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September 8, 2015

Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 310G.05, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

RE: File code CMS-1631-P

Dear Mr. Slavitt:

The Medicare Payment Advisory Commission welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016,” published in the *Federal Register*, vol. 80, no. 135, pages 41686 to 41966. We appreciate your staff’s ongoing efforts to administer and improve payment systems for physician and other health professional services, particularly considering the competing demands on the agency.

Our comments address the following provisions in the proposed rule:

- Improved payment for the professional work of care management services
- Valuation of specific codes
- Advance care planning services
- Chronic care management services for federally qualified health centers and rural health clinics
- Payment for biosimilars under Medicare Part B
- Physician Compare
- Quality programs for clinicians: Physician Quality Reporting System, value modifier, and the Merit-Based Incentive Payment System
- MACRA: Alternative payment models
- Physician self-referral updates

### **Improved payment for the professional work of care management services**

In the proposed rule, CMS reiterates its commitment to supporting primary care and its recognition that care management is one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth. CMS notes that because the current evaluation and management (E&M) codes in the fee schedule for physicians and other qualified health professionals (PFS) were designed with an overall orientation toward discrete services and procedures that have a definite beginning and end, those E&M codes may not reflect all the services and resources involved with furnishing certain kinds of care, particularly ongoing, comprehensive, coordinated care management for a panel of patients.

With the goal of improving the valuation of care management within Medicare's statutory structure for the PFS, the proposed rule—while not including specific proposals on the topic—requests stakeholder comments to assist CMS in developing proposals for rulemaking in 2016. In particular, CMS requests comments on whether the fee schedule should have codes that could be used in addition to, not instead of, the current E&M codes to recognize the different resources (particularly in cognitive work) specific to primary care and other cognitive specialties involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the existing E&M codes.

#### *Comment*

The Commission is concerned that the fee schedule provides inadequate support and is an ill-suited payment mechanism for primary care particularly and cognitive care more generally. Because of those concerns, the Commission recommended that Congress extend the primary care add-on payment using a per beneficiary payment mechanism. The Commission also supported the establishment of the chronic care management (CCM) code since—like a per beneficiary payment—it is also a beneficiary-centered payment approach rather than a service-oriented approach. The Commission prefers those beneficiary-centered approaches over the establishment of additional E&M codes that attempt to pay for each distinct care coordination activity.

#### *The fee schedule provides inadequate support for primary care*

The Commission shares CMS's concern about the current state of support for primary care. Primary care is essential for creating the coordinated health care delivery system of the future, but the Medicare fee schedule undervalues primary care relative to procedurally oriented care. Even though the relative payment for primary care services under the fee schedule has increased over the last decade, compensation for primary care practitioners is still substantially less than that of other specialties. For example, compensation in 2012 for nonsurgical procedural specialties (such as cardiology, dermatology, gastroenterology, and pulmonary medicine) and for radiology were on average \$475,000 and \$469,000, respectively, more than double that of the \$222,000 average for primary care specialties. Disparities in compensation could deter medical students from choosing primary care practice, deter current practitioners from remaining in primary care practice, and leave primary care services at risk of being underprovided.

*The fee schedule is an ill-suited payment mechanism for primary care*

The Commission has also become increasingly concerned that the fee schedule is an ill-suited payment mechanism for primary care. The fee schedule is oriented toward discrete services and procedures that have a definite beginning and end. In contrast, ideally, primary care services are oriented toward ongoing face-to-face and non-face-to-face care coordination for a panel of patients. Some patients in the panel will require the coordination of only preventive and maintenance services. Others will have multiple complex chronic conditions and will require extensive care coordination. The fee schedule is not well designed to support these behind-the-scenes care coordination activities, and it is precisely these activities that will be crucial in the move to a more coordinated and efficient health care delivery system in the future.

*The Commission recommended a per beneficiary payment for primary care*

Because of the imbalance in the fee schedule and the need for care coordination, the Commission recommended that Congress extend the primary care add-on payment using a per beneficiary mechanism. The Commission was motivated by the expiration of the Primary Care Incentive Payment Program (PCIP)—a service-oriented payment program—at the end of this calendar year. Replacing PCIP with a per beneficiary payment could serve as another step in moving Medicare’s payment for primary care from a service-oriented fee-for-service (FFS) payment approach toward a beneficiary-centered payment approach that encourages care coordination, including the non-face-to-face activities that are a critical component of care coordination.

