

August 8, 2017

MEDICARE PHYSICIAN FEE SCHEDULE: PROPOSED RULE FOR CY 2018

AT A GLANCE

At Issue

On July 13, the Centers for Medicare & Medicaid Services (CMS) released its [proposed rule](#) for calendar year (CY) 2018 with changes to the Medicare physician fee schedule (PFS) and other revisions under Medicare Part B. In addition to the standard update to PFS payment weights and rates, the rule would:

- Make significant additional site-neutral cuts in payment for services furnished in certain off-campus provider-based departments (PBDs) of a hospital;
- Expand payment for telehealth services to include psychotherapy for crisis, health risk assessments, care planning for chronic care management, and counseling visit to determine low-dose computed tomography eligibility;
- Delay until Jan. 1, 2019, the requirement that professionals report on consultation of appropriate use criteria for advanced diagnostic imaging;
- Make retroactive changes to Physician Quality Reporting System requirements for performance year 2016, to better align with the Medicare Access and CHIP Reauthorization Act of 2015 quality payment program.

Changes proposed in the rule generally would be effective Jan. 1, 2018.

Our Take:

We are extremely disappointed that CMS proposes further cuts to Medicare rates for services hospitals provide in “new” off-campus hospital outpatient departments. This proposal appears to have a questionable policy basis and is yet another blow to access to care for patients, including many in vulnerable communities without other sources of health care. Further, we remain concerned that the agency’s continued shortsighted policies on the relocation of grandfathered off-campus PBDs will prevent communities from having access to the most up-to-date services. With respect to payment for physician services, the AHA is pleased by a number of CMS’s proposals, including new telehealth services and a delay in implementation of appropriate use criteria for advanced diagnostic imaging to allow providers sufficient time to understand and implement the program requirements. However, we continue to urge the agency to take a more expansive approach toward coverage for telehealth services.

What You Can Do:

- ✓ Share this advisory with your chief medical officer, chief financial officer and other members of your senior management team, key physician leaders and nurse managers.
- ✓ Assess the potential impact of the proposed payment changes on your Medicare revenue and operations.
- ✓ Consider submitting comments by Sept. 11 to CMS to provide your feedback about the proposed policies and issues on which comment is requested.

Further Questions:

Contact Joanna Hiatt Kim, vice president for payment policy, at (202) 626-2340 or jkim@aha.org.



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BACKGROUND

On July 13, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule for calendar year (CY) 2018 with changes to the Medicare physician fee schedule (PFS) and other revisions under Medicare Part B. The proposed rule was published in the July 21 [Federal Register](#). Comments are due to CMS by Sept. 11. A final rule will be issued around Nov. 1, and changes generally would be effective Jan. 1, 2018.

CHANGES TO THE CY 2018 PFS

Conversion Factor

CMS proposes a total increase in payment rates of 0.28 percent in CY 2018. This includes an increase of 0.5 percent as required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), in addition to a budget neutrality adjustment and a misvalued code adjustment required under the Achieving a Better Life Experience Act of 2014. These adjustments result in a proposed conversion factor of \$35.9903 for CY 2018.

Payment for X-ray Imaging

The Consolidated Appropriations Act of 2016 requires a 7 percent reduction in payment amounts under the PFS for the technical component of X-ray imaging taken using computed radiography technology (including when billed as a global service) beginning in CY 2018. It requires an additional 3 percent reduction (for a total of a 10 percent reduction) in payments for such services beginning in 2023. To implement this provision, CMS proposes to create a modifier which must be listed on claims for X-rays taken using computed radiography technology, and to apply the payment reduction when the modifier is used.

Evaluation & Management (E/M) Guidelines

In response to stakeholder feedback that documentation and coding guidelines for E/M services are administratively burdensome and outdated, CMS solicits comment on how the agency might reform the guidelines, reduce the associated burden and better align E/M coding and documentation with the current practice of medicine. Specifically, the agency asks whether it would be appropriate to remove the documentation requirements for the history and physical exam, and instead allow medical decision making and/or time determine the level of the E/M visit.

Medicare Telehealth Services

New Telehealth Services. CMS proposes to add two new services to the list of Medicare-payable telehealth services:

- *Counseling visit to determine low-dose computed tomography (LDCT) eligibility (G0296)*. This service includes assessment of the patient's risk for lung cancer, shared decision making and counseling on the risks and benefits of LDCT.
- *Psychotherapy for crisis (90839, first 60 minutes; 90840, each additional 30 minutes)*. CMS notes that since these codes describe patients requiring urgent care and psychotherapeutic interventions to minimize the potential for psychological trauma, the distant site practitioner must be able to communicate with and inform staff at the originating site to the extent necessary to defuse the crisis and restore safety.

