

Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2016

On July 8, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that updates payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2016. This year, CMS is proposing a number of new policies, including several that are a result of recently enacted legislation. The rule also finalizes changes to several of the quality reporting initiatives that are associated with PFS payments, including the Physician Quality Reporting System (PQRS), the Physician Value-Based Payment Modifier (Value Modifier), and the Medicare Electronic Health Record (EHR) Incentive Program, as well as changes to the Physician Compare website on Medicare.gov.

This is the first PFS proposed rule since the repeal of the Sustainable Growth Rate (SGR) formula by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Through the proposed rule, CMS is beginning implementation of the new payment system for physicians and other practitioners, the Merit-Based Incentive Payment System (MIPS), required by the legislation.

The calendar year 2016 PFS proposed rule is one of several proposed rules that reflect a broader Administration-wide strategy to create a health care system that results in better care, smarter spending, and healthier people.

CMS is accepting public comments on the CY 2016 PFS proposed rule until September 8, 2015. The proposed rule will be published in the Federal Register on July 15, 2015. CMS will issue the final rule by November 1.

Background on the Physician Fee Schedule

The PFS pays for services furnished by physicians and other practitioners in all sites of service. These services include but are not limited to office visits, surgical procedures, diagnostic tests, therapy services, and certain preventive services.

In addition to physicians, the physician fee schedule pays a variety of practitioners and entities, including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities.

Payments are based on the relative resources typically used to furnish the service. Relative value units (RVUs)

are applied to each service for physician work, practice expense (PE), and malpractice (MP). These RVUs become payment rates through the application of a conversion factor, which is calculated using the formula set forth in statute.

PAYMENT PROVISIONS

Part B Drugs/Payment for Biosimilar Biological Products

In 2010, CMS issued regulations regarding payment for biosimilar biological products using a payment approach specified by the Affordable Care Act (ACA). CMS is proposing to update the regulations to clarify that the payment amount for a billing code that describes a biosimilar biological drug product is based on the average sales price (ASP) of all biosimilar biological products that reference a common biological product's license application.

Misvalued Code Target

The ACA instructed CMS to identify "misvalued codes" in the Physician Fee Schedule, which CMS does through the annual rulemaking process.

In the Protecting Access to Medicare Act of 2014 (PAMA), Congress set a target for adjustments to misvalued codes in the fee schedule for calendar years 2017 through 2020, with a target amount of 0.5 percent of the estimated expenditures under the PFS for each of those four years. Subsequently, the Achieving a Better Life Experience Act of 2014 (ABLE) accelerated the application of the target by specifying it would apply for calendar years 2016 through 2018, and increasing the target to 1 percent for 2016. If the net reductions in misvalued codes in 2016 are not equal to or greater than 1 percent of the estimated expenditures under the fee schedule, a reduction equal to the percentage difference between 1 percent and the estimated net reduction in expenditures resulting from misvalued code reductions must be made to all PFS services.

In this proposed rule, CMS is proposing a methodology for the implementation of this provision, which includes how net reductions in misvalued codes would be calculated. Based on that methodology, CMS has identified changes that achieve 0.25 percent in net reductions. However, CMS could make further misvalued

code changes in the final rule to move closer to the statutory goal of 1 percent based on public comment and new recommendations.

Misvalued Code Changes for Radiation Therapy

In 2012, CMS identified the codes for radiation therapy as potentially misvalued. The AMA provided recommended values for the new codes issued in 2015, including changes to the assumed number of services that are furnished with the capital equipment.

Based on information provided with the Relative Value Update Committee (RUC) recommendations for the increased use of the equipment, CMS is proposing to change the utilization rate assumption used to determine the per minute cost of the capital equipment by assuming that the equipment is generally used for 35 hours per week (a 70 percent utilization rate) instead of 25 hours per week (a 50 percent utilization rate). CMS is proposing to implement this change over two years. CMS is also seeking comment on additional sources of accurate data regarding how often the machines are in use.

Implementation of the Statutory Phase-In of Significant RVU Reductions

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

CMS is proposing to reduce a service by the maximum allowed amount (e.g., 19 percent) in the first year, and phase in of the percent remainder of the reduction in the second year. CMS believes that this approach avoids differential treatment due to an arbitrary cutoff (e.g., 19 percent reduction vs. 20 percent reduction).

Misvalued Code Changes for Lower GI Endoscopy Services

The AMA Current Procedural Terminology (CPT) Editorial Panel revised the lower gastrointestinal endoscopy code set for CY 2015 following identification of some of the codes as potentially misvalued. The RUC subsequently

provided recommendations to CMS for valuing these services. For 2016, CMS is proposing to implement the revised set of codes, including the revised values.

In the CY 2015 PFS proposed rule, CMS noted that that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. Due to changes in practice patterns, CMS considered establishing a uniform approach to valuation for all services that currently include moderate sedation in that rule.

