Oncology

Coding Update 2018

Oncology Reimbursement Meeting

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2018 CPT CODE UPDATES

Each year there are new codes, revised codes and updates to coding guidelines. For calendar year (CY) 2018, the section for bone marrow biopsy and aspiration has been revised, including the addition of a new procedure code for CY 2018:

Code	Description
38220	Diagnostic bone marrow; aspiration(s)
38221	Diagnostic bone marrow; biopsy(ies)
38222	Diagnostic bone marrow biopsy(ies) and aspiration(s)

Effective January 1, 2018 the following HCPCS procedure code has been deleted:

Code	Description
G0364	Bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service

The following new CPT® code replaces Category III code 0438T [Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance].

Code	Description
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

The following procedure code has undergone a change in descriptor for CY 2018:

Code	Description
76000	Fluoroscopy (separate procedure), up to 1 hour physician or other qualified healthcare professional time

Last, the following procedure codes have been deleted for CY 2018:

Code	Description
77422	High energy neutron radiation treatment delivery; single treatment area using a single port or parallel-opposed ports with no blocks or simple blocking
0301T	Destruction/reduction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter under ultrasound thermotherapy guidance
0438T	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance

HCPCS Level II Modifier 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 CP [Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim] is the only oncology-related HCPCS modifier deleted for CY 2018.

Due to changes in 340B Drug Pricing Program, the following modifiers have been created for CY 2018:

Modifier	Description
JG	Drug or biological acquired with 340B drug pricing program discount
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

The following modifier was created for imaging providers to use on a voluntary basis starting July 1, 2018 to show that the ordering professional consulted Appropriate Use Criteria for advanced diagnostic imaging (CT, MRI, PET, other nuclear medicine):

Modifier	Description
QQ	Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional

New modifiers have been created for reporting patient relationship categories as required by MACRA, effective January 1, 2018 on a voluntary basis:

Modifier	Description
X1	Continuous/broad services: for reporting services by clinicians, who provide the principal care for a patient, with no planned endpoint of the relationship; services in this category represent comprehensive care, dealing with the entire scope of patient problems, either directly or in a care coordination role; reporting clinician service examples include, but are not limited to: primary care, and clinicians providing comprehensive care to patients in addition to specialty care
X2	Continuous/focused services: for reporting services by clinicians whose expertise is needed for the ongoing management of a chronic disease or a condition that needs to be managed and followed with no planned endpoint to the relationship; reporting clinician service examples include but are not limited to: a rheumatologist taking care of the patient's rheumatoid arthritis longitudinally but not providing general primary care services
X3	Episodic/broad services: for reporting services by clinicians who have broad responsibility for the comprehensive needs of the patient that is limited to a defined period and circumstance such as a hospitalization; reporting clinician service examples include but are not limited to the hospitalist's services rendered providing comprehensive and general care to a patient while admitted to the hospital
X4	Episodic/focused services: for reporting services by clinicians who provide focused care on particular types of treatment limited to a defined period and circumstance; the patient has a problem, acute or chronic, that will be treated with surgery, radiation, or some other type of generally time-limited intervention; reporting clinician service examples include but are not limited to, the orthopedic surgeon performing a knee replacement and seeing the patient through the postoperative period
X5	Diagnostic services requested by another clinician: for reporting services by a clinician who furnishes care to the patient only as requested by another clinician or subsequent and related services requested by another clinician; this modifier is reported for patient relationships that may not be adequately captured by the above alternative categories; reporting clinician service examples include but are not limited to, the radiologist's interpretation of an imaging study requested by another clinician

2018 MPFS Final Rule

Since 1992, Medicare has paid for the services of physicians, nonphysician practitioners and certain other suppliers under the Medicare Physician Fee Schedule (MPFS). For reimbursement purposes, relative values are assigned to more than 7000 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 calendar year 2018 conversion factor (CF) is estimated to be $35.9996, which is only slightly higher than the 2017 conversion factor of $35.8887. The Estimated Impact Table that projects payment increases or decreases by specialty includes:

Specialty	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
Hematology/Oncology	$1,809	0%	0%	0%	0%
Radiation Oncology & Radiation Therapy Centers	$1,745	0%	1%	0%	1%

The most widespread specialty impacts of the final RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including finalized RVUs for new and revised codes. The estimated impacts for some specialties, including behavioral health specialists, radiation oncology, and podiatry, reflect increases relative to other physician specialties. These increases can largely be attributed to increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC).