In addition, CMS proposes to add four services that describe additional elements to services already on the telehealth list:

- *Interactive complexity (90785)*
- *Administration of patient-focused health risk assessment instrument (96160)*
- *Administration of caregiver-focused health risk assessment instrument for the benefit of the patient (96161)*
- *Comprehensive assessment of and care planning for patients requiring chronic care management services (G0506)*

These services would only be considered telehealth services if they are billed as an add-on to codes already on the telehealth list.

Elimination of the GT Modifier. Distant site practitioners who provide services to patients remotely via telehealth must bill modifier GT to identify telehealth services. However, in last year's PFS rulemaking, CMS also finalized a telehealth point-of-service (POS) code that distant site practitioners must use to identify services as telehealth, effective Jan. 1, 2017. CMS now proposes to eliminate the GT modifier on professional claims, stating that it is redundant with the POS code. However, since institutional claims do not use POS modifiers, distant site practitioners who bill under critical access hospital Method II billing must continue to use the GT modifier on institutional claims.

Comment Solicitation on Telehealth and Remote Patient Monitoring. CMS solicits comment on ways it might expand access to telehealth within its statutory authority and pay appropriately for services that take full advantage of communication technologies. The agency notes that it cannot change the statutory limitations regarding geography, patient setting or type of furnishing practitioner.

In addition, the agency solicits comment on whether to make separate payment for Current Procedural Terminology (CPT) codes that describe remote patient monitoring. CMS notes that remote patient monitoring services would not generally be considered Medicare telehealth services, since they involve interpretation of medical information without a direct interaction between the practitioner and patient. The agency is particularly interested in comments regarding CPT codes 99091 (collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver) and 99090 (analysis of clinical data stored in computers).

PROPOSED CHANGES TO QUALITY PROGRAMS

The MACRA mandates that CY 2018 is the final year for payment adjustments under both the Physician Quality Reporting System (PQRS) and the Value Modifier (VM), which will be supplanted by the new two-track physician quality payment program (QPP) beginning with CY 2019 payments. Additional resources on MACRA and the QPP can be found at www.aha.org/MACRA.

PQRS

The performance period for CY 2018 PQRS payment adjustment was CY 2016, and clinicians and groups had to submit performance period data to CMS by the end of March 2017. However, CMS proposes to retroactively lower the number of measures required for reporting from nine measures to six measures, the same number of measures that will be required under the new Merit-based Incentive Payment System (MIPS) affecting PFS payment starting in CY 2019. CMS also proposes to eliminate the PQRS requirement that clinicians and groups report a “cross-cutting” measure. Those clinicians that did not meet the previous PQRS standard of nine measures (including a cross cutting measure), but did report at least six measures, would therefore not be subject to the PQRS non-reporting penalty of 2.0 percent in CY 2018.

In explaining its proposed changes, CMS states it received stakeholder feedback that PQRS requirements were overly burdensome, and that they should be more closely aligned with the MIPS to reduce confusion.

Physician VM

CMS previously finalized maximum negative payment adjustments for CY 2018 of -2.0 percent for individual clinicians and groups of 10 or fewer clinicians, and -4.0 percent for groups of 10 or more clinicians. These adjustments would have applied to those clinicians and groups that did not submit PQRS data, and to poor performers in the program (i.e., those classified as “high cost” and “low quality” under the Quality Tiering Model, or QTM).

In order to provide a smoother transition into the QPP, CMS proposes to lower the VM's CY 2018 maximum negative adjustment to -1.0 percent for individual clinicians and groups under 10 clinicians, and -2.0 percent for groups of 10 or more clinicians. **This maximum negative adjustment would apply only to those clinicians and groups that fail to meet PQRS reporting requirements. All other individual clinicians and group practices of all sizes would be held harmless from downward payment adjustments under the VM for CY 2018.**

MACRA Patient Relationship Categories and Codes

MACRA requires CMS to develop and update through rulemaking a set of “patient relationship categories and codes” that specify the relationship between clinicians and patients at the time a service is furnished. The purpose of these codes is to facilitate the attribution of patients and episodes of care to clinicians according to the varying roles in which clinicians serve patients. CMS notes these codes could be used in measuring the costs of care. As deemed appropriate, CMS can also require clinicians to submit these codes with claims submitted starting on Jan. 1, 2018.

