

August 19, 2016

Andrew M. Slavitt, Acting Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Attention: CMS-1654-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Dear Acting Administrator Slavitt:

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,900 family physicians and medical students across the country. I am responding to the proposed rule titled, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model" as published by the Centers for Medicare & Medicaid Services (CMS) in the July 15, 2016, Federal Register.

The AAFP appreciates that this proposed rule continues a multi-year effort on the part of CMS to both prioritize and promote primary care as foundational to the Medicare program. The AAFP continues to assert that, to truly realize the value of family medicine and primary care, public and private payers cannot simply rely on delivery system reforms. Since Alternative Payment Models (APMs) and the Merit-Based Payment Incentive Payment System (MIPS) are built on fee for service, it is imperative to fix problems with fee for service and the AAFP appreciates that CMS is taking steps in that direction. Instead, CMS and private payers must make new investments in primary care to truly capture and realize the value proposition of family medicine and primary care. We view this proposed rule as another step in that direction.

We are pleased that CMS has made a commitment to improving payments for family medicine through the 2017 proposed Medicare physician fee schedule (PFS) and that proposed changes are estimated to result in approximately \$900 million in additional funding to primary care physicians. The AAFP urges CMS to maintain these payment changes in the final rule. We fully acknowledge that—through the proposed rule—CMS is attempting to reinvest in primary care as a practice and a profession, as well as an abundant resource for patients. Likewise, the AAFP

www.aafp.org

President Wanda Filer, MD York, PA

Javette C. Orgain, MD Chicago, IL

President-elect John Meigs, Jr., MD Brent, AL

Vice Speaker Oregon, WI

Board Chair Robert L. Wergin, MD Milford, NE

Alan Schwartzstein, MD Douglas E. Henley, MD Leawood, KS

Directors Yushu "Jack" Chou, MD, Baldwin Park, CA John Bender, MD, Fort Collins, CO Robert A. Lee, MD, Johnston, IA Michael Munger, MD, Overland Park, KS Executive Vice President Mott Blair, IV, MD, Wallace, NC John Cullen, MD, Valdez, AK Lynne Lillie, MD, Woodbury, MN

Gary LeRoy, MD. Dayton, OH Carl Olden, MD, Yakima, WA Marie-Elizabeth Ramas, MD, (New Physician Member), Mount Shasta, CA Richard Bruno, MD, (Resident Member), Baltimore, MD Tiffany Ho (Student Member), Baltimore, MD

Acting Administrator Slavitt Page 2 of 56 August 19, 2016

concurs that, by better-valuing primary care and care coordination, CMS is helping improve Medicare beneficiaries' access to services they need to stay well; while at the same time declaring that patients are better served when people have a team of health care professionals led by a primary care physician managing and coordinating their care. The AAFP applauds CMS for its commitment to improving payment for family physicians and other primary care physicians, since it is a top priority for the AAFP.

To improve the final 2016 Medicare physician fee schedule rule, in summary the AAFP:

- Agrees with CMS's use of an average of the three most recent years of available Medicare claims data as the best way to determine the specialty mix assigned to each code.
- Supports revisions to policies that create unnecessary barriers to the responsible and appropriate use of telemedicine services.
- Applauds CMS for its diligence in identifying and reviewing potentially misvalued codes.
- Continues to believe that evaluation and management (E/M) services are undervalued relative to procedural services, especially procedures with 10- and 90-day global periods and strongly challenge and expect CMS to hold providers of global surgical services to the same documentation standards and guidelines as providers of E/M services when providing a visit.
- Very much appreciates that this proposed rule continues a multi-year effort on the part of CMS to both prioritize and promote primary care as foundational to the Medicare program, especially since APMs and MIPS are based on fee for service.
- Is pleased to see that CMS estimates there will be no "Target Recapture Amount" by which to reduce payments made under the PFS in 2017.
- Appreciates CMS's efforts use more current data in all three Geographic Practice Cost Indices.
- Continues to support CMS in its efforts to adjust work relative value units (RVUs)
 commensurate with changes in intra-service and total time, as well as post-operative
 visits, despite Relative Value Scale Update Committee (RUC) recommendations to the
 contrary.
- Supports CMS's proposals to pay separately for complex chronic care management services and to pay for the codes in this family consistent with the RUC-recommended values and practice expense inputs.
- Has ongoing, significant concerns about the disproportional burden primary care
 physicians will face when trying to comply with Appropriate Use Criteria (AUC)
 requirements and therefore, strongly urges CMS to delay the implementation of this
 program so that AUC would be aligned with the forthcoming MIPS program in 2019,
 versus being introduced as a stand-alone program.
- Fully supports the expansion of the Medicare Diabetes Prevention Program.
- Strongly supports that patients be prospectively assigned a primary care physician or
 provider along with a simple process for the beneficiary to change the physician or
 provider to whom he or she was attributed. This approach promotes patient engagement
 and empowers beneficiaries and their families in directing their care.
- Supports that CMS recognizes these multiple problems and is creating ways to resolve them as the agency gains experience with collecting data used to calculate the value modifier.

II.A. Determination of Practice Expense Relative Value Units (PE RVUs) Summary

Acting Administrator Slavitt Page 3 of 56 August 19, 2016

CMS provides an overview and description of its practice expense methodology, noting that it uses an average of the three most recent years of available Medicare claims data to determine the specialty mix assigned to each code. CMS asks whether or not the incorporation of a new year of utilization data into a 3-year average mitigates the need for alternative service-level overrides, such as a claims-based (dominant specialty) or stakeholder-recommended approach (expected specialty) in the development of PE (and malpractice [MP]) RVUs for low-volume codes.

AAFP Response

In general, the AAFP is comfortable with CMS's proposals related to the determination of practice expense RVUs. In particular, the AAFP agrees with CMS's use of an average of the three most recent years of available Medicare claims data as the best way to determine the specialty mix assigned to each code.

II.B. Determination of Malpractice RVUs

Summary

CMS provides an overview of its malpractice RVU methodology and then notes that the proposed 2017 Geographic Practice Cost Indices (GPCI) update reflects updated malpractice premium data, collected for the purpose of proposing updates to the MP GPCIs. CMS further notes that it could use the updated malpractice premium data obtained for the purposes of the proposed GPCI update to propose updates to the specialty risk factors used in the calculation of malpractice RVUs. However, this would not be consistent with the policy CMS finalized in the 2016 PFS final rule comment period, in which it indicated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data and would remain unchanged between the 5-year reviews. Additionally, consistent with the law, only half of the adjustment to malpractice GPCIs would be applied for 2017 based on the new malpractice premium data. As such, CMS does not think it would be appropriate to propose to update the specialty risk factors for 2017 based on the updated malpractice premium data reflected in the proposed 2017 GPCI update. Therefore, CMS is not proposing to update the specialty-risk factors based on the new premium data collected for the purposes of the 3-year GPCI update for CY 2017. However, CMS seeks comment on whether it should consider doing so, perhaps as early as for 2018, prior to the next review and update of malpractice RVUs that must occur no later than CY 2020.

AAFP Response

The AAFP was supportive of the technical and policy changes that CMS made related to malpractice RVUs for the 2016 Medicare physician fee schedule. As such, we appreciate CMS's reluctance to change direction a year later and use the updated malpractice premium data gathered for purposes of GPCI data to propose updates to the specialty risk factors used in the calculation of malpractice RVUs in advance of the next 5-year review of those RVUs. That said, the AAFP has long supported the notion of using the most current and most accurate data when setting all three types of RVUs in the fee schedule. Thus, if, as indicated, CMS has more current and more accurate malpractice premium data, then CMS should consider using it to update the specialty-risk factors in its MP RVU methodology as early as 2018. Furthermore, by 2018, the adjustment of the malpractice GPCIs would be complete, so the potential "disconnect" in the use of the updated premium data would no longer be an issue.

II.C. Medicare Telehealth Services

Summary

Acting Administrator Slavitt Page 4 of 56 August 19, 2016

CMS discusses conditions that must be met in order for Medicare to pay for telehealth services; what services constitute a telehealth service in accordance with the definition of Medicare telehealth services and the requested additions to the list of Medicare telehealth services.

CMS notes several conditions must be met for Medicare to make payments for telehealth services, these include:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or other authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth-originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant-site practitioner furnishing the service.

Codes proposed for addition to the list of Medicare telehealth services, beginning in 2017, include:

- End stage renal disease (ESRD) related services 90967 through 90970. The required clinical examination of the catheter access site must be furnished face-to-face "hands on" (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA.
- Advance care planning (current procedural terminology (CPT) codes 99497 and 99498).
- Telehealth Consultations for a Patient Requiring Critical Care Services (GTTT1 and GTTT2)"

AAFP Comments

In light of the growing amount of evidence suggesting the effectiveness of various forms of telehealth services, the AAFP supports revisions to policies that create unnecessary barriers to the responsible and appropriate use of telemedicine services. While telemedicine services require a framework conducive to safe patient care, ethical use of technology, and appropriate reimbursements, some legislation and regulations established to achieve this have created barriers hindering the use of effective telemedicine services. Namely, the AAFP notes that it is possible to discriminate between payable and valid originating sites. This is such that CMS could allow a valid originating site to be included as an individual's home, work, or other location where the patient desires to receive care. Creating this payable-versus-valid distinction between originating sites would then enable a physician or eligible provider to provide telehealth services (which are on the list of recognized telehealth services) to valid originating sites for which the physician or provider at the distant site would receive reimbursement for provision of services (as is currently provided to distant-provider) sites, but no facility fee would be issued to the valid originating site. For those telehealth services that occur at a payable originating site, a facility fee would continue to be reimbursed to the payable originating site, as is the current practice.

Both the appropriateness of telemedicine/telehealth services as the modality of treatment, and the appropriateness of an originating site, should be determined by whether standards of care can be met for a given condition and clinical scenario. Standards of care are impacted by current technology capabilities, but should not be dictated by arbitrary policies or statutes that become antiquated as a result of improvements in technology capabilities.

The proposed rule notes, "An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous 'store-and-forward' technology when the originating site is part of a federal telemedicine

Acting Administrator Slavitt Page 5 of 56 August 19, 2016

demonstration program in Alaska or Hawaii." The AAFP points out that there is an appropriate use-case for asynchronous store-and-forward technology within telemedicine beyond defining use within federal telemedicine demonstration programs in Alaska and Hawaii. With the increasing burden placed upon the U.S. health care system by national physician and provider shortages, as well as the less-than-ideal access to available care, asynchronous store-and-forward technology should be an acceptable (e.g., reimbursable) form of technology within telemedicine. Synchronous versus asynchronous should not define whether or not a medical service was provided.

To further illustrate this point, we note that Medicaid, a branch of CMS itself, is increasingly reimbursing for use of store-and-forward telehealth technology. In July 2015, The Center for Connected Health Policy (the federally designated National Telehealth Policy Resource Center) conducted its <u>annual survey and analysis of state telehealth laws and reimbursement policies</u>, which revealed at least nine states that now offer some form of Medicaid reimbursement for use of store-and-forward telehealth technology. Increasing numbers of state Medicaid programs are reimbursing for store-and-forward technology in response to heightened awareness that improvements in technology are enabling standards of care to be met using telehealth as the modality for service for an increasing number of clinical conditions. We urge Medicare to likewise provide reimbursement for use of asynchronous store-and-forward technology.

Regarding the CPT codes added to the list of Medicare approved telehealth services; we appreciate the addition of those added codes and services, particularly the addition of codes 99497 and 99498 tied to advance care planning.

The AAFP disagrees with the proposal to deny adding CPT codes associated with observation visits. It is unacceptable to deny the addition of these codes and services for the reason stated. Namely, the proposed rule notes these codes were denied because, while the request to add these codes included evidence of the general benefits of observation, it did not include specific information demonstrating that the services described by these codes provided clinical benefit when furnished via telehealth. To this, the AAFP reiterates that it matters not whether medical services are provided via in-person encounters versus patient-facing telehealth; so long as the standard of care for the given condition can be met, clinical benefit exists and telemedicine should be an acceptable (e.g., reimbursable) modality for medical services. CMS itself, within the proposed rule for the Quality Payment Program (QPP), now considers telehealth services as patient-facing care encounters.

A physician is capable of assessing a patient's physical condition in an observational setting and determining an appropriate course of treatment via telemedicine routes of delivery. With the physician shortage issues and increasing lack of ideal access to care that can occur in any geographic region—most especially in rural areas—it is important that these services be allowed to be provided both as in-person or reimbursable telemedicine services. Patients in rural settings should not be denied access to needed observation care due to a lack of inclusion of these codes within the list of Medicare telehealth services. Furthermore, telehealth services are an important access point for patients with chronic conditions and multiple comorbidities where in-office visits may be difficult.

In regard to the proposed denial of the addition of CPT codes related to managing emergency department patients with telehealth services, the AAFP disagrees with denial of codes 99281, 99282 and 99283. CPT code 99281 represents a problem-focused history, problem-focused exam, and straightforward medical decision making, with severity of the presenting problem

classified as self-limited or minor. CPT code 99282 represents an expanded problem-focused history, expanded problem-focused exam, and low complexity medical decision making, with severity of the presenting problem being classified as low to moderate. CPT code 99283 represents an expanded problem-focused history, expanded problem-focused exam, and moderate-complexity medical decision making, with severity of the presenting problem being classified as moderate. None of these codes include what is categorized as a "detailed" or "comprehensive" history or exam; none of these codes include complexity in medical decision making that is categorized as "high;" and none of these codes include presenting problems of "high" or "high severity/immediate significant threat to life or physiological function." CMS should reconsider including these codes in the list of approved telemedicine services. Robotics and interactive telehealth communications technologies are increasingly being used effectively in the emergency department setting, both in urban and rural geographic locations. In urban locations, hospital-based robotics and telehealth communications are used to provide more efficient care to address emergency department overcrowding. In rural locations, telehealth services in the emergency department setting are used both to address the need for specialty services otherwise not available, as well as to address physician shortages. For instance, telestroke hub and spoke networks often involve the utilization of telehealth technologies in emergency departments in rural areas to facilitate timely assessment of patients, and transfer to appropriate facilities when needed. There is growing evidence that these telestroke networks can improve patient outcomes, as well as reduce overall care costs. Reimbursing physicians and eligible providers appropriately for emergency department care rendered via telehealth services can be critical in any geographic region, especially within rural areas, where primary care physicians may provide emergency department physician coverage using telehealth technologies due to an absence of available emergency department physician coverage otherwise. It is not appropriate to render those services as ineligible for reimbursement merely because evidence has not yet been submitted to support the clinical benefit of managing emergency department patients with telehealth. There is evidence demonstrating the value of telemedicine services in the delivery of emergency department services.

II.D. Potentially Misvalued Services under the Physician Fee Schedule *Summary*

Among its CY 2017 identification and review of potentially misvalued services, CMS proposes to examine 0-day global services that are typically (i.e. 50 percent of the time or more) billed with an evaluation and management (E/M) service with modifier 25. This proposal is limited to codes not reviewed in the last 5 years that have more than 20,000 in allowed service and includes 83 codes listed in Table 7 in the proposed rule.

Additionally, CMS proposes to begin collecting data on resources used in furnishing global surgical services, as required by section 1848(c)(8)(B) of the *Social Security Act* as added by *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA). CMS is proposing a three-pronged approach to collect timely and accurate data on the frequency of global services and inputs involved in furnishing them, including the procedure and the pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment. This approach would include:

- Comprehensive claims-based reporting about the number and level of pre- and postoperative visits furnished for 10- and 90-day global services.
- A survey of a representative sample of practitioners covering the activities involved, and the resources used, in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.

 A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some accountable care organizations (ACOs).

For the claims data collection, CMS contracted with the RAND Corporation to develop a set of time-based, post-operative visit codes that could be used for reporting care provided during the post-operative period. The recommended codes are distinguished by the setting of care and whether they are furnished by a physician/non-physician provider (NPP) or by clinical staff. All codes are intended to be reported in 10-minute increments. They are described in Table 9 of the proposed rule as follows:

TABLE 9—PROPOSED GLOBAL SERVICE CODES		
Inpatient	GXXX1 GXXX2 GXXX3	Inpatient visit, typical, per 10 minutes, included in surgical package. Inpatient visit, complex, per 10 minutes, included in surgical package. Inpatient visit, critical illness, per 10 minutes, included in surgical package.
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package.
	GXXX5 GXXX6	Office or other outpatient visit, typical, per 10 minutes, included in surgical package. Office or other outpatient visit, complex, per 10 minutes, included in surgical package.
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package.
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package.

CMS also proposes to use such codes to collect data on pre-operative services. None of these codes would be paid separately under the Medicare PFS (i.e., they would be reported for data collection purposes only).

The "typical" visit described by codes GXXX1 and GXXX5 would involve any combination or number of these activities:

- Review vitals, laboratory or pathology results, imaging, progress notes
- Take interim patient history and evaluate post-operative progress
- Assess bowel function
- Conduct patient examination with a specific focus on incisions and wounds, post-surgical pain, complications, fluid and diet intake
- Manage medications (for example, wean pain medications)
- Remove stitches, sutures, and staples
- Change dressings
- Counsel patient and family in-person or via phone
- Write progress notes, post-operative orders, prescriptions, and discharge summary
- Contact/coordinate care with referring physician or other clinical staff
- Complete forms or other paperwork

To report a "complex" code, the practitioner would be required to furnish services beyond those included in a typical visit and have documentation that indicates what services were provided that exceeded those included in a typical visit. According to CMS, some circumstances that might merit the use of the complex visit code are secondary management of a critically ill patient where another provider, such as an intensivist, is providing the primary management; primary management of a particularly complex patient, such as a patient with numerous comorbidities or high likelihood of significant decline or death; management of a significant complication; or

Acting Administrator Slavitt Page 8 of 56 August 19, 2016

complex procedures outside of the operating room (e.g., significant debridement at the bedside).