Payment Rates under the MPFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and services furnished by certain off-campus provider-based departments (PBDs) (collectively referenced in this Final Rule as nonexcepted items and services furnished by nonexcepted off-campus PBDs) shall not be considered covered OPD services for purposes of payment under the OPPS, and payment for those nonexcepted items and services furnished on or after January 1, 2017 shall be made under the applicable payment system. In the CY 2017 OPPS Final Rule with comment period, CMS finalized the MPFS as the "applicable payment system" for most nonexcepted items and services furnished by off-campus PBDs.

CMS estimated that for CY 2017, scaling the OPPS payment rates downward by 50 percent would strike an appropriate balance that avoided potentially underestimating the relative resources involved in furnishing services in nonexcepted off-campus PBDs as compared to the services furnished in other settings for which payment was made under the MPFS. CMS called this adjustment the "PFS Relativity Adjuster." The PFS Relativity Adjuster refers to the percentage of the OPPS payment amount paid under the MPFS for a nonexcepted item or service to the nonexcepted off-campus PBD under this policy.

CMS considered the 50 percent PFS Relativity Adjuster for CY 2017 to be a transitional policy until such time as there was more precise data to better identify and value nonexcepted items and services furnished by nonexcepted off-campus PBDs and billed by hospitals. In addition, certain services are not subject to the application of the Relativity Adjuster, such as clinical laboratory, drugs and biologicals and ambulance services. In addition, the radiation oncology G-codes will continue to be reported with

modifier PN, but are not subjected to the Relativity Adjuster; instead, payment is made at the technical non-facility based rate.

CMS believes they have been as transparent as possible in their approach, including the limitations related to data availability, and the inability to develop a precise adjustment to the relative payment rates that would account for differences between the two payment systems, while including OPPS packaging. Therefore, CMS finalized a PFS Relativity Adjuster of 40 percent for CY 2018, meaning that nonexcepted items and services furnished by nonexcepted off-campus PBDs would be paid under the MPFS at a rate that is 40 percent of the OPPS rate. CMS estimates that this change will result in total Medicare Part B savings of $12 million for CY 2018.

The 2018 Final Rule added that hospital supervision rules continue to apply for nonexcepted off-campus PBDs that furnish nonexcepted items and services. In addition, CMS did not propose to adjust payment for 340B acquired drugs in nonexcepted off-campus PBDs in CY 2018 but will be monitor drug utilization in these provider-based departments.

Telehealth Services

Section 1834 of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00. For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842 of the Act. Therefore, for CY 2018, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $25.76. CMS finalized the addition HCPCS code G0296 [Counseling visit to discuss need for lung cancer screening using low dose CT scan (LDCT) (service is for eligibility determination and shared decision making)] to the telehealth list for CY 2018.

Superficial Radiation Treatment Planning

In the CY 2015 MPFS final rule CMS noted that changes to the CPT® prefatory language limited the codes that could be reported when with superficial radiation treatment (SRT) delivery, described by CPT® code 77401 (radiation treatment delivery, superficial and/or orthovoltage, per day). The changes effectively meant that many other related services were bundled with CPT® code 77401, instead of being separately reported. For example, CPT® guidance clarified that certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be reported when furnished in association with superficial radiation treatment.

In the CY 2016 MPFS final rule with comment period, CMS commented that the RUC did not review the inputs for SRT procedures, and therefore did not assess whether changes in valuation were appropriate in light of the bundling of associated services. In addition, CMS solicited recommendations regarding whether or not it would be appropriate to add physician work for this service, even though physician work is not included in other radiation treatment services. As commenters were not in agreement as to whether the service should be valued with physician work, CMS introduced the possibility of creating a HCPCS G-Code to describe total work associated with the course of treatment for these services.

In the CY 2018 MPFS proposed rule, CMS proposed to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1 (Superficial radiation treatment planning and management related services). However, given the various concerns expressed by commenters, and the variety of potential solutions offered, CMS did not finalize the proposed separate payment and coding for planning and management services associated with SRT at this time. CMS will continue considering alternative solutions, but believes additional analysis is necessary.