As required by MACRA, CMS has followed an iterative process that began in mid-2016 to develop and solicit input on the patient relationship categories and codes. The process is described in greater detail in a document posted to CMS’s QPP [website](#). In the proposed rule, CMS solicits comment on whether the following five “operational categories” appropriately capture the relationships between patients and clinicians:

1. Continuous/broad services: 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 (e.g., primary care services and specialists providing comprehensive care to patients).
2. Continuous/focused services: Clinicians whose expertise is needed for the ongoing management of a chronic disease or a condition that needs to be managed and followed for a long time (e.g., a rheumatologist taking care of the patient’s rheumatoid arthritis longitudinally but not providing general primary care services).
3. Episodic/broad services: Clinicians who have broad responsibility for the comprehensive needs of the patients that is limited to a defined period and circumstance, such as a hospitalization (e.g., a hospitalist providing comprehensive and general care to a patient during a hospital stay).
4. Episodic/focused services: Clinicians who provide time-limited care. The patient has a problem, acute or chronic, that will be treated with surgery, radiation, or some other type of generally time-limited intervention (e.g., an orthopedic surgeon performing a knee replacement and seeing the patient through the postoperative period).
5. Only as ordered by another clinician: Clinicians who furnish care to the patient only as ordered by another clinician. CMS intends this category to be used for patient relationships that may not be adequately captured in the four categories described above (e.g., a radiologist interpretation of an imaging study ordered by another clinician).

CMS also proposes to translate the five operational categories above into Healthcare Common Procedure Coding System (HCPCS) Level II modifiers that could be *voluntarily* reported by clinicians with claims starting on Jan. 1, 2018. CMS states that they “anticipate that there will be a learning curve with respect to the use of these modifiers,” and that the agency intends to work with clinicians to ensure the codes are used appropriately.

OTHER PROPOSED CHANGES FOR CY 2018

Appropriate-use Criteria (AUC) for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act (PAMA) requires CMS to establish a program that promotes AUC for advanced diagnostic imaging. The statute requires that, beginning Jan. 1, 2017, payment may be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC. This policy applies only when applicable imaging services are provided in specific settings – a physician’s office, hospital outpatient department (including an emergency department), an ambulatory surgery center, and any other provider-led outpatient setting as determined by CMS.

CMS took initial steps to implement this policy in the CY 2016 PFS rule by defining AUC and specifying the process for developing them. In the CY 2017 PFS rule, CMS finalized a definition of, and requirements for, CDSMs. In that rule, the agency stated that the first qualified CDSMs would be specified on June 30, 2017, and that it anticipated that furnishing professionals would begin reporting on AUC consulted by the ordering professional as early as Jan. 1, 2018.

Instead, CMS [released](#) the first qualified CDSMs on July 13 when it released the CY 2018 PFS proposed rule. In addition, the agency now proposes that AUC consultation and reporting requirements would begin on Jan. 1, 2019. However, 2019 would be considered an “educational and operations testing year,” and CMS would pay claims regardless of whether they contain information on the required AUC consultation. CMS states that this would allow time for needed education and outreach efforts, for practitioners and stakeholders to prepare and for CDSMs to become more user-friendly and less burdensome. **The AHA has urged CMS to allow providers adequate time to implement the AUC requirements before they begin impacting payment, and is pleased with this proposal.**

Beginning Jan. 1, 2019, furnishing professionals would need to report on Medicare claims for applicable imaging services the following:

- which qualified CDSM was consulted by the ordering professional;

- whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC were not applicable to the service ordered; and
- the National Provider Identifier of the ordering professional (if different than the furnishing professional).

CMS proposes to establish a series of HCPCS G-codes that would describe the specific CDSM that was used by the ordering professional. Because there may be a lag between approval of a CDSM and establishment of a dedicated G-code for that mechanism, the agency would establish a generic G-code to be used if a more specific code did not yet exist for the clinician’s CDSM. CMS would also establish a G-code to indicate that a qualified CDSM was not consulted by the ordering professional.

CMS also plans to implement a voluntary reporting period, which it anticipates will begin in July 2018. Further, the agency notes that in the CY 2018 MACRA QPP [proposed rule](#), it proposed to give ordering professionals who consult AUC beginning Jan. 1, 2018, credit toward the Improvement Activities category of the MIPS.

