Oncology Reimbursement Coding Update 2017

BY CINDY PARMAN, CPC, CPC-H, RCC

There is a saying that "a change is as good as a rest," which may indeed be true. However, the 2017 final regulations, code updates, and other reimbursement changes once again bring challenges to oncology coding and billing. To help you update your respective chargemasters, fee schedules, and other reimbursement documents to ensure compliance with coding and billing guidelines, we've compiled all of the oncology-specific information you need to know going into 2017.

New & Revised Procedure Codes

Each year there are new codes, revised codes, and updates to coding guidelines. For calendar year (CY) 2017, a new procedure code has been created for the application of an on-body injector:

- **96377**: Application of on-body injector (includes cannula insertion) for timed subcutaneous injection.

According to code definition, code **96377** differs from code **96372** (therapeutic subcutaneous or intramuscular injection) because it describes the work of preparing and applying the on-body injector, rather than the manual injection of a drug.

The 2016 codes for moderate sedation were deleted, and replaced with these redefined codes:

- **99151**: Moderate sedation services provided by the same physician or other qualified healthcare professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient younger than 5 years of age.
- **99152**: Patient age 5 years or older.
- **+99153**: Each additional 15 minutes intraservice time. (List separately in addition to code for primary service.)
- **99155**: Moderate sedation services provided by a physician or other qualified healthcare professional other than the physician or other qualified healthcare professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient younger than 5 years of age.
- **99156**: Patient age 5 years or older.
- **+99157**: Each additional 15 minutes intraservice time. (List separately in addition to code for primary service.)

In addition, moderate sedation has been included by definition in a number of surgical and procedure codes in the *CPT© Manual*. This means that sedation will not be coded and charged separately for an increasing number of services.

In addition to the CPT procedure codes for moderate sedation, there is a new HCPCS code for gastrointestinal endoscopic services:

- **G0500**: Moderate sedation services provided by the same physician or other qualified healthcare professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older.

HCPCS Level II Code Updates

In addition to changes in procedure codes, there are new and updated HCPCS modifiers, some of which are discussed in more detail in other sections of this article. **Modifier L1** (Provider attestation that the hospital laboratory test is not packaged under the Hospital OPPS) is the only HCPCS modifier deleted for CY 2017.

As a result of changes to payments for off-campus provider-based departments, below are one new and one updated modifier for billing under the Outpatient Prospective Payment System (OPPS):

- **Modifier PN**: Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital.
- **Modifier PO**: Excepted service provided at an off-campus, outpatient, provider-based department of a hospital.

Additional new HCPCS Level II modifiers include:

- **Modifier FX**: X-ray taken using film
- **Modifier Q2**: Demonstration procedure/service (Note: this is an existing modifier with revised definition)
- **Modifier V1**: Demonstration modifier 1
- **Modifier V2**: Demonstration modifier 2
- **Modifier V3**: Demonstration modifier 3
- **Modifier ZB**: Pfizer/Hospira.

Modifier JW

Although not part of the year-end coding changes, CMS issued an update to the requirement for reporting **modifier JW** (drug amount discarded/not administered to any patient). Effective Jan. 1, 2017, all providers (hospitals, freestanding centers, and physician offices) will be required to use **modifier JW**, and they will continue to be required to document the amount of discarded drug in the individual patient's medical record. This policy change was announced in Transmittal 3538 (Change Request 9603), learn more at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf.

Medicare's discarded drug policy is located in Chapter 17 of the Medicare Claims Processing Manual. Briefly, it states that when a provider administers part of a single-use vial or other single-use package to a Medicare patient, and the rest of the container must be discarded, Medicare will pay both for the amount that was administered and the amount that was discarded. Note that this policy applies only to single-use containers or single-use vials. If part of a multi-use container is discarded, the provider may bill only for the amount that was actually administered to the patient.

The provider must report the drug on the claim as two separate charges: one claim line for the amount administered (with no modifier), and one claim line for the discarded drug amount, with **modifier JW**. For example, code **J9035** represents Avastin (bevacizumab), 1 unit per 10 mg. If a patient is given 980 mg from single use vials that total 1,000 mg, and the remainder of the last vial is discarded (20 mg), the provider should report the following:

- **J9035** x 98 units (administered 980 mg)
- **J9035-JW** x 2 units (wasted 20 mg).

Remember to price each line appropriately as well; the charge for the drug administered and the charge for the drug amount wasted should equal the total dollar amount of drug billed. Providers will be paid for both claim lines; CMS simply wants to track the amount Medicare pays for wasted drugs.

CMS states that **modifier JW** should not be used "if the billing unit is equal to or greater than the total actual dose and the amount discarded." For example, 2 mcg of sincalide is administered to a patient from a 5 mcg single use vial, and the remainder is discarded. Sincalide is reported with code **J2805** (Injection, sincalide, 5 micrograms). Since 1 unit of the code is equal to the total amount administered plus the amount discarded, the provider will report 1 unit of code **J2805** and **modifier JW** will not be applied.

Modifier JW is reported with drugs and biologicals (preparations made from living organisms, such as vaccines, antigens, antitoxins, etc.), with the exception of drugs provided under the Competitive Acquisition Program (CAP). Unless your contractor instructs otherwise, this modifier should not be applied to codes for radiopharmaceuticals, which are in a separate category.

Drugs Administered in Portable Pumps

MLN Matters published a special edition April 26, 2016, to clarify charging for prolonged drug and biological infusions started incident-to a physician's service using an external pump. Learn more at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1609.pdf.

In some situations, a hospital outpatient department or physician office may:

- Purchase a drug for a medically reasonable and necessary prolonged drug infusion;
- Begin the drug infusion in the outpatient department or physician office using a portable pump;
- Send the patient home for a portion of the infusion; and
- Have the patient return at the end of the infusion period.

According to these clarified instructions, the drug or biological is billable to the Medicare Administrative Contractor (MAC), even though the entire administration of the drug or biological did not occur in the physician's office or the hospital outpatient department. According to CMS, the drug or biological continues to meet the requirements for the incident-to benefit as the physician or hospital incurred a cost for the drug or biological and the administration of the drug began in the physician's office or hospital outpatient department incident-to a physician's services.

Medicare's payment for the administration of the drug or biological billed to the MAC also includes payment for all equipment used in furnishing the service. This means that equipment, such as the portable

Table 1. Current Biosimilar Codes and Modifiers

HCPCS CODE	DESCRIPTOR	SI	APC	EFFECTIVE DATE	MODIFIER
Q5101	Injection, filgrastim (G-CSF), biosimilar, 1 mcg	G	1822	03/06/2015	ZA – Novartis/Sandoz
Q5102	Injection, infliximab, biosimilar, 10 mg	K	1761	04/05/2016	ZB – Pfizer/Hospira

infusion pump used to begin administration of the drug or biological that the patient takes home to complete the infusion is not separately billable as durable medical equipment for a drug or biological paid under the incident-to benefit. This information was updated in *MLN Matters* (cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9749.pdf) to provide the following HCPCS code that will be used to report the administration charge:

- **G0498**: Chemotherapy administration, intravenous infusion technique; initiation of infusion in the office/other outpatient setting using office/other outpatient setting pump/supplies, with continuation of the infusion in the community setting (e.g., home, domiciliary, rest home or assisted living) using a portable pump provided by the office/other outpatient setting, includes follow-up office/other outpatient visit at the conclusion of the infusion.