CMS adds that they did not propose and are not making any changes to the coding or valuation for CPT® code 77401 (radiation treatment delivery, superficial and/or orthovoltage, per day) in this final rule. However, under the CPT® guidance that has been in effect for several years, certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be billed in addition to CPT® code 77401.

Work RVUs for New, Revised and Potentially Misvalued Codes

The 2018 Final Rule includes RVU updates; the following oncology codes were impacted:

HCPCS Code	Long Descriptor	CY 2017 Work RVU	CY 2018 Work RVU
19294	Preparation of tumor cavity with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy	NEW	3.00
38220	Diagnostic bone marrow; aspiration(s)	1.08	1.20
38221	Diagnostic bone marrow; biopsy(ies)	1.37	1.28
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	NEW	1.44
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed	NEW	3.03
77261	Therapeutic radiology treatment planning; simple	1.39	1.30
77262	Therapeutic radiology treatment planning; intermediate	2.11	2.00
77263	Therapeutic radiology treatment planning; complex	3.14	3.14
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	0.00	0.17

Several codes for infusion and injection services were reviewed as part of this Final Rule, but no Work RVU changes were made.

Evaluation and Management Guidelines

Most physicians and other billing practitioners bill patient visits to the MPFS under a relatively generic set of codes that distinguish level of complexity, site of care, and in some cases, between new or established patients. These codes are called Evaluation and Management (E/M) visit codes. For example, there are generally three levels of hospital and nursing facility inpatient E/M visit codes, and five levels of office or hospital outpatient E/M visit codes, that vary based on complexity and whether the patient is a new or established patient.

Billing practitioners must maintain information in the medical record to document that they have reported the appropriate level of E/M visit code. CMS maintains guidelines that specify the kind of information that is required to support Medicare payment for each level. According to CMS, stakeholders have long maintained that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, stating that they are too complex, ambiguous, and that they fail to distinguish meaningful differences among code levels. The guidelines have also not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity and potential upcoding given the frequently automated selection of code level.

CMS specifically sought comment whether it would be appropriate to remove the documentation requirements for the history and physical exam for all E/M visits at all levels. CMS believes MDM and time are the more significant factors in distinguishing visit levels, and that the need for extended

histories and exams is being replaced by population-based screening and intervention, at least for some specialties. In addition, an increase in the utilization of EHRs, and to some extent, shared health information via EHRs, may have changed the character of extended patient histories since the guidelines were established. Although CMS believes that MDM guidelines may also need to be updated, they believed that in the near term, it may be possible to eliminate the current focus on details of history and physical exam, and allow MDM and/or time to serve as the key determinant of E/M visit level.

As long as a history and physical exam are documented and generally consistent with complexity of MDM, CMS believes there may no longer be a need to maintain such detailed specifications for what must be performed and documented for the history and physical exam (for example, which and how many body systems are involved). CMS cautions that there may still be clinical or legal reasons for individual practitioners to document an extended history or physical exam (for example, where there are negative findings for certain body systems in support of differential diagnosis).

The public comments received illustrate the difficulty of utilizing or relying on such a relatively small set of codes to describe and pay for the work of a wide range of physicians and practitioners in many vastly different clinical contexts. In addition, the public comments illustrate that many of the issues with the E/M documentation guidelines are not simply a matter of undue administrative burden. CMS expects to continue to work on all of these issues with stakeholders in future years though they remain focused on revision of the current E/M guidelines in order to reduce unnecessary administrative burden. No changes to the E/M guidelines were issued as part of the CY 2018 Final Rule.

Payment for Biosimilar Biological Products

In the CY 2016 MPFS Final Rule with comment period, CMS finalized a proposal to amend regulation text to clarify that the payment amount for a biosimilar biological product is based on the ASP of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code. In general, this means that products that rely on a common reference product's biologics license application (that is, FDA's previous finding of safety, purity, and potency for the common reference product) are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products.