Proposed Changes to Site-neutral Payment Policy for Off-campus Provider-based Departments (PBDs)

Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that, with the exception of emergency department (ED) services¹, services furnished in off-campus PBDs that began billing under the hospital outpatient prospective payment system (OPPS) on or after Nov. 2, 2015 (referred to as “nonexcepted services”) are no longer paid under the OPPS. Instead, these services are covered and paid under “another applicable Part B payment system.” For CY 2017, CMS finalized the PFS as the applicable Part B payment system for most of nonexcepted services and set payment for most nonexcepted services at 50 percent of the OPPS rate.

Establishment of a Proposed Payment Rate for Nonexcepted Services in CY 2018. In the CY 2018 [PFS proposed rule](#), **CMS proposes significant reductions to the site-neutral payment rates. For CY 2018, the agency proposes to pay hospitals at 25 percent, rather than 50 percent, of the OPPS rate for nonexcepted services.** The agency estimates that this change will save Medicare Part B \$25 million in 2018 compared to 2017.

The AHA believes that this proposal has a questionable policy basis and is yet another blow to access to care for patients, including many in vulnerable communities without other sources of health care. Further, we remain concerned that CMS’s continued shortsighted policies on the relocation of grandfathered off-campus PBDs will prevent communities from having access to the most up-to-date services. We will continue to urge CMS to provide payments that are

¹ As well as services in off-campus PBDs meeting the additional “under development” exception in the 21st Century Cures Act.

adequate to cover the costs of providing care so that hospitals and health systems can continue to serve as the access point for community care.

CMS arrives at its proposed payment rate based solely on a comparison of the payment rate for a hospital outpatient clinic visit, which CMS notes reflects greater than 50 percent of services billed in off-campus PBDs, to the payments for similar outpatient visit services under the PFS. Specifically CMS compares the CY 2017 OPSS payment rate for a hospital outpatient clinic visit (HCPCS code G0463) to the difference between the 2017 nonfacility and facility PFS payment amount for the weighted average of outpatient visits (CPT codes 99201-99205 and CPT codes 99211-99215) billed by physicians in an outpatient hospital place of service. CMS then divides the PFS amount by the OPSS amount, to arrive at their “PFS Relativity Adjuster” of 25 percent.

CMS acknowledges that its proposed methodology does not take into consideration any comparison between the OPSS and PFS rates for other services commonly furnished in off-campus PBDs. It also acknowledges that it has disregarded other factors, such as the specific mix of services furnished by nonexcepted PBDs, differences between the packaging policies under OPSS versus the PFS, and other payment adjustments that differ between the two payment systems, which could contribute to the differences in aggregate payment amounts for a broader range of services. Instead, CMS states that for CY 2018, it will focus on ensuring that the agency does not overestimate the appropriate overall payments for nonexcepted services. It states, “Until we are able to study claims data, we believe that the comparison between the PFS and OPSS payment for the most common services furnished in off-campus PBDs, outpatient visits, is a better proxy than our previous approach.”

CMS request comments on its proposal, including on whether the agency should adopt a different PFS Relativity Adjuster, such as 40 percent, that represents a relative middle ground between the adjuster used in CY 2017 (50 percent) and their proposed 25 percent adjuster.

CMS also states that in most years, the proposed annual update to OPSS payments exceeds the proposed annual update to PFS payments. However, because its CY 2018 proposed adjustment to the site-neutral payment rate is “imprecise,” CMS does not intend to consider this differential in establishing the PFS Relativity Adjuster for CY 2018. The agency does note that this differential is a factor that suggests that the proposed PFS Relativity Adjuster may overestimate PFS nonfacility payment relative to OPSS payments and that in future years, and CMS intends to more precisely account for the differentials in the two update factors.