CMS notes that, as an alternative to the use of G-codes, it considered an approach using code 99024 (post-operative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a post-operative period for a reason(s) related to the original procedure). Levels of service would be noted via use of modifiers. CMS seeks comments on this alternative, as well as on whether time of visits could alone be a proxy for the level of visit and, if so, the feasibility and desirability of reporting CPT 99024 in 10-minute increments.

CMS proposes that the G-codes detailed above would be reported for services related to and within 10- and 90-day global periods for procedures furnished on or after January 1, 2017, through usual claims filing. CMS intends to allow physicians the flexibility to report the services on a rolling basis as they are furnished or to report all of the services on one claim once all have been furnished, so long as the usual claims filing requirements are met.

CMS would expect the patient's medical record to include documentation of the services furnished. Documentation that would be expected is an indication that a visit occurred or a service was furnished and sufficient information to determine that the appropriate G-code was reported.

CMS is not proposing any special requirements for inclusion of additional data on claims that could be used for linking the post-operative care furnished to a particular service. CMS will link the data reported on post-operative care to the related procedure using date of service, practitioner, beneficiary, and diagnosis. CMS solicits comment on the extent to which post-operative care may not be appropriately linked to related procedures, whether it should consider using additional variables to link these aspects of the care, and whether additional data should be required to be reported to enable a higher percentage of matching.

All physicians who provide a procedure that is a 10- or 90-day global period would be required to report the pre- and post-operative services furnished on a claim using the codes proposed above. CMS seeks comment on whether special provisions are needed to capture the pre- and post-operative services provided by residents in teaching settings.

In addition to the claims-based reporting, CMS is proposing to survey a large, representative sample of practitioners and their clinical staff in which respondents would report information about approximately 20 discrete pre- and post-operative visits, along with other global services such as care coordination and patient training. Under contract with RAND, CMS expects to obtain data from approximately 5,000 practitioners, with a response rate above 50 percent.

Finally, CMS proposes to collect primary data on the activities and resources involved in delivering services in and around surgical events in the ACO context by surveying a small number of ACOs (Pioneer and Next Generation ACOs). This effort would begin with an initial phase of primary data collection using a range of methodologies in a small number of ACOs. A survey of practitioners participating in approximately 4 to 6 ACOs using the survey instrument, along with the additional ACO-specific module, will be used to collect data on pre- and post-operative visits.

AAFP Response

Acting Administrator Slavitt Page 9 of 56 August 19, 2016

The AAFP applauds CMS for its diligence in identifying and reviewing potentially misvalued codes, and we appreciate the update on its efforts to validate RVUs of potentially misvalued codes via contracts with the Urban Institute and RAND Corporation. We support CMS's efforts in this regard and encourage it to continue this excellent and much needed work.

Among the initiatives for identifying and reviewing misvalued services in 2017, most relevant to family physicians is the review of 0-day global codes billed with an E/M service 50 percent or more of the time using modifier 25. Many of the codes listed in Table 7 are commonly done by family physicians.

Based on an analysis of the 83 codes identified in Table 7, it appears that only 21 services meet the CMS criteria and have not yet been reviewed to specifically address an E/M performed on the same date. Specifically, 37 codes do not meet screen criteria; they were either reviewed in the last 5 years and/or are not typically reported an E/M based on the data. For another 25 codes, the Relative Value Scale Update Committee (RUC) specifically stated on the summary of recommendation or in the RUC rationale that an E/M is typically reported with this service, and the RUC accounted for this in its valuation. The 1200x series of codes is an example; the AAFP helped present those codes to the RUC, and it was explicitly stated that the codes did not include E/M services. We agree that it is reasonable to review the relative value of the remaining 21 services.

CMS states in the proposed rule, "Since routine E/M is included in the valuation of 0-day global services, we believe that the routine billing of separate E/M services may indicate a possible problem with the valuation of the bundle, which is intended to include all the routine care associated with the service." In response, we must point out that, at least in primary care, patients often present with an undifferentiated diagnosis that requires the physician to do a relevant history and examination leading to medical decision making, which may include a decision to perform procedures, such as those listed in Table 7, at the same encounter. In this common scenario, we believe that it is entirely appropriate and necessary for the physician to report an E/M code with modifier 25 to reflect the significant and separately identifiable work represented by the history, exam, and medical decision making that subsequently led to performance of the procedure. We also note that performing the procedures in the same encounter as an E/M visit is a more patient-centered approach to care and supports the tenets of the Patient Centered Medical Home. It is a significant inconvenience for a patient to come back for a future visit to have a procedure performed when it could easily be completed during the same encounter as the E/M visit. The costs to patients (e.g. time off, travel) and to society can be significant.

It is also common in primary care for physicians to manage and treat multiple problems at the same encounter. Consequently, the evaluation and management of the patient during a visit that also involves a procedure listed in Table 7 will often extend well beyond the problem associated with the procedure. Again, in this common scenario, we believe that it is appropriate for the physician to report an E/M code with modifier 25 to reflect the significant and separately identifiable work represented by the history, exam, and medical decision making for multiple problems, over and above the problem that necessitated the procedure.

In sum, we are less convinced than CMS that "the routine billing of separate E/M services may indicate a possible problem with the valuation of the bundle." However, as stated, we still think it is reasonable to review the relative value of select codes in Table 7 and will plan to participate in

Acting Administrator Slavitt Page 10 of 56 August 19, 2016

that review, where appropriate, as part of our involvement in the Relative Value Scale Update Committee (RUC) process.

Regarding the proposed collection of data on resources used in furnishing global surgical services, we are glad to see CMS implementing this section of the law. We continue to believe that E/M services are undervalued relative to procedural services, especially procedures with 10- and 90-day global periods. As noted in the proposed rule, there is a dearth of information regarding the actual resources that go into providing those procedural services as compared to what CMS assumes they include when setting their current relative values. CMS's three-pronged data collection effort represents a much-needed first step in more appropriately valuing 10- and 90-day global surgical services, especially relative to existing E/M codes.

With respect to the claims-based data collection effort, we support CMS's notion of requiring physicians who provide 10- and 90-day global surgical services to report a non-payable code for each pre- and post-operative visit that they perform related to the procedure within the applicable global period. We agree with CMS that this approach seems like the best way to capture the number and level of visits, as the law requires.

We understand RAND's recommendation and CMS's decision to use G-codes rather than the existing CPT E/M codes for this purpose. In particular, we understand that use of the existing CPT E/M codes might have created confusion and led to unintentional overpayments, since these services are otherwise being reported for data collection purposes only.

We do disagree with the notion that existing E/M codes should not be used for data-gathering purposes in this effort simply because those "E/M codes are inadequately designed to capture the full scope of post-operative care." We have argued repeatedly that the current E/M codes are inadequate to capture the full scope of care provided in the office setting, period. Yet, CMS continues to mandate that the full spectrum of office visits be squeezed into the same ten 25-year-old E/M codes for that site of service. If "E/M codes are inadequately designed to capture the full scope of post-operative care," then they are most assuredly inadequate to capture the full scope of all care done in an office setting—especially in family medicine and primary care. Accordingly, we once again urge CMS to undertake the necessary effort to redefine, restructure, and revalue the existing E/M codes.

Regarding the proposal that a "typical" visit described by codes GXXX1 and GXXX5 involves "Writ(ing) progress notes, post-operative orders, prescriptions, and (a) discharge summary," we encourage CMS not only to include a discharge summary (which is a mere restating of the events that have occurred), but also to require that care plans provide the patient and other providers useful information to manage their care moving forward.

Also, in terms of the specific G-codes that CMS proposes to use, one question or concern we have involves CMS's definition of "complex" as distinct from "typical." According to the proposed rule, a complex visit may involve "management of a particularly complex patient, such as a patient with numerous comorbidities or high likelihood of dying, management of a significant complication, or management or discussion of a complex diagnosis." This definition is problematic in at least two respects. First, it uses the same word to define itself (e.g. a complex visit involves management of a complex patient or discussion of a complex diagnosis). Such a circular definition is not helpful. Second, most Medicare patients have multiple comorbidities. Thus, most visits will be "complex" under CMS's definition, even though CMS states that it expects the "vast majority" of visits will be "typical" rather than complex. If CMS decides to

Acting Administrator Slavitt Page 11 of 56 August 19, 2016

finalize its proposed coding structure for collecting data on pre- and post-operative visits, and if it expects the vast majority of visits to be "typical," then CMS must do a better job of more clearly and more narrowly defining "complex" in this context. It will be impossible to educate our members on the distinction based on the proposed definition.

Another question or concern that we have about the proposed G-codes relates to the following statement made by CMS in the proposed rule:

... we are proposing this new set of codes because we believe it provides us the most robust data upon which to determine the most appropriate way and amounts to pay for PFS surgical services. We believe that the codes being proposed would provide data of the kind that can reasonably be collected through claims data and that reflect what we believe are key issues in the post-operative care where the service is provided, who furnishes the service, its relative complexity, and the time involved in the service.

Again, our concerns are twofold. First, we are having trouble reconciling this statement with the the one CMS makes at the end of this section of the proposed rule: "Because these are new approaches to collecting data and in an area—global surgery—where very little data has previously been collected, we cannot describe exactly how this information would be used in valuing services." If CMS cannot describe how this information will be used in valuing services, then why does CMS believe it provides the most robust data upon which to determine the most appropriate way and amounts to pay for surgical services? We would have a lot more faith in CMS's proposal if CMS could articulate how it intends to use the data collected to subsequently value global surgical services. Indeed, it seems to us that the data-collection effort should be driven by the end use. We strongly encourage CMS to lay out a vision in the final rule for how its data collection efforts will, in fact, facilitate revaluation of global surgical services. Otherwise, the proposed effort will produce data which, while nice to know, is ultimately useless in fulfilling its intended purpose.

Second, CMS notes that who furnishes the service is a key issue. The AAFP agrees. However, the G-codes will not distinguish between visits provided by physicians and those provided by NPPs. Under the current global surgical payment system, post-operative visits are valued as if provided by a physician, even though they are often done by NPPs under conditions that do not meet Medicare's "incident to" requirements. That is part of the reason that we think the current codes are misvalued. The proposed G-code structure will not address that issue. If other data reported on the claim (e.g., "rendering provider") will address it, then we do not object. Therefore, we believe CMS must refine its proposal to further distinguish physician visits from NPP visits.

To the alternative of using code 99024 and a series of modifiers, we are inclined to agree with CMS that use of G-codes is preferable. It certainly seems simpler, in that the physician only needs to report a code rather than a code plus a modifier to represent the visit. Further, the descriptor for 99024 would need to be revised to include both pre- and post-operative visits and to capture time for CMS's purposes. We do not believe that could be done in time to implement the data-collection effort on January 1, 2017, as proposed, and we have no desire to see this effort further delayed. Finally, the law stipulates that the collected information must include the number and level of medical visits furnished during the global period, and use of code 99024 does not allow CMS to identify the level of medical visit furnished.

Acting Administrator Slavitt Page 12 of 56 August 19, 2016

We support CMS's intention to allow physicians the flexibility to report the services on a rolling basis as they are furnished or to report all of the services on one claim once all have been furnished. We also support CMS's expectation that the patient's medical record should include documentation of the services furnished, although we think CMS may have unfairly low expectations in this regard. Specifically, CMS proposes that documentation that would be expected is an indication that a visit occurred or a service was furnished and sufficient information to determine that the appropriate G-code was reported. Given the minimal description of those G-codes, this implies a minimum of documentation expected by CMS. We presume that this low bar on the part of CMS reflects its reading of the RAND report, which argued that "documentation requirements for surgeons to support the relevant E/M visit code would place undue administrative burden on surgeons" and "that many surgeons currently use minimal documentation when they provide a post-operative visit."

We strongly challenge and expect CMS to hold providers of global surgical services to the same documentation standards and guidelines as providers of E/M services when providing a visit. The administrative burden on surgeons should be no different and certainly no less than that on non-surgeons when it comes to documenting a visit with a patient. If many surgeons currently use minimal documentation when they provide a post-operative visit that is no excuse for expecting the same inadequate level of documentation going forward. To require anything less than the same level of documentation for all clinicians providing E/M services would be irresponsible and unfair and would defeat the very purpose of documenting the actual types and extent of these services in the post-operative period.

We appreciate CMS is not proposing any special requirements for inclusion of additional data on claims that could be used for linking the post-operative care furnished to a particular service. Remembering to report the proposed G-codes will be enough of a challenge. If CMS believes it can link the G-code data to the corresponding procedure using existing claims data, so much the better.

We agree with CMS's proposal to apply this required data reporting to all physicians who provide 10- and 90-day global surgical services for the reasons outlined in the proposed rule, even though this means that family physicians also will be impacted. We believe that this project is of sufficient value and magnitude that it merits universal application, as proposed. We understand that some critics may object that this approach is contrary to the legislative language to collect data from "a representative sample of physicians," because a sample is a subset of an entire population. In response, we note that not every physician will be subject to this data collection effort. Only those who provide 10- and 90-day global surgical services to Medicare patients will be required to do so. That is a subset of the entire physician population and, from our perspective, consistent with the statutory mandate to use "a representative sample of physicians."

We further note that the law does call for a representative sample of physicians, not procedures. Thus, to the extent that CMS is not limiting its effort to certain procedures, its proposal is consistent with the statute.

On whether special provisions are needed to capture the pre- and post-operative services provided by residents in teaching settings, our general answer would be "No." If the teaching physician is present for the key portion of the visit, the teaching physician should report the joint time spent by him/her and the resident with the patient (i.e., the entire visit service). Otherwise, if the teaching physician is not present for the key portion of the visit, then the service should not

Acting Administrator Slavitt Page 13 of 56 August 19, 2016

be reported. This approach would be most consistent with the way in which teaching physician services are currently reported in residency programs. We do not believe post-operative visits should qualify for the primary care exception, since they will not be reported with existing E/M codes that otherwise define what qualifies for that exception.

In general, we are supportive of the proposed survey of practitioners outlined by CMS. We agree with CMS that the proposed survey will be a good complement to the proposed claims-based data collection. CMS's plans to survey 5,000 practitioners and their clinical staff about 20 discrete pre- and post-operative visits each could net up to 100,000 observations, which, as CMS notes, should cover the full-range of surgical procedure code groups, even if the response rate is 50 percent, as CMS expects.

We caution CMS that even a 50-percent response rate may be unrealistic, and CMS and its contractor will need to work hard to reach it. We also caution CMS about asking physicians for the times for each pre-service, face-to-face, and post-service activity furnished during a visit. It is our experience, in and out of the RUC process, that asking physicians to report time for individual activities, rather than the encounter as a whole, can lead to an overestimation of actual time involved. In essence, the sum of the parts becomes greater than the whole. It may be preferable to ask for the total time of the encounter and then, if necessary, ask respondents to allocate that time among the activities furnished during the visit rather than asking them the time for each activity and summing those times to get the total length of the visit.

We are supportive of CMS's proposal to collect data on the activities and resources involved in delivering services in and around surgical events in the ACO context by surveying a small number of ACOs. Like CMS, we think this data collection may provide a unique and useful perspective on the matter at hand.

We note that CMS is likely to receive a significant amount of pushback to its proposal from some physician specialties. Ironically, it was those same specialties who advocated for the provision in the law that CMS is now trying to implement, because they were otherwise unhappy with CMS's plans to convert all 10- and 90-day global surgical services to 0-day global periods. Had CMS been allowed to implement its planned change in global surgical services, none of this proposed effort would have been necessary. The fact remains that Medicare has been hemorrhaging funds as a result of misvalued procedural services for decades. We urge CMS to stand firm in its efforts to otherwise excise, eviscerate, and amputate bloated relative values in the fee schedule. We will be happy to assist CMS in this particular operation to rationalize RVUs.

II.E. Improving Payment Accuracy for Primary Care, Care Management Services, and Patient-Centered Services

Summary

CMS proposes increased payments for several care management services; specifically, the regulation includes proposals that:

- Make separate payments for certain existing CPT codes describing non-face-to-face prolonged evaluation and management services.
- Revalue existing CPT codes describing face-to-face prolonged services.
- Make separate payments using new codes to describe the comprehensive assessment and care planning for patients with cognitive impairment (e.g., dementia).

Acting Administrator Slavitt Page 14 of 56 August 19, 2016

- Make separate payments using new codes to pay primary care practices that use interprofessional care management resources to treat patients with behavioral health conditions.
- Make separate payments using new codes to recognize the increased resource costs of furnishing visits to patients with mobility-related impairments.
- Make separate payments for codes describing chronic care management (CCM) for patients with greater complexity.
- Make several changes to reduce administrative burden associated with the CCM codes to remove potential barriers to furnishing and billing for these important services.

AAFP Response

The AAFP very much appreciates that this proposed rule continues a multi-year effort on the part of CMS to both prioritize and promote primary care as foundational to the Medicare program, especially since APMs and MIPS are based on fee for service. The AAFP continues to assert that, to truly realize the value of family medicine and primary care, public and private payers cannot simply rely on delivery system reforms and Alternative Payment Models (APMs). Instead, CMS and private payers must make new investments in primary care to truly captured and realize the value proposition of family medicine and primary care. These proposals are another step in the right direction.

We are pleased that CMS has made a commitment to improving payments for family medicine through the 2017 proposed Medicare PFS and that proposed changes are estimated to result in approximately \$900 million in additional funding to primary care physicians. We fully acknowledge that CMS, through the proposed rule, is attempting to reinvest in primary care, as a practice, as a profession, and as an abundant resource for patients. Likewise, the AAFP concurs that through better-valuing primary care and care coordination, CMS is helping improve Medicare beneficiaries' access to services they need to stay well, and that patients are better served when people have a team of health care professionals led by a primary care physician managing and coordinating their care.