The full amount drug or biological administered via pump will also be billed to the MAC. HCPCS Level II code **G0498** is reported by the physician office or outpatient hospital department that fills and initiates the portable pump. Last, Medicare states that this code is effective Jan. 1, 2016, so it may be necessary to retroactively file corrected claims.

Biosimilar Products

A biosimilar product has no clinically meaningful differences from a previously-approved reference product, only minor differences in clinically inactive components. CMS updates coding and billing information under the OPPS on a quarterly basis. The information effective July 1, 2016, included a reminder that OPPS claims for separately paid biosimilar biological products are required to include a modifier that identifies the manufacturer of the product. Current biosimilars codes and modifiers are shown in Table 1, above.

Biodegradable Material

This same quarterly updated document states that effective June 30, 2016, the following HCPCS Level II code was deleted:

- **C9743**: Injection/implantation of bulking or spacer material (any type) with or without imaging guidance (not to be used if a more specific code applies).

Code **C9743** was replaced with a Category III CPT code, effective July 1, 2016:

- **0438T**: Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.

This new code will be reported by the hospital for the technical service and by the physician for the professional service. Remember that Category III temporary procedure codes may not be reimbursed by all insurers, so check local payer policies for coverage.

Spacer material separates the anterior rectal wall from the prostate by injecting an absorbable hydrogel- or saline-filled balloon that naturally biodegrades within six months after implantation. The goal of utilizing spacer material is to reduce the radiation dose to the rectum. These materials generally maintain shape and position during treatment, and then degrade or break down within 6 months after implantation, after treatment has completed.

The full text of *MLN Matters MM9658* is located at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9658.pdf.

Smoking Cessation

According to CMS, effective Sept. 30, 2016, HCPCS codes **G0436** (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and **G0437** (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes) are deleted. The services previously represented by HCPCS codes **G0436** and **G0437** should be billed under existing CPT codes **99406** (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and **99407** (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes)

Table 2. Select Deleted Drug Codes & Their CY 2017 Code Replacements

2017 CODE		DELETED 2016 CODE	
J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units	**C9472**	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)
J9205	Injection, irinotecan liposome, 1 mg	**C9474**	Injection, irinotecan liposome, 1 mg
J9295	Injection, necitumumab, 1 mg	**C9475**	Injection, necitumumab, 1 mg
J9145	Injection, daratumumab, 10 mg	**C9476**	Injection, daratumumab, 10 mg
J9176	Injection, elotuzumab, 1 mg	**C9477**	Injection, elotuzumab, 1 mg
J9352	Injection, trabectedin, 0.1 mg	**C9480**	Injection, trabectedin, 0.1 mg
J8670	Rolapitant, oral, 1 mg	**Q9981**	Rolapitant, oral, 1 mg
J0883	Injection, argatroban, 1 mg (for non-ESRD use)	**C9121**	Injection argatroban, per 5 mg
J0884	Injection, argatroban, 1 mg (for ESRD on dialysis)		
J1942	Injection, aripiprazole lauroxil, I mg	**C9470**	Injection, aripiprazole lauroxil, 1 mg
J7320	Hyaluronan or derivative, Genvisc 850, for intra-articular injection 1 mg	**Q9980**	Hyaluronan or derivative, Genvisc 850, for intra-articular injection 1 mg
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection 1 mg	**C9471**	Hyaluronan or derivative, Hymovis, for intra-articular injection 1 mg
J2182	Injection, mepolizumab, 1 mg	**C9473**	Injection, mepolizumab, 1 mg
J2840	Injection, sebelipase alfa, 1 mg	**C9478**	Injection, sebelipase alfa, 1 mg
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	**C9479**	Instillation, ciprofloxacin otic suspension, 6 mg
J2786	Injection, reslizumab, 1 mg	**C9481**	Injection, reslizumab, 1 mg

respectively. The full text of *MLN Matters* MM9768 is located at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9768.pdf.

Advanced Illness

The second quarter 2016 issue of *Coding Clinic for HCPCS*, included the following new codes:

- **S0311**: Comprehensive management and care coordination for advanced illness, per calendar month
- **S3854**: Gene expression profiling panel for use in the management of breast cancer treatment.

HCPCS codes that begin with the letter "S" are not accepted by Medicare, but may be reimbursed by other insurers, such as Blue Cross Blue Shield.

Telehealth

Effective Jan. 1, 2017, there are two new HCPCS codes for critical care telehealth:

- **G0508**: Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth
- **G0509**: Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.

Mobility Assistance & Care Planning

There is an add-on HCPCS code that will be reported in addition to a patient office visit for patients that use special mobility equipment and an add-on code for comprehensive care planning:

- **G0501**: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient

Table 3. Replacement HCPCS Codes & Definitions for Select Drugs for CY 2017

2017 CODE	2017 DEFINITION	2016 CODE	2016 DEFINITION
J7201	Injection, factor IX, fc fusion protein, (recombinant), Alprolix, 1 IU	**J7201**	Injection, factor IX, fc fusion protein, (recombinant), 1 IU
J0573	Buprenorphine/naloxone, oral greater than 3 mg, but less than or equal to 6 mg	**J0573**	Buprenorphine/naloxone, oral greater than 3 mg, but less than or equal to 3.1 to 6 mg
J0570	Buprenorphine implant, 74.2 mg	**N/A**	
J1745	Injection, infliximab, excludes biosimilar, 10 mg	**J1745**	Injection, infliximab, 10 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg	**J3357**	Injection, ustekinumab, 1 mg
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension, 100 ml	**J7340**	Carbidopa 5 mg/ levodopa 20 mg enteral suspension
P9072	Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit	**P9072**	Platelets, pheresis, pathogen reduced, each unit

lift, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient, evaluation and management visit (list separately in addition to primary service).

- **G0506**: Comprehensive assessment of and care planning by the physician or other qualified healthcare professional for patients requiring chronic care management services, including assessment during the provision of a face-to-face service (billed separately from monthly care management services). (Add-on code, list separately in addition to primary service.)

Drug Codes

Effective Jan. 1, 2017, there are new codes, revised codes, and replaced codes for drugs, biologicals, and substances. Following are new drug HCPCS codes not impacted by code definition changes:

- **C9482**: Injection, sotalol hydrochloride, 1 mg
- **C9483**: Injection, atezolizumab, 10 mg
- **J1130**: Injection, diclofenac sodium, 0.5 mg.