Other Site-neutral Payment Policies. CMS does not propose to make any other changes to its site neutral policy in CY 2018. This includes retaining its problematic policy that the relocation of an existing PBD will result in it losing its excepted status and being paid at the site-neutral rate, except in extraordinary circumstances. Further, for CY 2018, CMS continues to propose that:

- hospitals would bill on the institutional claim (UB04/837I) using the claim line modifier “PN” to indicate that the service is a nonexcepted item or service;
- the geographic adjustments used under the OPSS will apply to nonexcepted payments;
- the following OPSS payment adjustments would not be applied to nonexcepted services: outlier payments, the rural sole community hospital adjustment, the cancer hospital adjustments, transitional outpatient payments, the Hospital Outpatient Quality Reporting Program payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service;
- nonexcepted hospital partial hospitalization (PHP) program services would be paid at the community mental health center (CMHCs) per diem rate;
- the supervision rules that apply for hospitals would apply for nonexcepted services in off-campus PBDs; and
- beneficiary cost-sharing rules that apply under the PFS apply for all nonexcepted items and services furnished by off-campus PBDs, regardless of the cost-sharing obligation under the OPSS.

Payment in CY 2019 and Future Years. CMS continues to believe that by enacting Section 603 of the BiBA, Congress intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPSS for services they furnish there. Therefore, the agency still intends that its payment policy ultimately equalize payment rates between nonexcepted off campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services they furnish.

CMS states that its current approach does not result in payment rates being equal on a procedure-by-procedure basis, but rather only moves toward equalizing payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs. Therefore, for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician’s office. CMS remains concerned that such specialty-specific patterns in payment differentials could result in continued incentives for hospitals to buy certain types of physician offices and convert them to nonexcepted off-campus PBDs. However, continuing a policy similar to the one proposed would allow hospitals to continue billing through a facility claim form and would allow for continuation of the other OPSS-like policies more suitable for hospital outpatient departments.

Therefore, for CY 2019 and for future years, CMS intends to examine updated claims data² in order to determine not only the appropriate PFS Relativity Adjuster, but also whether additional adjustments to the methodology are appropriate. The agency’s goal would be to attain site-neutral payments that promote a level playing field under

²A full year of claims data regarding the mix of services reported using the “PN” modifier (from CY 2017) will first be available for use in PFS rate-setting for CY 2019.

Medicare between physician office settings and nonexcepted off-campus PBD settings, without regard to the kinds of services furnished by particular off-campus PBDs. The agency solicits comments on potential changes to its methodology that would better account for these specialty-specific patterns.

New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

RHCs are paid an all-inclusive rate for medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). FQHCs are paid under the FQHC PPS, based on the lesser of the FQHC PPS rate or their actual charges. In the CY 2016 PFS final rule, CMS finalized a policy that allows RHCs and FQHCs to receive an additional payment for chronic care management (CCM) services outside of the RHC and FQHC payment methodologies. Now, in an effort to ensure that RHC and FQHC patients have access to the new CCM services included in the PFS, CMS proposes to establish two new codes for use by RHCs and FQHCs, effective for services provided on or after Jan. 1, 2018.

First, CMS proposes to create a new general care management code, GCCC1, for RHCs and FQHCs. The payment amount would be set at the average of the three national non-facility PFS payment rates for the CCM and general behavioral health integration (BHI) codes and updated annually based on the PFS amounts. The three codes are:

- 20 minutes or more of CCM services (99490);
- At least 60 minutes of complex CCM services (99487); and
- 20 minutes or more of BHI services (G0507).

RHCs and FQHCs could bill using GCCC1 when the requirements for any of these three codes are met. GCCC1 could be billed alone or in addition to other services furnished during the RHC or FQHC visit. However, it may only be billed once per month per beneficiary, and could not be billed if other care management services (such as transitional care management or home health care supervision) are billed for the same time-period. More specific detail on how RHCs and FQHCs may use code GCCC1 begins on page 34083 of the proposed rule.

Second, CMS proposes to create a psychiatric collaborative care model (CoCM) code for RHCs and FQHCs, GCCC2. The payment for this code will be set at the average of the two national non-facility PFS payment rates for CoCM codes, to be updated annually based on the PFS amounts. The two codes are:

- 70 minutes or more of initial psychiatric CoCM services (G0502); and
- 60 minutes or more of subsequent psychiatric CoCM services (G0503).

RHCs and FQHCs could bill using GCCC2 when the requirements for either of these codes are met. GCCC2 could be billed alone or in addition to other services furnished

during the RHC or FQHC visit. However, to prevent duplication of payment, this code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the proposed GCCC1 code, are billed for the same time period. More specific detail on how RHCs and FQHCs may use code GCCC2 begins on page 34086 of the proposed rule.

