

August 26, 2016

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-1654-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 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model,” published in the *Federal Register*, vol. 81, no. 136, pages 46162 to 46476. 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:

- Potentially misvalued services under the physician fee schedule
- Separate payment for behavioral health integration
- Primary care and care management services
- Value-based payment modifier and physician feedback program
- Proposed expansion of the Diabetes Prevention Program model
- Incorporating beneficiary preference into ACO assignment
- Reports of payments or other transfers of value to covered recipients

Potentially misvalued services under the physician fee schedule

Collecting data on resources used in furnishing global services

The payment rate for many surgical services includes the procedure itself and certain services that are provided immediately before and after the procedure; CMS calls this group of services the

global package. There are three categories of global codes based on the number of post-operative days included in the package:

- 0-day global codes, which include the procedure and pre-operative and post-operative physician services on the day of the procedure;
- 10-day global codes, which include the same services as the 0-day global codes plus physician visits related to the procedure during the 10 days after the procedure; and
- 90-day global codes, which include the same services as the 0-day global codes plus pre-operative services furnished one day before the procedure and post-operative services during the 90 days after the procedure.

In its proposed and final rules for the physician fee schedule for 2015, CMS raised several concerns with the 10-day and 90-day global codes, such as: the agency does not use actual data on services furnished to update the rates for these codes, a study conducted by the Office of Inspector General (OIG) found strong evidence that the current RVUs for global codes may not reflect the typical number and level of post-operative visits, and whether CMS has the ability to regularly update the RVUs for these codes to reflect changes in medical practice and health care delivery. In the OIG's study, they reviewed a sample of medical records for several types of global surgical codes and counted the number of post-operative visits that were actually provided by the surgeons. For a majority of the claims they examined, the OIG found that physicians provided fewer visits during the post-operative period than were included in the payment for the global package.

To improve the accuracy of payment for global codes, CMS finalized a proposal to convert the 4,200 10-day and 90-day global codes to 0-day global codes. Under this policy, providers would bill separately for all pre-operative visits that occur before the day of the procedure and post-operative visits that occur after the day of the procedure.

MACRA prohibited CMS from implementing this policy change and required the agency to develop a process to collect data to value global surgical services. This information must include the number and level of medical visits and other items and services provided during the global period. Every four years, CMS is required to reassess the value of collecting this information and may discontinue the data collection if there is an alternative source of information to value global surgical codes. In addition, CMS is authorized to withhold up to 5 percent of the payment to practitioners for services that are subject to the data collection effort until the data are reported. Beginning in 2019, CMS must use this information to improve the accuracy of payment rates for global services.

In this proposed rule, CMS proposes a rigorous effort to collect data on the resources used in providing pre- and post-operative care during a 10-day or 90-day global period. This information would be used to revalue global surgical codes on a rolling basis beginning in 2019. The data collection effort would involve three parts:

- Claims-based reporting on the number and level of pre- and post-operative visits provided during the global period;

- A survey of a representative sample of practitioners about the activities and resources used to provide pre- and post-operative visits during the global period; and
- A survey of pre- and post-operative care delivered by accountable care organizations (ACOs).

CMS believes that a claims-based reporting approach would provide the most robust data for determining the method and amounts to pay for surgical services. Under this approach, all practitioners would be required to submit claims with new G codes for each visit provided during the pre- and post-operative period of a global code, even though they are not paid separately for these services. Practitioners would continue to receive global surgical payments rates during the data collection period. The new codes would indicate the setting of the visit (inpatient or outpatient), whether it was furnished by a practitioner or clinical staff, whether it was typical or complex, and the visit's length of time (in 10-minute increments). For example, code GXXX5 would indicate a typical office or outpatient visit provided by a practitioner, per 10 minutes. Visits that are more complex than the typical visit involve additional services and more complicated patients (e.g., patients with many comorbidities or a high likelihood of significant decline or death). In addition, there would be two G codes for services provided by phone, internet, or other electronic means, outside of a face-to-face visit. CMS proposes to link claims for pre- and post-operative services to the related surgical procedure using the date of service, practitioner, beneficiary, and diagnosis.

CMS proposes to require that all practitioners who bill for global surgical services—rather than a sample of practitioners—report claims for pre- and post-operative services. CMS contends that it would be too difficult to create a sample because it lacks information on the provider characteristics that drive variation in the amount and type of post-operative care. In addition, CMS is concerned that a sample would not provide enough data to accurately value all surgical procedures.

In addition to claims-based reporting, CMS proposes to survey a representative sample of about 5,000 practitioners about the activities and resources (e.g., surgical dressings and clinical staff time) used to provide pre- and post-operative services during the global period. The sample of practitioners would be stratified by specialty, geography, and practice type. Practitioners would report detailed information on about 20 post-operative visits provided during a fixed reporting period (e.g., two weeks). The information would include the surgical procedure on which the global period is based, specific activities furnished during the visit, times for each activity, who performed each activity, and practice expenses (e.g., supplies and clinical staff time). In addition, the survey information would allow CMS to validate the claims data.