CMS indicated that they want to promote innovation, provide more options to patients and physicians, and encourage competition to drive prices down. Based on the review of comments received, CMS will change the Part B biosimilar payment policy to provide for the separate coding and payment for products approved under each individual abbreviated application, rather than grouping all biosimilars with a common reference product into a single code. This policy change should encourage greater manufacturer participation in the marketplace and the introduction of more biosimilar products, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment.

In addition, CMS anticipates that this policy change will provide physicians with greater certainty about biosimilar payment. In turn, this should affect utilization of these products, creating more demand that would help increase competition. As a result of the policy change CMS anticipates greater access to biosimilar biological products and that more price competition between more products will occur because there will be more products available. The change in policy could lead to additional savings for Medicare and its beneficiaries over the long-term by increasing the utilization of products that are less expensive than reference biologicals.

Effective January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same HCPCS code. CMS will issue detailed guidance on coding, including instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers. Completion of these changes is planned to occur as soon as

possible, but is not expected to be complete by January 1, 2018. CMS anticipates that this will be done by mid-2018 and they will issue further instructions using subregulatory means, such as change requests, transmittals to contractors and the ASP website.

Patient Relationship Categories and Codes

The Quality Payment Program (QPP) aims to improve health outcomes, promote smarter spending, minimize the burden of participation, and provide fairness and transparency in operations. These aims are centered on improving beneficiary outcomes and engaging patients through patient-centered policies, and enhancing clinician experience through flexible and transparent program design and interactions with easy-to-use program tools.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was enacted on April 16, 2015. Section 101 of MACRA amended section 1848 of the Act to create a new subsection entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. This Section requires the development of care episode and patient condition groups, and classification codes for such groups. To facilitate the attribution of patients and episodes to one or more clinicians, this Section requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service.

Section 1848 of the Act requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). Applicable practitioners are defined as a physician assistant, nurse practitioner, clinical nurse specialist, and a certified registered nurse anesthetist; and beginning January 1, 2019, such other eligible professionals as specified by the Secretary. Procedure code modifiers that describe patient relationship categories include:

Modifier	Patient Relationship Category
X1	Continuous/broad services
X2	Continuous/focused services
X3	Episodic/broad services
X4	Episodic/focused services
X5	Only as ordered by another clinician

CMS also finalized the requirement that Medicare claims submitted for items and services furnished by a physician or applicable nonphysician practitioner on or after January 1, 2018 should include one of the HCPCS modifiers listed above, as well as the NPI number of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). During the initial period while clinicians are gaining familiarity with these requirements, the HCPCS modifiers may be voluntarily reported. By allowing for a voluntary approach to reporting, CMS plans to gain information about the patient relationship codes, allow for a longer period of education and outreach to clinicians on the use of the codes and refine the codes as necessary.

CMS will provide a voluntary 25-minute training/instruction manual and a one-time 60-minute webinar for practice manager or billing/coding staff who seek further knowledge to be able to report these new HCPCS modifiers correctly. Although there are a total of five HCPCS modifiers, CMS expects one out of the five usually will be reported. The practice manager or billing/coding staff who may decide to study only one HCPCS modifier or only the whole training manual or participate in just the webinar may experience a lesser burden than the estimate provided above, resulting in a lower information burden cost.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 (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 are criteria that 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 (PLEs) 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 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, 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.

Clinical Decision Support Mechanisms (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 also established a timeline and process for CDSM developers to apply to have their CDSMs qualified, and the first list of qualified CDSMs was published in July 2017.

In the CY 2017 MPFS final rule, CMS identified the circumstances specific to ordering professionals under which consulting and reporting requirements are not required. These include orders for applicable imaging services: (1) for emergency services when provided to individuals with emergency medical conditions as defined in section 1867 of the Act; (2) for an inpatient and for which payment is made under Medicare Part A; and (3) by ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year.

Numerous commenters requested clarification regarding who is required to perform the consultation of AUC through a qualified CDSM. Commenters questioned whether a designee within an ordering professional's practice could consult on behalf of the ordering professional and whether an ordering professional could delegate consultation authority to another individual, a third party vendor or contracted agent. Several commenters supported this notion, noting that state laws allow professionals

to delegate to qualified individuals in practice under the supervision of a physician the ability to assist with advanced imaging orders. Some commenters supported delegation only to the ordering professional's staff while other commenters opposed allowing consultation by anyone other than the ordering professional, and are concerned that other types of individuals and stakeholders are preparing to circumvent this requirement by performing consultations on behalf of ordering professionals.