The AAFP applauds CMS for its commitment to improving payment for family physicians and primary care physicians. We fully support the proposals to accomplish the following principles:

- Improve payment for care management services provided in the care of beneficiaries
 with behavioral health conditions (including services for substance use disorder
 treatment) through new coding, including three codes used to describe services
 furnished as part of the psychiatric collaborative care model (CoCM) and one to address
 behavioral health integration (BHI) more broadly.
- Improve payment for cognition and functional assessment, and care planning for beneficiaries with cognitive impairment.
- Adjust payment for routine visits furnished to beneficiaries whose care requires additional resources due to their mobility-related disabilities.
- Recognize for Medicare payment the additional CPT codes within the chronic care
 management family (for complex CCM services) and adjust payment for the visit during
 which CCM services are initiated (the initiating CCM visit) to reflect resources associated
 with the assessment for, and development of, a new care plan.
- Recognize for Medicare payment CPT codes for non-face-to-face Prolonged E/M services by the physician (or other billing practitioner) that are currently bundled, and increase payment rates for face-to-face prolonged E/M services by the physician (or other billing practitioner) based on existing RUC recommended values.

Acting Administrator Slavitt Page 15 of 56 August 19, 2016

The AAFP supports the proposal to recognize and pay under Medicare Part B "GPPP7: Comprehensive assessment of and care planning by the physician or other qualified health care professional (QHP) for patients requiring CCM services, including assessment during the provision of a face-to-face service (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service)" and "GDDD1: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management visit (Add- on code, list separately in addition to primary procedure)." However, we urge CMS to issue further guidance on the medical necessity of these codes and their documentation requirements. Such guidance should be straightforward, streamlined, and not create unnecessary administrative burdens for primary care practices. We urge CMS to consult closely with the AAFP in the development of this guidance.

The AAFP is pleased that CMS recognizes the work of codes being developed through the CPT process, in particular the restructured and former Chronic Care Coordination Workgroup to establish a new Emerging CPT and RUC Issues Workgroup in which the AAFP participates. We encourage CMS to continue to consider the issues raised through these efforts in future rulemaking.

CMS seeks input on the intersection and delineation of the prolonged service codes with CCM and TCM services and feedback on the potential intersection of the prolonged service CPT codes 99358 and 99359 with proposed code GPPP7 (comprehensive assessment of and care planning for patients requiring CCM services). In general, we would make two points in this regard. First, as proposed, there are no limits on multiple providers of different specialties or different groups providing the excluded services. We believe that this is appropriate, as it would be expected and accepted for two or more providers under different groups to be allowed payment for reviewing the same patient record that affects the care they will be delivering to that patient. Second, a given physician should not be allowed to report codes 99358 and 99359 for the same patient during the same time he or she reported CCM, TCM, or GPPP7. CCM, TCM, and GPPP7 encompass non-face-to-face care provided to the patient during a given period of time that would be duplicated if the physician is also allowed to report 99358 and 99359 during the same time period.

Regarding the proposed new BHI codes—GPPP1, GPPP2, GPPP3, and GPPPX—the AAFP observes that there is potential confusion in their application by primary care physicians who also provide CCM and complex chronic care management (CCCM). Behavioral diagnosis codes are listed within the Medicare Chronic Conditions Warehouse (CCW) and may be among the chronic conditions addressed via CCM and CCCM. We do not expect that CMS would pay for both BHI and CCM or CCCM provided to the same patient during the same time period. It would be helpful for CMS to more clearly delineate when it expects the BHI codes to be used relative to the CCM and CCCM codes (e.g. a beneficiary with a single chronic mental health condition).

Further clarification is especially needed regarding the proposed code for "care management services for behavioral health conditions" (GPPPX). It is not clear from the proposed rule precisely which services, practitioners, patients, and circumstances would qualify for the billing of the GPPPX code.

We generally recommend that CMS adopt appropriate, but not unduly restrictive, billing requirements that delineate practitioners' eligibility, supervision requirements, patient eligibility,

Acting Administrator Slavitt Page 16 of 56 August 19, 2016

patient agreement requirements, and scope of service elements related to GPPPX. Similar to CCM and CoCM services, we would recommend patients be seen for an initiating visit and that beneficiary consent should be given prior to being enrolled in the program. There should be continuity of care with a designated member of the care team. A written plan of care, as described below, should be developed and shared with the patient; while a comprehensive assessment of the patient's psychiatric condition, as well as any medical, functional, and psychosocial needs, should be performed and updated as necessary. All services should be documented in the patient's medical record and available to other treating professionals.

In any case, we think that the BHI codes, especially GPPPX, should have similar parameters to 99490 (patient assessment, documented services, electronic communication, etc.). And in response to CMS's request for input on how assessments and care planning would compare, we note that Medicare published the relevant elements of a care plan on page 5 of its CCM white paper (below).

"A comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:

- Problem list;
- Expected outcome and prognosis;
- Measurable treatment goals;
- Symptom management;
- Planned interventions and identification of the individuals responsible for each intervention;
- Medication management;
- Community/social services ordered;
- A description of how services of agencies and specialists outside the practice will be directed/coordinated; and
- Schedule for periodic review and, when applicable, revision of the care plan."

We think a similar care plan would be relevant to BHI services.

We agree there should be an initial visit with the beneficiary before the BHI codes (GPPP1, GPPP2, GPPP3 and GPPPX) can be billed. We also support allowing the same types of services to serve as the initiating visit for CCM services and the BHI codes. Likewise, beneficiary consent should be consistent for all the BHI codes and between BHI and CCM/CCCM codes.

The AAFP appreciates that the proposed rule acknowledges that stakeholders have advised that CMS should waive the applicable Part B coinsurance for primary care services, and we recognize that CMS currently lacks statutory authority to waive the coinsurance for such services. The AAFP will continue to work with Congress and policy makers to provide CMS with the authority to waive coinsurance for important primary care services.

We appreciate that CMS is proposing several changes in the payment rules for CCM services. We agree with only requiring the initiating visit for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services. The AAFP also supports the proposal to create a new add-on G-code that would improve payment for visits that qualify as initiating visits for CCM services.

Acting Administrator Slavitt Page 17 of 56 August 19, 2016

CMS discusses their belief that the CPT language more accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs than CMS's current language does. In addition, the 24/7 access would be for "urgent" needs rather than "urgent chronic care needs," because CMS believes after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions. The AAFP supports improved access to care for patients, and in our experience, the distinction between urgent and urgent chronic care needs has been a problematic point when providing education to primary care physicians on CCM services. In this context, the AAFP supports CMS's proposal to simplify matters by requiring 24/7 access for urgent needs with the understanding that such access is to the care team rather than a single individual (e.g. the primary care physician) on the team. If CMS finalizes this proposal, we urge the agency to effectively communicate this understanding and corresponding expectations to the patient, physicians, and the rest of the care team staff involved in CCM.

CMS proposes to remove the requirement that the individuals providing CCM after hours must have access to the electronic care plan. This proposal reflects CMS's understanding that flexibility in how practices can provide the requisite 24/7 access to care, as well as continuity of care and management of care transitions, for their CCM patients can facilitate appropriate access to these services for Medicare beneficiaries. CMS states that this proposal is not intended to undermine the significance of standardized communication methods as part of effective care. The AAFP believes that in the cases where care is being delivered by staff within the practice, the removal of this requirement makes sense and is supportable. However, we are concerned that many practices have outsourced this function to third-party companies that have moved into the industry of providing remote care management service via telephone and Internet contact only. They do not live in the areas and do not know the patients. They do not have interactions with the office staff and physicians other than these electronic communications. With the removal of this CCM requirement, there would be little to no oversight or guidance for these companies. Thus, we urge CMS to make these changes cautiously and carefully.

CMS also discusses the belief that it should not require the use of any specific electronic technology in managing a beneficiary's care transitions as a condition of payment for CCM services. Instead, CMS is proposing to simply require the billing practitioner to create and exchange/transmit continuity of care document(s) timely with other practitioners and providers. The AAFP appreciates this flexibility and asks CMS to clearly define "timely" in this context. We believe "timely" means within 30 days.

The AAFP fully supports the CMS proposal simplifying the current requirement to provide the beneficiary with a written or electronic copy of the care plan, by instead adopting the less complicated CPT language specifying that a copy of the care plan must be given to the patient or caregiver.

CMS then proposes to specify that, instead of obtaining a written agreement, the physician could document in the beneficiary's medical record that this information was explained, further noting whether the beneficiary accepted or declined CCM services. The AAFP appreciates this proposal, since it has been a major hurdle for not just family physicians, but physicians in general, to overcome.

Unfortunately, the current process also circumvents two problems. Patients are not able to dispute the services and resulting charges claiming they were uninformed. A physical signature

Acting Administrator Slavitt Page 18 of 56 August 19, 2016

is obtained proving they consented to the services. With other services, such as transitional care management (TCM), that involve only one face-to-face visit, patients tend to state the services were not rendered if they did not have hands physically laid on them. By relaxing the consent requirement for CCM and allowing for a template of "the patient was educated regarding CCM services and agrees to proceed with the program" to be plugged into documentation, the AAFP is concerned this could create documentation and auditing problems. Secondly, under current requirements of a signed and dated consent, the physician delivering the service can support or appeal claims when issues arise involving other providers billing for conflicting CCM claims. Given the strong arguments for both removing the requirement to obtain written consent and the protection such consent provides physicians, we support removing this requirement as proposed, recognizing this does not prevent a physician from obtaining a written consent in cases where they believe such consent would be beneficial.

CMS also proposes to remove the language requiring beneficiary authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services. We support this proposal as being already a part of *HIPAA* rules.

The AAFP fully supports CMS's efforts to ensure that CCM requirements for RHCs and federally qualified health centers (FQHCs) are not more burdensome than those for practitioners billing under the Medicare physician fee schedule.

CMS seeks comment on whether there are circumstances where multiple care-planning codes could be furnished without significant overlap. The agency proposes to specify that GPPP6 may serve as a companion or primary E/M code to the prolonged service codes—those that are currently separately paid, as well as those CMS proposes to separately pay beginning in 2017, but is interested in input on whether any overlap exists among these services. The AAFP reminds CMS that when the cognitive and functional assessment code set was written, a separate E/M code could be billed on the same date of service provided a distinct service was delivered, i.e., for a different and unrelated diagnosis. Documentation must clearly and concisely reflect this information and be able to stand alone.

One issue unfortunately not included in the proposed 2017 Medicare PFS that would improve payment accuracy for primary care and patient-centered services is a proposal to improve the value and effectiveness of the Medicare annual wellness visit (AWV). As the AAFP and others communicated to CMS both in an April 30, 2015, letter and through subsequent meetings with CMS officials, there continues to be strong concern about the potential misuse of the AWV by commercial, non-physician entities. The AAFP believes that the AWV encourages Medicare beneficiaries to engage with their primary care physician or other usual source of care on an annual basis for prevention and early detection of illness, and we are concerned that there are commercial entities that are subverting that benefit and may be misleading patients. We strongly urge CMS to investigate this issue and engage with the AAFP in a conversation about how to protect patients in this matter. The AAFP believes that part of the AWV's benefit is to encourage Medicare beneficiaries to access their usual source of care on an annual basis for prevention and early detection of illness, the treatment of which that source of care could provide or manage. We believe that the AWV facilitates an ongoing relationship between the provider and the beneficiary. This is consistent with the tenets of continuity of care, the process by which the patient and his or her physician are cooperatively involved in ongoing health care management toward the goal of high quality, cost-effective medical care. Continuity of care is rooted in a longterm patient-physician partnership in which the physician knows the patient's history and can integrate new information, such as that obtained from an AWV, into his or her decisions using a

Acting Administrator Slavitt Page 19 of 56 August 19, 2016

whole-patient perspective. Patients may be precluded from AWV benefits due to commercial entities that often have no prior relationship with the patient and have no intention of caring for the patient after the AWV is done. This must be prevented, and CMS should ensure Medicare beneficiaries are fully informed so as to encourage that they seek and receive connected, continuous, and comprehensive primary care. At a minimum, CMS should require anyone performing an AWV to provide results to a patient's designated primary care physician or usual source of care, as well as provide a means for physicians to determine whether or not Medicare has already paid for an AWV for the patient in the past 12 months.

II.G. Target for Relative Value Adjustments for Misvalued Services Summary

CMS discusses the provision of the law that establishes an annual target for reductions in Medicare PFS expenditures resulting from adjustments to relative values of misvalued codes. The target for CY 2017 is 0.5 percent. In the regulatory impact analysis, CMS estimates that the CY 2017 net reduction in expenditures resulting from proposed adjustments to relative values of misvalued codes to be 0.51 percent. Since, if finalized, this amount would exceed the 0.5 percent target established in the law, there is no "Target Recapture Amount" by which to reduce payments made under the Medicare physician fee schedule.

For purposes of this calculation, CMS is proposing to include changes in values of the CY 2016 interim final codes toward the CY 2017 misvalued code target. CMS notes that both of the changes in valuation for the CY 2016 interim final codes, from year 1 to year 2 (CY 2015 to CY 2016) and from year 2 to year 3 (CY 2016 to CY 2017), have taken place during years that occur within the misvalued code target provision. CMS therefore believes that any adjustments made to these codes based on public comment should be considered towards the achievement of the target for CY 2017, just as any changes in valuation for these same CY 2016 interim final codes previously counted towards the achievement of the target for CY 2016. CMS seeks public comments regarding this proposal and notes that, after this year, there will be far fewer instances of interim final codes and changes that are best measured over 3 years.

AAFP Response

The AAFP supports CMS's proposal. It is consistent with a suggestion that the AAFP made in response to the CY 2016 proposed rule, in which we advocated for CMS to include 2015 interim final values in the calculation of the 2016 misvalued code target. We are especially pleased to see that CMS estimates there will be no "Target Recapture Amount" by which to reduce payments made under the PFS in 2017.

II.H. Phase In of Significant RVU Reductions

Summary

Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, practice expense, and malpractice RVUs shall be phased in over a 2-year period. CMS has previously finalized a methodology to implement this provision that limits the year-one reduction for the service to 19 percent. Since CY 2016 was the first year in which CMS applied the phase-in transition, CY 2017 will be the first year in which a single code could potentially be subject to RVU reductions greater than 20 percent for two consecutive years.

CMS proposes to reconsider in each year, for all codes that are not new or revised codes and including codes that were assigned a phase-in value in the previous year, whether the total

Acting Administrator Slavitt Page 20 of 56 August 19, 2016

RVUs for the service would be otherwise decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this proposed policy, the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new and revised), including those codes with phase-in values in the previous year. In other words, for purposes of the 20-percent threshold, CMS proposes that every service is evaluated anew each year, and any applicable phase in is limited to a decrease of 19 percent.

AAFP Response Section 1848(c)(7) states:

Effective for fee schedules established beginning with 2016, for services that are not new or revised codes, if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2 year period.

The plain reading of that provision is that, for services that are not new or revised codes, if the total RVUs for a service for a year (e.g., 2016) 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 (e.g., 2015), the applicable adjustments in work, practice expense, and malpractice RVUs must be phased-in over a 2-year period (e.g., 2016 and 2017).

CMS's proposal twists this plain reading of the law to effectively extend the phase-in period well beyond the two years prescribed by the statute. To use the example provided in the proposed rule, if CMS were to adopt a 50 percent reduction in total RVUs for an individual service and limit the reduction in any particular year to a decrease of 19 percent in total RVUs compared to the year before, it would take four years to phase in that 50 percent reduction, rather than the two years prescribed by the statute.

We appreciate CMS's desire to insulate the providers of these affected services from the impact of such reductions, but that desire does not permit CMS to ignore or misinterpret the law as written. In addition, why should Medicare patients have to pay a higher fee for such overvalued services when identified as such? Furthermore, in the budget-neutral environment in which the fee schedule exists, CMS's proposal would delay the benefit of such reductions to everyone else in the fee schedule beyond the two years that they must already wait under section 1848(c)(7). The law does not justify such a delay and Medicare patients should not have to pay a higher fee during an unnecessary time of transition.

Accordingly, we recommend that CMS implement the law as written. Thus, if the maximum year-one reduction is 19 percent, the remaining reduction must apply in year two. We do not believe there is any other legitimate way to read this section of the law.

II.I. Geographic Practice Cost Indices (GPCIs)

Summary

As required, CMS is proposing to update its GPCIs. In the case of the work and practice expense GPCIs, the proposed update mainly involves using more recent data from the Bureau of Labor Statistics Occupational Employment Statistics program. In the case of the malpractice GPCI, the update involves using more-recent premium data, as well as some technical

Acting Administrator Slavitt Page 21 of 56 August 19, 2016

refinements, such as calculating the average premiums for each specialty using issuer market share for only available companies. Currently, CMS first calculates the average premiums by insurer and specialty and then imputes premium values for specialties for which it did not have specific data, before adjusting the specialty-specific premium data by market share weights.

In addition to updating its GPCI methodology, CMS is proposing extensive revisions to its payment structure in California, based on section 1848(e)(6) of the Act as added by section 220(h) of the *Protecting Access to Medicare Act* (PAMA). CMS is also proposing to modify its calculation of the GPCIs in Puerto Rico. Specifically, CMS proposes to assign the national average of 1.0 to each GPCI index in Puerto Rico, just as it does in the U.S. Virgin Islands. In 2016, the work GPCI in Puerto Rico is 1.0, but the practice expense and malpractice GPCIs are 0.705 and 0.293, respectively.

AAFP Response

As a matter of <u>policy</u>, the AAFP supports the elimination of all geographic adjustment factors from the Medicare physician fee schedule, except for those designed to achieve a specific public policy goal (e.g., to encourage physicians to practice in underserved areas). As such, we continue to oppose use of the GPCIs in setting Medicare physician fees.

That said, we recognize the law requires use of the GPCIs and also requires CMS to review and, if necessary, update those GPCIs at least once every three years. We appreciate CMS's efforts to comply with the law in this regard and support its intention to use more current data in all three GPCIs.