Bendamustine is a chemotherapy drug used for lymphoma and leukemia. For CY 2017, there is a new code for Bendeka™ (**J9034**, Injection Bendamustine HCl [Bendeka], 1 mg) and the existing code has been revised to apply only to Treanda™ (**J9033**, Injection, bendamustine HCl [Treanda], 1 mg).

New drug HCPCS codes for clotting factors effective Jan. 1, 2017, include:

- **C9140**: Injection, factor VIII (antihemophilic factor, recombinant), (Afstyla), 1 IU
- **J7179**: Injection, von Willebrand factor (recombinant), (Vonvendi), 1 IU vwf:rco
- **J7202**: Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
- **J7207**: Injection, factor VIII, (antihemolytic factor, recombinant), pegylated, 1 IU
- **J7209**: Injection, factor VIII, (antihemolytic factor, recombinant), (Nuwiq), 1 IU
- **J7175**: Injection, factor X, (human) 1 IU.

HCPCS codes that will be deleted on Jan. 2017, include:

- **C9139**: Injection factor IX, albumin fusion protein (recombinant), Idelvion, 1 IU
- **C9137**: Injection, factor VIII, (antihemolytic factor, recombinant), pegylated, 1 IU
- **C9138**: Injection, factor VIII, (antihemolytic factor, recombinant), (Nuwiq), 1 IU.

Table 2, page 4, shows select deleted codes and their replace codes for CY 2017. Table 3, above, lists replacement HCPCS codes and definitions for select drugs for CY 2017.

Effective Jan.1, 2017, the following HCPCS codes have been deleted and not replaced:

- **J0760:** Injection, colchicine, per 1 mg
- **J1590**: Injection, gatifloxacin, 10 mg.

Update: National Correct Coding Initiative Policy Manual

The 2017 edition of the NCCI Policy Manual includes the following instruction:

- CPT codes **77280–77290** (simulation-aided field settings) should not be reported for verification of the treatment field during a course of intensity modulated radiotherapy (IMRT) treatment.

This policy will be effective Jan. 1, 2017, and will impact physicians, freestanding radiation treatment centers, and hospital outpatient departments. OI

Hospital Regulatory Update

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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 the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule.

In CY 2017, outpatient hospital payment rates will increase by 1.7 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 Program requirements. The CY 2016 conversion factor of $73.725 increases to $75.001 for CY 2017, but for hospitals that fail to meet the OQR (Outpatient Quality Reporting) requirements, the conversion factor will drop to $73.411. CMS will once again continue the policy of providing additional payments to the 11 designated cancer hospitals so that the hospital's payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals. In addition, outlier payments will be triggered when the hospital's cost for furnishing a service exceeds two thresholds:

- Multiplier threshold: The cost must be at least 1.75 times the Ambulatory Payment Classification (APC) payment amount (no change from CY 2016); and
- Fixed-dollar threshold: The cost must also exceed the APC payment amount by at least $3,825; up from $3,250 last year.

Off-Campus Provider-Based Departments

CMS finalized policies to implement Section 603 of the Bipartisan Budget Act of 2015, which requires that certain items and services furnished by specific off-campus hospital outpatient departments will no longer be paid under the OPPS reimbursement mechanism beginning Jan. 1, 2017. Currently, Medicare pays for the same services at a higher rate if those services are provided in a hospital outpatient department rather than a physician's office. This payment differential has provided an incentive for hospitals to acquire physician offices in order to receive the higher rates. This acquisition trend and difference in payment has been highlighted as a long-standing issue of concern by Congress, the Medicare Payment Advisory Commission, and the Department of Health and Human Services Office of Inspector General (OIG). This difference in payment also increases costs for the Medicare program and raises the cost-sharing liability for beneficiaries.

Therefore, CMS is issuing an interim final rule with comment period (IFC) in conjunction with the OPPS final rule to establish new payment rates under the Medicare Physician Fee Schedule (MPFS) for items and services provided by certain off-campus provider-based departments (PBDs) in CY 2017. These new interim final rates adopted in the IFC will permit hospitals to be paid for furnishing items and services that may no longer be paid under the OPPS, and CMS believes this will reduce incentives for hospitals to acquire independent physician practices and convert them into more highly paid outpatient facilities. Physicians furnishing professional services in this setting will continue to be paid on the CMS1500 claim form and will be paid at the facility rate under the MPFS, in the same manner as all physicians practicing in an outpatient facility setting.

Hospitals will be paid under the MPFS at these newly established MPFS rates for non-excepted items and services, which will be billed on the UB04 claim (institutional claim) with a new claim line modifier:

- **Modifier PN**: Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital.

CMS states that non-excepted off-campus PBDs must report **modifier PN** on each UB04 claim line to indicate a non-excepted item or service. *All* non-excepted items and services billed by a hospital on an institutional claim with **modifier PN** will be paid under the MPFS at the rate established in this final rule. For CY 2017, the payment rate for these services will generally be 50 percent of the OPPS rate (with limited exceptions, such as separately payable drugs). Other OPPS policies, such as packaging of integral services, will continue to apply. CMS continues to seek comments on these new payment mechanisms and payment rates, and will make adjustments as necessary through future rulemaking.

CMS also finalized several policies regarding which off-campus PBDs and which items and services are "excepted" from the payment changes, and will therefore continue to be paid under OPPS

reimbursement. Excepted items and services furnished after Jan. 1, 2017, include:

- Services rendered by a dedicated emergency department;
- Items and services performed in an off-campus PBD that was billing for covered outpatient department services furnished prior to Nov. 2, 2015, and has not impermissibly relocated or changed ownership; or
- Services performed in a PBD that is "on the campus" (within 250 yards) of the hospital or a remote location of the hospital.

With respect to the relocation of an excepted off-campus PBD, CMS finalized the proposal that items and services must continue to be furnished and billed at the same physical address of the off-campus PBD to be considered excepted from Section 603 requirements. The final relocation policy includes a notable change from the proposed rule to allow these off-campus PBDs to relocate temporarily or permanently without loss of excepted status due to extraordinary circumstances outside the hospital's control, such as natural disasters. However, these exceptions for extraordinary circumstances will be reviewed by the CMS Regional Office and are expected to be rare and unusual.

In the CY 2017 OPPS proposed rule, CMS noted that it had received questions from some hospitals regarding whether an excepted off-campus PBD could expand the number or type of services the department furnished and still maintain excepted status. In response to public comments regarding the expansion of services performed in an excepted off-campus PBD, CMS is not finalizing its original proposal. Instead, CMS will monitor the expansion of clinical service lines by off-campus PBDs and continue to consider whether a potential limitation of service line expansion should be adopted in the future.