According to CMS, section 1834 of the Act requires an ordering professional to consult specified AUC through a qualified CDSM, and communicate information on that consultation to the furnishing professional. Based on the varying opinions presented by stakeholders and the number of commenters who raised these questions, CMS will consider developing policy to address this issue. CMS is also not moving forward with requiring reporting of AUC consultation information on Medicare claims using a combination of G-codes and modifiers. Rather, CMS will evaluate a simplified method of reporting during the voluntary reporting period using a single modifier while continuing to work with stakeholders to explore using a standardized unique AUC consultation identifier.

CMS finalized a voluntary period during which early adopters can begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program will begin with an educational and operational testing period and during this time CMS will continue to pay claims whether or not they correctly include such information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020, and furnishing professionals must report the AUC consultation information on the Medicare claim for these services.

The following modifier was created for imaging providers to use on a voluntary basis starting July 1, 2018 to show that the ordering professional consulted Appropriate Use Criteria for advanced diagnostic imaging:

Modifier	Description
QQ	Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional

Applicable settings currently include physician offices, hospital outpatient departments and ambulatory surgical centers. CAH patients who are furnished an advanced diagnostic imaging service in an applicable setting, but the claim for that imaging service is not paid under one of the applicable payment systems, would not require consultation and reporting of the AUC consultation.

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 (CT, MRI and PET scans). 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.

CMS estimates the AUC consulting requirement to result in an annual burden of 1,425,000 hours at a cost of $275,139,000. These updates to the AUC program will not result in claims denials in CY 2018; therefore, these proposals would not impact CY 2018 physician payments under the MPFS. The Congressional Budget Office estimates that this initiative would save approximately $200 million over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes a payment deduction for computed tomography equipment that is not up to a current technology standard.

2018 OPPS Final Rule

The Hospital Outpatient Prospective Payment System (HOPPS or 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. The 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. CMS estimates that total OPPS payments for calendar year (CY) 2018 (including beneficiary cost-sharing) to the approximately 3900 facilities paid under the OPPS will increase by approximately $690 million over CY 2017 payments.

In CY 2018, CMS estimates that outpatient hospital payment rates will increase on average by 1.4 percent, with urban hospitals experiencing a 1.3 percent increase and rural hospitals receiving an average 2.7 percent increase. The calendar year 2017 conversion factor of $75.001 increases to $78.636 for CY 2018, 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. CMS will also maintain the policy of providing additional payments to the eleven 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.

Outliers will be triggered in CY 2018 when the hospital's cost for furnishing a service exceeds a fixed-dollar threshold of $4150.00, combined with the multiple threshold of 1.75 times the APC payment rate.

Critical Access Hospital (CAH) Supervision

In both the CY 2009 and CY 2010 OPPS final rules with comment period, CMS clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, Critical Access Hospitals (CAHs), and in provider-based departments (PBDs) of hospitals. Since CY 2011, there has been a suspension on the enforcement of the direct supervision requirement for CAHs and small rural hospitals (less than 100 beds), with the latest freeze on enforcement expiring on December 31, 2016. Stakeholders commented that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision.

The primary reason stakeholders cited for this request is the difficulty that CAHs and small rural hospitals have in recruiting physicians and nonphysician practitioners to practice in rural areas. These commenters noted that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be directly supervised by a hospital emergency department physician or nonphysician practitioner because of the volume of emergency patients or lack of specialty expertise.

In the 2018 final rule with comment period, CMS is reinstating the non-enforcement policy for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals for both CY 2018 and CY 2019. The purpose of this non-enforcement policy is to give these CAHs and small rural hospitals additional time to comply with the supervision requirements for outpatient therapeutic services and to give all parties time to submit specific services to be evaluated by the Hospital Outpatient Payment (HOP) Advisory Panel for a recommended change in supervision level.

340B Drug Pricing

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS). The 340B Program allows participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize

scarce Federal resources as much as possible, reaching more eligible patients and providing care that is more comprehensive.