Medicare Electronic Health Record (EHR) Incentive Program

CMS proposes to align the reporting requirements for physicians that chose to electronically report clinical quality measures in the PQRS program through the PQRS portal for the 2016 reporting period and have the submission meet the quality measure reporting requirements of the EHR Incentive Program. Specifically, CMS proposes that reporting six electronic clinical quality measures (eCQMs) for the EHR Incentive Program without a domain requirement will meet the 2016 PQRS reporting requirement as well as the transition year of the MACRA QPP reporting requirement. CMS does not propose changes to the previously finalized requirements for eCQM reporting in 2016 for eligible professionals reporting eCQMs through attestation to the Medicare EHR Incentive Program, for eligible professionals participating in the Medicaid EHR Incentive Program, or for eligible hospitals and critical access hospitals in the Medicare EHR Incentive Program.

Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule (CLFS)

On June 23, 2016, CMS issued a final rule implementing a new “market-based” payment system for clinical diagnostic laboratory tests paid under the CLFS. Under the CLFS final rule, certain “applicable” laboratories (which largely do not include hospital laboratories or physician office laboratories) are required to report to CMS private payor laboratory test payment information. In general, the payment amount for a test on the CLFS furnished on or after Jan. 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the information that is collected during a data collection period and reported during a data reporting period.

CMS established the first data collection period as Jan. 1, 2016 through June 30, 2016. The first data reporting period was Jan. 1, 2017 through May 31, 2017.

To better understand the applicable laboratories’ experience with the data reporting, data collection and other compliance requirements, CMS requests comments on a number of questions in the proposed rule.

Solicitation of Public Comments on Biosimilars

In the 2016 PFS final rule, CMS finalized a policy to make clear that the payment amount for a biosimilar biological product is based on the average sales price (ASP) of all National Drug Codes assigned to the biosimilar biological products included within the same billing and payment code. Beginning on Jan. 1, 2016, products that rely on a common reference product’s biologics license application are grouped into the same

payment calculation for determining a single ASP payment limit and a single HCPCS code is used for such biosimilar products.

The comments received in response to the 2016 rulemaking were diverse, with some commenters supporting CMS's policy and others opposing it and instead recommending that CMS determine a payment amount for each biosimilar biological product. CMS is interested in assessing the effects of the Medicare payment policy on the biosimilar biological product marketplace, particularly if the policy is fostering a robust, and competitive marketplace and encouraging innovation. CMS is also interested in better understanding if and how the innate differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars. While CMS is not proposing a change to their existing payment policy at this time, the agency requests comments on a number of issues regarding the Medicare Part B biosimilar biological product payment policy.

Medicare Shared Savings Program (MSSP)

CMS proposes a number of changes to the MSSP aimed to better account for primary care services when assigning beneficiaries to an accountable care organization (ACO), reduce the application burden for ACOs and better align the quality reporting program with the MACRA QPP. Below is a summary of key proposed changes.

Accounting for RHC and FQHCs in Beneficiary Assignment. The 21st Century Cures Act requires CMS to assign beneficiaries to MSSP ACOs based not only on utilization of primary care services furnished by physicians, as is currently done, but also based on utilization of services furnished by RHCs and FQHCs, for performance years beginning on or after Jan. 1, 2019. CMS proposes to implement this requirement by treating all services provided by an RHC or FQHC in the same way as a primary care service provided by a primary care physician. This means that RHCs and FQHCs would no longer be required to identify through attestation the physicians who directly provide primary care services. Instead, any service provided by an RHC or FQHC, even if provided by a non-physician practitioner, would qualify as primary care for the purposes of beneficiary assignment. CMS states that this will reduce the burden for ACOs that include RHCs and FQHCs, and advance its goal of assigning beneficiaries to the ACO that is primarily responsible for the beneficiary's overall care.

Definition of Primary Care Services. CMS proposes to add to its definition of primary care services new codes for chronic care management (99487, 99489, G0506) and behavioral health integration (G0502, G0503, G0504, G0507) that were finalized in the CY 2017 PFS rulemaking. For performance year 2019 and beyond, these services would be considered when calculating the amount of primary care provided for purposes of beneficiary assignment.

Reducing MSSP Application Burden. CMS proposes to streamline certain documentation and certification requirements components of the MSSP program application and the application for Track 3 ACOs seeking a waiver of the skilled nursing

facility (SNF) three-day stay rule. Specifically, CMS proposes to eliminate from the SNF waiver the requirements of a narrative describing financial relationships that exist between the ACO, SNF affiliates and acute care hospitals, and documentation demonstrating that each SNF on the ACO's list of affiliates has an overall rating of three or higher under the CMS 5-star Quality Rating System. The agency notes that these requirements increase burden and do not add value to the agency's ability to review and approve SNF affiliates.