It is important to remember that the site-neutral rates only apply to facilities that began billing Medicare after Nov. 2, 2015. For those off-campus provider-based departments that were billing Medicare prior to this date, CMS will continue to require the following modifier on all excepted services:

- **Modifier PO**: Excepted service provided at an off-campus, outpatient, provider-based department of a hospital.

As a result, hospitals will append either the **PN** or **PO modifier** to every code for all outpatient hospital services furnished in an off-campus PBD of the hospital. These modifiers 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 reporting of these modifiers should be referred to CMS Regional Offices.

Packaged Services

The OPPS currently packages many categories of items and services that are typically provided as part of the primary hospital outpatient service. According to CMS, packaging encourages hospital efficiency, flexibility, and long-term cost containment, as well as promoting the stability of payment for services over time. For CY 2017, CMS will continue to refine packaging policies under the OPPS. Updates to packaging include:

- CMS finalized its proposal to align the packaging logic for all of the conditionally packaged services so that packaging occurs at the claim level, rather than date of service. According to CMS, this promotes consistency and ensures that items and services provided during a hospital stay are packaged even when the care spans more than a single service date.
- CMS previously adopted a policy to exclude molecular pathology tests from the laboratory packaging policy because these tests may have a different pattern of clinical use than more common and routine laboratory tests. As part of this final rule, CMS finalized the proposal to expand this laboratory test packaging exclusion to advanced diagnostic laboratory tests (ADLTs) that meet the same criteria.
- In CY 2014, CMS implemented **modifier L1** to allow for separate payment of laboratory tests when these tests were the only services on the claim or when the laboratory tests were unrelated to the other services on the claim. For CY 2017, CMS will discontinue separate payment for unrelated laboratory tests, and as a result the following modifier will be discontinued:
  - **Modifer L1**: Provider attestation that the hospital laboratory test(s) is not packaged under the hospital OPPS.

Comprehensive APCs

A comprehensive APC (C-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, on one claim submission regardless of service date, and will receive a single payment for the total service and collect a single beneficiary copayment for the procedure and related services and supplies.

Effective Jan. 1, 2015, CMS implemented C-APCs for single fraction stereotactic radiosurgery (SRS, procedure codes **77371** and **77372**) and intraoperative radiation therapy (IORT), although CMS has reassigned intraoperative radiation therapy codes **77424** and **77425** from a breast surgery C-APC to the Level 7 Radiation

Therapy C-APC. Table 4, right, identifies brachytherapy catheter or needle insertion codes and their related procedures that are designated as C-APCs effective Jan. 1, 2017.

CMS finalized a proposal to create 25 additional C-APCs, bringing the total to 62; most of these represent major surgical procedures, but one new C-APC involves allogeneic hematopoietic stem cell transplantation. Allogeneic hematopoietic stem cell transplantation (HSCT) involves the intravenous infusion of hematopoietic stem cells derived from the bone marrow, umbilical cord blood, or peripheral blood of a donor to a recipient. As provided in the Medicare Claims Processing Manual, donor acquisition charges for allogeneic HSCT include charges for the costs of several services. These services include, but are not necessarily limited to:

- National Marrow Donor Program fees
- Tissue typing of donor and recipient
- Donor evaluation
- Physician pre-procedure donor evaluation services
- Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services, among others)
- Post-operative and post-procedure evaluation of donor
- The preparation and processing of stem cells.

When the allogeneic stem cell transplant occurs in the hospital outpatient setting, providers are instructed to report stem cell donor acquisition charges for allogeneic HSCT separately in Field 42 on Form CMS-1450 (or UB-04) by using revenue code **0819** (Organ Acquisition: Other Donor). Revenue code **0819** charges should include all services required to acquire hematopoietic stem cells from a donor, as defined earlier, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes.

Based on current analysis of several longstanding issues and stakeholder input, CMS proposed to create a new **C-APC 5244** (Level 4 Blood Product Exchange and Related Services) and to assign procedures described by CPT code **38240** (hematopoietic progenitor cell [HPC]; allogeneic transplantation per donor) to this C-APC. The creation of a new C-APC for allogeneic HSCT would allow for the costs for all covered outpatient services, including donor acquisition services, listed on the claim to be packaged into the C-APC payment rate. CMS will analyze these costs using its comprehensive cost accounting methodology to establish future C-APC payment rates.

After consideration of the public comments received, CMS **established C-APC 5244** (Level 4 Blood Product Exchange and Related Services), with the modification to exclude claims that do not include donor acquisition costs reported with revenue code

Table 4. Brachytherapy Catheter or Needle Insertion Codes and Related Procedures Designated as C-APCs, Effective Jan. 1, 2017

2017 C-APC	CODES ASSIGNED TO APC
5091	**19499**: Unlisted breast procedure
5092	**19298**: Breast brachytherapy button & tube catheter placement
5093	**19296**: Breast brachytherapy balloon catheter placement
5113	**20555**: Placement of needles/catheters into muscle and/or soft tissue for subsequent interstitial radioelement application
5153	**31643**: Diagnostic bronchoscope, catheter placement
5165	**41019**: Placement of needles/catheters into head and/or neck region for radioelement application
5302	**43241**: Upper GI endoscopy, catheter placement
5341	**55920**: Placement of needles/catheters into pelvic organs and/or genitalia (except prostate) for radioelement application
5414	**57155**: Insertion of uterine tandem and/or vaginal ovoids **58346**: Insertion of Heyman capsules for clinical brachytherapy

Table 5. CY 2017 Radiation Therapy APCs & Final APC Code Assignments

2017 C-APC	TITLE	CODES ASSIGNED TO APC
5621	Level 1 Radiation Therapy	77401, 77402, 77407, 77789, 77799
5622	Level 2 Radiation Therapy	0394T, 77412, 77600, 77750, 77767, 77768
5623	Level 3 Radiation Therapy	77385, 77386, **77422**, 77423, 77470, 77520, 77610, 77615, 77620, 77761, 77762
5624	Level 4 Radiation Therapy	0395T, 77605, 77763, 77770, 77771, 77772, 77778
5625	Level 5 Radiation Therapy	77522, 77523, 77525
5626	Level 6 Radiation Therapy	77373
5627	Level 7 Radiation Therapy	77371, 77372, **77424**, **77425**

0819 from rate setting. CMS also established a final payment rate for new **C-APC 5244** of $27,752 for CY 2017.

Pain Management

Physicians and other healthcare providers have expressed concern that patient safety questions about pain management in the Hospital Value-Based Purchasing program may influence prescribing practices. While there is no empirical evidence of such an effect, CMS finalized the removal of the pain management dimension of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey to eliminate any financial pressure clinicians may feel to overprescribe medications. CMS will continue the development of alternative questions related to provider communications and pain, and will solicit comments in future rulemaking.