MedPAC examined Medicare Part B spending for chemotherapy drugs and drug administration services at both 340B and non-340B hospitals for a 5-year period from 2008 to 2012 and found that "Medicare spending grew faster among hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program at any time during [the study] period." According to CMS, this is just one example of drug spending increases that are correlated with participation in the 340B Program and calls into question whether Medicare's current policy to pay for separately payable drugs (assigned status indicator "K") at ASP+6 percent is appropriate in view of the discounted rates at which 340B hospitals acquire such drugs.

In addition, the Government Accountability Office (GAO) found that "in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B disproportionate share hospitals than at non-340B hospitals." GAO believes that this indicates beneficiaries at 340B hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the non-340B hospitals in GAO's analysis. Based on a study of almost 500 drugs billed in the hospital outpatient setting in 2013, the Office of Inspector General (OIG) found that, for 35 drugs, the "difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone was greater than the amount a covered entity spent to acquire the drug."

It is estimated that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B Program in 2013. In addition, the number of hospitals participating in the program has grown from 583 in 2005, to 1365 in 2010, and 2140 in 2014. In its November 2015 report entitled "Part B Payments for 340B-Purchased Drugs," the OIG found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately $1.3 billion in 2013. Both MedPAC (Medicare Payment Advisory Committee) and OIG have recommended alternative drug payment methodologies for hospitals that participate in the 340B Program. Such changes would allow the Medicare program and Medicare beneficiaries to pay less for drugs when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program.

For CY 2018 CMS is exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment in CY 2018. CMS did not propose to adjust payment for 340-acquired drugs in nonexcepted off-campus provider-based departments (paid under a non-OPPS reimbursement methodology), but may consider adopting such a policy in CY 2019.

In addition, in this final rule with comment period, CMS established two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program – one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program. CMS will collect information on an ongoing basis on which drugs billed to Medicare were acquired under the 340B Program.

Therefore, pediatric hospitals, cancer hospitals and SCH hospitals that are excluded from the discount will be required to report the following informational modifier for tracking and monitoring purposes:

Modifier	Description
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

Effective January 1, 2018 this informational modifier will facilitate collection and tracking of 340B claims data for OPPS providers that are excepted from the payment in adjustment in CY 2018; use of this modifier will not trigger a payment adjustment and these providers will continue to receive ASP+6 percent payment for separately payable drugs.

Also effective January 1, 2018 providers who subject to the 340B payment adjustment will report the following modifier to identify that a drug was acquired under the 340B Program.

Modifier	Description
JG	Drug or biological acquired with 340B drug pricing program discount

The application of the JG modifier will trigger the adjustment for the 340B-acquired drug to be paid at ASP-22.5 percent. This Medicare requirement aligns with modifiers already mandated in several States under their Medicaid programs. Therefore, this option should pose less of an administrative burden for providers.

To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increasing the payment rates by 3.2 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018.

Site-of-Service Price Transparency

Section 4011 of the 21st Century Cures Act enacted on December 13, 2016, added information to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center (ASC). For CY 2018 and each subsequent year, HHS will make available to the public via a searchable website the estimated payment amount for many items and services under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service. CMS anticipates that this website will be available in early CY 2018.

Packaged Services

CMS states that packaging is an inherent principle of a prospective payment system. The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Packaging and bundling payments for multiple interrelated services into a single payment create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, resulting in long-term cost containment.

In the CY 2015 OPPS Final Rule, CMS conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100; these were primarily minor diagnostic tests and procedures frequently performed with a primary service. Conditional packaging means that the services will be separately paid by Medicare when they are the only procedure performed on a date of service. Excluded from this packaging in CY 2015 were certain low-cost drug administration services.

According to CMS, the exclusion of these drug administration services is an example of inconsistent application of their packaging policy. Based on the analysis of CY 2016 claims data, the geometric mean cost for APC 5691 (Level 1 Drug Administration) is approximately $37 and the geometric mean cost for APC 5692 (Level 2 Drug Administration) is approximately $59. In addition, Medicare data show that these drug administration services are generally provided as part of another separately payable service, which meets the intent of the ancillary services conditional packaging policy.