Finally, to the extent that GPCIs are required under the law, we support CMS's proposal to assign the national average of 1.0 to each GPCI index in Puerto Rico. We agree that it makes sense to treat Puerto Rico and the U.S. Virgin Islands similarly in this respect, and we note that this proposal will provide a much-needed increase in Medicare allowances to physicians practicing in Puerto Rico.

II.J. Payment Incentive for the Transition from Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services

Summary

Effective for services furnished on or after January 1, 2017, section 1848(b)(9)(A) of the Act, as added by section 502(a)(1) of the *Consolidated Appropriations Act*, reduces by 20 percent the payment amounts under the PFS for the technical component (including the technical component portion of a global service) of imaging services that are X-rays taken using film. Section 1848(b)(9) of the Act also requires implementation of the reductions in payment for X-rays through appropriate mechanisms, which can include the use of modifiers.

To implement the provisions of sections 1848(b)(9)(A) of the Act, CMS proposes to establish a new modifier (modifier "XX") to be used on claims, as allowed under the section 1848(b)(9)(D) of the Act. Beginning January 1, 2017, this modifier would be required on claims for X-rays that are taken using film. The modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally. The use of this proposed modifier to indicate an X-ray taken using film would result in a 20-percent reduction for the technical component of the X-ray service, as specified under section 1848(b)(9)(A) of the Act.

AAFP Response

Acting Administrator Slavitt Page 22 of 56 August 19, 2016

Many family physicians still provide plain film X-rays in their practices. We understand that the law now requires Medicare to discount the payment amount for the technical component of those X-rays by 20 percent beginning in 2017. Thus, we do not question CMS's proposal to implement the law as written.

However, we do question <u>how</u> CMS is proposing to implement it. CMS proposes that every time a physician provides the technical component of an X-ray service involving film, he or she must append modifier "XX" to the imaging service code to denote that CMS should reduce the payment by 20 percent. In other words, the physician or the physician's staff must take an extra step (i.e., an administrative hassle) when filing such claims for the "privilege" of having their pay reduced by 20 percent. Failure to do so would presumably result in an overpayment to the physician, which is another administrative hassle.

Assuming that the technical component of the service codes in question is done more than half of the time using film, then we would suggest CMS take the inverse approach to implementing section 1848(b)(9)(A). Namely, we would suggest that CMS automatically apply the 20-percent reduction to the technical component of those codes unless the physician appends modifier "XX" to indicate that the service was done by means other than film and therefore not subject to the reduction. This approach would "reward" physician practices who have to take the added step of appending the modifier, where appropriate, and it would avoid inadvertent overpayments resulting from failure to use the modifier.

II.L. Valuation of Specific Codes

2. Methodology for Proposing Work RVUs

Summary

CMS goes to some length to explain its adjustments to work RVUs, especially when it observes that the physician total or intra-service time for a code has significantly decreased while the work RVU is proposed to stay the same or decrease very little. CMS emphasizes that it does not believe that there is a one-to-one relationship between time and work (i.e., they don't have to change by the same percentage). However, it is obligated to consider both time and intensity in establishing work RVUs.

CMS is interested in receiving comments on whether, within the restrictions of the statute, there are alternative suggestions for methods that changes in time should be accounted for when it is evident that the survey data or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resource costs of time for codes describing PFS services. CMS also is seeking comment on potential alternatives, including the application of the reverse building block methodology, to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

AAFP Response

The AAFP continues to support CMS in its efforts to adjust work RVUs commensurate with changes in intra-service and total time, as well as post-operative visits, despite RUC recommendations to the contrary. The AAFP agrees with CMS's changes and encourages CMS to continue to identify and address such incongruities. In our experience, it is routine to encounter recommended decreases in physician time and/or post-procedure visits combined with RUC recommendations to maintain or increase the work RVUs. The AAFP agrees with CMS that when physician time decreases, physician work should decrease comparatively, absent a compelling argument that the intensity of the service has increased sufficiently to offset the decrease in physician time. We do not have any alternative suggestions for how CMS

Acting Administrator Slavitt Page 23 of 56 August 19, 2016

should make these adjustments. We believe the approaches that CMS has taken to date are reasonable and defensible.

II.L.5. Valuation of Specific Codes

(25) Abdominal Aortic Ultrasound Screening (CPT 767X1) Summary

For CY 2017, the CPT editorial panel created a new code—CPT 767X1—to describe abdominal aortic ultrasound screening, which is currently described by Healthcare Common Procedure Coding System (HCPCS) G-code G0389. The specialties that surveyed CPT code 767X1 for the RUC were vascular surgery and radiology, and the direct practice expense inputs recommended by the RUC included an ultrasound room. Based on an analysis of Medicare claims data, the dominant specialties furnishing the service are family medicine and internal medicine, which CMS believes more typically use a portable ultrasound device rather than an ultrasound room. Therefore, CMS is proposing to accept the RUC-recommended work value of 0.55, as well as the RUC-recommended PE inputs for this service, but seeks comment regarding whether or not it would be more accurate to substitute a portable ultrasound or handheld device for an ultrasound room for CPT code 767X1.

CMS also notes that while the phase in of significant reductions in RVUs would not ordinarily apply to new codes, CMS believes it appropriate to consider this change from a G-code to a CPT code to be fundamentally similar to an editorial coding change, since the service is not described differently. Therefore, CMS proposes to apply the phase in to this service by comparing the previous value of the G-code to the value for the new CPT code.

AAFP Response

First, we want to comment on who is most commonly providing this service. Medicare claims data from 2015 show internal and family medicine as the top two provider specialties of the current code—G0389, but only when the technical component is billed separately. This occurred just 7,214 times in 2015. When the global service was billed to Medicare—a more frequent event at 92,948 occurrences—the top provider specialty was diagnostic radiology (28 percent) followed by internal medicine (26 percent), cardiology (19 percent), and family medicine (14 percent). Given the relative claims volume involved, we do not think it is correct to say that family medicine is among the "dominant specialties furnishing the service."

We agree with CMS that when family physicians provide this service, they more typically use a portable ultrasound device rather than an ultrasound room. We cannot speak to whether other specialties do or do not use portable devices in this regard. We also agree with CMS's proposal to accept both the RUC-recommended work value of 0.55, as well as the RUC-recommended PE inputs, for this service, including an ultrasound room, unless the specialties who provide this service more often than family medicine indicate that their members also typically use a portable ultrasound or hand-held device rather than an ultrasound room. Finally, we agree with CMS that, in situations such as this, where a CPT code is replacing a G-code verbatim, it is appropriate to apply a phase in by comparing the previous value of the G-code to the value for the new CPT code.

(34) Parent, Caregiver-focused Health Risk Assessment (CPT Code 961X0) Summary

In October 2015, the CPT editorial panel created two new PE-only codes, 961X0 [Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument] and 961X1 [Administration of caregiver-

Acting Administrator Slavitt Page 24 of 56 August 19, 2016

focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument]. For CPT code 961X0, CMS is proposing the RUC-recommended direct PE inputs. For CPT code 961X1, the service is furnished to a patient who may not be a Medicare beneficiary, and thus, CMS does not believe it would be eligible for Medicare payment. CMS is proposing to assign a procedure status of 'I' (Not valid for Medicare purposes) for CPT code 961X1.

CMS notes that it believes that code 961X0 describes a service that is frequently reasonable and necessary in the treatment of illness or injury, such as when there has been a change in health status. However, when the service described by CPT code 961X0 is explicitly included in another service being furnished, such as the annual wellness visit (AWV), this code should not be billed separately. CMS also notes that this service should not be billed separately if furnished as a preventive service, as it would describe a non-covered service. CMS also is seeking comment on whether this service may be better categorized as an add-on code and welcomes stakeholder input regarding whether or not there are circumstances when this service might be furnished as a stand-alone service.

AAFP Response

We appreciate CMS's proposal to use the RUC-recommended direct PE inputs in setting the PE RVUs for code 961X0. We agree with CMS that administration of a health risk assessment (HRA) is explicitly included in the work of Medicare's AWV and that, therefore, code 961X0 should not be reported in conjunction with a Medicare AWV.

We believe that CMS has raised a valid question about the stand-alone nature of code 961X0, and we are hard pressed to envision a situation in which a patient would present to the family physician solely for the purpose of having a HRA administered. Typically, code 961X0 would be done in conjunction with an E/M service in family medicine. As such, we are open to the idea of re-categorizing code 961X0 as an add-on code. However, in our view, if CMS does so, that should not impact the direct PE inputs or the proposed PE RVUs. All of the RUC-recommended clinical staff time for 961X0 is in the service period (consistent with an add-on code) and does not duplicate E/M clinical staff time functions. The same is true for the minimal medical supplies recommended for this code.

As noted, in the proposed rule, CMS fails to publish RUC-recommended practice expense (PE) values for code 961X1 (Administration of caregiver-focused health risk assessment for the benefit of the patient), assigning it status indicator 'l' (invalid for Medicare purposes). CMS states that it believes the "typical patient is not a Medicare beneficiary" as the reason behind its actions.

However, in the May 11, 2016, bulletin, "Maternal Depression Screening and Treatment: A Critical Role for Medicaid in the Care of Mothers and Children," CMS espouses the "importance of early screening for maternal depression and clarifies the pivotal role Medicaid can play in identifying children with mothers who experience depression and its consequences." Given that CMS is the agency responsible for administration of several key federal health care programs—including Medicaid—CMS's failure to value code 961X1 in the proposed rule is diametrically opposed to its policy on maternal depression screening.

A large body of literature documents the clear medical implications of parental and family mental health on a child's functioning (Ashman et al. 2008; http://www.ncbi.nlm.nih.gov/pubmed/18211728 and NICHD 1999;

Acting Administrator Slavitt Page 25 of 56 August 19, 2016

https://www.nichd.nih.gov/news/releases/Pages/depression.aspx). As one example, maternal depression has been recognized to have a significant negative effect on neonatal and infant responsiveness. Assessing for caretaker conditions may be indicated as part of primary medical well-child care (American Academy of Pediatrics Task Force on Mental Health, 2010; http://pediatrics.aappublications.org/content/126/5/1032.full), at any medical encounter where atypical parent/child interactions are observed, and during encounters where mental health professionals are caring for children and adolescents. (Weissman, Myrna M. et al. 2006; http://jama.jamanetwork.com/article.aspx?articleid=202585).

More recently, the National Institutes for Health (NIH) launched an initiative, National Child and Maternal Health Education Program: Moms' Mental Health Matters, to raise awareness among pregnant and postpartum mothers, their families, and health care providers about depression and anxiety during pregnancy and after the baby is born. The NIH is clearly endorsing identifying and managing maternal mental health conditions for the benefit of the child. The service described by the new code, 961X1, provides a payment avenue for this recommended service.

There are other patients for whom this service is appropriate, and these patients are potentially Medicare-covered adults. These would include geriatric patients who are cared for by another adult who may themselves have significant physical or mental health difficulties. The same may be true for non-elderly adults whose physical or cognitive status renders them incapable of independent living and dependent on another adult caregiver. Some examples might be intellectually-disabled adults, seriously disabled military veterans, and adults with significant musculoskeletal or central nervous system impairments.

During the February 2015 CPT editorial panel meeting, it was recommended that a new code be developed to allow the administration of HRA to a caregiver for benefit of the patient. This would allow the service to be reported for the patient, rather than for the caregiver upon whom the screening service is rendered. As such, the need for this service has been clearly endorsed by a wide panel of medical professionals.

For all of these reasons, we think CMS should recognize and pay for 961X1 within the Medicare program. Failing that, CMS should, at a minimum, publish RVUs for the service for the benefit of Medicaid programs and other payers who may recognize the service and otherwise rely on the RVUs in the resource-based relative value scale to set their own fees.

(38) Prolonged Evaluation and Management (E/M) Services (CPT codes 99354, 99358, and 99359)

Summary

CMS is proposing to make separate payment for codes 99358 and 99359. CMS currently bundles payment for both of these codes with the payment for other services. CMS is also proposing values for services in this family of codes based on the RUC-recommended values, including for CPT code 99354, which would increase the current work RVU to 2.33. Likewise, CMS is proposing to adopt the RUC-recommended work values of 2.10 for CPT code 99358 and of 1.00 for CPT code 99359.

AAFP Response

The AAFP supports CMS's proposals to pay separately for codes 99358 and 99359 and to pay for the codes in this family consistent with the RUC-recommended values.

Acting Administrator Slavitt Page 26 of 56 August 19, 2016

(39) Complex Chronic Care Management Services (CPT codes 99487 and 99489) Summary

For CY 2017, CMS is proposing to change the procedure status for CPT codes 99487 and 99489 from B (bundled) to A (active). CMS is also proposing to adopt the RUC-recommended values for work, 1.00 work RVUs for CPT code 99487 and 0.50 work RVUs for CPT code 99489, as well as direct PE inputs consistent with the RUC recommendations.

AAFP Response

The AAFP supports CMS's proposals to pay separately for complex chronic care management services and to pay for the codes in this family consistent with the RUC-recommended values and PE inputs.

(41) Behavioral Health Integration: Psychiatric Collaborative Care Model (HCPCS codes GPPP1, GPPP2, and GPPP3) and General Behavioral Health Integration (HCPCS code GPPPX)

Summary

To value HCPCS codes GPPP1, GPPP2, and GPPP3, CMS is proposing to base the portion of the work RVU that accounts for the work of the treating physician (e.g., the primary care physician) or other qualified health care professional on a direct crosswalk to the proposed work values for the complex CCM codes, CPT codes 99487 and 99489. To value the portion of the work RVU that accounts for the psychiatric consultant, CMS is estimating 10 minutes of psychiatric consultant time per patient per month and a value of 0.42 work RVUs, based on the per minute work RVUs for the highest volume codes typically billed by psychiatrists. Since the behavioral health care manager in the services described by HCPCS codes GPPP1, GPPP2, and GPPP3 should have academic credentials with specialized training in behavioral health, CMS is proposing a new clinical labor type for the behavioral health care manager, L057B, at \$0.57 per minute, based on the rates for genetic counselors in the direct PE input database. The number of minutes in question corresponds to the number in the code descriptor in each case (i.e., 70 for GPPP1, 60 for GPPP2, and 30 for GPPP3). CMS is seeking comment on all aspects of these proposed valuations.

To value HCPCS code GPPPX, CMS is proposing a work value based on a direct crosswalk from CPT code 99490 (chronic care management services), a work value of 0.61 RVUs. To account for the care manager minutes in the direct PE inputs for HCPCS code GPPPX, CMS is proposing to use clinical labor type L045C, which is the labor type for social workers/psychologists and has a rate of \$0.45 per minute. CMS's assumption is that the amount of clinical staff time involved is 20 minutes.

AAFP Response

The AAFP commends CMS for creating G-codes (GPPP1-GPP3) that parallel the recently approved CPT codes that describe services consistent with the psychiatric collaborative care model (CoCM), which aims to improve the integration of physical and mental health care. We think that the proposed work RVUs for all four codes, at least as they relate to the primary care physician's work, make sense and are supportable. We also think that the clinical staff type identified by CMS for each code is acceptable and that the staff times assumed for GPPP1-GPP3 are defensible, given the code descriptors.

With respect to the physician work of the psychiatrist, we recommend that CMS consider crosswalking codes *GPPP1*, *GPPP2*, and *GPPP3* to the same E/M services, 99487 and 99489 respectively, as the primary care physician, as opposed to 90836, Psychotherapy, 45 minutes

Acting Administrator Slavitt Page 27 of 56 August 19, 2016

with patient and/or family member when performed with an evaluation and management service. The proposed crosswalk does not reflect the actual nature or the work involved in this model, and consequently, the proposed work RVU of 0.42 is inappropriate. As we understand it, the focus of the psychiatrist's work is not psychotherapy. Instead, it is medical in nature and equivalent to the medical decision making of an evaluation and management (E/M) service. Patients enrolled in the collaborative care program are typically those who have not responded to standard care, or are patients who need additional psychiatric evaluation and engagement prior to making a decision to refer for specialty care. As noted in the proposed rule, "the psychiatric consultant advises and makes recommendations, as needed for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated with treatment of psychiatric disorders and referral for specialty care..." These are E/M services and not psychotherapy. The patients discussed are those who are not improving or whose condition is worsening.

Consequently, we think the work of the psychiatrist consultant is identical to that of the primary care physician in all three codes. The psychiatrist is evaluating the patient's condition based on the data provided by the behavioral health care manager and formulating treatment recommendations which typically requires a moderate level of medical decision making (99204, 99214, etc.) based on the severity of the presenting problems and/or the lack of improvement. This medical evaluation and the derived treatment recommendations are communicated by the behavioral health care manager to the primary care physician. Hence, we think the work of the psychiatric consultant in all three codes (GPPP1, GPPP2, and GPPP3) should be valued at the same level as the primary care physician (1.17, 1.00 and 0.50 RVUs respectively).

Related to the practice expenses, we urge CMS to allow the behavioral health care manager (BHCM) to work off-site, under the general supervision of the treating physician or other qualified health care professional (QHP), similar to the current requirements for care managers for chronic care management (CCM) and transitional care management (TCM) services. CMS has indicated in the proposed rule that it expects that the BHCM would furnish services incident to services of the treating physician/QHP; be a member of the clinical staff of the treating physician/QHP; and work on-site at the location where the treating physician/QHP furnishes services to the beneficiary. For TCM and CCM services, CMS originally proposed requiring that care managers be part of the clinical staff of the treating physician/QHP, and that they also be physically on-site with that physician/QHP. CMS subsequently decided to simply require that the care manager is employed by the practice, and CMS ultimately allowed the care manager to work under the general supervision of the physician/QHP. The Advancing Integrated Mental Health Solutions (AIMS) Center at the University of Washington has trained practices of all sizes, including solo practices and small rural clinics, in the collaborative care model. In smallto medium-sized practices, a single BHCM may work for two or more clinics or practices. Additionally, practices in rural and some urban/suburban areas may be unable to find a qualified person in their region to fill the position. A number of sites that have successfully adopted the model—and demonstrated its effectiveness in improving care—have shared a BHCM who functions out of one office and visits the other sites on an as-needed basis and/or who works remotely using the telephone and telemedicine/video technology to accomplish the work of this model. For psychiatric collaborative care management services, the BHCM must be available at all times to serve their entire patient population, even when they are physically working at another practice or clinic. Thus, it is crucial that the BHCM be given the flexibility to work under general supervision and off-site, when necessary.