To establish an approach to valuation for all services that include moderate sedation, CMS plans to revalue these codes based on the best data about the provision of moderate sedation. CMS is seeking recommendations from the RUC and other interested stakeholders for valuation of the work associated with moderate sedation alone before proposing an approach that allows Medicare to make payments based on the resource costs associated with the moderate sedation or anesthesia services that are being furnished.

Additionally, CMS is proposing to identify anesthesia procedure codes 00740 and 00810 as potentially misvalued.

“Incident to” Policy for Calendar Year 2016

In the calendar year 2014 PFS final rule, CMS required that, as a condition for Medicare Part B payment, all “incident to” services and supplies must be furnished in accordance with applicable state law. The definition of auxiliary personnel was also clarified to require that the individual furnishing “incident to” services must meet any applicable requirements to provide such services, including licensure, imposed by the state in which the services are furnished.

For 2016, CMS is proposing to clarify that the billing physician or practitioner for “incident to” services must also be the supervising physician or practitioner. Additionally, CMS is proposing to require that auxiliary personnel providing “incident to” services and supplies cannot have been excluded from Medicare, Medicaid, or other Federal health care programs by the Office of Inspector General, or have had their enrollment revoked for any reason at the time that they provide such services or supplies.

Potential Expansion of Comprehensive Primary Care Initiative (CPCI)

Through the Comprehensive Primary Care Initiative (CPCI), the CMS Innovation Center is testing the impact of collaborating with 38 other payers – both private and public – to better coordinate care for Medicare beneficiaries by providing population-based care management fees and shared savings opportunities for approximately 480 primary care practice sites in seven markets.

Through the proposed rule, CMS is soliciting comment on issues related to potential expansion of the CPCI. CMS is not proposing an actual expansion at this time.

Physician Value-Based Payment Modifier

The Value-Based Payment Modifier (Value Modifier) provides for differential payments under the PFS to physicians, groups of physicians, and other eligible professionals (EPs) based on the quality and cost of care they furnish to beneficiaries enrolled in the traditional Medicare Fee-for-Service (FFS) program.

Under the Value Modifier Program, performance on quality and cost measures can translate into payment incentives for EPs who provide high quality, efficient care, while EPs who underperform may be subject to a downward adjustment. This program is set to expire in CY 2018, as a new comprehensive program, required by MACRA, called the Merit-Based Incentive Program (MIPS) begins in CY 2019. These requirements help provide a smooth transition from the Value Modifier to MIPS.

This year, CMS proposes the following key provisions:

- To use CY 2016 as the performance period for the CY 2018 Value Modifier;
- To apply the Value Modifier to nonphysician EP-only groups -- e.g., Physician Assistants (PAs), Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs) and nonphysician EP solo practitioners, beginning with the CY 2018 payment adjustment period;
- To continue to apply the CY 2018 Value Modifier based on participation in the PQRS by groups and solo practitioners;
- To apply the quality-tiering methodology to all groups and solo practitioners that satisfactorily report PQRS

and are determined to be in Category 1 for the CY 2018 payment adjustment period. Groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception finalized in the CY 2015 PFS final rule with comment period (79 FR 67937) - that groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018;

- To waive application of the Value Modifier for groups and solo practitioners, as identified by Tax Identification Number (TIN), if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the Value Modifier participated in the Pioneer ACO Model, CPCI, or other similar Innovation Center model during the performance period, beginning with the CY 2017 payment adjustment period;
- To continue to set the maximum upward adjustment under the CY 2018 Value Modifier at: +4.0 times an adjustment factor (to be determined after the conclusion of the performance period), for groups with ten or more EPs; +2.0 times an adjustment factor, for groups with between two to nine EPs and physician solo practitioners; and +2.0 times an adjustment factor for groups and solo practitioners that consist only of nonphysician EPs; and
- To set the amount of payment at risk under the CY 2018 VM to -4.0 percent for groups with ten or more EPs, -2.0 percent for groups with between two to nine EPs and physician solo practitioners, and -2.0 percent for groups and solo practitioners that consist only of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

Physician Self-Referral Updates

The physician self-referral law prohibits: (1) a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

Recruitment and Retention:

The ACA expanded access to health care coverage to those previously uninsured, increasing the need for primary care providers (including nonphysician practitioners), particularly in remote and underserved areas. CMS is proposing to establish a new exception to permit payment to physicians for the purpose of employing nonphysician practitioners. CMS also plans to clarify the geographic service area for FQHCs and RHCs using the physician recruitment exception and make certain technical corrections.

Updating Physician-Owned Hospital Requirements:

The ACA established new restrictions on physician-owned hospitals, including setting a baseline physician ownership percentage that they cannot exceed and requiring them to state on their websites and in their advertising that they are owned by physicians.