Radiation Oncology Services

Section 1833(t)(2)(A) of the Social Security Act requires CMS to develop a classification system for covered outpatient department services. In accordance with these provisions, CMS developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs). The APCs are organized so that each group is homogenous, both clinically and in terms of resource use. As part of its continuing review of the structure of APC families, CMS finalized the proposal to reduce the number of clinical APCs for Therapeutic Radiation Treatment Preparation from 4 levels to 3 levels:

- **APC 5611**: Level 1 Therapeutic Radiation Treatment Preparation
- **APC 5612**: Level 2 Therapeutic Radiation Treatment Preparation
- **APC 5613**: Level 3 Therapeutic Radiation Treatment Preparation.

Essentially, CMS consolidated prior Level 1 & Level 2 procedure codes into Clinical **APC 5611** (Level 1), with the exception of code **77306** (teletherapy isodose plan; simple), which remains in **APC 5612**. All codes previously listed in Level 3 have been assigned to Level 2, and all codes previously listed in Level 4 are now included in Level 3. With regard to reimbursement, the following procedures that will now be reimbursed at the Level 1 payment are expected to decrease approximately 29.5 percent:

- **77280**: Therapeutic radiology simulation-aided field setting; simple
- **77333**: Treatment devices, design and construction; intermediate.
- **77370**: Special medical radiation physics consultation.

In addition to these APC changes, code **77422** and intraoperative radiation treatment delivery codes **77424** and **77425** were also reassigned to different APC categories (see bold text in Table 5, above).

Once again, CMS will continue paying for low-dose rate prostate brachytherapy using composite **APC 8001**. In order for hospitals to receive the higher composite APC reimbursement, both code **77778** (Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed) and **55875** (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) must be billed on the same claim. The Medicare Prescription Drug Improvement and Modernization Act of 2003 requires CMS to continue to separate payment for brachytherapy sources in CY 2017 and subsequent years. These sources

are reimbursed on a prospective basis, with 2017 payment rates set using the 2015 geometric mean unit codes for each source. CMS assigned new **status indicator E2** (Items and services for which pricing information and claims data are not available) to HCPCS code **C2644** (Brachytherapy source, cesium-131 chloride solution, per millicurie) because this code was not reported on CY 2015 claims.

Medical Oncology & Hematology Services

CMS assigned new CY 2017 CPT code **96377** (Application of on-body injector [includes cannula insertion] for timed subcutaneous injection) to **status indicator N** (Items and Services Packaged into APC Rates) to indicate that the service is paid under the OPPS; however, its payment is packaged into the payment for other services. Some commenters disagreed with the proposed status indicator assignment of N for code **96377**, and indicated that this is a primary service, not an add-on procedure, that represents a complete and unique drug administration service that a hospital performs for the subcutaneous administration of Neulasta® with the on-body injector. The commenters stated that the service is similar to the drug administration service described by procedure code **96372** (Therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular), which is assigned to **APC 5692** (Level 2 Drug Administration) with a proposed payment rate of approximately $53. CMS stated they do not believe that the resources necessary to deliver the Neulasta service warrants separate payment under the OPPS. Because payment for CPT code **96377** will be packaged, the payment for use of the on-body injector will be included in the payment for the primary service (for example, chemotherapy administration or a clinic visit) that is reported on the same service date as code **96377**.

(*continued on page 13*)

Table 6. Pass-Through Status for Drugs & Biologicals that will Expire Dec. 31, 2016

CY 2017 HCPCS CODE	CY 2017 LONG DESCRIPTOR	FINAL CY 2017 SI	FINAL CY 2017 APC
C9497	Loxapine, inhalation powder, 10 mg	K	**9497**
J1322	Injection, elosulfase alfa, 1mg	K	**1480**
J1439	Injection, ferric carboxymaltose, 1 mg	N	**N/A**
J1447	Injection, TBO-Filgrastim, 1 microgram	N	**N/A**
J3145	Injection, testosterone undecanoate, 1 mg	N	**N/A**
J3380	Injection, vedolizumab, 1 mg	K	**1489**
J7181	Injection, factor XIII a-subunit, (recombinant), per IU	N	**N/A**
J7200	Factor IX (antihemophilic factor, recombinant), Rixubus, per IU	N	**N/A**
J7201	Injection, factor IX, fc fusion protein (recombinant), per IU	N	**N/A**
J7205	Injection, factor VIII fc fusion (recombinant), per IU	K	**1656**
J7508	Tacrolimus, extended release, (Astragraf xl), oral, 0.1 mg	N	**N/A**
J9301	Injection, obinutuzumab, 10 mg	N	**N/A**
J9308	Injection, ramucirumab, 5 mg	K	**1488**
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	K	**1466**
Q4121	Theraskin, per square centimeter	N	**N/A**

Table 7. Drugs & Biologicals With Pass-Through Status in CY 2017

CY 2016 HCPCS CODE	CY 2017 HCPCS CODE	CY 2017 LONG DESCRIPTOR	CY 2017 SI	CY 2017 APC
A9586	**A9586**	Florbetapir f18, diagnostic, per study dose, up to 10 mci	G	**1664**
N/A	**A9588**	Fluciclovine f-18, diagnostic, 0.1 mCi	G	**9052**
N/A	**A9587**	Gallium Ga-68, dotatate, diagnostic, 1 mCi	G	**9056**
N/A	**C9140**	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 IU	G	**9043**
C9137	**J7207**	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 IU	G	**1844**
C9138	**J7209**	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per IU	G	**1846**
C9139	**J7202**	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 IU	G	**9171**
C9349	**Q4172**	PuraPly, and PuraPly Antimicrobial, any type, per sq cm	G	**1657**
C9447	**C9447**	Injection, phenylephrine and ketorolac, 4 ml vial	G	**1663**
C9460	**C9460**	Injection, cangrelor, 1 mg	G	**9460**
C9461	**A9515**	Choline C 11, diagnostic, per study dose	G	**9461**
C9470	**J1942**	Injection, aripiprazole lauroxil, 1 mg	G	**9470**
C9471	**J7322**	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	**9471**
C9472	**J9325**	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	**9472**
C9473	**J2182**	Injection, mepolizumab, 1 mg	G	**9473**
C9474	**J9205**	Injection, irinotecan liposome, 1 mg	G	**9474**
C9475	**J9295**	Injection, necitumumab, 1 mg	G	**9475**
C9476	**J9145**	Injection, daratumumab, 10 mg	G	**9476**
C9477	**J9176**	Injection, elotuzumab, 1 mg	G	**9477**
C9478	**J2840**	Injection, sebelipase alfa, 1 mg	G	**9478**
C9479	**J7342**	Instillation, ciprofloxacin, otic suspension, 6 mg	G	**9479**
C9480	**J9352**	Injection, trabectedin, 0.1 mg	G	**9480**
C9481	**J2786**	Injection, reslizumab, 1 mg	G	**9481**
C9482	**C9482**	Injection, sotalol hydrochloride, 1 mg	G	**9482**
C9483	**C9483**	Injection, atezolizumab, 10 mg	G	**9483**
N/A	**J0570**	Buprenorphine implant, 74.2 mg	G	**9058**
J0596	**J0596**	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	**9445**