Acting Administrator Slavitt Page 28 of 56 August 19, 2016

The AAFP commends CMS for creating GPPPX, which again aims to improve the integration of physical and mental health care. However, we disagree with the CMS proposed clinical staff time (absent an AMA RUC survey) of 20 minutes for GPPPX. The code descriptor for GPPPX says "at least 20 minutes of clinical staff time," so CMS has assumed the minimum, rather than the typical, in calculating direct PE inputs, just as it did with 99490. As such, the CMS proposal undervalues the service for any patient requiring more than the minimum necessary to report the code. We believe the typical patient will require more than the minimum of 20 minutes. In its recommendations for code 99490, the RUC estimated that the typical patient would require 60 minutes of clinical staff time. To the extent that CMS is otherwise crosswalking the proposed value of GPPPX to 99490, then we think CMS should follow the RUC recommendation and allocate 60 minutes of clinical staff time to this code, especially in the absence of an appropriate add-on code. Lacking time-specific data from practitioners themselves (which will hopefully be supplied in a future RUC survey), we believe the initial proposal for a behavioral health integration (BHI) code with a time interval of 20 minutes is inappropriate.

(42) Resource-intensive services (HCPCS code GDDD1) Summary

CMS believes that the physician work and time for HCPCS code GDDD1 is most accurately valued through a direct crosswalk from CPT code 99212. Therefore, CMS is proposing a work RVU of 0.48 and a physician time of 16 minutes for HCPCS code GDDD1. CMS is seeking comment on whether these work and time values accurately capture the additional physician work typically involved in furnishing services to patients with mobility impairments.

Regarding practice expenses, CMS believes that a direct crosswalk to the clinical staff-time associated with CPT code 99212, which is 27 minutes of LN/LPN/MTA (L037D) accurately represents the additional clinical staff time required to furnish an outpatient office visit or TCM to a patient with a mobility-related disability. CMS is also proposing to include as direct PE inputs, 27 minutes for a stretcher (EF018) and a high/low table (EF028), and 27 minutes for new equipment inputs associated with the following: a patient lift system, wheelchair accessible scale, and padded leg support positioning system. CMS is seeking comments on whether these inputs are appropriate, and whether any additional inputs are typically used in treating patients with mobility impairments.

AAFP Response

The AAFP supports the proposed valuation of this code.

(43) Comprehensive Assessment and Care Planning for Patients with Cognitive Impairment (HCPCS code GPPP6)

Summary

CMS believes that the physician work and time for this code would be accurately valued by combining the work RVUs from CPT code 99204 (level 4 office or other outpatient visit for the E/M of a new patient) and half the work RVUs for HCPCS code G0181 (physician supervision of a patient receiving Medicare-covered services furnished by a participating home health agency). Therefore, CMS is proposing a work RVU of 3.30. For direct PE inputs, CMS is proposing 70 total minutes of time for RN/LPN/MTA (L037D). CMS is seeking comment on these valuation assumptions and would welcome additional information on the work and direct PE associated with furnishing this service.

AAFP Response

Acting Administrator Slavitt Page 29 of 56 August 19, 2016

The AAFP participated in a RUC survey and presentation of the CPT version of this code at the April 2016 RUC meeting. It is our understanding that the AMA RUC staff communicated the RUC's recommendations related to this code in May. We encourage CMS to review and adopt the RUC's recommendations in lieu of what CMS has proposed for code GPPP6.

(44) Comprehensive Assessment and Care Planning for Patients Requiring Chronic Care Management (HCPCS code GPPP7) Summary

For CY 2017, CMS is proposing to make payment for the resource costs of comprehensive assessment and care planning for patients requiring CCM services through HCPCS code GPPP7 as an add-on code to be billed with the initiating visit for CCM for patients that require extensive assessment and care planning. In valuing this code, CMS believes that a crosswalk to half the work and time values of HCPCS code G0181 (physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present)) accurately accounts for the time and intensity of the work associated with furnishing this service over and above the work accounted for as part of the separately billed initiating visit. Therefore, CMS is proposing a work RVU of 0.87 and 29 minutes of physician time. CMS is also proposing 36 minutes for a RN/LPN/MTA (L037D) as the only direct PE input for this service.

AAFP Response

We appreciate CMS's proposal to make payment for the resource costs of comprehensive assessment and care planning for patients requiring CCM services. However, we disagree with the crosswalk that CMS proposes to use and, by extension, the physician work that CMS proposes to assign to this code. For purposes of this discussion, we will tentatively agree with CMS that the physician time involved is approximately 30 minutes.

As noted elsewhere in the proposed rule, CMS proposes code GPPP7 "be billable for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner." As such, code GPPP7 is a face-to-face service, whereas G0181, by definition, is not. CMS also states elsewhere in the proposed rule that code GPPP7 is to be used "when the billing practitioner initiating CCM personally performs extensive assessment and care planning outside of the usual effort described by the billed E/M code" or annual wellness visit (AWV) or initial preventive physical examination (IPPE) code. As such, GPPP7 is an extension or prolonging of an E/M code, which, again, is not the case with G0181.

Accordingly, we do not think that code G0181 represents an appropriate crosswalk for valuing code GPPP7. Instead, we would encourage CMS to use code 99355 [prolonged E/M or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes], which has 1.77 work RVUs. Like code GPPP7, code 99355 represents a prolonged E/M service and involves 30 minutes of physician time face-to-face with the patient.

Consistent with our suggestion to use code 99355 as a more appropriate crosswalk for physician work, we think CMS should use the same code to crosswalk direct PE inputs. That means if CMS agrees that 99355 is an appropriate crosswalk for physician work, the clinical staff time should be 13 minutes rather than 36. We believe that the clinical staff time associated with this code will be less than the physician time (not more, as CMS proposes). As described by CMS, the time involved with code GPPP7 is principally physician time rather than staff time. We believe that 13 minutes of clinical staff time to support the anticipated 30 minutes of

Acting Administrator Slavitt Page 30 of 56 August 19, 2016

physician time is sufficient and appropriate. In any case, we agree with CMS that the appropriate staff type is a RN/LPN/MTA (L037D).

IIII.A. Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Summary

To enable RHCs and FQHCs to effectively contract with third parties to furnish aspects of CCM and TCM services, CMS proposes to revise §405.2413(a)(5) and §405.2415(a)(5) to state that services and supplies furnished incident to TCM and CCM services can be furnished under general supervision of a RHC or FQHC practitioner. The proposed exception to the direct supervision requirement would apply only to auxiliary personnel furnishing TCM or CCM incident to services, and would not apply to any other RHC or FQHC services. The proposed revisions for CCM and TCM services and supplies furnished by RHCs and FQHCs are consistent with §410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the physician fee schedule (PFS).

AAFP Response

On behalf of its members in RHCs and FQHCs, the AAFP supports CMS's proposal and encourages CMS to finalize it in the final rule this fall, effective for CCM and TCM services with dates of service on or after January 1, 2017.

III.C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services Summary

The *Protecting Access to Medicare Act* establishes a program under the Medicare fee-for-service program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. This policy requires physicians ordering certain imaging services—magnetic resonance, computed tomography, nuclear medicine, and positron emission tomography imaging—for Medicare beneficiaries to consult with AUC applicable to the imaging modality.

In the 2016 proposed Medicare PFS, CMS stated that AUC "crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast." The 2016 final Medicare PFS addressed the initial component of the AUC program by outlining requirements to use an evidence-based, transparent process for developing AUC and establishing a process to identify provider-led entities to become qualified to develop, modify, or endorse AUC.

In late June, CMS posted an initial list of qualified entities. These include:

- American College of Cardiology Foundation
- American College of Radiology
- Brigham and Women's Physicians Organization
- CDI Quality Institute
- Intermountain Healthcare
- Massachusetts General Hospital, Department of Radiology

- National Comprehensive Cancer Network
- Society for Nuclear Medicine and Molecular Imaging
- University of California Medical Campuses
- University of Washington Physicians
- Weill Cornell Medicine Physicians Organization

Acting Administrator Slavitt Page 31 of 56 August 19, 2016

The 2017 proposed Medicare PFS focuses on the next component of the Medicare AUC program and includes proposals for priority clinical areas, clinical decision-support mechanism (CDSM) requirements, the CDSM application process, and exceptions for ordering professionals for whom consultation with AUC would pose a significant hardship. CDSMs are the electronic tools through which a clinician consults AUC to determine the level of clinical appropriateness for an advanced diagnostic imaging service for that particular patient's clinical scenario.

CMS has developed and proposed eight priority, clinical areas that it believes reflect both the significance and prevalence of some of the most disruptive diseases in the Medicare population. They are:

- Chest pain
- Abdominal pain
- Headache, traumatic and nontraumatic
- Low back pain

- Suspected stroke
- Altered mental status
- Lung cancer
- Cervical or neck pain

These eight clinical areas account for roughly 40 percent of Part B advanced diagnostic imaging services paid for by Medicare in 2014. CMS seeks feedback on the proposed list of priority clinical areas and recommendations for other clinical areas that should be included in the future.

Noting that a list of qualified CDSMs is not yet available and will not be available by January 1, 2017, CMS will not require ordering professionals to meet this requirement by that date. At the earliest, the first qualified CDSMs will be specified on June 30, 2017. CMS anticipates that physicians may begin reporting as early as January 1, 2018.

CMS proposes three exceptions to the AUC consultation and reporting requirements:

- For an applicable imaging service ordered for an individual with an emergency medical condition:
- For applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A; and
- For an ordering professional who CMS determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access.

AAFP Response

The AAFP has ongoing, significant concerns about the disproportional burden primary care physicians will face when trying to comply with AUC requirements. We believe that AUC requirements will place more burdens on primary care physicians than on other providers and add an unnecessary level of complexity to the already complex Medicare system that severely overtaxes our members. CMS notes AUC "could have a particular impact on primary care physicians since their scope of practice can be quite vast." The AAFP agrees. It is of significant concern that although this is the case, there is a dearth of dialogue within the regulatory impact analysis section of the proposed rule that should prudently be included surrounding the proposed expansion of the AUC program development outlining CDSM criteria. The proposed rule would enable CDSMs to exist either as integrated within electronic health records (EHRs) or as stand-alone applications. An impact assessment of stand-alone CDSM applications is a necessary component of impact analysis. Stand-alone CDSM applications can pose significant interoperability issues, as well as significant workflow issues for clinicians. Not only do stand-

Acting Administrator Slavitt Page 32 of 56 August 19, 2016

alone CDSMs require ongoing duplicative efforts on behalf of clinicians, but decision support, as to the appropriateness of ordering an advanced diagnostic imaging study, is only as accurate as the data available upon which to base that recommendation. If clinical data within the standalone CDSM is not comprehensive and robust, similar to clinical data present within the EHR, the accuracy of ordering recommendations will be negatively impacted. All physicians will be impacted by the extraordinary administrative burden associated with duplicative data entry into stand-alone CDSMs, but ultimately this will impact family physicians to a disproportionate degree. Stand-alone CDSMs would be highly undesirable from a clinician perspective. Any potential requirement for duplicative manual entry of patient information should be avoided as this siphons precious time away from patient-physician interactions during care encounters and can detract from optimal outcomes, which is the opposite from the intent of this rulemaking. The undue administrative burden associated with duplicative clinical data entry also contributes to physician burnout in a time when physician shortages and access to care is already of significant concern.

We are equally concerned that this substantial addition of administrative burden remains an unproven benefit to quality or cost reduction. CDSMs are yet another component of health information technology (IT) that physicians must purchase and work with health IT vendors to integrate either within or with existing information systems in place. CMS greatly overestimates the level of interoperability that will be achieved when AUC requirements go into effect. Furthermore, now that value-based payment is required under MACRA, CMS must limit additional requirements that are not tied specifically to value. Primary care physicians have enough on their plates preparing for MACRA. They do not need and their patients will not benefit from having AUC requirements added on top.

The AAFP, therefore, strongly urges CMS to delay the implementation of this program so that AUC would be aligned with the forthcoming MIPS program in 2019, versus being introduced as a stand-alone program. With the passage and implementation of MACRA, which begins to align payment with value in earnest, the need for AUC requirements has been supplanted, and those requirements will now likely hinder, rather than improve effective care. Notwithstanding this overarching recommendation and our continued concerns, we offer the following feedback on the proposed AUC policies.

Evidence-based AUC for imaging is purported to assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients. Ultimately though, a physician's clinical judgement must always play a role in selecting an imaging study. Even highly sophisticated cognitive computing algorithms have difficulty with negation involved in decision-making when multiple comorbid conditions exist. This is why a physician's clinical judgment should be allowed to outweigh recommendations from consulted AUC. This should be done without the inclusion of the event within the numerator of data used to determine whether the ordering physician is demonstrating outlier-ordering patterns. CDSM functionality should be present to allow the ordering physician to document why a consulted AUC recommendation is overridden based on clinical judgment. Ultimately, AUC requirements are nothing more than glorified prior authorizations built to be another layer of administrative burden and unneeded bureaucracy for primary care physicians.

The proposed rule discusses how, ideally, physicians would interact directly and "seamlessly" with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow. While we agree that would be ideal, it is ultimately unrealistic at this point in time, and we remain skeptical that CMS can effectively mandate or describe an ideal clinical workflow

Acting Administrator Slavitt Page 33 of 56 August 19, 2016

through regulations, since practice transformation evolves faster than regulations can change. Furthermore, we believe CDSM and EHR vendors should prioritize the ability for their products to prepare for MACRA by handling MIPS measures and reporting CPIA rather than focus on AUC requirements.

CMS discusses that adhering to common interoperability standards, CDSMs could both ensure integration of patient-specific data from EHRs and allow clinicians to optimize the time spent using the tool. The AAFP reminds CMS that interoperability standards have existed as part of CEHRT since 2011, and yet the health care community still does not have wide-scale interoperability. We, therefore, are concerned that AUC standards will have the same, marginal level of impact.

Additionally, both the 2016 Medicare PFS final rule, as well as this proposed rule, reference two potential approaches for AUC development by public-led entities (PLEs). Namely, this includes a comprehensive approach to AUC development and a focused approach to AUC development. CMS notes the belief that, "a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee a number of sets of AUC developed by different PLEs, and an array of CDSMs from which clinicians may choose." The AAFP strongly cautions, while flexibility within rulemaking is often needed and appreciated, when there is a lack of evidence on effective implementation strategies, lack of standardization can and often does equate to undue complexity and a host of health IT options that will likely not lead to seamless, workflowintegrated solutions. This adds significant administrative complexity for physicians in selecting, implementing, using, and reporting AUC. We caution that there is a wide variation within CDSM infrastructures and functionality, and a wide variety of AUC sets may result in the same implementation phenomenon observed with CEHRT implementation. Clinicians may select and implement a CDSM and AUC from a chosen qualified PLE only to discover AUC specificity or CDSM functionality does not meet their needs, leaving the clinician with undue burdens both administratively, as well as with capital investment costs associated with switching their CDSM and PLE selections. It could be beneficial to put forth a standardized, comprehensive set of AUC, yet allow individual PLEs to develop additional specialized sets of AUC.

Regarding the identification of outliers, we remind CMS that a component of MIPS is resource use, which addresses outliers. Therefore, use of AUC for outlier identification is a duplicative effort and not necessary. We recommend against its use for these purposes.

We understand that CMS desires feedback related to specific operational considerations (e.g. reporting and claims processing) that CMS should take into account and include in future rulemaking. CMS is particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G-codes or HCPCS modifiers.

We understand that, under section 1834(q)(4)(B) of the Act, Medicare claims for applicable imaging services furnished in applicable settings can only be paid under the applicable payment systems if certain information is included on the claim, including:

- Which qualified CDSM was consulted by the ordering professional for the service;
- Whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC, or whether no criteria in the CDSM were applicable to the patient's clinical scenario; and
- The national provider identifier (NPI) of the ordering professional.

Acting Administrator Slavitt Page 34 of 56 August 19, 2016

When CMS implements this provision of the law, therefore, it will be reasonable to require the ordering physician to indicate on the order which qualified CDSM he or she consulted and his or her NPI. How the ordering physician indicates on the order should be left to the discretion of the ordering physician based on the system he or she uses, and in consultation with the imaging providers to whom he or she most often sends those orders.

The rendering provider can then determine whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC, or whether no criteria in the CDSM were applicable to the patient's clinical scenario, and communicate all of the required information to CMS in a manner stipulated by CMS. Family physicians will typically be ordering rather than rendering providers. Accordingly, we defer to CMS and the specialties that most commonly provide the advanced imaging services in question how to operationalize section 1834(q)(4)(B) of the Act for claims processing purposes.

Finally, the AAFP concurs with the proposal that if an eligible professional (EP) is excepted from the EHR Incentive Program payment adjustment, then that ordering professional is excepted from the requirement to consult AUC through a qualified CDSM. This should be an automatic exception that does not require an additional application on behalf of the physician. Though the AAFP concurs with proposed exception criteria, we note the identified criteria are not inclusive of all appropriate exception criteria. Additionally, any physician who does not have access to an integrated CDSM and AUC should receive an automatic hardship exception due to the complexity of workflow and the fact that the accuracy of decision support recommendations from stand-alone CDSMs are contingent upon the presence of comprehensive, current, and accurate clinical data.