CMS proposes to update the regulations to clarify that a broad range of actions comply with the website and advertising requirements. CMS also proposes conforming changes that better align the regulations to the statute so that the baseline physician ownership percentage includes all physicians rather than only those physicians who refer to the hospital.

Reducing Burden Through Clarifying Terminology and Providing Policy Guidance:

The ACA established a self-disclosure protocol that allows CMS to settle overpayments resulting from physician self-referral law violations. Review of self-disclosures indicates that clarifying terminology and providing policy guidance could reduce perceived or actual technical noncompliance without risk of abuse. Additionally, the proposed rule provides additional guidance to address uncertainty from recent court.

CMS proposes the following changes:

- To clarify that the writing required in the exceptions can be a collection of documents and make the terminology that describes the types of arrangements consistent throughout the regulations;
- To clarify that the term of a lease or personal services arrangement need not be in writing if the arrangement lasts at least 1 year and is otherwise compliant.
- To allow expired leasing and personal services arrangements to continue on the same terms if otherwise compliant;

- To allow a 90-day grace period to obtain missing signatures without regard to whether the failure to obtain the signature was inadvertent;
- To clarify that DHS entities can give items used solely for certain purposes to physicians;
- To clarify that a financial relationship does not necessarily exist when a physician provides services to patients in the hospital if both the hospital and the physician bill independently for their services;
- To update obsolete language in the exception for ownership in publicly traded entities to allow over-the-counter transactions and delete certain unnecessary language;
- To establish a new exception to permit timeshare arrangements for the use of office space, equipment, personnel, supplies and other services that will benefit rural or underserved areas;
- To clarify that compensation paid to a physician organization cannot take into account the referrals of any physician in the physician organization, not just a physician who stands in the shoes of the physician organization; and
- To seek comments on physician self-referral changes and guidance needed to advance alternative payment models and value-based purchasing.

MACRA Changes to Medicare Physician and Practitioner Opt-Out

Prior to MACRA, the statute indicated that the longest interval for which a Medicare opt-out affidavit from a physician or practitioner can be effective is two years.

Section 106(a) of MACRA indicates that opt-out affidavits filed on or after the date that is 60 days after the date of enactment automatically renew every two years. Physicians and practitioners are able to rescind their opt-out status if they notify CMS at least 30 days prior to the start of the next two-year period. CMS proposes conforming existing regulations to the MACRA requirement.

Request for Input on the MACRA

In addition to repealing the SGR formula, MACRA established MIPS and encouraged participation in alternative payment models.

To help with implementation, CMS is requesting input on a number of pieces of MACRA, including the selection of low-volume threshold, the definition of clinical practice improvement activities, and input on how to define a physician-focused payment model, as discussed in section 101(e) of MACRA.

CMS plans on sending out a Request for Information later this year seeking comment on a broader range of issues surrounding MACRA implementation.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

In the Protecting Access to Medicare Act (PAMA), Congress required that providers that order advanced diagnostic imaging services consult with appropriate use criteria via a clinical decision support mechanism. CMS is required to specify appropriate use criteria from among those developed or endorsed by national medical professional specialty societies and provider-led entities not later than November 15, 2015.

PAMA also requires CMS to approve clinical decision support mechanisms by April 1, 2016, requires additional information be collected on the Medicare claim form by January 1, 2017, and requires that the claims information be used to develop a prior authorization program by January 1, 2020.

CMS is proposing to provide definitions for areas of the statute that require clarification. For example, a definition is required for “provider-led entity” in order to identify which organizations are eligible to develop or endorse appropriate use criteria. In addition, CMS proposes to establish a process by which the agency will identify clinical areas of priority, specify appropriate use criteria, and lay out a timeline to accomplish these goals.

QUALITY PROVISIONS

Modifications to the Physician Quality Reporting System

CMS tracks the quality of care provided to Medicare beneficiaries through the Physician Quality Reporting System (PQRS).

The proposals for this year reflect CMS’ intent to continue to implement the PQRS by proposing requirements for the 2018 PQRS payment adjustment consistent with the requirements for the 2017 PQRS payment

adjustment. CMS proposes to establish the same criteria for satisfactory reporting and, in lieu of satisfactory reporting, satisfactory participation in a qualified clinical data registry (QCDR), that was established for the 2017 PQRS payment adjustment, which is generally to require the reporting of nine measures covering three National Quality Strategy domains. If an individual EP or group practice does not satisfactorily report or satisfactorily participate while submitting data on PQRS quality measures, a 2% negative payment adjustment would apply in 2018. The adjustment (98% of the fee schedule amount that would otherwise apply to such services) would apply to covered professional services furnished by an individual EP or group practice during 2018.