Last, CMS believes that conditional packaging of these drug administration services will promote equitable payment between the physician office and the hospital outpatient department. After reviewing the comments submitted, CMS finalized the policy to conditionally package low-cost drug administration services assigned to APCs 5691 and 5692, with the exception of add-on codes and preventive services. Therefore, the following drug administration services relating to oncology will be conditionally packaged (Status Indicator Q1) for CY 2018:

APC 5691--Level 1 Drug Administration		
Code	**Descriptor**	**SI**
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	Q1
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion	Q1
96549	Unlisted chemotherapy procedure	Q1

APC 5692--Level 2 Drug Administration		
Code	**Descriptor**	**SI**
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)	Q1
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Q1
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	Q1
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic	Q1
96405	Chemotherapy administration; intralesional, up to and including 7 lesions	Q1

With respect to payment for a conditionally packaged low-cost drug administration service and an unconditionally packaged drug, the drug administration service is separately payable when not billed on the same claim as a HCPCS code with status indicator "S", "T", or "V". Payment for the threshold-packaged drug would be packaged with the payment for the highest paying separately payable procedure reported on the claim. For example, if a threshold-packaged drug, a low-cost drug administration service, and a clinic visit are reported on the same claim, payment for both the drug and drug administration service would be packaged with the clinic visit payment.

In the CY 2014 OPPS Final Rule, CMS finalized a policy to unconditionally package procedures described by add-on codes. However, in response to stakeholder comments on the appropriateness of packaging drug administration add-on codes, these services were not packaged at that time. CMS did not propose to package drug administration add-on codes for CY 2018, but solicited comments on this policy in the Proposed Rule. Many commenters raised concerns about the appropriateness of packaging drug administration add-on codes, given the variation in clinical treatment protocols. The commenters believed that packaging drug administration service add-on codes could create a barrier to access for

drugs and biologicals with a long infusion time. CMS indicated that they appreciated all comments, and would take them into consideration for future rulemaking.

Oncology Comprehensive-APCs

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, 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 January 1, 2015 CMS implemented C-APC 5627 (Level 7 Radiation Therapy) for single fraction stereotactic radiosurgery (SRS, procedure codes 77371 and 77372). For CY 2018, CMS will continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment.

CMS also performed data collection through the use of modifier "CP" [Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim] and identified some additional services that are adjunctive to the primary SRS treatment and reported on a different claim submission. CMS stated that the "CP" modifier was actually used by only a small number providers, in spite of the mandatory requirement for its application. The data collection period for SRS claims with modifier "CP" will conclude on December 31, 2017. Accordingly, CMS is deleting this modifier for CY 2018 and discontinuing its required use. CMS will continue to analyze the CY 2016 and CY 2017 data, and will consider whether or not to repackage all adjunctive services into the cranial SRS C-APC.

In the CY 2017 OPPS Final Rule, CMS finalized 25 new C-APCs. Some of the HCPCS codes assigned to these C-APCs described surgical procedures for inserting brachytherapy catheters or needles, and other related brachytherapy procedures such as the insertion of tandem and/or ovoids or Heyman capsules. In this prior Final Rule, CMS noted that public comments were received indicating that some claims for brachytherapy insertion did not also include a brachytherapy treatment delivery code. The brachytherapy insertion codes with concerns included:

Code	Descriptor
20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
41019	Placement of needles, catheters or other devices into head and/or neck region for subsequent interstitial radioelement application
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy

58346	Insertion of Heyman capsules for clinical brachytherapy

CMS analyzed claims that included brachytherapy insertion codes assigned to this group and determined that several of these codes are frequently billed without an associated brachytherapy treatment code. Although CMS proposed to establish a code edit that requires a brachytherapy treatment code with a brachytherapy insertion code is billed, in this Final Rule they decided not to implement this edit. However, CMS reminded hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT® and CMS instructions, as applicable. CMS added that they will continue to examine the issues involving ratesetting for brachytherapy insertion procedures assigned to C-APCs.

CMS is also finalizing their proposal to delete composite APC 8001 (LDR Prostate Brachytherapy Composite), assign HCPCS code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator "J1" and to provide payment for this procedure through the C-APC methodology. This means that when code 55875 is the primary service reported on a hospital outpatient claim, payment for all adjunctive services reported on that claim will be packaged into the primary service.