*The Commission prefers beneficiary-centered payment approaches rather than paying for each distinct care coordination activity*

The Commission is not supportive of creating additional E&M codes for each distinct care coordination activity. The transaction costs of submitting and processing claims for each activity would be administratively burdensome for practitioners and CMS. Moreover, it would incentivize practitioners to increase the volume of the activities with new codes rather than incentivizing the provision of the right balance of care coordination activities for providing efficient and high-quality care. Instead of additional codes for new services, we believe CMS should pursue a per beneficiary payment mechanism for these kinds of services. Reimbursement paid through a per beneficiary payment provides practitioners with more flexibility to optimize the delivery of care. We also prefer the CCM code established by CMS, which—like the Commission’s recommended per beneficiary payment—also provides a payment linked to a patient. The Commission views the CCM and the Commission’s recommended per beneficiary payment as complementary.<sup>1</sup>

Our comments on additional E&M codes also represent our perspective on the discussion in the proposed rule about “Collaborative Care” for beneficiaries with common behavioral health conditions. Briefly, CMS describes “Collaborative Care” as care that is provided by a primary care team, consisting of a primary care provider and a care manager, who both work in collaboration with a psychiatric consultant, such as a psychiatrist. While the Commission is concerned about Medicare

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<sup>1</sup> See page 106 of Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC.

beneficiaries with behavioral health conditions, and while the Collaborative Care model may prove to be a quality-improving and cost-effective option, the Commission prefers beneficiary-centered payment approaches that allow practitioners flexibility in addressing the needs of their patient population rather than payment approaches that are tied to a particular care model design. Therefore, as with our comments above on additional codes for E&M, the Commission prefers reimbursement to be paid in the form of a per beneficiary payment established by CMS.

### **Valuation of specific codes**

Under this section, CMS proposes changes to the relative value units (RVUs) for external beam radiation treatment services. The cost of the equipment used to deliver radiation treatment (a linear accelerator, or linac) is a key factor in determining the payment rates for these services. CMS calculates the equipment cost for a specific service by multiplying the assumed number of minutes it is used for each service by the per minute cost of the equipment. The per minute cost of the equipment is based on the equipment's estimated useful life, purchase price, and the number of hours per week that CMS assumes the equipment is used. CMS's default assumption for most types of equipment—including a linac machine—is that they are used 50 percent of the time that a physician's office is open for business, or 25 hours per week.

CMS proposes to increase the equipment use rate assumption for linac from 50 percent to 70 percent. The American Medical Association's (AMA's) Current Procedural Terminology (CPT) Editorial Panel introduced new codes for external beam radiation treatment services that replaced older codes, and the Relative Value Scale Update Committee (RUC) recommended values for these new codes. Under the previous CPT codes, CMS assumed that different types of linac machines were used to provide different types of radiation treatment. For the new CPT codes, however, the RUC has recommended that CMS assume that a newer type of linac is used to furnish all types of radiation treatment.

Under the prior assumption that the newer linac machine was only used for one type of radiation treatment, CMS estimates that this type of linac accounted for 45 million minutes of radiation treatment for all beneficiaries per year. Under the new assumption that the newer type of linac is used for all radiation treatment services, CMS estimates that this type of linac would account for 65 million minutes of radiation treatment per year. This represents a 45 percent increase in the total amount of time that the newer linac equipment is in use. To account for this increased use, CMS proposes to raise the equipment use rate assumption for this type of linac from 50 percent to 70 percent and to phase in this change over two years. The savings from this change would be budget neutral within the fee schedule. CMS believes that this proposed change in the use rate for this type of equipment is conservative because data from a staffing survey conducted by the American Society of Radiology Technicians support a use rate higher than 70 percent.

### *Comment*

Although we have not independently validated the data that CMS presents to support its proposed change, we agree in principle with CMS's proposal to increase the equipment use rate assumption for the newer type of linac. If practitioners increase (or decrease) their use of a particular type of

equipment, the use rate assumption for that equipment item should also change. Ideally, CMS would use a normative standard for this assumption based on an expectation that efficient providers would not purchase expensive equipment unless they could use it at close to full capacity (i.e., at a rate higher than 70 percent). In the context of expensive diagnostic imaging equipment, we recommended that CMS adopt a normative standard in which providers are assumed to use these machines at close to full capacity. However, we recognize that CMS is required by statute to use “actual data” on equipment use to calculate RVUs, such as the data cited in the proposed rule.

### **Advance care planning services**

The Institute of Medicine (IOM) describes advance care planning as referring to the whole process of discussion of end-of-life care, clarification of values and goals, and embodiment of preferences through written documents and medical orders. The definition makes a distinction between advance care planning and advance directives (documents and medical orders written or completed by patients such as living wills) with advance directives making up one component of the broader concept of advance care planning.<sup>2</sup>

For calendar year 2016, CMS is proposing to pay separately for advance care planning services by adopting two new physician-developed CPT codes created by the CPT Editorial Panel, valued by the Relative Value Scale Update Committee (RUC), and officially released by the AMA on January 1, 2015:

- CPT code 99497 for the first 30 minutes of face-to-face advance care planning with the physician or other qualified health professional and the patient, family member(s) and/or surrogate; and
- Add-on CPT code 99498 for each additional 30 minutes.