(table continued on page 12)

(*continued from page 11*)

Table 7. Drugs & Biologicals With Pass-Through Status in CY 2017 (*continued*)

CY 2016 HCPCS CODE	CY 2017 HCPCS CODE	CY 2017 LONG DESCRIPTOR	CY 2017 SI	CY 2017 APC
J0695	**J0695**	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	**9452**
J0875	**J0875**	Injection, dalbavancin, 5 mg	G	**1823**
J1833	**J1833**	Injection, isavuconazonium sulfate, 1 mg	G	**9456**
J2407	**J2407**	Injection, oritavancin, 10 mg	G	**1660**
J2502	**J2502**	Injection, pasireotide long acting, 1 mg	G	**9454**
J2547	**J2547**	Injection, peramivir, 1 mg	G	**9451**
J2860	**J2860**	Injection, siltuximab, 10 mg	G	**9455**
J3090	**J3090**	Injection, tedizolid phosphate, 1 mg	G	**1662**
N/A	**J7179**	Injection, von Willebrand factor (recombinant), (Vonvendi), 1 IU vwf:rco	G	**9059**
J7313	**J7313**	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	**9450**
J7503	**J7503**	Tacrolimus, extended release, (Envarsus xr), oral, 0.25 mg	G	**1845**
J8655	**J8655**	Netupitant (300mg) and palonosetron (0.5 mg)	G	**9448**
J9032	**J9032**	Injection, belinostat, 10 mg	G	**1658**
J9039	**J9039**	Injection, blinatumomab, 1 mcg	G	**9449**
J9271	**J9271**	Injection, pembrolizumab, 1 mg	G	**1490**
J9299	**J9299**	Injection, nivolumab, 1 mg	G	**9453**
Q5101	**Q5101**	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	**1822**
Q9950	**Q9950**	Injection, sulfur hexafluoride lipid microsphere, per ml	G	**9457**
C9459	**Q9982**	Flutemetamol F18, diagnostic, per study dose, up to 5 mci	G	**9459**
C9458	**Q9983**	Florbetaben F18, diagnostic, per study dose, up to 8.1 mci	G	**9458**

(*continued from page 10*)

Blood & Blood Products

In the CY 2017 OPPS proposed rule, CMS recommended continuing to establish payment rates for blood and blood products using the current blood-specific cost-to-charge ratio (CCR) methodology. After consideration of the public comments received, CMS finalized this proposal.

As discussed in the CY 2016 OPPS final rule, CMS is in the process of examining the current set of HCPCS P-codes for blood products. Because these codes were created many years ago, CMS is considering whether this code set would benefit from some code descriptor revisions, updating, and/or consolidation to make these codes properly reflect current product descriptions and utilization while minimizing redundancy and eliminating potentially outdated descriptors.

In the CY 2017 OPPS proposed rule, public comments were requested and CMS asked the blood product stakeholder community whether the current blood product HCPCS P-code descriptors with the associated granularity best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. A number of detailed responses were received, and these comments will be taken into consideration in the development of proposals to update codes that describe blood products.

Pass-Through Drug Payments

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. CMS currently accepts applications for pass-through status on a quarterly basis, but this status expires on an annual basis. Beginning in CY 2017, pass-through status will expire on a quarterly basis so that the biological will receive pass-through status for as close to three full years as possible.

CMS included a list of the drugs for which pass-through status will expire on Dec. 31, 2016, in the final rule (see Table 6, page 10).

Payment for drugs and biologicals with pass-through status under the OPPS in CY 2017 will be made at the rate of ASP+6 percent. However, hospitals will actually receive no extra payment for most of these pass-through drugs because they would receive the difference between the regular OPPS drug payment and the pass-through payment. At this time, both of these payment amounts are ASP+6 percent, so the difference is $0. Hospitals will receive payment for pass-through drugs that are classified as "policy-packaged," such as diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs, since the regular OPPS drug payment for these biologicals is $0. The drugs and biological listed in Table 7, pages 11 and 12, will continue or have been granted pass-through status for CY 2017.

Drugs and therapeutic radiopharmaceuticals without pass-through status are paid separately only if the average per diem cost is greater than that year's packaging threshold. For CY 2017, the threshold is $110, up from $100 in CY 2016. CMS adds that packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. CMS is also continuing its policy of making a single packaging decision for all dosages of a drug that is available in multiple dosages that have separate HCPCS codes.

Other Provisions

In addition to the major provisions listed above, the 2017 OPPS final rule addresses restructuring of the imaging APCs, the Ambulatory Surgical Center (ASC) payment update, the hospital Value-Based Purchasing Program, the hospital Outpatient Quality Reporting (OQR) Program, Medicare Conditions of Participation for Organ Transplant programs, and the Electronic Health Record (EHR) Incentive Program. OI

Physician & Freestanding Center Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other suppliers under the Medicare Physician Fee Schedule (MPFS). For reimbursement purposes, relative values are assigned to 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 CY 2017 conversion factor is estimated to be $35.8887, which is slightly higher than the 2016 conversion factor of $35.8043. Table 8, below, shows the estimated impact that projects payment increases or decreases by specialty (without considering the potential conversion factor change).

Primary Care

Historically, care management and cognitive work has been bundled into the evaluation and management visit codes used by all specialties. This has meant that payment for these services has been distributed equally among all specialties that report visit codes, instead of being targeted toward practitioners who manage care or primarily

Table 8. Estimated Impact of Projected Payment Increases or Decreases by Specialty*

SPECIALTY	ALLOWED CHARGES (MIL)	IMPACT OF WORK RVU CHANGES	IMPACT OF PE RVU CHANGES	IMPACT OF MP RVU CHANGES	COMBINED IMPACT
Hematology/Oncology	$1,751	0%	0%	0%	0%
Radiation Oncology	$1,726	0%	0%	0%	0%
Radiation Therapy Centers	$44	0%	0%	0%	0%

LEGEND

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.
Allowed Charges: The aggregate estimated PFS allowed charges for the specialty based on CY 2015 utilization and CY 2016 rates.
Impact of Work RVU Changes: This column shows the estimated CY 2017 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.
Impact of Practice Expense RVU Changes: This column shows the estimated CY 2017 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.
Impact of Malpractice RVU Changes: This column shows the estimated CY 2017 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.
Combined Impact: This column shows the estimated CY 2017 combined impact on total allowed charges of all the changes in the previous columns.

* Without considering the potential conversion factor change.

provide cognitive services. CMS believes the focus of the healthcare system has shifted to delivery system reforms, such as patient-centered medical homes, clinical practice improvement, and increased investment in primary and comprehensive care management and coordination services for chronic and other conditions. This shift requires more centralized management of patient needs and extensive care coordination among practitioners and providers, often on a non-face-to-face basis across an extended period of time.