In CY 2017, CMS finalized C-APC 5244 (Level 4 Blood Product Exchange and Related Services) for allogeneic hematopoietic stem cell transplantation. 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/post-procedure evaluation of donor, and the preparation and processing of stem cells.

HCPCS code 38205 describes blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic; a donor acquisition cost for an HSCT. In order to be consistent with other donor acquisition costs and ensure that the costs for allogeneic HSCT are captured accurately, CMS will change the status of procedure code 38205 from "B" (OPPS non-allowed service) to "S" (Significant procedure not subject to multiple procedure discounting) and assign this code to APC 5242 (Level 2 Blood Product Exchange and Related Services).

Brachytherapy Sources

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 requires CMS to continue to separate payment for brachytherapy sources. These sources are reimbursed on a prospective basis, with 2018 payment rates set using the 2016 geometric mean unit costs for each source. For CY 2018, CMS assigned status indicator "U" (Brachytherapy sources, paid under OPPS; separate APC payment) to HCPCS codes C2636 (Brachytherapy, linear, non-stranded, palladium-103, per 1 mm), and C2645 (Brachytherapy planar, palladium-103, per square millimeter).

Blood and Blood Products

In the CY 2018 OPPS Final rule, CMS finalized the proposal to establish payment rates for blood and blood products using the current blood-specific Cost-to-Charge Radio (CCR) methodology. CMS also finalized their proposal for reporting pathogen-reduced platelets and rapid bacterial testing for platelets. Essentially, the changes involve replacing the temporary HCPCS Q codes with permanent HCPCS Level II codes:

2017 Code	Definition	2018 Code	Definition
Q9987	Pathogen(s) test for platelets	**P9100**	Pathogen(s) test for platelets
Q9988	Platelets, pheresis, pathogen-reduced, each unit	**P9073**	Platelets, pheresis, pathogen-reduced, each unit

Bipartisan Budget Act of 2018 Signed into Law

On February 9, 2018 the Bipartisan Budget Act of 2018 was signed into law, https://www.congress.gov/115/bills/hr1892/BILLS-115hr1892enr.pdf. There are several provisions within the law which will change and/or impact healthcare in the coming years. The following are some of the highlights to be aware of.

- **Sec. 53106. Physician fee schedule update** – The conversion factor (CF) increase originally set by MACRA in 2015 for CY 2019 was set to increase 0.5% from CY 2018. This CF is to be used as the base rate for the upcoming MIPS and APM payment programs. The Bipartisan Budget Act of 2018 changed the increase in CY 2019 from 0.5% to only 0.25%.
- **CBO estimate reflects 2% sequestration extended** – The Congressional Budget Office (CBO) estimate for the Bipartisan Budget Act of 2018 reflects the 2% sequestration will be extended through CY 2027
- **Sec. 51009. Transitional Payment Rules for Certain Radiation Therapy Services under the Physician Fee Schedule** – The CMS G-codes for radiation therapy treatments and IGRT, billed by physicians and office settings/freestanding cancer centers under MPFS, will be extended through December 31, 2019. This is a full year extension of the PAMA regulation which had the G-codes ending December 31, 2018.
- **Sec. 50201. Extension of work GPCI floor** – The work GPCI floor value was amended and extended to now reflect January 1, 2020 instead of January 1, 2018 as the end date
- **Sec. 50412. Increased civil and criminal penalties and increased sentences for Federal health care program fraud and abuse**
- **Sec. 50413. Reducing the volume of future EHR-related significant hardship requests** – Exemptions will be easier to obtain from Advancing Care Information MIPS category and EHR Meaningful Use Program. Additionally, the requirement that meaningful use standards become more stringent over time has been removed
- **Sec. 53113. Sunsetting exclusion of biosimilars from Medicare part D coverage gap discount program**
- **Sec. 51003. Technical Amendments to Public Law 114-10 (MACRA and MIPS Program)** – CMS will now set the performance thresholds for years 2-5; originally CMS had to use the mean or median Composite Performance Score (CPS) as the performance threshold beginning in year three. CMS will be allowed to set the Cost performance category in years 2-5 for MIPS. Cost will account for 10% of each score in 2018 and required to represent 30% of each score in 2019.