CMS also proposes to adopt the values RUC recommended for these codes (work RVUs, time, and direct physician expense inputs).

### *Comment*

Advance care planning may influence quality of care and patient and family satisfaction by allowing patients to maintain control of their care. Many people nearing the end of life may not be physically or mentally capable of making their own care decisions. If patients have not stated the kind of care they want in advance, care givers and family members may not be able to honor patients’ preferences. Therefore, the Commission is supportive of separate payment for advance care planning services. Components of the service and documentation requirements should be established to ensure the effective and appropriate use of the services.

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<sup>2</sup> Institute of Medicine 2014. *Dying in America: Improving quality and honoring individual preferences near the end of life*. Washington, DC, The National Academies Press.

## **Chronic care management services for federally qualified health centers and rural health clinics**

CMS is proposing to allow federally qualified health centers (FQHCs) and rural health clinics (RHCs) to receive payment for CCM services. Generally, FQHCs and RHCs only bill through the FQHC and RHC payment systems and do not bill under the fee schedule, except in certain circumstances in which a service is not part of the FQHC or RHC benefit but is otherwise covered by Medicare.

A CCM code became payable under the fee schedule effective in 2015 for beneficiaries with two or more chronic conditions, and it covers 20 minutes of non-face-to-face services per month provided on behalf of the beneficiary. The provider billing for the CCM code must obtain beneficiary consent to bill for the code. Only one CCM code is payable per month per beneficiary.

CMS is proposing to add a payment to the per diem payment (for FQHCs) and the all-inclusive rate (for RHCs) when a FQHC or RHC provides CCM. The FQHC and RHC would not bill for the CCM code through the fee schedule but would receive the payment directly through the FQHC and RHC payment systems.

### *Comment*

The Commission strongly supports the development of payment models that further comprehensive primary care and chronic care management. However, we are concerned that the policy to permit FQHCs and RHCs to bill CCM services could result in higher spending for services already included in existing federal funding streams.

We raise two issues. First, existing Medicare payment and the Public Health Service Act grants for FQHCs may already contemplate the type of care coordination that is part of the CCM code. Second, CMS is proposing to have FQHCs and RHCs bill through their payment system for CCM services, which means that the additional spending does not trigger a budget-neutrality adjustment.<sup>3</sup> This is in contrast to the CCM provided through the fee schedule, which was subject to a budget-neutrality adjustment when the code was introduced.

The Medicare program currently pays for FQHCs and RHCs using a single encounter-based payment for a bundle of services. For FQHCs, CMS has stated in prior guidance that “The PPS is designed to reflect the cost for all the services associated with a comprehensive primary care visit, even if not all the services occur on the same day.”<sup>4</sup> In addition, the regulations for FQHCs receiving Section 330 Public Health Service Act grants state that FQHCs must:

Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center’s catchment area.<sup>5</sup>

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<sup>3</sup> Under Section 1848(c)(2)(B)(ii)(II) of the Social Security Act, adjustments to the fee schedule’s relative values cannot exceed \$20 million, which applies a budget-neutrality adjustment to new and revised codes under the fee schedule.

<sup>4</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Specific payment codes for the federally qualified health center prospective payment system (FQHC PPS). April 1.

<sup>5</sup> 42 CFR 51c.

These statements could be interpreted as indicating that FQHCs and RHCs receive payments that already contemplate the type of comprehensive chronic care services that the CCM code describes.

CMS is proposing to add the payments to the FQHC and RHC payment systems, which will not trigger a budget-neutrality adjustment. The CCM payments through the fee schedule are offset, while the CCM payments through FQHCs and RHCs are not offset. The increase in spending is material: CMS estimates that the proposal would increase spending by \$2 billion over the next 10 years, with \$0.5 billion in beneficiary spending and \$1.5 billion in Medicare spending.

### **Payment for biosimilars under Medicare Part B**

The NPRM discusses how the average sales price (ASP) payment system will handle biosimilar products. CMS proposed that all biosimilar products that rely on a common reference product's biologics license application under the Food and Drug Administration's (FDA's) approval process will be grouped into the same billing code and receive the same payment rate. This means that all biosimilar products associated with a particular reference product will be paid under a single billing code and receive a payment equal to 100 percent of the weighted average ASPs for the biosimilar products plus a constant dollar add-on equal to 6 percent of the reference product's ASP. This proposal does not address payment for the reference biologic. The reference biologic would remain in its own billing code and continue to be paid 106 percent of its own ASP.