In summary, we strongly urge CMS to delay implementation of the AUC section until such time as the following conditions are fully met:

- There is evidence to demonstrate that AUC improve quality of care.
- MACRA is fully implemented.
- Any AUC requirements are fully aligned with MACRA.
- Sets of AUC for the same diagnostic imaging modality, developed by different PLE's, are standardized.
- CDSM are fully interoperable with EHRs.
- At least one CDSM with a comprehensive set of AUC, which is fully interoperable with certified-EHR technology (CEHRT), is freely available.
- CDSM communicate AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition in an automated manner and do not require any separate action or use by a physician.

At that point in time, we encourage CMS to implement this provision in a slow, measured, and iterative manner, so it does not burden primary care physicians with administrative tasks and obstacles to care delivery. We also encourage CMS to engage in robust physician education as part of the implementation process.

IIII.D. Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments

Summary

In 2013, CMS published the final rule, titled "Transparency Reports and Reporting of Physician Ownership or Investment Interests." It requires manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) to submit annually information

Acting Administrator Slavitt Page 35 of 56 August 19, 2016

about certain payments or transfers of value made to physicians and teaching hospitals (covered recipients). The law also requires applicable manufacturers and group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on payments or other transfers of value provided to such physician owners or investors. Commonly referred to as either the CMS Open Payments Program or Sunshine Act, this policy creates transparency around the nature and extent of relationships that exist between drug, device, biologicals, medical supply manufacturers, physicians, and teaching hospitals.

In 2015 CMS issued final regulations that specifically:

- Deleted the definition of "covered device:"
- Removed the continuous medical education (CME) exclusion;
- Expanded the marketed name reporting requirements to biologicals and medical supplies; and
- Required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

CMS discusses that various stakeholders have provided feedback regarding aspects of the Open Payment Program and that the agency has identified areas in the rule that might benefit from revision.

AAFP Response

CMS asks several questions and seeks comments to inform future rulemaking.

CMS Question: We would like to know if the nature of payment categories as listed at §403.904(e)(2) are inclusive enough to facilitate reporting of all payments or transfers of value to covered recipient physicians and teaching hospitals. We also seek feedback on further categorization of reported research payments.

AAFP Response: The AAFP recommends removing category xv - "Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program." While the CME exemption was removed from the final rule, accredited or certified CME does not meet CMS's definition of an indirect payment. Within accredited or certified CME, grantors may not and do not "require, instruct, direct or otherwise cause" the educational provider organization to provide payment to a covered recipient. Such grants should not be reported under the Sunshine Act. Having category xv as a payment category creates further confusion as to what is reportable.

CMS Question: Although there is a 5-year record retention requirement at §403.912(e), our regulations are currently silent on how long applicable manufacturers and applicable GPOs remain obligated to report on past years of payments or ownership or investment interests. We are soliciting feedback on how many years an applicable manufacturer or applicable GPO should continue to monitor and report on past program years for Open Payments reporting purposes.

AAFP Response: The AAFP recommends reporting on past payments up to one year in order to minimize the reporting burden.

CMS Question: We are continuing to refresh all years of program data in addition to newly submitted payment records. We are interested in receiving feedback on how many years of

Acting Administrator Slavitt Page 36 of 56 August 19, 2016

Open Payments data is relevant to our stakeholders to help us determine how many years to continue to publish and refresh annually on our website. In addition, we are looking for feedback on how many years may be useful or relevant to Open Payments data users as archive files available for download on our website.

AAFP Response: The AAFP recommends 3 to 5 years worth of data. As a CME provider, the AAFP could potentially use the data as an additional reference when checking conflict of interest (COI) forms for those involved in CME activities. The AAFP CME COI form requires relationships with commercial interests to be disclosed within +/- 12-month period. The AAFP-produced journals require a disclosure of a 36-month period.

CMS Question: We are constantly striving to ensure that all published Open Payments data is valid and reliable. As part of this effort we are seeking comment on a requirement for applicable manufacturers and applicable GPOs to pre-vet payment information with covered recipients and physicians owners or investors before reporting to the Open Payments system, which we understand is an increasingly common practice. Specifically, we would like feedback on prevetting based on threshold payment values or random samplings of covered recipients. We are also interested in hearing how applicable manufacturers and applicable GPOs are successfully pre-vetting payment or transfer of value records.

AAFP Response: The AAFP wholeheartedly supports this pre-vetting of payment information with covered recipients. This would be of great value to our physician members. We encourage CMS to finalize this proposal.

CMS Question: With respect to all solicitations, we are requesting an estimate of the time and cost burden associated with reporting for purposes of compliance with the Paperwork Reduction Act.

AAFP Response: The AAFP estimates that AAFP staff spends roughly 370 hours a year at a cost of \$17,064 to comply with the Open Payment program. Some of the work associated with these numbers includes:

- Discussing interpretation and compliance with current and potential funding sources;
- Educating and providing guidance to internal staff about the Sunshine Act and how it impacts (or could impact) their funded program;
- Providing budget guidance for funded programs to minimize reporting budget specific to the Sunshine Act:
- Reviewing contracts/agreements for Sunshine Act-related language for reporting requirements and working with internal partners to ensure AAFP can meet the stated requirements; and
- Following up with faculty and/or learners at a CME activity regarding reporting or potential reporting requirements.

III.E. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio Data

Summary

As part of the annual bidding process, Medicare Advantage (MA) organizations submit bids for each plan they wish to offer in the upcoming contract year. As required by law, data supporting medical loss ratios (MLR) are submitted annually to CMS by MA plans and Part D sponsors.

Acting Administrator Slavitt Page 37 of 56 August 19, 2016

CMS proposes to release two new sets of data annually: MA bid pricing data and Part C and Part D MLR data. CMS hopes that making this data publicly available will assist public research, future policymaking efforts, and beneficiaries in making enrollment decisions. The MA bid pricing data would be at least five years old and would exclude information treated as proprietary.

CMS proposes to authorize the public release of MA bid pricing data for the MA plan bids that were accepted or approved by the agency for a contract year. CMS proposes that the annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved for a contract year that is at least five years prior to the upcoming calendar year (CY).

AAFP Response

Consistent with AAFP policy on <u>transparency</u>, the AAFP supports the purposes of this proposal. This information could help patients, caregivers, and others in determining health care costs.

Proposal

CMS solicits comment on the proposed 5-year delay for reducing competitive disadvantages to Medicare Advantage Organizations (MAOs).

AAFP Response

While the AAFP agrees with the idea of reducing competitive disadvantages to MA organizations, a 5-year delay in information isn't as useful to patients or others. Releasing the information earlier would provide more actionable data. Cost landscapes change drastically from year to year based on saturation, access to care, and available technology. <u>AAFP policy</u> supports actively employing public education to reduce health care costs.

Proposal

CMS solicits comments explaining whether a shorter period would suffice to protect MAOs from competitive harm associated from the disclosure of confidential commercial information or if a longer period is necessary to adequately protect the information and assure the continued submission of accurate data.

AAFP Response

MACRA currently requires a look-back period on performance and resource use to determine payments. The AAFP encourages CMS to employ the same look-back period to health plans to provide an even field of comparison.

c. Exclusion from Release

Summary

CMS proposes that several types of MA bid pricing information be excluded from the data releases. First, CMS notes that they are not proposing to release Part D bid pricing data in this rule. For this reason, the exclusion from release as proposed is information pertaining to the Part D prescription drug bid amount for an MA plan offering Part D benefits. CMS considers this exclusion to include the following amounts in the MA bid pricing tools (BPT) that pertain to the Part D premiums: the Part D basic premium before and after application of beneficiary rebate amounts; the Part D supplemental premium before and after application of beneficiary rebate amounts; the combined MA plus Part D total plan premium; and the target Part D basic premium.

AAFP Response

Acting Administrator Slavitt Page 38 of 56 August 19, 2016

With drug prices rapidly increasing, being front and center in the media, and affecting most Americans, the AAFP believes the Part D bid pricing data should also be released. This information could be useful to patients and others considering this issue. The AAFP's transparency policy states in part that data should be transparent.

Proposal

Another category of information that CMS proposes to exclude from release is the supporting documentation that MA organizations submit to CMS to support the actuarial bases of each MA plan bid. These materials are collected outside of the BPT templates so this proposed exclusion would be operationalized by withholding from release any materials submitted as part of an MA bid that were not part of the BPT worksheet submission. Supporting documentation for each MA plan bid can consist of multiple text, spreadsheet, and email files. MAOs submit the first round of supporting documentation with the initial bid submission. Subsequently, during the bid review process, CMS reviewers may communicate requests for additional supporting documentation, and in response, MAOs may submit multiple updated versions of an MA's plans BPT and additional supporting documentation. There are no standard formats for supporting documentation. A range of files (Word, Adobe, Excel, and email formats) may be uploaded for each of the MA plan bids, and there is no way to identify clearly which data elements in any of the supporting documentation for an MA plan bid applies to the final accepted version of the bid. Supporting documentation often links a particular plan bid to an MAO's broader pricing such as financial arrangements with providers. CMS believes that such analytical information at a regional or national level could be commercially sensitive information in a way that the cost and enrollment estimates in the BPT are not. Such strategic pricing and contracting information could provide an unfair commercial advantage to certain entities, such as new market entrants. who would not need to release such strategic information. CMS is concerned whether release of supporting documentation could have a chilling effect on the scope of information provided by MAOs for future bidding and our ability to accurately evaluate bids. CMS relies on MAOs to provide detailed explanations of the bids in order for CMS to fully understand the judgment calls underlying the assumptions reflected in the bids. If MAOs believe that the explanations and additional information are not protected from disclosure, they may provide less information and less explanation.

AAFP Response

The AAFP believes that financial arrangements with physicians should be kept confidential.

Proposal

CMS proposes to exclude from release any information identifying Medicare beneficiaries and other individuals. CMS believes that this identifying information should be excluded from a public data release to protect the privacy of individuals, including but not limited to protecting the confidentiality of information about Medicare beneficiaries.

AAFP Response

The AAFP agrees with this proposal.

(d) Timing of MA Bid Pricing Data Release *Proposal*

CMS proposes the timing of the release of MA bid pricing data limited by the exclusions. CMS proposes that the annual release would occur after the first Monday in October. CMS selected the first Monday in October as the date after which the release could occur each year because the annual bidding cycle has come to a close at this point and CMS completed the approval of

Acting Administrator Slavitt Page 39 of 56 August 19, 2016

MA plan bids for the upcoming contract year (calendar year). For example, after the first Monday in October 2016, the bids for contract year 2017 have been accepted. Thus, a public release in December 2016 or January 2017 would be a release of the final accepted MA bid pricing data for a contract year not more recent than 2012.

AAFP Response

Should the previously proposed 3-year versus 5-year window be approved? We anticipate the most recent data to be released for 2015.

Proposal

CMS is soliciting comments on the approach that they are proposing for the public release of MA bid pricing data based on a 5-year lag in the data, and whether that is the appropriate timeframe to apply to this data release.

AAFP Response

While the AAFP agrees with the idea of reducing competitive disadvantages to MAOs, a 5-year delay in information isn't as useful to patients or others. Releasing the information earlier would provide more actionable data. We propose a 3-year delay.

5. Other Approaches to Release of MA Bid Pricing Data *Proposal*

CMS is considering whether to release MA bid pricing data on a shorter timeframe than the proposed 5-year lagged timeframe, which could be as recent as MA bid pricing data from the previously concluded MA contract year.

AAFP Response

The AAFP would agree with this proposal.

Proposal

Finally, CMS is seeking comment regarding whom they should release more recent MA bid pricing data. Specifically, should such a release be made fully available to the public at large, or only to researchers who have studies approved through an application process and who are subject to our longstanding data-sharing procedures?

AAFP Response

The AAFP believes that more recent data should be released to all.

Proposal

CMS also seeks comment on whether research results from the analysis of MA bid pricing data should be subject to additional restrictions, such as a prohibition of publication of MA bid pricing data at the plan level or prohibitions on the identification of the applicable MAO that submitted the data.

AAFP Response

The AAFP believes that data should be made available without restrictions. This aligns with the AAFP's <u>transparency</u> policy.

- 7. Proposed Regulatory Changes for Release of MLR Data
- a. Proposed Addition of §422.2490 and §423.2490 Authorizing Release of Part C and Part D Medical Loss Ratio Data

Acting Administrator Slavitt Page 40 of 56 August 19, 2016

Proposal

CMS proposes to release the Part C MLR data and Part D MLR data, respectively, for each contract for each contract year, and no earlier than 18 months after the end of the applicable contract year.

AAFP Response

The AAFP agrees with this proposal.

b. Exclusions from the release of Part C and Part D MLR data.

For the purpose of this data release, CMS would exclude four categories of information from the release of Part C and Part D MLR data.

Proposal

CMS proposes to exclude from release any narrative information that MAOs and Part D sponsors submit to support the amounts that they include in their MLR reports, such as descriptions of the methods used to allocate expenses. MAOs and Part D sponsors are required to describe the methods they used to allocate expenses, including incurred claims, quality improvement expenses, federal and state taxes and licensing or regulatory fees, and other non-claims costs. A detailed description of each expense element should be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized. CMS believes that descriptions of expense allocation methods should be excluded because MAOs and Part D sponsors may be required to provide information that is pertinent to more than the individual MA or Part D contract for which the MLR report is being used (such as an MAO's or Part D sponsor's proprietary approach to setting payment rates in contracts with providers, or its strategies for investing in activities that improve health quality). CMS is concerned that MAOs and Part D sponsors would be reluctant to submit narrative descriptions that include information that they regard as proprietary if they know that it will be disclosed to the public, which could impair our ability to assess the accuracy of their allocation methods.

AAFP Response

The methods used should be made available. The AAFP <u>transparency policy</u> states in part that data and the process should have transparency. The method or process used is important in determining if the data is accurate.

Proposal

CMS proposes to exclude from release any information identifying Medicare beneficiaries or other individuals.

AAFP Response

The AAFP agrees with this proposal.

c. Timing of release of Part C and Part D MLR data.

Summary

CMS is proposing to release the MLR data specified in this rule for each MA and Part D contract on an annual basis no earlier than 18 months after the end of the contract year to which the MLR data applies. CMS is proposing to follow the commercial MLR approach in making the data the agency receives in MLR reports available to the public. For Part C and Part D MLR reporting, the data is due about 12 months after the end of the contract year. After CMS receive

Acting Administrator Slavitt Page 41 of 56 August 19, 2016

MAO's and Part D sponsor's MLR reports, CMS anticipates that it will take up to six months for them to review and finalize the data submitted by MAOs and Part D sponsors.

AAFP Response

The AAFP agrees with this proposal.

III.H. Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately Summary

Existing law prohibits individual physicians that bill through their tax identification number (TIN) of an ACO to participate in PQRS outside the ACO. Typically, 98 percent of ACOs satisfactorily report quality data. However, 2 percent of ACOs failed to report quality data successfully, leading to automatic payment adjustments imposed on their ACO members under both PQRS and the value-based payment modifier (VBPM) in 2017. This rule proposes to allow individual EPs and groups reporting using the group practice reporting option (GPRO) to report separately from the ACO fails to report for 2017 and 2018 payment adjustments, as long as they report through a third-party vendor.

CMS is identifying CY 2016 as a secondary reporting period for 2017 payment adjustments if the ACO failed to report quality data successfully in 2015. Thus, 2016 data would be used to determine 2017 payment adjustments, 2018 payment adjustments, or both. CMS is eliminating the need to register with a GPRO when using third-party entities, since the vendor is able to identify data as group data. For individuals and groups, this means they could report PQRS using a qualified registry, qualified clinical data registry (QCDR), or EHR (direct or data submission vendor). This excludes the claims reporting option for individuals and excludes the web interface and certified survey vendor options for groups.

Reporting during this secondary reporting period allows individuals and groups to avoid automatic downward VBPM adjustment, but they would not be eligible for upward adjustment. This option is not available for EPs that reported outside the Shared Savings Program.

CMS will re-process 2017 claims once they determine if reporting was successful.

AAFP Response

We support this proposal as written. However, there may be rare instances where an ACO successfully reported for the 2017 payment adjustment period, but does not successfully report for the 2018 payment adjustment period. In such cases, affected providers will not choose to incur the additional time and expense to report outside the ACO during the 2016 reporting period, since they will not yet know that their ACO did not successfully report for the 2018 payment year.

Since reporting in 2017 for the 2019 payment year will be changed under MACRA/MIPS, we realize it may be more challenging to designate an additional secondary reporting period for the 2018 payment year for those providers who are members of an ACO that failed to report for the 2018 payment adjustment year. We urge CMS to use flexibility to determine a method to open a secondary reporting period in 2017 for such situations.

III.I. Medicare Advantage Provider Enrollment

Summary

Acting Administrator Slavitt Page 42 of 56 August 19, 2016

To receive payment for a furnished Medicare Part A or Part B service or item, or to order, certify, or prescribe certain Medicare services, items, and drugs, a provider or supplier must enroll in Medicare. The enrollment process requires the provider or supplier to complete, sign, and submit to its assigned Medicare contractor the appropriate form CMS-855 enrollment application. The CMS-855 application form captures information about the provider or supplier that is needed for CMS or its contractors to screen the provider or supplier, and determine whether the provider or supplier meets all Medicare requirements. This screening prior to enrollment helps to ensure that unqualified individuals and entities do not bill Medicare and that the Medicare trust funds are accordingly protected. Data collected and verified during the enrollment process generally includes, but is not limited to:

- Basic identifying information (for example, legal business name, tax identification number);
- State licensure information;
- Practice locations; and
- Information regarding ownership and management control.

CMS proposes to require physicians, providers, and suppliers to be screened and enrolled in Medicare in order to contract with a MAO to provide Medicare-covered items and services to beneficiaries enrolled in Medicare Advantage health plans. This proposal creates consistency with enrollment requirements for all other Medicare (Part A, Part B, and Part D) programs, as well as a requirement that health care providers in a Medicaid managed care plan's network be screened and enrolled with the state Medicaid program. This proposal also prevents Medicare Advantage participation by health care providers or suppliers that have had their Medicare enrollment revoked or have been excluded by the office of the inspector general.

