Physician & 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). 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 2016 conversion factor is estimated to be $35.8279, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under MACRA (Medicare Access and CHIP Reauthorization Act of 2015), and the 0.77 percent target recapture adjustment required by statute. CMS notes that "several specialties, including gastroenterology and radiation oncology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and inputs used to develop RVUs for the codes that describe particular services." Table 6, right, shows the estimated impact of projected payment increases or decreases by specialty (without considering the potential conversion factor change).

Terminology Update

This year, CMS states that throughout the 2016 MPFS Final Rule with comment period and unless otherwise noted, the term "practitioner" is used to describe both physicians and those non-physician practitioners (NPPs) who are permitted to separately bill Medicare under the Physician Fee Schedule.

Radiation Treatment & Image Guidance Codes

While the new CPT procedure codes for brachytherapy services will be used in all practice settings (hospitals, freestanding cancer treatment centers, and physician offices), there remain different treatment delivery and image guidance codes for the hospital and freestanding radiation centers for CY 2016. The 2016 MPFS Final Rule includes a lengthy discussion of issues and challenges involved in setting RVUs for the new CPT procedure codes. As a result, CMS has decided not to implement these new procedure codes for MPFS reimbursement; the G-codes will continue to be reported during CY 2016. CMS states that "significant changes" are required to the codes themselves before CMS can develop accurate payment rates. These changes would include:

- Developing a code set that recognizes the differences in costs between kinds of imaging modalities.
- Making sure that this code set facilitates valuation that incorporates the cost of imaging based on how frequently it is actually provided.
- Developing treatment delivery codes that are structured to differentiate payment based on equipment resources used.

Equipment Utilization Rate for Linear Accelerators

The 2016 MPFS Final Rule states that: *"The cost of the capital equipment is the primary determining factor in the payment rates for these services."* For each procedure code, the equipment costs are estimated based on multiplying the assumed number of minutes the linear accelerator is used for each treatment by the per-minute cost of the specific piece of equipment. CMS currently uses two default equipment usage assumptions when allocating capital equipment costs to practice expense (PE) RVUs:

1. The equipment is available to be used during what are assumed to be regular business hours for a physician's office: 10 hours per day, 5 days per week (50 hours per week), and 50 weeks per year.
2. The equipment is in use only 50 percent of the time it is available for use. This translates to 25 hours per week out of a 50-hour work week.

Based on RUC (Relative Value Update Committee) recommendations for the new and revised radiation treatment delivery and image guidance codes, CMS believes that a usage assumption of 50 percent is inaccurate for the linear accelerator used in radiation treatment services. Further review indicates a 45 percent increase in the amount of time a treatment machine is used (a total of 95 percent of equipment

usage time). As a result, CMS proposed to use a 70 percent assumption rate for the amount of time a linear accelerator is used on a daily basis, phased in over two years. This means that the equipment utilization rate for CY 2016 will be 60 percent and for CY 2017 it will be 70 percent. The more frequently a piece of equipment is used, the lower the reimbursement for each individual treatment. As a result, treatment delivery payments could see a reduction in both CY 2016 and CY 2017.

Superficial Radiation Treatment Delivery

In the CY MPFS 2015 Final Rule with comment period, CMS requested additional information on the physician work involved in superficial radiation therapy (code **77401**), and which services should be considered inclusive in this service. Conflicting comments were received, and CMS is considering the development of a new code that would include all work associated with the delivery of superficial radiation.

Lung Cancer Screening

On Feb. 5, 2015, CMS issued an NCD for Medicare coverage of a lung cancer screening counseling and shared decision-making visit, and for appropriate beneficiaries, annual screening with low dose computed tomography (LDCT) as an additional preventive benefit. The new HCPCS Level II codes for these services include:

- **G0296**: Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making).
- **G0297**: Low dose CT scan (LDCT) for lung cancer screening.

CMS added that as long as the NCD requirements for the counseling and shared decision-making visit are met, the counseling visit may be billed on the same day as a medically necessary E/M service or with an annual wellness visit. **Modifier 25** (significant, separately identifiable service) would be required on code **G0296**, as well as separate documentation for the counseling visit. Because the counseling visit and LDCT are covered as preventive benefits, there is no patient co-payment or deductible for these services. These new codes and APC assignments are effective Feb. 5, 2015, (the date the NCD was finalized) and may be billed under the MPFS beginning Jan. 1, 2016. Of importance, CMS states that it is in the process of developing claims processing, coding, and billing instructions for those services performed in CY 2015.