The third data collection activity proposed by CMS would involve surveying a small number of Pioneer and Next Generation ACOs on the activities and resources involved in delivering pre- and post-operative services. CMS is interested in learning whether ACOs spend more time and effort on post-operative services because they have an incentive to coordinate and improve care for their beneficiaries.

CMS proposes to require mandatory participation by providers in these three data collection activities. Although the agency has the authority to withhold a portion of Medicare payments to practitioners until the data are reported, it does not propose to initially use this authority because CMS believes that providers will comply with the data reporting requirements. However, if CMS finds that compliance is not acceptable, it might impose a payment withhold in the future.

Comment

We agree with CMS's concerns about the current global surgical payment policy. The number and type of post-surgical visits in the package for a given code are likely to change over time as medical practice and the patient population changes. If CMS's assumptions of the number and type of visits are inaccurate, the RVUs for global codes will also be inaccurate.

The Commission believes that it is very important to pay accurately for global surgical services because the overvaluing of surgical services leads to an undervaluing of other services, including primary care. Mispriced services in the fee schedule contributes to an income disparity between primary care and specialty physicians. In addition, overvalued services may be subject to unwarranted volume growth.

The Commission supported CMS's initial proposal to convert all 10-day and 90-day global codes to 0-day global codes. Although we continue to support CMS's efforts to improve payment accuracy for global codes, we believe that the agency's three proposed data collection efforts (requiring all practitioners to submit claims data on pre- and post-operative visits, surveying a sample of 5,000 practitioners, and surveying a small number of ACOs) is too burdensome and costly for providers and CMS. Instead, CMS should adopt a single approach: collect data on pre- and post-operative services from a sample of efficient providers who furnish global codes, with mandatory participation by the sampled providers. This survey would be less burdensome on providers and would give CMS the information it needs to improve the accuracy of both the physician work and practice expense components of surgical services.

CMS should design a survey that captures the most relevant information on services delivered during the global period, such as the number and level of pre- and post-operative visits, the setting, the length of time of each visit, the presence of post-surgical complications, and direct practice expense inputs (i.e., medical supplies, medical equipment, and clinical staff time). CMS should stratify the sample by practitioner specialty, geography, setting, and types of services furnished. The agency should also limit the sample to practices that are likely to be more efficient (e.g., larger practices with economies of scale, surgeons who participate in ACOs and bundled payment models) because Medicare's payment rates should be benchmarked to the cost of efficient providers rather than the average provider.¹ The Commission supports paying providers who participate in the survey to cover their administrative costs of collecting and reporting data. However, we also recognize that MACRA grants CMS the authority to withhold 5 percent of practitioners' Medicare payments for global surgical services until they complete a survey.

¹ Medicare Payment Advisory Commission. 2014. Context for Medicare payment policy and recommendations. December 9. [http://medpac.gov/documents/congressional-testimony/testimony-context-for-medicare-payment-policy-and-recommendations-\(energy-and-commerce\).pdf](http://medpac.gov/documents/congressional-testimony/testimony-context-for-medicare-payment-policy-and-recommendations-(energy-and-commerce).pdf).

We recognize CMS’s concern that collecting data from a sample of practitioners—rather than all of them—may not provide enough data to accurately value all 4,200 surgical procedures with a 10 or 90-day global period. Therefore, CMS should design the survey with a sufficient sample size to collect data on the codes that account for a high share of Medicare’s payments for global surgical services to ensure that these codes are valued more accurately. For other global codes, CMS could adjust their RVUs based on the average percent change of the surveyed codes in the same family of services.

Home dialysis codes as potentially misvalued

CMS is proposing to identify the home dialysis monthly capitation payment (MCP) codes (CPT codes 90963 through 90970) as potentially misvalued. CMS’s proposal is based on the concern that compared to Medicare’s payment rate for managing in-center dialysis beneficiaries, the lower MCP payment rate for managing home dialysis beneficiaries may discourage physicians from prescribing home dialysis. As shown below, for in-center dialysis beneficiaries, Medicare currently pays physicians a MCP rate that is based on the beneficiary’s age (less than 2 years, 2 years through 11 years, 12 years through 19 years, and 20 years of age or more) and number of visits per month (one, two to three, or four or more visits per month); by contrast, for home dialysis beneficiaries, Medicare pays physicians a MCP rate that is based only on the beneficiary’s age.

Table 1. Difference in payment for monthly capitation payments for in-center and home dialysis, proposed 2017 payment

Dialysis type	In-center, patients age 20 yrs or older	Home, patients age 20 yrs or older
4+ visits per month	\$287.63	---
2-3 visits per month	\$241.48	\$241.12
1 visit per month	\$186.75	---

Note: Proposed 2017 payment is based on the proposed conversion factor of 35.7751. These codes are for patients age 20 and older, which make up the majority of dialysis patients.