For a product to obtain FDA approval as a biosimilar, the product must be shown to be highly similar to the reference product (notwithstanding minor differences in clinically inactive components) and have no clinically meaningful differences from the reference product in terms of safety, purity, and potency. To obtain FDA approval as a biosimilar, the manufacturer must demonstrate biosimilarity based on data from analytical studies, animal studies, and a clinical study or studies, unless FDA determines some of these components are unnecessary in the case of a particular product.

#### *Comment*

The Commission believes that Medicare should pay similar rates for similar care. With respect to biosimilar products, this principle may suggest paying the reference biologic and the biosimilar products under the same billing code. (This would mean Medicare's payment to the physician would be the same for the reference biologic and biosimilar products and be equal to ASP plus 6 percent determined based on the combined sales for both the reference and biosimilar products). Such an approach may have several benefits that merit consideration.

Reference biologics receive patent protection and 12 years of exclusivity before a biosimilar can enter the market, during which time the reference biologic faces little price competition. Once the patent and exclusivity periods elapse, competitive biosimilar manufacturers are able to enter the market facing less risk than the reference biologic manufacturer and able to produce a similar product at lower cost. Once a biosimilar enters the market, paying the biosimilar and the reference biologic the same rate would be expected to spur more price competition than paying each of these

products separate rates. Under a single payment rate, the biosimilar and reference products would all face the same incentive to compete based on price and quality and generate the best price for beneficiaries (who are liable for 20 percent cost sharing for Part B drugs) and taxpayers. The effect of including the reference product and biosimilars in a single billing code was considered by the Congressional Budget Office in 2008 when they estimated that an abbreviated approval process for biosimilars would generate more savings if the reference product and biosimilars were assigned to the same Medicare Part B billing code rather than separate billing codes.<sup>6</sup>

However, it appears that CMS may not currently have the statutory authority to pay the reference biologic under the same billing code as biosimilar products. Instead, CMS has proposed paying all biosimilar products associated with a particular reference product at the same rate (that is, paid for under a single billing code at a rate equal to 100 percent of the weighted average ASP for the biosimilars plus a constant dollar add-on equal to 6 percent of the reference product's ASP).

From the perspective of paying similar rates for similar care, we believe that CMS's proposal to pay the same rate for all biosimilars associated with a specific reference product is reasonable. If multiple biosimilar products exist for a particular reference biologic, each biosimilar product would have obtained FDA approval as being highly similar to the reference biologic. Using a constant dollar add-on based on the reference product for the biosimilars' payment helps put the biosimilars and reference product on similar competitive footing. Of course, the physician would continue to be responsible for the selection and administration of the biologic and would continue to decide which product is appropriate for a given patient.

Putting all biosimilars in the same billing and payment code would be expected to spur more price competition among biosimilars than if each biosimilar received its own billing and payment code. As a result, CMS's proposal would be expected to lead to lower prices, which would mean a better price for beneficiaries and taxpayers, as well as potentially greater access to these products. The proposal may also lay the ground work to consider including the reference biologic and biosimilars in the same billing and payment code in the future as discussed above.

There have been concerns raised by the industry that moving to a single code for biosimilars will undercut the willingness of biosimilar manufacturers to enter the market. The Commission strongly supports the development of a biosimilar market. Pharmaceutical prices are expected to increase, making the Medicare program less sustainable and straining beneficiary resources – a competitive biosimilar market is vital. Because the market for many reference biologics is large, biosimilar manufacturers would be expected to have a strong incentive to produce a lower cost product in order to capture profitable market share from the reference biologic. And the biosimilar manufacturers will face less risk (than the reference manufacturer) in bringing their products to market. These basic market dynamics would be expected to result in biosimilar manufacturers being willing to enter the market.

Nonetheless, some of the biosimilar manufacturers argue that the upfront costs of a biosimilar are so high that forcing them to compete with other biosimilars via a single billing code will undercut

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<sup>6</sup> Congressional Budget Office. 2008. Budget options, volume one: Health care.



the development of this market. In other words, separate billing codes will artificially keep prices higher than they otherwise would be under a single billing code. And in turn, these higher prices will encourage biosimilars to enter the market. The Commission believes that this argument – price protections will lead to stronger competition – is unsupported by a fact base and thus should be considered only if the biosimilar industry can present credible evidence regarding how their market is fundamentally different than other markets. Such evidence would be greatly strengthened if all biosimilar manufacturers were willing to be transparent about the costs and expected revenues associated with bringing their biosimilar products to market.

