by the Affordable Care Act (ACA), CMS has been engaged in a vigorous effort over the past several years to identify and review potentially misvalued codes and make adjustments where appropriate. CMS and the RUC (Relative Value Update Committee) have taken several steps to improve the review process, examining potentially misvalued services in the following seven categories:

1. Codes and families of codes for which there has been the fastest growth
2. Codes and families of codes that have experienced substantial changes in PEs
3. Codes that are recently established for new technologies or services
4. Multiple codes that are frequently billed in conjunction with furnishing a single service
5. Codes with low relative values, particularly those that are often billed multiple times for a single treatment
6. Codes which have not been subject to review since the implementation of the Resource-based Relative Value Scale (RBRVS, the so-called 'Harvard-valued codes')
7. Other codes determined to be appropriate by the Secretary.

Section 220(c) of the Protecting Access to Medicare Act of 2014 further expanded the categories of codes to be examined by adding nine additional categories:

1. Codes that account for the majority of spending under the PFS
2. Codes for services that have experienced a substantial change in the hospital length of stay or procedure time
3. Codes for which there may be a change in the typical site of service since the code was last valued
4. Codes for which there is a significant difference in payment for the same service between different sites of service
5. Codes for which there may be anomalies in relative values within a family of codes
6. Codes for services where there may be efficiencies when a service is furnished at the same time as other services
7. Codes with high intra-service work per unit of time
8. Codes with high PE RVUs
9. Codes with high cost supplies.

After considering the comments received, CMS stated that it is appropriate to finalize the high-expenditure screen as a tool to identify potentially misvalued codes.

However, given the resources required over the next several years to revalue the services with global periods, CMS will concentrate its efforts on these valuations. Therefore, the agency is not finalizing the codes identified through the high-expenditure screen as potentially misvalued at this time. This means that codes **77263** (Complex clinical treatment plan), **77334** (Complex treatment device), **96372** (Therapeutic injection), **96375** (Therapeutic intravenous push, each additional drug), **96401** (Chemotherapy injection, non-hormonal antineoplastic), and **96409** (Chemotherapy push, each additional drug) will not be reviewed at this time. CMS will re-run the high-expenditure screen at a future date, and at that time will propose the specific set of codes to be reviewed that meet the high expenditure criteria.

After publication of the CY 2014 Physician Fee Schedule final rule with comment period, CMS was made aware that, due to a clerical error, the clinical labor type for CPT code **77293** (Respiratory Motion Management Simulation [list separately in addition to code for primary procedure]) was entered as L052A (Audiologist) instead of L152A (Medical Physicist), which has a higher cost per minute. CMS has corrected the clinical labor type for this service.

Stereotactic Radiosurgery

In the CY 2014 PFS final rule, CMS summarized comments received about whether CPT codes **77372** and **77373** would accurately reflect the resources used in furnishing the typical SRS delivery if there were no coding distinction between robotic and non-robotic delivery methods. SRS services furnished using robotic methods were billed in the non-hospital setting using contractor-priced HCPCS Level II G-codes **G0339** (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) and **G0340** (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment). Last year, CMS indicated that it would consider deleting these codes in future rulemaking. However, after considering comments regarding the appropriate inputs to use in pricing the SRS services, CMS concluded that it lacks sufficient information to make a determination about the appropriateness of deleting the G-codes and paying for all SRS/SBRT services using the CPT codes. Therefore, CMS will not delete the G-codes for CY 2015, but will instead work with stakeholders to identify an alternate approach and again reconsider this issue in future rulemaking.

Establishing RVUs

CMS is going to adopt a new process for publicly sharing the proposed values for new and revised procedure codes prior to implementation, but this process will not begin until CY 2016. To allow an opportunity for public input into the values for the 2015 CPT code sets for radiation therapy, CMS will not adopt these new codes under the PFS until CY 2016. CMS describes the implementation of the new process as follows:[2]

As suggested by some commenters, we will use CY 2016 as a transition year. In the PFS proposed rule for CY 2016, we will propose values for the new, revised, and potentially misvalued codes for which we receive the RUC recommendations in time for inclusion in the CY 2016 proposed rule. We will also include proposals for the two code sets delayed from CY 2015 in the CY 2016 proposed rule, as discussed above. For those new, revised, and potentially misvalued codes for which we do not receive RUC recommendations in time for inclusion in the proposed rule, we anticipate establishing interim final values for them for CY 2016, consistent with the current process. Beginning with valuations for CY 2017, the new process will be applicable to all codes. In other words, beginning with rulemaking for CY 2017, we will propose values for the vast majority of new, revised, and potentially misvalued codes and consider public comments before establishing final values for the codes; use G-codes as necessary in order to facilitate continued payment for certain services for which we do not receive RUC recommendations in time to propose values; and adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive RUC recommendations in time to propose values.