CMS proposes to make changes to the PQRS measure set to add measures where gaps exist, as well as to eliminate measures that are topped out, duplicative, or are being replaced with a more robust measure. If all measure proposals are finalized, there will be 300 measures in the PQRS measure set for 2016. Also, as recently authorized under MACRA, CMS proposes to add a reporting option that will allow group practices to report quality measures data using a QCDR.

Please note that the 2018 PQRS payment adjustment is the last adjustment that will be issued under the PQRS. Following the 2018 PQRS payment adjustment, adjustments to payment for quality reporting and other factors will be made under MIPS, as required by MACRA. CMS is also seeking comment related to other MACRA provisions in this rule.

Physician Compare

As part of the 2016 PFS proposed rule, CMS will continue its phased approach to public reporting on Physician Compare. In addition to continuing existing policies, such as making all individual and group-level PQRS measures available for public reporting, CMS also proposes several new policies:

- To include an indicator on profile pages for individual eligible professionals (EPs) who satisfactorily report the new PQRS Cardiovascular Prevention measures group in support of Million Hearts and group practices and individual EPs who receive an upward adjustment for the Value Modifier;
- To make individual-level QCDR measures available for public reporting, and, new to 2016, to publicly report group-level QCDR measures;

- To publicly report an item (or measure)-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology. More on this item below;
- To include in the downloadable database the Value Modifier tiers for cost and quality, noting if the group practice or EP is high, low, or neutral on cost and quality; a notation of the payment adjustment received based on the cost and quality tiers; and an indication if the individual EP or group practice was eligible to but did not report quality measures to CMS; and
- To publicly report in the downloadable database utilization data for individual EPs.

Consistent with existing policies, all data must meet the minimum sample size of 20 patients and prove to be statistically valid and reliable. For individual and group-level measures, CMS will publicly report all measures submitted, reviewed, and deemed valid and reliable in the Physician Compare downloadable file. However, not all measures will be included on the Physician Compare profile pages.

Physician Compare Benchmark

Based on diverse stakeholder outreach and the recommendation of the CMS Technical Expert Panel (TEP), CMS proposes to publicly report an item (or measure)-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology, which is annually based on the PQRS performance rates most recently available. Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark would allow consumers to more easily evaluate the published information by providing a point of comparison between groups and between individuals. On Physician Compare, the benchmark would be displayed as a five star rating.

The Medicare EHR Incentive Program

Clinical Quality Measure (CQM) Submission

CMS is proposing to revise the definition of certified EHR technology to require certification of EHR technology in accordance with criterion proposed by the Office of the National Coordinator for Health Information Technology in relation to CMS's form and manner requirements for electronic submission of CQMs certified electronic health record technology.

Medicare Shared Savings Program

The Medicare Shared Savings Program (Shared Savings Program) was established to promote accountability for a patient population, coordinate items and services under parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery through provider and supplier participation in an Accountable Care Organization (ACO). The CY 2016 PFS proposed rule includes proposals specific to certain sections of the Shared Savings Program regulations and solicits feedback from stakeholders on the following:

- Adding a measure of Statin Therapy for the Prevention and Treatment of Cardiovascular Disease in the Preventive Health domain of the Shared Savings Program quality measure set to align with PQRS;
- Preserving flexibility to maintain or revert measures to pay for reporting if a measure owner determines the measure no longer aligns with updated clinical practice or causes patient harm;
- Clarifying how PQRS-eligible professionals participating within an ACO meet their PQRS reporting requirements when their ACO satisfactorily reports quality measures; and
- Amending the definition of primary care services to include claims submitted by Electing Teaching Amendment hospitals and exclude claims submitted by Skilled Nursing Facilities.

ADVANCE CARE PLANNING

The proposed rule also seeks comment on a proposal that would better enable seniors and other Medicare beneficiaries to make important decisions that give them control over the type of care they receive and when they receive it.

Consistent with recommendations from the American Medical Association (AMA) and a wide array of stakeholders, CMS proposes to establish separate payment and a payment rate for two advance care planning services provided to Medicare beneficiaries by physicians and other practitioners. The Medicare statute currently provides coverage for advance care planning under the "Welcome to Medicare" visit available to all Medicare beneficiaries, but they may not need these

services when they first enroll. Establishing separate payment for advance care planning codes provides beneficiaries and practitioners greater opportunity and flexibility to utilize these planning sessions at the most appropriate time for patients and their families.

The AMA Current Procedural Terminology (CPT) Editorial Panel and the AMA Relative Value Update Committee (RUC) recommended new CPT codes and associated payment amounts for calendar year 2015. CMS did not make the new codes payable for 2015 in order to allow the public full opportunity to comment on whether Medicare should pay separately for these services and, if so, how much beginning January 1, 2016.

For Medicare beneficiaries who choose to pursue it, advance care planning is a service that includes early conversations between patients and their practitioners, both before an illness progresses and during the course of treatment, to decide on the type of care that is right for them.