Finally, some stakeholders contend that there are benefits to being able to track which biosimilar product was given to a particular beneficiary through separate Healthcare Common Procedure Coding System (HCPCS) codes in administrative claims data for the purposes of monitoring adverse events. FDA tracks adverse events through the FDA's Adverse Events Reporting System, which relies on reports from manufacturers, providers, and patients. To complement this approach, the FDA is developing the Sentinel System to allow the agency to request information from data partners (such as academic medical centers, health care systems with electronic health records, and federal partners such as CMS, the Department of Veterans Affairs, and the Department of Defense) to evaluate potential safety. If the Secretary concludes that Medicare claims data identifying biosimilars could be helpful to supplement these efforts, we believe CMS could develop a way that would distinguish these products on claims without the creation of separate HCPCS codes (e.g., through reporting of this information via National Drug Codes (NDCs), modifiers, or other claims fields).

### **Physician Compare**

Presently, Physician Compare contains providers' names and contact information, education and training, certification and specialty information, whether the provider accepts assignment, and whether the physician satisfactorily reported for the purposes of the electronic health record (eHR) payment adjustment or the Physician Quality Reporting System (PQRS) payment adjustment. Additional detail on the specific quality measures for large physician groups who use one of the PQRS reporting mechanisms is available through a separate downloadable file.

In this rulemaking, CMS is proposing to add a check mark indicating whether a clinician has received an upward adjustment through the value-based payment modifier, starting with the 2016 reporting year. CMS has also requested comments about adding additional data in the future to the Physician Compare website, including Open Payments information (financial relationships between physicians and health care manufacturing companies), all quality measures that clinicians can report through the various PQRS methods, payment and utilization data, and Medicare Advantage (MA) network information as well as MA quality.

### *Comment*

The Commission supports making the quality measures that clinicians report to CMS public in an easily accessible way. However, we agree with CMS's concern that too many measures on Physician Compare without context may mislead consumers seeking information to help them

choose a provider. We support CMS's stated intent to study which kinds of information help beneficiaries make choices about their clinician and to use the findings to help guide the information that is included on the Physician Compare website.

We also support CMS linking to the Open Payments data from the individual Physician Compare web pages and also providing a link to the spending and volume data. Providing information through Physician Compare about which providers are in MA networks could also be of high value to beneficiaries. However, CMS should only do so if they can ensure that it reflects accurate information available regarding physician participation in MA plans.

### **Quality programs for clinicians: Physician Quality Reporting System, value modifier, and the Merit-Based Incentive Payment System**

Under current law, CMS oversees three key quality measurement programs for physicians and other health professionals: PQRS, the value-based payment modifier (value modifier), and payment adjustments for the meaningful use of electronic health records (eHR meaningful use). In this NPRM, CMS is proposing policies for the 2018 value modifier and the 2018 PQRS payment adjustment, which will both be based on 2016 reporting, hence their inclusion in this rule.<sup>7</sup>

**PQRS:** Under current law, eligible professionals who do not satisfactorily report under the PQRS will receive a payment adjustment of –2 percent beginning in 2015, through 2018.<sup>8</sup> To avoid a payment adjustment in 2018, eligible professionals must submit data on nine PQRS measures in 2016, covering at least three of the National Quality Strategy domains. If fewer than nine measures apply to an eligible professional, they must report on the measures that apply to them for more than 50 percent of their patients.

Presently there are six different ways clinicians can report PQRS measures: claims, qualified registry, eHR (direct eHR products and eHR data submission vendor products), the Group Practice Reporting Option (GPRO) web interface, certified survey vendors (for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS survey), and qualified clinical data registries (QCDRs).

In this rulemaking, CMS outlines:

- a clarification of the definition of *eligible professional* for the purposes of PQRS;
- the requirements for qualified registries and QCDRs;
- the process for successfully reporting in 2016 to avoid the 2018 payment adjustment;
- the addition of a CAHPS beneficiary survey for large groups reporting through the GPRO;
- a call for PQRS measures; and
- additions, deletions, and changes to the measure set for PQRS.

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<sup>7</sup> Eligible professionals who do not meet the meaningful use of electronic health record standard will receive a payment adjustment of –2 percent in 2016 and at least –3 percent in 2017 and 2018 (and could reach –4 percent in 2018).

<sup>8</sup> In 2018, the individual payment adjustments under meaningful use, PQRS, and the value modifier will be phased out, in preparation for the Merit-Based Incentive Payment System (MIPS) payment adjustments to start in 2019.

**Value modifier:** Current law requires that CMS develop and apply a value-based payment modifier (value modifier) to individuals billing under the fee schedule. This value modifier must adjust fee schedule payments for each clinician based on the quality of care provided to Medicare beneficiaries as compared with the cost of that care. By law, the value modifier first applied to payments in 2015, and using a phased approach starting with the largest physician practices, will apply to all physicians and groups of physicians in 2017.