This means that while hospitals will use the new CPT procedure codes for radiation treatment delivery and image guidance, physicians and freestanding radiation treatment centers will use HCPCS Level II G-codes referenced in Table 1, page 3. CMS further states:[2]

There is substantial work to be done to assure the new valuations for these codes accurately reflect the coding changes. Accordingly we are delaying the use of the revised radiation therapy code set until CY 2016 when we will be able to include proposals in the proposed rule for their valuation. We are maintaining the inputs for radiation therapy codes at the CY 2014 levels. [Note: Due to budget neutrality adjustments and other system-wide changes, the payment rates may change.] Since the code set has changed and some of the CY 2014 codes are being deleted, we are creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes that will not be recognized by Medicare for CY 2015 are denoted with an "I" (Not valid for Medicare purposes). [Table 1, page 3] *lists the G-codes that we are creating and the CY 2014 CPT codes that they are replacing.*

CMS also finalized the interim RVUs for hyperthermia and HDR brachytherapy, and increased the equipment time from 86 minutes to 104 minutes for codes **77373** (SBRT), **77422**, and **77423** (neutron treatment). Last, the RUC made a recommendation regarding the practice expense inputs for digital imaging services. CMS accepted

the RUC recommendations to remove the film supply and equipment items and to allocate minutes for a desktop computer as a proxy for the PACS (Picture Archiving and Communication System) workstation as a direct expense. This policy impacts new brachytherapy isodose plan codes **77316**, **77317**, and **77318**.

Locum Tenens

In the 2015 proposed PFS rule CMS indicated concern about the operational and program integrity issues that result from the use of substitute physicians to fill staffing needs or to replace a physician who has permanently left a medical group or employer. There are concerns that a physician who has left a group may still have claims filed in his or her name and NPI (national provider identification) number, as well as the SSA requirement for the locum tenens identifying information to be submitted with each claim. As a result, CMS solicited comments on the policy for substitute physician billing arrangements. Through this solicitation, the agency hoped to understand better current industry practices for the use of substitute physicians and the impact that policy changes limiting the use of substitute physicians might have on beneficiary access to physician services. CMS received a few comments on the issues raised in this solicitation and will carefully consider these comments in any future rulemaking on this subject.

Concerns with the 10-day and 90-day Global Packages

CMS supports bundled payments as a mechanism to incentivize high-quality, efficient care. Although on the surface, the PFS global codes appear to function as bundled payments similar to those Medicare uses to make single payments for multiple services to hospitals under the Inpatient and Outpatient Prospective Payment Systems, CMS believes that these global codes function significantly differently than other bundled payments. Another concern is that payment for the PFS global packages relies on valuing the combined services together. This means that there are no separate PFS values established for the procedures or the follow-up care, making it difficult to estimate the costs of the individual global code component services. After consideration of all the comments received regarding this proposal, CMS finalized the proposal to transition and revalue all 10- and 90-day global surgery services with 0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. Medically reasonable and necessary visits would be billed separately during the pre- and post-operative periods outside of the day of the surgical procedure. This change will affect some brachytherapy procedures and related surgical services.

Open Payments Update

The Open Payments program establishes a system for annual reporting and increasing public awareness of financial relationships between drug and device manufacturers and certain healthcare providers. The Open Payments program requires applicable manufacturers to report payments or other transfers of value they make to physicians and teaching hospitals to CMS. In its final rule, CMS finalized four changes to this program:[2]

1. CMS is deleting the definition of "covered device" as it is duplicative of the definition of "covered drug, device, biological, or medical supply," which is already defined in regulation.
2. CMS is deleting the Continuing Education Exclusion in its entirety. According to CMS, eliminating the exemption for payments to speakers at certain accredited or certifying continuing medical education (CME) events will create a more consistent reporting requirement, and will also be more consistent for consumers who will ultimately have access to the reported data.
3. CMS will require the reporting of marketed name and therapeutic area or product category of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological, or medical supply.
4. CMS will require applicable manufacturers to report stocks, stock options, or any other ownership interest as distinct categories. This will enable the collection of more specific data regarding the forms of payment made by applicable manufacturers.

Based on public comments and manufacturers' need to update their systems according to the new requirements, these changes will be implemented for data collection in CY 2016.

Other Issues

In addition to the specific topics listed above, CMS also provided details on the Physician Compare Website, the Electronic Health Record Incentive Program, the Medicare Shared Savings Program, value-based modifiers, the Physician Self-Referral Prohibition, and Physician Quality Reporting Systems. OI

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