AAFP Response

CMS states they do not believe that this proposed rule would have a significant impact on MA organizations' ability to establish networks of contracted providers that meet CMS' MA network requirements. While the AAFP does not feel that this change would create significant impact on the numbers of providers, the AAFP has been and continues to be concerned about network adequacy. Reducing the number of physicians participating in these networks could create access problems for patients. The AAFP has written several letters to CMS expressing our concern about this very topic. In a sign-on letter to CMS dated February 12, 2015, organizations expressed their concern about CMS' formula used to determine network adequacy using a physician-to-covered-persons ratio analysis that does not appear to assess the full-time equivalent (FTE) status of those physicians. Physicians frequently practice part time in multiple locations, thereby distorting the physician-to-covered-persons ratio. CMS should require that the insurer calculate the FTE of physicians, so the physician-to-covered-person ratio is properly analyzed. CMS must ensure family physicians are appropriately represented in MA provider networks.

CMS proposes to add to language to the MA organization application requirements requiring MA organizations to provide documentation that all applicable providers and suppliers are enrolled in Medicare in an approved status. CMS believes that this would assist them in the MA organization application process by requiring MA organizations to provide assurance that the designated providers and suppliers are properly screened and enrolled in Medicare. While the AAFP supports this proposal, our concern is physicians may be erroneously placed in an unapproved status. CMS must ensure the process is accurate. If the physician is placed in an unapproved status, CMS should provide the physician 90 days to appeal the status.

Acting Administrator Slavitt Page 43 of 56 August 19, 2016

Furthermore, the timeframe in which patients are notified should be adequate for them to find another primary care physician.

The agency proposes to extend this requirement to suppliers, not just limit it to providers. In this same section, CMS also proposes to add a requirement for MA organizations to comply with the provider and supplier enrollment requirements. The AAFP agrees with this proposal.

CMS proposes provisions that would give it the authority to terminate a contract if an MA organization or Program of All-Inclusive Care for the Elderly (PACE) organization fails to meet provider and supplier enrollment requirements and payment prohibitions. Continuity of care for Medicare patients is critical. The AAFP asks CMS to ensure that if changes are made during the benefit year (e.g. Medicare terminates a contract with an MA organization), patients would be allowed to continue with their physicians on an in-network basis until the next enrollment period, and subject to the physician's consent.

CMS also proposes to impose sanctions if an MA organization or PACE organizations fails to meet provider and supplier enrollment requirements. The AAFP agrees with this proposal.

III.J. Proposed Expansion of the Diabetes Prevention Program Model Summary

The Medicare Diabetes Prevention Program is a structured lifestyle intervention that includes dietary coaching, lifestyle intervention, and moderate physical activity, all with the goal of preventing the onset of diabetes in individuals who are pre-diabetic. The clinical intervention consists of 16 intensive "core" sessions of a curriculum in a group-based, classroom-style setting that provides practical training in long-term dietary change, increased physical activity, and behavior change strategies for weight control. After the 16 core sessions, less-intensive monthly follow-up meetings helps ensure that the participants maintain healthy behaviors. The primary goal of the intervention is at least 5 percent average weight loss among participants.

In March 2016, the U.S. Department of Health and Human Services (HHS) announced that the CMS Office of the Actuary certified that expansion of the Medicare Diabetes Prevention Program model would reduce net Medicare spending. The expansion was also determined to improve the quality of patient care without limiting coverage or benefits.

CMS proposes to expand the Medicare Diabetes Prevention Program within Medicare beginning January 1, 2018. The agency proposes to designate services in the Medicare Diabetes Prevention Program as "additional preventive services" under Medicare Part B, since CMS considers the services of this program to be consistent with other types of additional preventive services. Through expansion, more Medicare beneficiaries will be able to access the benefits of the program. CMS seeks public comment on how the program should:

- Allow CDC-recognized Diabetes Prevention Program organizations to enroll in Medicare beginning on January 1, 2017.
- Reimburse programs for diabetes prevention sessions attended and the achievement and maintenance of a minimum weight loss.
- Require CDC-recognized Diabetes Prevention Program entities to submit claims to Medicare using standard claims forms and procedures, submitted electronically in batches.
- Define eligible pre-diabetic beneficiaries based on body mass index (BMI) in addition to hemoglobin A1C tests, or plasma glucose levels.

Acting Administrator Slavitt Page 44 of 56 August 19, 2016

- Develop program integrity policies to monitor and audit Medicare Diabetes Prevention Program entities.
- Establish site-of-service requirements.
- Provide education, training, and technical assistance on Medicare enrollment, data security, claims submission, and medical record keeping for Medicare Diabetes Prevention Program entities.
- Collect quality metrics for payment and public reporting to guide beneficiary choice of entities.
- Be expanded over time, such as nationally in the first year or phased in gradually.

AAFP Response

The AAFP fully supports the expansion of the Medicare Diabetes Prevention Program. The AAFP support these services being furnished by both physician and non-physician, community-based organizations that are recognized by the CDC to provide these services to Medicare beneficiaries diagnosed with pre-diabetes.

We are pleased that CMS proposes to designate the Medicare Diabetes Prevention Program as an "additional preventive service" available under Medicare Part B, meaning that Medicare beneficiaries can utilize this service without being subjected to beneficiary co-pays. The AAFP concurs with CMS that the Medicare Diabetes Prevention Program services are generally consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries, and we support the proposal to use the agency's waiver authority to waive section 1861(ddd)(1)(B) of the Act with respect to the Medicare Diabetes Prevention Program services, because they have been recommended by the Community Preventive Services Task Force, which is similar to the U.S. Preventive Services Task Force (USPSTF).

However, it remains unclear to the AAFP why the proposed rule discusses that using the national coverage determination (NCD) process to implement the Medicare Diabetes Prevention Program would create implementation problems even though the proposed rule proposes to create a new supplier class. The AAFP encourages CMS to expand evidence-based prevention services through both the NCD and proposed rule processes.

We also support the proposal that the Medicare Diabetes Prevention Program expanded model use the CDC-approved curriculum. We applaud CMS for promoting and expanding an evidence-based intervention program targeted to individuals with pre-diabetes and the proposed criteria are consistent with AAFP and USPSTF recommendations. Evidence shows that even a modest amount of weight loss can improve health outcomes and that adopting healthier lifestyles (increased activity, better diet) alone, without significant weight loss, can have an impact. It may not prevent diabetes, but it may reduce other risks such as heart disease.

Since even a modest amount of weight loss improves health outcomes, the AAFP is concerned with the proposal that beneficiaries who meet the coverage criteria would be able to enroll in the Medicare Diabetes Prevention Program only once. Though we acknowledge that CMS must ensure that the program is actually working for the beneficiary, we also urge CMS to allow beneficiaries that previously failed the program to attempt the program again.

Regarding the CMS proposal to permit CDC-recognized organizations that are not already enrolled in Medicare to apply to enroll any time on or after January 1, 2017, the AAFP is supportive. Likewise, we agree that existing Medicare providers and suppliers that wish to bill

Acting Administrator Slavitt Page 45 of 56 August 19, 2016

for Medicare Diabetes Prevention Program services would have to inform CMS of that intention and satisfy all other requirements, but would not need to enroll a second time.

CMS seeks comments on whether to require that coaches enroll in the Medicare program in addition to obtaining an NPI. Since payments are made to the CDC-recognized organization, we do not see the need to have a coach enroll if they obtain an NPI. It seems that coaches would only need to obtain NPIs as long as CMS specifies that coaches cannot bill Medicare directly for their services and that claims must come from the Medicare Diabetes Prevention Program organization's TIN.

The AAFP supports the proposal that existing Medicare providers and suppliers who lose CDC recognition would lose their Medicare billing privileges with respect to Medicare Diabetes Prevention Program services, but may continue to bill for other non-Medicare Diabetes Prevention Program services for which they are eligible to bill.

Regarding table 35 in the proposed rule, the Medicare Diabetes Prevention Program payment model, in general, the AAFP found the table unnecessarily confusing. The parenthetical reference to "(non-cumulative)" seems to contradict the subsequent maximum totals, which appear cumulative. The AAFP suggest that CMS use a simpler method that pays an amount per session per beneficiary multiplied by the number of sessions, and then add additional payment depending on the patient's weight loss percentage.

Regarding the proposal that Medicare Diabetes Prevention Program records be retained for seven years from the date of service, the AAFP agrees. This timeframe generally is in alignment with states' required maintenance of medical records.

The AAFP supports the proposals to allow community-referrals, self-referral by patients, and referrals by physicians and other health care practitioners for qualifying patients. CMS should also require non-health care Medicare Diabetes Prevention Program providers to ask beneficiaries about their usual source of care and mandate that programs must share results with the beneficiary's self-identified primary care physician or usual source of care in the name of continuity of care.

CMS seeks input on the quality metrics that should be reported by Medicare Diabetes Prevention Program suppliers. From the Core Quality Measures Collaborative, we urge CMS to use #0421 BMI screening and follow up (percent of patients 18 or older with a documented BMI and current visit or in the previous six months and that BMI falls outside of normal parameters and a follow-up plan is documented at current encounter or in the previous six months).

Finally, CMS seeks comment on whether to expand the Medicare Diabetes Prevention Program nationally or use a phased-in approach. The AAFP encourages CMS to implement a national program since a national roll out avoids variable Medicare benefits depending on where a beneficiary lives. However, if CMS does not feel ready to implement a national roll out, we understand that a phased-in roll out done properly is preferable to a botched national roll out.

III.K. Medicare Shared Savings Program (MSSP)

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard Summary

In the effort to align with initiatives, CMS proposes to add, and in some cases to replace existing quality measures. Specifically, the summary is to align the Medicare Shared Savings Program

Acting Administrator Slavitt Page 46 of 56 August 19, 2016

(MSSP) quality measure set with the measures recommended by the Core Quality Measures Collaborative for reporting through the CMS web interface under the Quality Payment Program (QPP) proposed rule.

CMS seeks feedback in replacing the documentation of current medication in the medical record measure (ACO 39) by re-introducing medication reconciliation (ACO-12) in the care coordination/patient safety domain.

AAFP Response

The AAFP supports this change since medicine reconciliation documentation holds a higher value in improving population health than documentation of current medication in the medical record.

Proposal

CMS plans to add ACO-44, Use of Imaging Studies for Low Back Pain (NQF # 0052) in the care coordination/patient safety category. Other changes include the retirement or replacement of ACO-30, Documentation of Current Medications in the Medical Record; ACO-21, Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented; ACO-31 Heart Failure (HF) Beta Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD); ACO-33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy–for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40 percent); two ambulatory sensitive conditions, ACO-9 and ACO-10.

AAFP Response

The AAFP supports the above changes as they correspond with the Core Quality Measure Collaborative Measure Set, which ensures alignment, harmonization, and the avoidance of competing quality measures among payers.

Proposal

CMS seeks feedback on the addition of 43 Ambulatory Sensitive Conditions Acute Composite (AHRQ PQI # 91), a composite measure reporting conditions related to dehydration, bacterial pneumonia, and urinary tract infections to the care coordination/patient safety domain. This measure will be risk adjusted for demographic variable and comorbidities.

AAFP Response

The AAFP appreciates the pay-for-reporting phase allowed in this measure due to its absence in the Core Quality Measure Collaborative Measure Set. Data conveyed back to the ACO allows the organization to compare itself against the national average in an effort to drive improvement in ambulatory sensitive conditions. A quarterly feedback report on this measure is a necessary step to enable a rapid-cycle Plan-Do-Study-Act (PDSA). If CMS cannot provide quarterly feedback reports, a longer phase-in approach would be necessary. Current quarterly feedback would allow the ACO to review data to make the necessary process changes. Changes need to occur not only at practices, but also with patients. Patients need to be educated to call the primary care provider first, rather than seeking care in the emergency room, which may or may not result in a hospital admission for an ambulatory sensitive condition.

b. Improving the Process Used to Validate ACO Quality Data Reporting Summary

The summary changes from CMS address the number of records to be reviewed per measure, the number of audit phases, the calculation of an audit match rate, and consequences if the

Acting Administrator Slavitt Page 47 of 56 August 19, 2016

audit matches rate falls below 90 percent. CMS proposes to modify regulation in order to conduct the quality validation audit in a single step, rather than the current multi-phased (three phase) process.

CMS is seeking input on increasing the number of records audited per measure to achieve a level of confidence that the true audit match rate is within five percentage points of the calculated result. CMS is not proposing a specific number of records that would be requested for purposes of ACO quality validation audits. Based on the analysis, CMS does not anticipate more than 50 records will be requested per audited measure. The ACO will not have the opportunity to correct and resubmit data for any measure with a >10 percent mismatch. The overall audit match rate would be derived by dividing the total number of audited records that match the information reported in the web interface by the total number of records audited. If the ACO fails an audit, the overall quality score will be adjusted proportional to its audit performance. If an audit rate is less than 90 percent, the ACO may be required to submit a corrective action plan (CAP) for CMS approval.

AAFP Response

The AAFP appreciates a streamlined audit process. However, CMS needs to clarify how many measures will be included in an audit. Is this a condensed version to achieve a level of confidence or simply the number of charts needed for each measure? Is this summary due to a large number of quality audits or mismatches? If so, could this be related to an interface issue within CMS? CMS should communicate to the ACO who conducts the audit. There may be instances the ACO has a legitimate reason to appeal an audit. In such cases, we would appreciate the ability for an appeal even if it does not meet the 90 percent threshold.

c. Technical Changes Related to Quality Reporting Requirement Summary

CMS proposes to make technical revisions to ensure stakeholder understanding of the definition of the quality performance standard.

AAFP Response

The AAFP thanks CMS, as this will reduce confusion.

d. Technical Change to Application of Flat Percentage for Quality Benchmarks Summary

CMS has a current methodology to address clustered and topped-out measures by converting performance rates to ratios. However, CMS has determined that converting measures calculated and reported as ratios into benchmarks expressed in percentiles and percentages created confusion in the interpretation of quality results, and may yield results that are contrary to the intended purpose of using flat percentages.

AAFP Response

The AAFP appreciates the CMS approach to reduce confusion. However, in all reports, CMS needs to clearly indicate to the TIN's performance measures that are percentages verses ratios.

e. Incorporation of Other Reporting Requirement Related to the PQRS Summary

Current regulations prohibit ACO participant, TINs, and the EPs billing through those TINs, from participating in PQRS outside of the Shared Savings Program, such that these entities may not independently report for purposes of PQRS apart from the ACO.

Acting Administrator Slavitt Page 48 of 56 August 19, 2016

If the ACO fails to satisfactorily report all the ACO GPRO measures through the CMS web interface, each EP who bills under the TIN of an ACO participant within the ACO will receive a downward adjustment. CMS believes it is necessary to protect the EP that participates in ACOs that fail to satisfactorily report the ACO GPRO measures.

AAFP Response

The AAFP appreciates CMS's acknowledgement that ACOs in the past may have failed to satisfactorily report all ACO GRPO measures through the interface and has developed proposed rules to address this issue. The AAFP supports this summary as written. However, there may be rare instances where an ACO successfully reported for the 2017 payment adjustment period, but not for the 2018 payment adjustment period. We urge CMS to use flexibility to determine a method to open a secondary reporting period in such situations.

- f. Alignment with the Quality Payment Program (QPP)
- 1. Background and introduction to the Quality Payment Program *Summary*

QPP in the quality performance category will use information submitted by the ACO through CMS web interface to assess each EP billing under the TIN of an ACO participant. The QPP proposes to aggregate EP reported data to calculate an ACO score, which is applied to each participating EP.

The definition of an Advanced Alternative Payment Model (AAPM) is one that meets several criteria including requiring participants to use certified-EHR technology (CEHRT). Only tracks 2 and 3 of the MSSP have the potential to meet all criteria necessary for AAPM designation. In order to meet the CEHRT requirement, the MSSP must hold ACOs accountable for their participant eligible clinicians use of CEHRT by applying a penalty or reward based on the degree of use of CEHRT (such as percentage of EP that are using CEHRT or care coordination or other activities they perform using CEHRT).

2. Proposals Related to Sunsetting PQRS and EHR Incentive Program Alignment Summary

Alignment with APM Reporting Requirements under the Quality Payment Program. ACO, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure which aligns with the eligibility criteria that require ACOs to define care coordination processes, which may include use of enabling technologies such as CEHRT.

The VM, PQRS, and the EHR Incentive Programs are sunsetting, and the last quality reporting period under these programs is proposed to be 2016, which would impact payment in 2018. The quality reporting under the QPP, as proposed, would begin in 2017 for payment year 2019.

AAFP Response

The AAFP supports the proposed sections 1 and 2, as written.

3. Proposals related to alignment with the QPP *Summary*

In the QPP proposed rule, CMS outlined criteria for an Advanced APMs, the limited APMs through which EPs would have the opportunity to become Qualified Participants. The proposal also indicates only Shared Saving tracks 2 and 3 would appear to meet the proposed financial risk standard to bear more than nominal amount of risk for monetary losses.

Acting Administrator Slavitt Page 49 of 56 August 19, 2016

Under the QPP proposed rule, the number of Eligible Clinicians (ECs) who must use CEHRT or how CEHRT must be used in an AAPM is not specified. Also, the AAPM must require at least 50 percent of ECs who are enrolled in Medicare to use certified health IT functions. CMS believes it was appropriate to propose an alternative criterion for CEHRT use of the Shared Savings Program. CMS proposes an alternative criteria to allow the Shared Savings Program to satisfy the EHR criteria if it holds APM entities accountable for their ECs use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use (such as the percentage of ECs that use CEHRT or the engagement in care coordination or other activities using CEHRT). The specifications of the EHR measure will align with QPP by assessing the ACO on the degree of CEHRT use by all providers and suppliers designated as an EC under the QPP proposed rule that are participating in the ACO, rather than only focusing on the degree of use of primary care in the ACO.

AAFP Response

The AAFP agrees with the above proposals.