CMS also proposes to eliminate certain requirements for initial MSSP applications. Specifically, applicant ACOs would no longer be required to submit with the MSSP application supporting documents or narratives regarding:

- specified processes, such as how the ACO will promote evidence-based medicine, promote beneficiary engagement internally report quality and cost metrics and promote coordination of care;
- the ACO's organization and management structure; and
- distribution of shared savings payments.

Instead, the agency would request such information only if it was needed to fully assess the ACO's application to determine program eligibility.

Web interface measures. In the MACRA QPP proposed rule issued June 20, CMS proposed to make substantive changes to three measures used to assess performance for MSSP participants. The measures to be addressed are:

- ACO-17 Tobacco Use: Screening and Cessation Intervention (ACO-17)
- Influenza Immunization Measure (ACO-14)
- Body Mass Index Screening and Follow-Up Plan (ACO-16)

CMS reviewed the proposed changes to these measures to determine if they would necessitate a change in how they are used to assess ACO performance under the Shared Savings Program. CMS believes the proposed measurement changes do not require that the measures be re-categorized as pay-for-reporting for the 2018 performance year. Instead, CMS proposes to update the measure specifications through sub-regulatory guidance, and retain the current phase-in schedule.

In the future, CMS expects that there could be substantive changes made under the QPP program affecting Shared Savings Program performance measures in ways that necessitate re-designation to pay-for-reporting. CMS speculates that, given the timing of the QPP proposals and the timing for establishing performance benchmarks for the Shared Savings Program, it may be necessary to have flexibility to designate a pay-for-performance measure as pay-for-reporting just before or following the start of a performance year outside of the formal rulemaking process. **Therefore, CMS proposes to modify the rules to include the right for CMS to re-designate a measure as pay-for-reporting when a substantive change to a CMS web interface measure is made under the QPP program.** CMS explains that "substantive changes made to CMS web

interface measures under the QPP (such as when the substantive change to a measure results in an issue with sampling, calculating performance, or the calculating the quality benchmark) may make it inappropriate to hold an ACO accountable for performance on the measure for the time needed for CMS to obtain the information necessary to calculate a quality benchmark for the substantively changed measure in advance of a performance year and/or until ACOs gain experience reporting the measure, as substantively changed.”

Validation of ACO Quality Data Reporting. In the CY 2017 PFS final rule, CMS made several changes to the Shared Savings Program quality validation audit process, in part to align it with other quality programs. Specifically, the changes include auditing enough medical records to achieve a 90 percent confidence interval; conducting the audit in a single phase; and calculating an overall audit performance rate. At the end of the audit process, if the overall match rate between the quality data reported and the medical records provided by the ACO is below 90 percent, CMS adjusts the ACO’s overall quality score proportional to its audit performance (absent unusual circumstances). CMS calculates the audit-adjusted quality score by multiplying the ACO’s overall quality score by the ACO’s overall audit match rate. For example, if an ACO’s quality score is 75 percent and the ACO’s audit match rate is 80 percent, the ACO’s audit-adjusted quality score would be 60 percent. That score will be used to determine the percentage of any earned savings that the ACO may share, or the percentage of any losses for which the ACO is accountable. CMS also finalized a requirement that an ACO that has an audit match rate of less than 90 percent may be required to submit a corrective action plan.

A recent CMS analysis indicates that the average match rate of ACOs audited in calendar year 2016 was 72 percent and the median performance was 80 percent. CMS believes that ACOs continue to experience challenges in understanding certain aspects of measure specifications, coordinating collection of information across many different providers and practices, and satisfying the requirements for supporting documentation. CMS believes that the 90 percent match rate may be too high and could inappropriately penalize ACOs for errors that are unrelated to care quality. (CMS notes that the match rate threshold under the Hospital Inpatient Quality Reporting (HIQR) Program, which has a longer history, is 75 percent.) The agency says that the match rate should be based on actual ACO experience in order to focus on holding ACOs accountable for clinically related mismatches in reporting quality measures as they continue to gain experience with how to measure, report and improve quality under the program.

Therefore, CMS proposes to revise the regulations to indicate that if an ACO has a match rate below 80 percent, absent unusual circumstances, it would adjust the ACO’s overall quality score proportional to the ACO’s audit performance.