In this rule, CMS lays out proposed rules for the 2018 value modifier.<sup>9</sup> Specific proposals include:

- clarification of the group size calculation;
- exclusion of non-clinical professionals from the value modifier;
- clarification of policy in situations where eligible professionals also participate in an accountable care organization or Innovation Center model;
- establishing thresholds for the maximum positive and negative value modifier adjustments in 2018; and
- other technical changes to the cost and quality components of the 2018 value modifier calculation.

The value modifier is calculated in two steps for each clinician or group at the tax identification number level. First, an eligible professional must successfully report on a minimum number of quality measures through PQRS. Those who do not successfully report through PQRS are subject to an automatic negative payment adjustment under the value modifier (in addition to the PQRS penalty).

<b>Table 1. Measures included in the value modifier</b>	
<b>Quality measures</b>	The PQRS measures reported by the clinician
	Patient experience (CAHPS measures)
	Claims-calculated measure: all-cause readmissions
	Claims-calculated measure: potentially preventable admissions (acute conditions)
	Claims-calculated measure: potentially preventable admissions (chronic conditions)
<b>Cost measures</b>	Per capita costs: all beneficiaries
	Per capita costs: beneficiaries with diabetes
	Per capita costs: beneficiaries with coronary artery disease
	Per capita costs: beneficiaries with chronic obstructive pulmonary disease
	Per capita costs: beneficiaries with heart failure
	Medicare spending per beneficiary (MSPB)

Note: PQRS (Physician Quality Reporting System). CMS may elect to not use some measures for certain clinicians if there are insufficient numbers. Only large groups must report the CAHPS measures.

Clinicians who do successfully report PQRS measures then move to the cost and quality tiering process (based on the measures in Table 1). The quality and cost measures are risk adjusted, and there is an attribution process for the claims-based measures. Clinicians' value modifiers are calculated based on their performance relative to others in the same specialty.

<sup>9</sup> CMS proposes that in 2018 all physicians, nurse practitioners, clinical nurse specialists, physician assistants, and certified registered nurse anesthetists be subject to the value modifier. Practitioners outside of these categories (e.g., therapists) would not be subject to the value modifier.

<b>Table 2. Maximum value modifier payment adjustments, 2018</b>				
		<b>Low quality</b>	<b>Average quality</b>	<b>High quality</b>
<b>Physicians, NPs, PAs, CNSs, and CRNAs in groups with 10 or more eligible practitioners</b>	Low cost	0.0%	+2.0x	+4.0x
	Average cost	-2.0%	0.0%	+2.0x
	High cost	-4.0%	-2.0%	0.0%
	Didn't report PQRS	-4.0%	-4.0%	-4.0%
<b>Physicians, NPs, PAs, CNSs, and CRNAs in groups with 1-9 eligible practitioners</b>	Low cost	0.0%	+1.0x	+2.0x
	Average cost	-1.0%	0.0%	+1.0x
	High cost	-2.0%	-1.0%	-0.0%
	Didn't report PQRS	-2.0%	-2.0%	-2.0%

Note: NP (nurse practitioner), PA (physician assistant), CNS (clinical nurse specialist), CRNA (certified registered nurse anesthetist), PQRS (Physician Quality Reporting System). The amount of the total value modifier increase (x) will be calculated after the end of the performance period based on the penalties and downward adjustments. There is an additional payment adjustment of +1.0x for clinicians or groups with average or high quality who have an average beneficiary risk score in the 25<sup>th</sup> percentile or higher.

In 2018, the maximum value modifier payment adjustment will vary by group size, and there is also an additional payment increase for clinicians or groups who treat higher-severity patients (Table 2). The value modifier is budget neutral overall, and so the maximum increase for the highest-performing clinicians or groups will be calculated from the total penalties and downward adjustments.

**The Merit-Based Incentive Payment System:** The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) makes a number of significant changes to the quality programs for physicians and other health professionals. In addition to repealing the sustainable growth rate, it establishes two paths for statutory updates for providers billing under the fee schedule. Under the first path, providers who participate in a qualifying alternative payment model (APM) would be eligible for bonuses from 2019 through 2024 and higher updates thereafter.

Under the second path, the FFS path, providers who do not sufficiently participate in a qualifying APM would receive no updates between 2020 and 2025 and a lower update thereafter than those on the APM path. Providers on the FFS path would also be subject to a new Merit-Based Incentive Payment System (MIPS). The MACRA legislation would phase out the individual PQRS, value modifier, and eHR adjustments in 2018, but it allows CMS to retain the measurement process for use in the MIPS.