For CY 2017, CMS finalized a variety of coding and payment changes as part of an ongoing effort to improve payment for primary care services. These updates include:

- Separate payment for codes describing non-face-to-face prolonged evaluation and management services
- Existing procedure codes that are revalued to describe prolonged face-to-face services
- Separate reimbursement for new codes that describe comprehensive assessment and care planning for patients with cognitive impairment, mobility-related impairment, and patients with behavioral health conditions.

Last, CMS will make separate payments for codes describing chronic care management for patients with greater complexity (refer to HCPCS codes **G0501** and **G0506**). CMS believes that these coding and payment changes will improve healthcare delivery for the types of services holding the most promise for healthier people and smarter spending and advance the agency's health equity goals.

Telehealth Services

CMS finalized the addition of ESRD-related services, advance care planning services, and critical care consultation codes to the current telehealth services list. CMS states that although the agency expects these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, there will not be a significant impact on PFS expenditures.

CMS also finalized a payment policy regarding the use of a new place of service code (**02 – Telehealth**), with telehealth defined as the location where health services and health-related services are provided or received, through telecommunications technology. Of note, the originating site will not use this place of service code. In addition, place of service code **02** will be used in addition to—not instead of—**modifiers GT** (Via interactive audio and video telecommunications) and **GQ** (Via asynchronous telecommunications system). The 2017 fee for code **Q3014** (Telehealth originating site facility fee) will be $25.40, up from $25.10 in CY 2016.

Physician Self-Referral Update

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), enacted on Dec. 19, 1989, added section 1877 to the Social Security Act. Section 1877, also known as the physician self-referral law:

1. Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and
2. Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services.

CMS has reissued regulatory provisions prohibiting certain per-unit-of-service compensation formulas for determining rental charges in the exceptions for the rental of office space, rental of equipment, fair market value compensation, and indirect compensation arrangements. These provisions are necessary to protect against potential abuses, such as overutilization, steering patient choice, the potential reduction in quality of care and patient outcomes. CMS believes that most parties comply with these regulatory provisions since they originally became effective on Oct. 1, 2009, and the reissued regulation text is identical to the existing regulation text.

Qualified Medicare Beneficiaries

Federal law prohibits providers from collecting Medicare Part A and B deductibles, coinsurance, or copayments from beneficiaries enrolled in the Qualified Medicare Beneficiaries (QMB) Program. The QMB program is a Medicaid program that helps low-income individuals with Medicare cost-sharing liability. Under QMB, state Medicaid programs are supposed to pay these patients' Medicare cost-sharing, but Federal law allows the states to limit their payment to the difference between the Medicare payment and the Medicaid rate. Since Medicaid generally reimburses at a lower rate than Medicare, this usually means the provider does not receive any additional payment beyond the Medicare allowance.

Providers are required to accept the Medicare reimbursement (and Medicaid allowance, if any) as payment in full and may not bill the patients for any balance. The same rules apply to dual eligible beneficiaries who are enrolled in both Medicaid and Medicare Advantage plans. In July 2015 CMS released a study finding that confusion and inappropriate balance billing persisted, even in the presence of laws that prohibit these collections.

Some commenters noted that it can be difficult for providers to identify these beneficiaries, and CMS stated it is actively exploring additional mechanisms for Medicare providers to readily identify the QMB status of these patients. Regardless, CMS states that Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. CMS further recommends that providers take steps to educate themselves and their staff about QMBs to ensure that cost-share is not inappropriately collected prior to

treatment or billed to the patient after services are rendered.

Global Surgical Period

Since the inception of the MPFS, CMS has valued and paid for certain services, such as surgery, as part of global packages that include the procedure and the services typically provided during the period immediately before and after the procedure. There are three primary categories of global packages that are defined based on the number of post-operative days included in the global period: 0-day, 10-day, and 90-day.

In the CY 2015 final rule with comment period, 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. However, MACRA was enacted into law on April 16, 2015, and included a paragraph that prohibits CMS from implementing this global surgery policy change. MACRA requires CMS to develop, through rulemaking, a process to gather information needed to value surgical services and requires that this data collection shall begin no later than Jan. 1, 2017.

As part of the 2017 MPFS final rule, CMS also set forth guidelines for data collection regarding resources used when furnishing global services. The claim-based collection strategy reduces the burden on practitioners by requiring reporting only on high-volume/high-cost procedures, using an existing procedure code (**99024**, Postoperative follow-up visit, normally included in the surgical package), allowing some provider groups to report voluntarily while mandating larger practices in designated states to comply with reporting. Practitioners are encouraged to begin reporting post-operative visits for procedures furnished on or after Jan. 1, 2017, but the requirement to report will be effective for services related to global procedures furnished on or after July 1, 2017.

In mid-2017 CMS will also be surveying a large national sample of about 5,000 practitioners. Individuals in this group will be asked to describe 20 postoperative visits furnished to Medicare patients or other patients during the reporting period. Information to be collected includes:

- Procedure codes and dates of service for the global procedure
- Procedure place of service
- Procedural complications
- The level of the visit using existing codes
- Specific activities on the day of the visit
- Total time
- Practice expense items
- Other prior or anticipated care.

CMS will also send monitors to a small number of sites for direct observation, as well as survey Accountable Care Organizations (both Pioneer and Next Generation) about their global services.

CMS has statutory authority to withhold up to 5 percent of the practitioner's Medicare payment for noncompliance with required reporting. The agency does not plan to use this authority in 2017, but will consider using it in future years if claims-based reporting is not acceptable. At this time, the list of procedures that must be reported is not available; CMS will determine the codes for which reporting is required and display the list on the CMS website. Last, if the aggregated data result in proposals to revalue any global packages, that revaluation will be done through notice and comment rulemaking at a future time.

Potentially Misvalued Codes

The Protecting Access to Medicare Act of 2014 (PAMA) establishes an annual target for reductions in MPFS expenditures resulting from adjustments to RVUs of misvalued codes. If the estimated net reduction in expenditures for a year is equal or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner through an adjustment to the conversion factor. This policy applies to calendar years 2017 through 2020, with a target amount of 0.5 percent of the estimated expenditures under the MPFS for each of those four years.

CMS estimates the 2017 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.32 percent. Since this amount does not meet the 0.5 percent target established by the Achieving a Better Life Experience (ABLE) Act of 2014, payments under the MPFS must be reduced by the difference between the target for the year and the estimated net reduction in expenditures, known as the target recapture amount. This results in an estimated 0.18 percent decrease in the 2017 conversion factor.

Services Billed With Modifier 25

CMS states that several high volume procedure codes are typically reported with **modifier 25** (Significant, separately identifiable evaluation and management service on the same day of the procedure or other service), which unbundles payment for visits from the procedure; CMS believes that these services may be misvalued. As a result, CMS has identified 19 services that it intends to review as potentially misvalued and indicates that it will investigate this policy further in future rulemaking. None of the surgical procedures identified would be routinely performed by medical oncologists, hematologists, or radiation oncologists.