Incident-To Update

The 2016 MPFS Final Rule includes yet another clarification that the physician or non-physician practitioner who bills for incident-to services (i.e., the individual listed on the claim form as the performing provider) must be the individual who provided direct supervision of the auxiliary personnel who performed the services. This means that although the physician of record for an individual patient may have ordered a particular service, the practitioner who provides the direct supervision in the office is the provider name that is billed on the claim form.

In addition, CMS explicitly prohibits the provision of incident-to services by auxiliary personnel who have been excluded from federal health programs or who have had their enrollment revoked. There were no changes to the definition of an incident-to service or to the list of non-physician

Table 6. Estimated Impact of Projected Payment Increases or Decreases by Specialty*

SPECIALTY	Allowed Charges (millions)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
Hematology/Oncology	$1,788	0%	0%	0%	0%
Radiation Oncology	$1,766	0%	-2%	0%	-2%
Radiation Therapy Centers	$52	0%	-2%	0%	-1%

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.

Allowed Charges: The aggregate estimated MPFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates.

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

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

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

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

*Without consideration of the potential conversion factor change.

practitioners who can perform services that are billed incident-to by a physician. CMS provided the following definitions in the MPFS Final Rule:

"Consistent with this terminology, when referring in this discussion to the physician or other practitioner furnishing the service, we are referring to the physician or other practitioner who is billing for the incident-to service. When we refer to the "auxiliary personnel" or the person who "provides" the service, we are referring to an individual who is personally performing the service or some aspect of it as distinguished from the physician or other practitioner who bills for the incident-to service.

As described in this Final Rule with comment period, incident-to a physician's or other practitioner's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's or other practitioner's personal professional services in the course of diagnosis or treatment of an injury or illness."

Off-Campus Provider-Based Departments

Although not included in the 2016 MPFS Final Rule with comment period, CMS announced in *MLN Matters* MM9231 (Aug. 6, 2015) that there would be two place of service codes billed by physicians on CMS1500 claim form when services are performed in the outpatient hospital setting:

1. **POS Code 19**: A portion of an *off-campus hospital provider-based department,* which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
2. **POS Code 22**: A portion of a *hospital's main campus,* which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

These place of service codes were effective Jan. 1, 2016, and are required on all Medicare professional claims for outpatient hospital services. Other insurers may or may not require this level of outpatient facility differentiation.

Potentially Misvalued Codes

In the CY 2015 MPFS 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. This same Act 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.

Consistent with amendments made by the ACA, CMS has been engaged in a vigorous effort over the past several years to identify and review potentially misvalued codes and make adjustments where appropriate. CMS and the RUC have taken several steps to improve the review process, examining potentially misvalued services in several categories. In the 2016 MPFS Final Rule, CMS stated that it intended to proceed with a review of the high expenditure screen for 2016, while excluding codes with a 10-day or 90-day global period. The top 20 codes by specialty were identified, with patient visits excluded from review, as well as any codes that have already been reviewed since calendar year 2010. Table 7, right, shows the final list of potentially misvalued codes identified through the high expenditure specialty screen, specific to services that may be performed by medical or radiation oncologists.

Part B Drugs

Section 3139 of the ACA amended the Act to define a biosimilar biological product and a reference biological product and to provide for Medicare payment of biosimilar biological products using ASP methodology. A biosimilar biological product is defined as a biological product approved under an abbreviated application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). A reference biological product for a biosimilar biological product is defined as the biological product licensed under section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

CMS stated that because of the degree of similarity that biosimilars share with their reference products, it is appropriate to price biosimilar products in groups in a manner similar to how multiple source or generic drugs are currently priced. After considering all comments, CMS stated that the payment amount for a biosimilar biological product is based on the ASP of all NDCs (National Drug Codes) assigned to the biosimilar biological products included within the same billing and payment code.

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.

An ordering physician/practitioner (including hematologists, medical oncologists, and radiation oncologists) will access AUC through a clinical decision support (CDS) tool, such as a CDS module in an electronic health record (EHR) or a web-based system. The ordering professional will enter patient information into the CDS tool, and it will provide immediate feedback about the appropriateness of the proposed imaging exam. Under PAMA, ordering physicians/practitioners will be required to consult AUC and to communicate the results of this consultation to the entity that furnishes the imaging study. When the imaging provider bills Medicare, it will then be required to include information on the claim about the ordering physician's consultation with AUC. This requirement applies to imaging studies billed under the Physician Fee Schedule, the Outpatient Prospective Payment System, and the Ambulatory Surgical Center Payment System. It does not apply to inpatient studies billed under Part A, to certain emergency studies, or to ordering physicians/practitioners who qualify for a hardship exception.

CMS 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. PAMA called for CMS to meet the following deadlines:

- Establish AUC by Nov. 15, 2015.
- Establish CDS by April 1, 2016.
- Implement AUC consultation by ordering physicians/practitioners by Jan. 1, 2017.
- Identify "outlier" ordering professionals for services furnished after Jan. 1, 2017.