CMS would assess the performance of clinicians under the MIPS in four categories: quality, resource use, clinical practice improvement activities, and meaningful use of certified eHR technology. Each MIPS-eligible professional would receive a composite score, using weights specified in the statute for each category. Each professional's MIPS score would be measured against a performance threshold and would result in an upward, downward, or neutral adjustment to their payments. The maximum MIPS payment adjustment is established in the law (Table 3).

These basic MIPS adjustments are to be budget neutral. There is also an additional appropriation for eligible professionals who perform in the highest tier of performance.

2019	4%
2020	5%
2021	7%
2022 and later	9%

*Comment*

The Commission appreciates the work that CMS has put into developing the various quality systems for clinicians. CMS in particular has made a concerted effort to synchronize reporting methods and measures across its programs—eHR, PQRS and value modifier. CMS has made significant strides in ensuring that most provider specialties have PQRS measures they can report and a range of ways to report.

We also appreciate the conceptual difficulty in developing systems of quality and resource use measurement for individual clinicians. Measurement of clinician performance is complex and complicated by the difficulty of attributing outcomes to clinician activities and the need for appropriate risk adjustment. A further complication is the reliability of quality measurement at the individual clinician level. Outcomes measures are more likely to reflect meaningful differences to patients, but these types of measures have poor reliability at the individual provider level. On the other hand, it is relatively straightforward for the program to measure processes of care, but these are less meaningful to patients and can reinforce the incentive to “do more services” inherent in FFS.

Consequently, the complexity of Medicare’s resulting quality measurement systems for clinicians cannot be overstated. Clinicians can report PQRS measures using six different methods, and presently there are around 300 PQRS measures. Further adding to the challenge is the requirement for CMS to develop an individual value modifier for nearly every single clinician billing under the fee schedule. In the first year of the value modifier, among those groups who did elect cost and quality tiering, CMS reported that 75 percent were assessed as average.<sup>10</sup>

It is unlikely that a system with this level of complexity will be effective at signaling high or low performance to the public and will not provide clinicians with the information that they need to improve their performance.

In previous comment letters and reports, the Commission has taken the view that this complexity is an indication that the efforts required to assess the performance of individual clinicians and redistribute payments across them may not be worth the resources and effort required.

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<sup>10</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. *2015 Value-Based Payment Modifier Program experience report*. Baltimore, MD: CMS.

The enactment of the MACRA legislation provides an opportunity to pause and reset expectations for Medicare's ability to assess clinician performance at the individual level. Consolidating the three clinician-level adjustments (eHR, PQRS, and value modifier) into one assessment system, which MACRA does, is a first step. We would urge CMS to not just rebuild the new MIPS assessment system on top of the existing PQRS measures and value modifier structure.

For clinicians who organize into or join groups that assume clinical and financial accountability for their patients, the Commission supports assessing performance on the basis of a small number of measures primarily focused on outcomes (such as potentially avoidable hospital admissions, emergency department visits, and readmissions) as discussed in our June 2014 Report to the Congress. But these population-based outcome measures might not be appropriate for adjusting FFS Medicare payments for services obtained from providers who have not explicitly agreed to be responsible for a population of beneficiaries.

So how can the program move forward? One option, foreshadowed by CMS's experience with the value modifier, is that the Medicare FFS program may only be able to identify extreme outliers in terms of cost or quality performance. No matter the level of effort applied, the national Medicare program is unlikely to develop a system that can classify more than a minority of clinicians as being significantly different than their peers.

A performance measurement framework like the MIPS could be a method for identifying these extreme and persistent outliers, for whom a payment adjustment might be appropriate. This approach may represent the most that can be achieved in terms of assessing performance for individual clinicians who are not organized into larger entities.

Adopting a streamlined approach to the quality measurement system for clinicians will allow a more rational use of resources and effort for both CMS and providers and, in our view, would not result in a degradation of quality. With such a streamlined approach, CMS could then turn its attention to other models of payment, such as the administration of the alternative payment model provisions of the law, where groups of providers could assume financial and clinical risk for patients and be assessed on a few key outcome measures.

### **MACRA: Alternative payment models**

In the NPRM, CMS has stated its intent to issue a request for information (RFI) as it develops policies on APMs. The questions in the RFI will include topics such as the criteria for assessing physician-focused payment models and the definition of nominal financial risk for eligible APM entities, among many others. In the NPRM, CMS also asks for comments on approaches to implementing any of the topics and comments on any other related concerns.

