Physician and Freestanding Center Regulatory Update

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Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other suppliers under the Medicare Physician Fee Schedule (MPFS or PFS). 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 2018 conversion factor is estimated to be $35.9996, which is only slightly higher than the 2017 conversion factor of $35.8887. The Estimated Impact Table (Table 6, page 22) projects payment increases or decreases by specialty (without considering the potential conversion factor change).

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) Relative Value Scale Update Committee (RUC).

Evaluation and Management Guidelines

Most physicians and other billing practitioners bill patient visits to the PFS 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 on 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 medical decision-making (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, the agency believes 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 the agency remains 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.

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 Jan. 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 Jan. 1, 2019, such other eligible professionals as specified by the Secretary. Procedure code modifiers that describe patient relationship categories include:

- **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 non-physician practitioner on or after Jan. 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 will usually 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.

Payment Rates under the PFS for Non-excepted Items and Services Furnished by Non-excepted Off-Campus PBDs 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 non-excepted items and services furnished by non-excepted off-campus PBDs) shall not be considered covered OPD services for purposes of payment under the OPPS, and payment for those non-excepted items and services furnished on or after Jan. 1, 2017, shall be made under the applicable payment system. In the CY 2017 OPPS final rule with comment period, CMS finalized the PFS as the "applicable payment system" for most non-excepted 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 non-excepted off-campus PBDs as compared to the services furnished in other settings for which payment was made under the PFS. 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 non-excepted item or service to the non-excepted 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 non-excepted items and services furnished by non-excepted 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 it has been as transparent as possible in its 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, for CY 2018 CMS finalized a PFS Relativity Adjuster of 40 percent, meaning that non-excepted items and services furnished by non-excepted off-campus PBDs would be paid under the PFS 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 non-excepted off-campus PBDs that furnish non-excepted items and services. In addition, CMS did not propose to adjust payment for 340B acquired drugs in non-excepted off-campus PBDs in CY 2018 but will be monitor drug utilization in these PBDs.

Telehealth Services

Section 1834 of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from Oct. 1, 2001, through December 31, 2002, at $20. For telehealth services furnished on or after Jan. 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 of the following services to the telehealth list for CY 2018:

- **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.
- **90839:** Psychotherapy for crisis; first 60 minutes.
- **90840:** Psychotherapy for crisis; each additional 30 minutes. List separately in addition to code for primary service.

Although CMS did not receive specific requests for additional telehealth codes, four additional services will be added to the telehealth list. All four of these codes are add-on codes that describe additional elements of services currently on the telehealth list and would only be considered telehealth services when billed as an add-on to codes already on the telehealth list. These codes are:

- **90785:** Interactive complexity. List separately in addition to the code for primary procedure.
- **96160:** Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument
- **96161:** Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.
- **G0506:** Comprehensive assessment of and care planning for patients requiring chronic care management services. List separately in addition to primary monthly care management service.

In the case of CPT codes **96160** and **96161**, and HCPCS code **G0506**, CMS recognized that these services may not always be performed in-person with a physician or billing practitioner. Ordinarily, services that are typically not considered to be face-to-face services do not need to be on the list of Medicare telehealth services; however, these services would only be considered Medicare telehealth services when billed with a base code that is also on the telehealth list and would not be considered Medicare telehealth services when billed with codes not on the Medicare telehealth list.

Payment for Biosimilar Biological Products

In the CY 2016 Medicare Physician Fee Schedule 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 average sales price (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, the 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 it wants to promote innovation, provide more options to patients and physicians, and encourage competition to drive prices down. Based on the review of the 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 Jan. 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 Jan. 1, 2018. CMS anticipates that this will be done by mid-2018 and the agency will issue further instructions using sub-regulatory means, such as change requests, transmittals to contractors, and the ASP website.

Superficial Radiation Treatment Planning

In the CY 2015 PFS final rule, CMS noted that changes to the CPT prefatory language limited the codes that could be reported 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 PFS 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 from stakeholders 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 PFS 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 it did not propose and is 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; Table 7, page 23, lists the oncology codes that are impacted:

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

AUC 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 CY 2018 PFS 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 PFS 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 PFS 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 Dec. 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 Jan. 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 Jan. 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: **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. Critical Access Hospital (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 PFS. 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 Updates to the Quality Payment Program

On Nov. 2, 2017, CMS issued the CY 2018 Updates to the Quality Payment Program (QPP), which included information on the launch of the "Patients Over Paperwork" initiative, a collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. In addition, CMS states that it is working to implement the Quality Payment Program in a way that provides provider flexibility and simplifies the program.

The 21st Century Cures Act, enacted in 2016, includes provisions affecting the Advancing Care Information performance category for the QPP's current transition year and future years. CMS is implementing these provisions, some of which apply to the MIPS transition year. Last, CMS worked to provide clarity and additional details on many aspects of the program including the APM scoring standard and the All-Payer Combination Option.

Other Issues

In addition to the major provisions listed above, the 2018 PFS final rule addresses the potentially misvalued codes, payment incentive for the transition from traditional X-ray imaging to digital radiography, the 2018 PQRS program, the value-based modifier, the Medicare Diabetes Prevention Program, Physician Self-Referral Update, and the Medicare Shared Savings Program. OI

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Table 6. CY 2018 Estimated Impact Table

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%

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 2013 utilization and CY 2014 rates.

Impact of Work RVU Changes: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.

Impact of Practice Expense RVU Changes: This column shows the estimated CY 2015 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.

Impact of Malpractice RVU Changes: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.

Combined Impact: This column shows the estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns.

Table 7. Work RVUs for New, Revised, and Potentially Misvalued Codes

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

Resources

The following is a list of resources used when compiling these coding and regulatory updates:

2018 Medicare OPPS Final Rule: federalregister.gov/documents/2017/11/13/2017-23932/medicare-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

2018 Medicare Physician Fee Schedule Final Rule: federalregister.gov/documents/2017/11/15/2017-23953/medicare-programs-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

2018 Updates to the Quality Payment Program: federalregister.gov/documents/2017/11/16/2017-24067/medicare-programs-cy-2018-updates-to-the-quality-payment-program-and-quality-payment-program-extreme