Proposal

CMS seeks feedback on the modification of ACO-11 to remove the reference to primary care physicians. The modifications in the specifications of ACO-11 will be extensive and will require ECs to gain familiarity with the reporting requirements under the QPP proposed rule. CMS proposes that this measure would be considered a newly introduced measure and set at the level of complete and accurate reporting for the first two reporting period for which reporting of the measures is required according to CMS rules at 425.502 (a) (4).

AAFP Response

The AAFP agrees with the proposed change. It is necessary that the measure should be pay for reporting for the first two performance years. If implementation of MACRA MIPS and APMs does not occur on January 1, 2017, then this measure should not be pay for reporting for 2017 and 2018 as proposed, but instead should be pay for reporting for the first two performance years, based on date of implementation of MACRA MIPS and APMs.

Proposal

CMS seeks input during pay-for-performance years. The assessment of EHR adoption is measured based on a sliding scale.

AAFP Response

The AAFP supports this proposal. These rules are in place in the MSSP program and standardizing expectations across programs reduces complexity. Requiring only one EC within the ACO to have met requirements for complete and accurate reporting as defined in QPP proposed rule is of course preferred over requiring all ECs within the ACO to have met this requirement. However, we refer CMS to the AAFP's official comments recommending revision of the Advancing Clinical Information category of the QPP.

Proposal

CMS seeks feedback on a policy that would require the EHR measure to be pay-forperformance in all performance years including the first year of an ACO first agreement period.

AAFP Response

Acting Administrator Slavitt Page 50 of 56 August 19, 2016

CMS should adhere to the current requirements. ECs need sufficient time to become familiar with requirements associated with an ACO. Changes to pay-for-performance to include all performance years would discourage an EC from joining an ACO.

Proposal

To avoid confusion and duplicative rulemaking, any future changes to the CMS web interface measures would be proposed through rulemaking for the QPP and would be applicable to ACO quality reporting under the Shared Savings Program.

AAFP Response

The AAFP applauds CMS on this summary to avoid confusion and duplicative rule making.

4. Incorporating Beneficiary Preference into ACO Assignment *Summary*

In the Physician Fee Schedule (PFS) final rule released November 2011, the beneficiary assignment was determined on plurality of the beneficiaries' primary care services during the performance year. In the 2015 PFS final rule, CMS implemented a new two-sided performance based risk track—Shared Savings Program track 3. Under track 3, beneficiaries are prospectively assigned to the ACO at the beginning of the performance year using the same two-step methodology, based on the most recent 12 months for which data is available. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list. Examples include beneficiary enrollment in Medicare Advantage or no longer lives in the United States or U.S. territories and possessions. This is based on the most recent available data in beneficiary records at the end of the performance year.

The beneficiary is not excluded if he/she chooses to receive most or all of primary care outside of the ACO. No beneficiaries are added to the ACO prospective assignment list at the time of reconciliation because he/she chooses to receive the plurality of care during the performance year from ACO professional participating in the ACO.

CMS received stakeholder comments requesting beneficiaries voluntarily align with the ACO in which their primary health care provider participates. This will improve patient centeredness of the assignment methodology.

CMS seeks input on the implementation of an automated approach to determine the provider who the fee-for-service (FFS) beneficiary believes is responsible for coordinating his or her overall care (i.e. his or her main doctor). This approach would use information collected in an automated and standardized way directly from beneficiaries through one of the following: a system established by CMS, such as MyMedicare.gov; 1-800 Medicare; or Physician Compare (with_a link to MyMedicare.gov). CMS would issue either directly or indirectly (through template language) all written communication to beneficiaries detailing the process.

AAFP response

In terms of primary care physician attribution, the AAFP strongly supports that patients be prospectively assigned a primary care physician or provider along with a simple process for the beneficiary to change the physician or provider to whom he or she was attributed. This approach promotes patient engagement and empowers beneficiaries and their families in directing their care.

Acting Administrator Slavitt Page 51 of 56 August 19, 2016

However, there are design considerations based on learnings from the Pioneer ACO program that must be considered. As a result, AAFP recommends CMS pilot the proposed approach with some modifications (e.g. pairing with cognitive care and prevention codes) given the potential burden on practices and variability in beneficiary ability to engage.

While AAFP supports the beneficiary being more involved in assignment, we are concerned about the potential burden to primary care practices and patients. Medicare beneficiaries may not understand the ambiguous term "main doctor," nor understand the purpose of selecting a "main doctor." Due to various health conditions, the beneficiary's "main doctor" might mean a cardiologist or pulmonologist and not the primary care physician. How will CMS educate patients to select a "main doctor?" Also, many beneficiaries may not have access to a computer and will not understand how to navigate the Medicare.gov site. Utilizing a 1-800 number creates issues for older adults that are hard of hearing. The AAFP suggests using claims submitted by providers using the codes for initial Medicare visits, annual wellness visits, chronic care management, and advanced care planning as a means to assign beneficiaries. This process would be less cumbersome to administer by CMS and simpler and more streamlined approach for beneficiaries and the primary care physician.

Proposal

CMS seeks input about making an automated mechanism available for beneficiaries to voluntarily align with the provider or supplier they believe is responsible for coordinating their care. This begins starting early in 2017 for assigning beneficiaries to ACOs in all three tracks for the 2018 performance year. In tracks 1 and 2, voluntarily alignment will occur on a quarterly basis.

AAFP Response

While AAFP supports prospective assignment of beneficiaries, the AAFP has concerns with voluntary alignment as stated above. It would be challenging for beneficiaries to self-assign. Since there is a lack of research on effective patient attestation approaches, CMS should begin with a pilot to understand the burden on primary care practices and ability to engage beneficiaries, as well as study the impacts on ACO performance and beneficiary health relative to ACOs that are not in the pilot. In order to improve the likelihood of success, prior to roll out, the AAFP strongly suggests this be pilot-tested and implemented on a very small scale to track 1 participants. This is a more appropriate approach since track 1 does not have downside risk associated with it. A rapid cycle PDSA on a smaller scale to track 1 participants would help test this approach and CMS could make changes to the marketing and education of beneficiaries to increase beneficiary participation and ensure accuracy of the beneficiary's selection of a "main doctor."

Proposal

Feedback is requested from CMS that if a beneficiary aligns with a provider or supplier who is not participating in an ACO as an ACO professional, the beneficiary would not be eligible for alignment to an ACO. This is the case even if the beneficiary would have otherwise been assigned to an ACO under the claims-based approach.

AAFP Response

Patients can and do make mistakes allowing the physician no control over cost. Patients may not understand the impact of fragmented care and beneficiaries can access care wherever they choose. CMS should consider a side-by-side comparison in a small-test market running self-

Acting Administrator Slavitt Page 52 of 56 August 19, 2016

assignment verses claims for alignment to an ACO. After review and sharing of results, CMS could determine the most appropriate approach.

Proposal

If the automated voluntary alignment process is not operationally ready for implementation under the proposed timeframe, CMS would implement a manual voluntary alignment process for track 3 ACOs only. If it is determined (by no later than spring 2017) that an automated voluntary alignment process is not ready for implementation to allow beneficiaries to voluntary align with the ACO across all three tracks for the 2018 performance year, then CMS would implement an alternative manual voluntary alignment process. This process would allow beneficiaries to align with track 3 ACO for the 2018 performance year until such time that an automated process is available. Regardless of the process, manual or automatic, CMS is proposing to begin to incorporate beneficiary attestation into the assignment methodology for Shared Savings Program effective for assignment for the 2018 performance year.

AAFP Response

The AAFP is very concerned that a manual process would increase the likelihood of errors. If a tested automated voluntary alignment for attestation is not operational, CMS should not implement a manual process. The implementation of a new approach on such a large scale will not result in success. Implementation needs to be delayed or tested on a small scale with track 1 participants to improve processes and ensure success before program-wide implementation could be accomplished.

Proposal

CMS is seeking comments on whether voluntary alignment is an appropriate mechanism for assigning beneficiaries retrospectively to an ACO. Specifically, is it appropriate to assign a beneficiary to an ACO professional whose services include being responsible for the overall care, but the beneficiary did not receive a plurality of primary care services from the ACO professional in the ACO during the performance year? CMS seeks comment on whether including voluntary alignment information in the assignment algorithm should be discretionary. That is to ask whether the ACO should be permitted to opt in or out of voluntary alignment.

Further, should CMS exclude a beneficiary from an ACO prospective assignment list for a performance year if later during the performance year the beneficiary voluntarily aligns with a health care provider that is not an ACO professional in the ACO? Under the proposed automated voluntary alignment, a beneficiary designation of a health care provider is responsible for coordinating their overall care and would stay, in effect, until the beneficiary chooses to make a subsequent change. CMS feels requiring the beneficiary to update his or her designation to be burdensome.

AAFP Response

The AAFP supports beneficiary attestation to help facilitate patient engagement. The ability to opt in or out of voluntary alignment gives the ACO discretion to choose the best path for success in the management of their patient population. However, we have concerns this methodology has not been fully tested and been proven successful. This is especially concerning for MSSP track 3 where the risk is the highest. Beneficiaries that seek care outside of their "main doctor," move, or vacation in different locations through the year poses a threat to providing quality, cost-effective care in this population.

To make this proposal successful, CMS should consider the following:

Acting Administrator Slavitt Page 53 of 56 August 19, 2016

- Pilot this proposal in a small market, taking successes, challenges, and barriers into consideration prior to roll out in a larger population.
- Check self-assignment against the current claims-based approach.
- Massive education with the same messaging from CMS, the media, and the beneficiary's "main doctor" would improve the likelihood of success of this initiative.
- Work with other payers to standardize the terms to identify the beneficiary's "main doctor."
- Codes that identify the "main doctor," such as chronic care management, transitional
 care management, advanced care planning, and annual wellness visit. This should be
 considered in a pilot program to fully test this initiative.

3. Skilled Nursing Facility (SNF) 3-Day Rule Waiver Beneficiary Protections Summary

In the June 2015 final rule, CMS limited the waiver to ACOs in track 3. Under the prospective assignment methodology used in track 3 (other than through exclusions), beneficiaries are assigned in advance to the ACO for the entire performance year. All ACOs electing to participate in track 3 will be offered the opportunity to apply for a waiver of the skilled nursing facility (SNF) 3-day rule. In general, CMS requires the SNF to inform a beneficiary in writing about services and fees before the beneficiary is admitted to the SNF.

There is no way for the SNF affiliate to know in real time that a beneficiary continues to be prospectively assigned to the ACO. The SNF affiliate must rely on the assignment list (provided quarterly); exclusion lists (provided by CMS to the ACO); and communicated by the ACO to its SNF affiliates, ACO participants, and ACO providers/suppliers. The beneficiary does not receive notification regarding his or her eligibility for the SNF 3-day rule waiver prior to receiving SNF services under the waiver.

In order to protect beneficiaries from potential financial liability related to the SNF 3-day rule, CMS will establish a similar 90-day grace period for beneficiaries in MSSP. This would protect beneficiaries who were prospectively assigned to a waiver-approved ACO at the beginning of the performance year, but later excluded from assignment to the ACO. CMS feels there would be very few instances where it would be appropriate for SNF services to qualify for payment under the 90-day grace period. CMS would make payments for SNF services furnished to such a beneficiary under the terms of the SNF 3-day rule waiver if specific conditions were met.

AAFP Response

The AAFP appreciates that the SNF 3-day rule has been difficult to administer, and at times has placed beneficiaries responsible for the costs of SNF services they thought were covered. AAFP is in agreement with the SNF 3-day waiver 90-day grace period as proposed. A grace period less than 90 days would result in errors and be difficult for all parties.

4. Technical Changes

a. Financial reconciliation for an ACO that falls below 5,000 beneficiaries *Summary*

Currently, regulations indicate that if at any time during the performance year an ACO-assigned population falls below 5,000, the ACO may be subject to actions as described in 425.216 and 425.218. The regulations further indicate that while under a corrective action plan (CAP), the ACO remains eligible for shared savings and losses and the minimum savings rate (MSR) and minimum loss rate (MLR) (if applicable) are set "at a level consistent with number of assigned beneficiaries." An ACO participating in risk-based tracks are not limited to financial reconciliation

Acting Administrator Slavitt Page 54 of 56 August 19, 2016

under a variable MSR/MLR that is based on the number of assigned beneficiaries. In June 2015, CMS finalized a policy that provides ACOs under two-sided performance-based risk contracts an opportunity to choose among several options for establishing their MSR/MLR. The ACO may choose from a menu of non-variable MSR/MLR options. In the event an ACO falls below the beneficiary threshold at the time of financial reconciliation, the ACO participating under the two-sided risk track would be eligible to share in savings or losses and the MSR/MLR will be set at a level consistent with the choice that the ACO made at the start of the agreement period.

AAFP Response

The AAFP is concerned that if CMS implements patient attestation and the numbers fall below 5,000 beneficiary thresholds, the ACO may be held accountable for a panel that does not reflect accurate attestation. The AAFP does appreciate that CMS understands that a beneficiary population may fall below the threshold and intends to put this change in place for those ACO entities.

b. Requirement of Merged or Acquired TINs Summary

To take into account claims billed by the TINs of practices that have been acquired by sale or merger for the purpose of meeting the minimum assigned beneficiary threshold, CMS proposes establishing a more accurate financial benchmark and determining the prospective or preliminary prospective assignment list for the upcoming performance year as outlined in this guidance. A technical change to 425.204 (g) is to clarify that the merged acquired TIN is not required to remain Medicare enrolled after it has been merged or acquires and is not responsible for billing Medicare.

AAFP Response

The AAFP supports this proposal as written.

III.L. Value-Based Payment Modifier and Physician Feedback Program Summary

Starting in 2015, CMS was required to establish a value-based payment modifier (VBPM) and apply it to specific physicians and groups of physicians. CMS is required to apply the value modifier (VM) to all physicians and groups of physicians by January 1, 2017. The VM is required to be budget neutral.

In the 2016 final Medicare physician fee schedule, CMS discussed how MACRA stipulates that the VM shall not be applied to payments for items and services furnished on or after January 1, 2019, since MACRA establishes that the Merit-Based Incentive Payment System (MIPS) shall apply to payments for items and services furnished on or after January 1, 2019.

In the 2017 proposed Medicare physician fee schedule (PFS), the agency proposes to update the VM informal review policies and establish how the quality and cost composites under the VM would be affected if unanticipated program issues arise. In addition, CMS is proposing to permit eligible professionals that participate in a Medicare Shared Savings Program to report to the PQRS outside the ACO for purposes of the PQRS payment adjustment.

AAFP Response

Acting Administrator Slavitt Page 55 of 56 August 19, 2016

We appreciate that CMS is not proposing any significant changes to the reporting requirements for the VM, PQRS, and EHR Incentive Program, because 2016 is the last reporting year for those three programs.

We appreciate that CMS is proposing to update the VM informal review policies and establish how the quality and cost composites under the VM would be affected for the CY 2017 and CY 2018 payment adjustment periods "in the event that unanticipated program issues arise." However, the AAFP is extremely alarmed since CMS has already struggled implementing this program, and we are gravely concerned that the need for proposed updates to the "informal" review of data are indicative of a trouble-ridden, overly-complicated, and error-prone system. Much of the proposed rule's discussion in this area sounds ominous and appears to foreshadow future problems with CMS collecting and properly interpreting data used to calculate the VM.

The proposed rule outlines the "diversity and magnitude of the errors," which simply do not bode well for CMS properly building the MIPS track using principles and processes in the PQRS and VM programs. It is disturbing that CMS was unable to determine the accuracy of PQRS data submitted via EHR and QCDR for the 2014 performance period due to data integrity issues We appreciate the agency acknowledging and attempting to address these tenacious problems.

Likewise, we appreciate that CMS acknowledges that these previous errors "...create uncertainty for groups and solo practitioners about their final VM payment adjustment making it difficult for them to plan and make forecasts." We agree with the agency's disclosure that:

Due to the volume and complexities of the informal review issues, the inconsistency of available PQRS data to calculate a TIN's quality composite, the case-by-case nature of the informal review process, and the condensed timeline to calculate an accurate VM upward payment adjustment factor, we believe that we need to update the VM informal review policies and establish in rulemaking how the quality and cost composites under the VM would be affected if unanticipated issues arise (for example, the program issues described above, errors made by a third-party such as a vendor, or errors in our calculation of the quality and/or cost composites).

We support that CMS recognizes these multiple problems and is creating ways to resolve them as the agency gains experience with collecting data used to calculate the VM.

The agency admits it does not know yet how the VM would impact solo practicing physicians and those in groups with 2+ eligible professionals, but indicates that information will be published in the final rule. If the proposed policy goes into effect and gives a zero adjustment to those that may have been previously penalized, it would reduce the size of the bonus to high performers. We support this initial approach and encourage CMS to revisit it as the agency gains further experience with the program.

In section III.L.b of the proposed rule, CMS proposes to use the data reported to the PQRS by the eligible professional(s) outside of the ACO to determine whether the TIN would fall in category 1 or category 2 under the VM. CMS proposes to apply the two-category approach (finalized for the 2018 VM) based on participation in the PQRS by groups and solo practitioners to determine whether groups and solo practitioners that participate in a Shared Savings Program ACO, but report to the PQRS outside of the ACO, would fall in category 1 or category 2 under the VM. The AAFP supports these proposals.

Acting Administrator Slavitt Page 56 of 56 August 19, 2016

Finally, CMS recognizes that groups and solo practitioners taking advantage of a secondary reporting period for the 2017 VM will have missed the deadline for submitting an informal review request for the 2017 VM. Therefore, the agency proposes the informal review submission periods for these groups and solo practitioners would occur during the 60 days following the release of the Quality and Resource Use Reports (QRURs) for the 2018 VM. The AAFP also supports this proposal.

We appreciate the opportunity to comment on the 2017 proposed Medicare physician fee schedule. For any questions you might have, please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Robert L. Wergin, MD, FAAFP

12 Weyn MD

Board Chair