Valuation of Moderate Sedation Services

In prior rulemaking, CMS noted that practice patterns for certain procedures appear to be changing, with anesthesia increasingly being separately reported for these procedures even though payment for sedation services was included in the payment to the physician furnishing the primary procedure. In response, the American Medical Association (AMA) CPT Editorial Panel created new codes for reporting moderate sedation and the Specialty Society Relative Value Update Committee provided CMS with recom-

mended values for the moderate sedation codes and recommended adjustments to valuation of the procedure codes.

As part of this final rule, CMS is finalizing values for the new moderate sedation codes and adopting a uniform methodology for valuation of the procedural codes that currently include moderate sedation as an inherent part of the procedure. Table 9, right, shows a list of codes related to oncology services that will be impacted.

Phase-In of Significant RVU Reductions

PAMA specified that if the total RVUs for a service would otherwise be decreased by an estimated amount equal to or greater than 20 percent, the adjustments must be phased-in over a two-year period. This requirement applies only to services described by existing codes and not to services described by new or revised codes.

In the 2017 MPFS final rule, CMS finalized the proposal to reconsider in each year whether the total RVUs for the service would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this policy the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new or revised), including those codes with phase-in values in the previous year. CMS identified three radiation oncology codes with significant RVU reductions in 2017:

- **77332**: Treatment devices, design and construction; simple
- **77334**: Treatment devices, design and construction; complex
- **77470**: Special treatment procedure.

CMS identified procedure code **77470** through the high expenditures by specialty screen, and proposed the RUC-recommended work RVU of 2.03. However, according to CMS the description of service and vignette describe different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and practice expense (PE) RVUs. CMS solicited comments on information that would clarify this apparent disparity to help determine appropriate PE inputs. In addition, the agency solicited comments to determine if creating two HCPCS G-codes, one that describes the work portion of this service and one that describes the practice expense portion, may be a potentially more accurate method of valuing and paying for the service or services described by this code. CMS states:

According to the description of work provided for this service, the physician performs cognitive work, such as planning, consideration of test results, and therapeutic treatment contingency planning that is in addition to what he or she would typically be performing for most radiation treatments. Meanwhile, the radiation therapist handles the treatment devices, performs tasks such as positioning the patient, and helps facilitate the scan of the patient. We believe that this may describe activities that are fundamentally disconnected. To illustrate our concern, we offer the example that this is akin to a physician removing a mole from a patient's hand while the clinical staff places a cast on the patient's foot; we see no compelling clinical evidence to indicate that the two tasks are related. In addition, the disparate diagnoses described by the vignettes further calls into question the degree to which the work and PE components are interrelated. While we agree that there should not be separate coding for each possible diagnosis for a particular service, in trying to accurately assess relative value, we believe that the work and PE components should be valued under unified assumptions about the typical service. We are finalizing the RUC-recommended work RVU and PE inputs as proposed; however, we continue to have serious concerns about the validity of this coding.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

PAMA requires CMS to establish a program to promote utilization of appropriate use criteria (AUC) for advanced diagnostic imaging services. Advanced diagnostic imaging services include diagnostic imaging exams performed using CT, MR, and nuclear medicine, including PET. AUC help professionals who order and furnish imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual patient. CMS can only approve AUC that are developed or endorsed by provider-led entities, such as national professional medical specialty societies. In most cases the AUC will be evidence-based and CMS can approve more than one set of AUC for a given imaging service.

The 2017 MPFS final rule lists the first eight priority clinical areas for the AUC:

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Cervical or neck pain.

Ordering professionals will be required to consult AUC for *all* advanced imaging services, not just those in priority clinical areas, as long as the service is furnished in an applicable setting such as office or outpatient hospital and paid under an applicable payment system like the MPFS or OPPS. However, the priority clinical areas will be used to identify outlier ordering professionals in the future.

Medicare will initially pay for the imaging study regardless of whether it was recommended by the AUC. Eventually,

(*continued on page 19*)

Table 9. Codes for Oncology Services Impacted by Sedation Codes

CODE	DESCRIPTION
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time or subsequent to) partial mastectomy, includes imaging guidance
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple
32553	Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intrathoracic, single or multiple
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (e.g., anesthetic, neurolytic agent) or fiducial marker(s) (including endoscopic ultrasound examination of the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
49411	Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple
49418	Insertion of tunneled intraperitoneal catheter (e.g., dialysis, intraperitoneal chemotherapy instillation, management of ascites), complete procedure, including imaging guidance, catheter placement, contrast injection when performed, and radiological supervision and interpretation, percutaneous
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session, multi-source Cobalt 60 based
77600	Hyperthermia, externally generated; superficial (i.e., heating to a depth of 4 cm or less)
77605	Hyperthermia, externally generated; deep (i.e., heating to depths greater than 4 cm)
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
0301T	Destruction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter and ultrasound thermotherapy guidance

(*continued from page 17*)
however, CMS will identify those ordering professionals who are consistently failing to follow AUC recommendations, and these "outliers" will be required to obtain prior authorization for advanced imaging studies they wish to order. CMS will address outlier calculations, which may be used to determine whether clinicians will be subject to prior authorization.

The MPFS final rule also addressed clinical decision support mechanism (CDSM) requirements, stating that CDSMs are "electronic tools through which a clinician consults AUC to determine the level of clinical appropriateness for an advanced diagnostic imaging service for that particular patient's clinical scenario." CMS finalized the CDSM application to allow for preliminary qualification or full qualification based on whether the applicant can demonstrate that all requirements are met at the time of application. The application deadline for the first round of preliminary and full qualifying CDSMs is March 1, 2017.

The first list of qualified CDSMs will be posted no later than June 30, 2017, and CMS expects furnishing professionals to be required to begin reporting on Jan. 1, 2018. In addition, CMS is considering the mechanisms for appending AUC consultation information to the Medicare claim and will issue that information as part of the 2018 rulemaking. Among the mechanisms CMS is considering are the use of HCPCS G codes and HCPCS modifiers. Current exceptions to the use of AUC include:

- Patients with emergency medical conditions (including situations where such a condition is suspected but not yet confirmed)
- Inpatients (the Inpatient Prospective Payment System is not an applicable payment system)
- The ordering professional has a hardship exception, such as practicing in a rural area without sufficient Internet access.

CMS recognizes that the number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad.

Other Issues

In addition to the major provisions listed above, the 2017 MPFS final rule addresses the Medicare Shared Savings Program (MSSP), Medicare Advantage provider enrollment, expansion of the Diabetes Prevention Program Model, the value-based payment modifier and physician feedback program, and recoupment or offset payments to providers sharing the same taxpayer identification number. OI

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