Due to the timing of the PAMA legislation, CMS was unable to meet the November 2015 deadline for establishing AUC, and this will in turn delay the other steps. In the 2016 MPFS Final Rule, CMS stated that it expects to establish rules and requirements for CDS mechanisms (including the process for communicating the AUC consultation information between providers and on the claim) during 2016 for the 2017 rulemaking cycle. Approved CDS mechanisms should be in place in summer of 2017.

Advance Care Planning

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning services:

- **99497**: Advance care planning, including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or

Table 7. Potentially Misvalued Codes Performed by Medical and/or Radiation Oncologists

CODE	DESCRIPTION
31575	Laryngoscopy, flexible fiberoptic; diagnostic
38221	Bone marrow; biopsy, needle or trocar
51720	Bladder instillation of anticarcinogenic agent (including retention time)
77263	Therapeutic radiology treatment planning; complex
77334	Treatment devices, design and construction; complex
77470	Special treatment procedure
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96372	Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular
96374	Therapeutic, prophylactic or diagnostic injection; IV push, single or initial drug
96375	Therapeutic, prophylactic or diagnostic injection; each additional sequential IV push of a new substance/drug
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic
96409	Chemotherapy administration; IV push, single or initial substance/drug
96411	Chemotherapy administration; IV push, each additional substance/drug

other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.

- **+99498:** Each additional 30 minutes. (List separately in addition to code for primary procedure).

In the CY 2016 MPFS Final Rule, these services were assigned a status indicator of "I" (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services). For CY 2016, CMS will provide reimbursement for these services, and the agency recommends that when a beneficiary elects to receive advance care planning, the practitioner should notify the patient that Part B cost sharing (e.g., co-payment and/or deductible) will apply for this optional, voluntary service in the same manner as for other physician services. CMS also states that it will monitor utilization over time to ensure that these codes are used appropriately. This means, in part, that only one physician member of the patient's multispecialty care team will be permitted to bill for advance care planning within a reasonable time period.

Last, CMS clarified that a number of comments were received on existing or recommended practice patterns for the provision of advance care planning services, including recommendations for individuals who could perform this service as part of a global care team. CMS states in the MPFS Final Rule:

"We note that the CPT code descriptors describe the services as furnished by physicians and other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore, only these practitioners may report CPT codes ***99497*** *or* ***99498****.*

We agree with commenters that advance care planning as described by the proposed CPT codes is primarily the provenance of patients and physicians. Accordingly, we expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision."

CMS added that these codes will be separately payable to the billing physician or practitioner in both facility and non-facility settings and are not limited to particular physician specialties. In response to specific comments, CMS agreed that advance care planning can be separately reimbursed when performed at the same time as an annual wellness visit. **Modifier 33** (preventive services) would be reported on the advance care planning charge in this scenario, and the patient would not have a co-payment or deductible.

Other Issues

In addition to the specific topics listed above, CMS also provided details on the Physician Compare Website, the Electronic Health Record Incentive Program, the Medicare Shared Savings Program, the Value-Based Modifier, Physician Self-Referral Updates, and Physician Quality Reporting Systems. CMS also received a number of comments in response to the request for recommendations on how to improve Medicare compensation mechanisms for primary care services and collaborative care. Many commenters complained specifically about the administrative burden associated with billing for transitional care and chronic care. These comments will be considered during future rulemaking.

Bipartisan Budget Act of 2015

While not part of the MPFS Final Rule, the Bipartisan Budget Act of 2015 was signed into law on Nov. 2, 2015, and includes the following:

Sec. 101. Amendments to the Balanced Budget and Emergency Deficit Control Act of 1985. Subsection 101(b) provides for the implementation of the sequester of direct spending as if the amendments in subsection 101(a) had not been made. The President is required by law to implement the sequester of direct spending ordered on February 2, 2015 and the one in the Sequestration Preview Report for Fiscal Year 2017 as if the amendments in subsection 101(a) had not been made. 2 Subsection 101(c) reduces spending by $14 billion in fiscal year 2025 by requiring the President to sequester the same percentage of direct spending in 2025 as will be sequestered in 2021. It also replaces the arbitrary dips and increases in the Medicare sequester percentages in 2023 and 2024 with a flat two-percent rate as applies under current law in fiscal years 2016 through 2022.

This means that Congress extended the annual 2 percent sequestration reduction of Medicare provider reimbursement one more year, into 2025. This pay cut, created by the sequestration provisions of the Budget Control Act of 2011, was supposed to expire in 2021, but Congress has now added additional years to this reimbursement reduction. OI