#### *Comment*

Beginning in 2019, eligibility for the 5 percent bonus for physicians and other health professionals will be contingent on participation in an APM. Thus, there will be great interest in the definition of those entities and what constitutes participation. The Commission will likely comment, in some

detail, on the topics that will be raised in the RFI and future rulemaking. At this point we limit ourselves to outlining some key policy considerations and a potential direction. Relevant questions include:

- Will the 5 percent bonus be sufficient to move providers out of FFS, or are other incentives such as regulatory relief in APMs needed?
- Will pressure in FFS be needed to move providers toward APMs?
- How large does the population served by the APM need to be to detect meaningful improvements?
- How can we ensure that measures used to assess APM performance are robust enough to detect changes and be understandable by clinicians?
- How should the program be set up to minimize the burden on providers and simplify administration by CMS?
- How should beneficiaries share in savings through APMs?
- How can the level of risk be sufficient to motivate change but not so great as to threaten clinician viability?
- How can the program ensure that the same savings are not shared multiple times, putting the financial status of the trust fund at risk?

CMS's decisions on these key policy questions will need to be considered in the context of both current technical limitations as well as the state of development of potential APMs.

An ideal model could incorporate the following elements:

- The APM is at risk for each beneficiary's total spending (Parts A, B and potentially D);
- There is a central APM entity that assumes the risk and can be identified;
- The risk is two-sided and sufficiently large to motivate improvement, and providers get regulatory relief;
- The APM is responsible for a large enough number of beneficiaries to ensure that CMS can detect changes in spending or quality with some certainty;
- The APM can be categorized as a standardized type of alternative payment model (so that CMS can certify groups of APMs as a class, rather than individually);
- Beneficiaries are attributed to only one APM; and
- The risk to the taxpayer and beneficiaries of excess spending is minimized.

This description is not intended to preclude other options; the Commission plans to consider a wide range of approaches. However, given the limits on current measurement techniques and the current status of development of APMs, we will be looking for a strong justification to move off of the elements described above. Further issues include the robustness of risk adjustment and the nature of the contract between CMS and the APM entities. The Commission looks forward to assisting CMS and the Secretary in working through these issues in the RFI and in future rule making.

### **Physician self-referral updates**

MACRA requires the Secretary, in consultation with the Office of Inspector General (OIG), to submit a report to the Congress on options for amending fraud and abuse laws and regulations to permit shared savings or gainsharing arrangements. The report must describe how these options would address accountability, transparency, and quality, including how best to limit incentives to reduce or limit medically necessary care. In addition, the Secretary, in consultation with the OIG, is required to submit a report to the Congress on the applicability of fraud and abuse laws to alternative payment models.

To inform these two reports, and to aid CMS in determining whether additional rulemaking or guidance is desirable, CMS asks for comments regarding the impact of the physician self-referral law on health care delivery and payment reform. Among other questions, CMS asks whether there is a need for new exceptions to the self-referral law to support shared savings or gainsharing arrangements.

### *Comment*

There are three potential legal barriers to gainsharing (or shared accountability) arrangements: the physician self-referral law; the civil monetary penalty (CMP) provision in the Social Security Act, which prohibits hospitals from offering physicians financial incentives to reduce services to Medicare patients; and the anti-kickback statute. The Commission has recommended that the Congress grant the Secretary the authority to allow gainsharing arrangements between physicians and hospitals with safeguards to ensure that cost-saving measures do not reduce quality or influence physician referrals.<sup>11</sup> Under gainsharing, physicians and hospitals agree to share savings from changes to clinical care in the hospital, which encourages cooperation among providers in reducing internal hospital costs and Medicare spending and improving quality.

MACRA changed the CMP provision to allow hospitals to offer physicians financial incentives to reduce or limit medically unnecessary services to Medicare patients (previously, this provision prohibited hospitals from offering physicians financial incentives to reduce or limit *any* services to Medicare patients). This change makes it easier for the Secretary to allow gainsharing arrangements. However, the physician self-referral law—which prohibits physician referrals to a hospital with which the physician has a financial relationship unless that relationship fits within an exception—may prohibit certain types of gainsharing arrangements. Therefore, the Commission supports the development of a new exception to the self-referral law that would allow gainsharing arrangements with appropriate protections for patients and the Medicare program. In addition, the OIG should develop a safe harbor to the anti-kickback statute for gainsharing arrangements.

### **Conclusion**

The Commission appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. We also value the ongoing cooperation and collaboration between

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<sup>11</sup> Medicare Payment Advisory Commission. 2005. *Report to the Congress: Physician-owned specialty hospitals*. Washington, DC: MedPAC.



Andrew Slavitt  
Acting Administrator  
Page 17

CMS and Commission staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, the Commission's Executive Director.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." The signature is written in a cursive style with a large initial 'F' and a distinct 'M.D.' at the end.

Francis J. Crosson, M.D.  
Chairman

FJC/mm/kb