CMS also proposes to amend the method by which it adjusts an ACO’s overall quality score to reflect the ACO’s audit performance. The agency would revise the current methodology, under which the audit-adjusted quality score is calculated by multiplying the ACO’s overall quality score by the ACO’s audit match rate. Instead, **CMS proposes that for each percentage point difference between the ACO’s match rate and the**

match rate considered passing the audit, the ACO's overall quality score would be adjusted downward by 1 percent. Thus, if CMS adopts the proposal to establish an 80 percent match rate as the threshold, and the ACO's match rate is 75 percent, then CMS would adjust the ACO's overall quality score downward by 5 percent. CMS provides the following illustration: Assuming a match rate threshold of 80 percent, an ACO with an overall quality score of 90 percent would have an audit-adjusted quality score of 85.50 percent, that is, $(90 - [.05 \times 90]) = 85.50$.

Further, CMS proposes a conforming change to reflect the 80 percent match rate threshold for potentially requiring a corrective action plan. The agency also notes it will periodically review the audit match threshold and seek to increase the match rate over time. It also could consider implementing a higher match rate for ACOs that have been in the program longer. CMS seeks comment on an alternative approach to revise the rules to adjust the ACO's overall quality score if an ACO has a match rate below 75 percent. CMS says it did not propose this approach because the results of its analysis indicate a median match rate of 80 percent, suggesting that a match rate of 75 percent would be too low.

Medicare Diabetes Prevention Program (MDPP) Model

In the CY 2017 PFS rule, CMS expanded the Center for Medicare & Medicaid Innovation's diabetes prevention program demonstration as a permanent program, beginning Jan. 1, 2018. CMS now proposes to change the start date to April 1, 2018, in order to ensure that MDPP suppliers have sufficient time to enroll in the program after the final CY 2018 PFS rule is published. In addition, CMS proposes a number of new policies related to the MDPP:

- **Covered services:** CMS proposes a two-year limit on Medicare coverage for ongoing maintenance sessions, with a total of up to three years of MDPP services. Participants would receive core services for the first six months in the program, followed by core maintenance sessions in the second six months in the program, then up to two years of ongoing maintenance sessions.
- **Beneficiary eligibility:** CMS clarifies that, while beneficiaries with a prior history of Type 1 or Type 2 diabetes are not eligible for MDPP services, beneficiaries with a history of gestational diabetes are not excluded. Further, the agency clarifies that beneficiaries who are diagnosed with end-stage renal disease after receiving MDPP services would lose eligibility. Finally, CMS proposes that beneficiaries who are diagnosed with diabetes after they have started the first core session would continue to be eligible for MDPP services.
- **Supplier payment:** CMS proposes to pay MDPP using a performance-based payment structure, which would tie payment to performance goals based on beneficiary attendance and/or weight loss. Total maximum payment per beneficiary would be \$810, made to MDPP suppliers periodically over the course of services. The periodic payments would be made based on factors including

the beneficiary's completion of a specified number of MDPP sessions and achievement of the required minimum weight loss associated with a reduced incident of Type 2 diabetes. Once the required minimum weight loss is achieved and the 12-month core services period ends, suppliers would receive three-month interval performance payments for ongoing maintenance sessions, but those payments would be made only when the required weight loss is maintained.

- **Beneficiary incentives:** CMS proposes to allow MDPP suppliers to provide in-kind patient engagement incentives to promote improved beneficiary health and reductions in Medicare spending. The incentive must be reasonably connected to the curriculum taught by the MDPP supplier and be a preventive item or service, or an item or service that advances a clinical goal for an MDPP beneficiary. Such items or services could include things such as gym memberships, onsite child care, digital scales and pedometers.

CMS also proposes policies and procedures related to supplier application and enrollment in the MDPP.

NEXT STEPS

The AHA encourages members to submit comments on how CMS's proposals would affect their facility.

Comments are due Sept. 11 by 5 p.m. ET and may be submitted electronically at <http://www.regulations.gov>. Follow the instructions for "submitting a comment."

CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

Via regular mail

Centers for Medicare & Medicaid
Services
Dept. of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013

Via overnight or express mail

Centers for Medicare & Medicaid
Services
Dept. of Health and Human Services
Attention: CMS-1676-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

FURTHER QUESTIONS

Please contact Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or jkim@aha.org with further questions.