Comment

Presently there is a difference in the monthly capitation payment for clinicians when the patient is being dialyzed in their home versus in a center (Table 1). In general, the monthly capitation payment for home dialysis is fixed at the rate for 2-3 visits per month for patients treated in a center. (In other words, clinicians providing more than three visits to patients being dialyzed at home would not receive an increase in payment, whereas clinicians providing more than three visits to patients being dialyzed in a center would receive an increase in payment).

The reason for this difference in payment is not clear. From a review of claims, 75 percent of beneficiaries receiving dialysis in the home come in to a dialysis facility to meet with their nephrologist. The monthly capitation payment service describes the same set of services, whether provided to beneficiaries receiving in-center dialysis or home dialysis. This suggests that the monthly capitation payment for patients receiving home dialysis is misvalued, or that both sets of monthly capitation payments (for in-center patients as well as home dialysis patients) are misvalued.

We agree that CMS should review these services as potentially misvalued. In the interim, CMS should move to minimize or eliminate the difference in valuation for the monthly capitation payment based on where the patient is receiving dialysis, given that these codes describe the same set of services. In addition to the MCP codes describing the same type of services, the Commission believes that dialysis beneficiaries should have access to the different types of dialysis treatment – in-center dialysis, home hemodialysis, and peritoneal dialysis (which is usually performed at home). Eliminating the payment difference could help achieve this goal.

Separate payment for behavioral health integration (BHI)

Many Medicare beneficiaries with behavioral health conditions seek treatment from their primary care providers. Care management for these beneficiaries may include extensive discussion, information sharing, and planning between a primary care clinician and behavioral health provider. CMS refers to this practice broadly as behavioral health integration (BHI). A specific evidence-based model for BHI called the psychiatric Collaborative Care Model (CoCM) typically is provided by a primary care team, consisting of a primary care provider and a behavioral health (BH) care manager who works in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with regular assessments of clinical status using validated tools and modification of treatment as appropriate. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations.

For CY 2017, CMS proposes to create new codes for behavioral health integration services. The American Medical Association's Current Procedural Terminology (CPT) panel has approved three codes that describe services furnished consistent with the CoCM, but these codes will not be valued by CY 2017. In the meantime, CMS proposes to pay for services described by three non-CPT CoCM-related codes, and an additional code to address BHI more broadly:

1. GPPP1—initial CoCM, first 70 minutes in the 1st calendar month of BH manager activities. Includes patient outreach/engagement; initial assessment; consult with psych consultant; patient registry and tracking follow-up and progress; documentation; brief interventions using evidence-based techniques
2. GPPP2—subsequent CoCM, first 60 minutes in subsequent month of BH manager activities. Includes tracking follow-up and progress; weekly consult with psych consultant; ongoing collaboration/coordination with primary care provider; interventions; monitoring outcomes
3. GPPP3—initial or subsequent CoCM, each additional 30 minutes in calendar month of BH manager activities, in consult with psychiatric consultant
4. GPPPX—care management services for BH conditions, at least 20 minutes of staff time per calendar month

CMS proposes that the CoCM service would be appropriate for patients with a newly-diagnosed behavioral health condition, who need help getting treatment or who need treatment beyond what the clinician has provided, or require further assessment before referral. The service would

terminate when treatment goals are attained or the patient is referred to a psychiatric care provider. If treatment goals are not obtained or the patient is not referred, the service could continue to be provided and billed for. CMS also does not propose a limit on the number of providers who could bill the code per beneficiary per month. The CoCM services do not require an in-person visit between the beneficiary and the billing provider, however the billing provider must initiate the service.

Comment

The Commission appreciates CMS's effort to improve the care of Medicare beneficiaries, more fully integrate behavioral health and physical health, and ensure that beneficiaries receive the screening and services most appropriate for them. The clinician community, particularly primary care clinicians, often must address the behavioral health needs of their patients. Furthermore, some primary care clinicians may not have the resources (either financial or staff) or the specialized knowledge to manage these conditions for their patients. A benefit of treating beneficiaries with lower acuity of behavioral health need in the primary care office is that it could improve continuity of care and improve follow-up, help with the integration between behavioral and physical health, and retain specialty psychiatric referrals for patients with more severe and acute psychiatric disorders.

We agree with CMS that there is a lack of integrated support for primary care practices treating the behavioral health of their beneficiaries. The current fee for service payment system does not support these activities, and adding new codes to the fee schedule is one mechanism for explicitly paying for these activities. However, the Commission is concerned with CMS's proposal to add additional codes to the fee schedule for CoCM and BHI. We are concerned that the proposals will result in increased spending without beneficiaries seeing any improvement in their care.

We plan to pursue work over the coming cycle assessing other potential options for improving the care of Medicare beneficiaries with behavioral health needs. These could include assessing the valuation of codes used frequently by psychiatrists, clinical social workers, psychologists or therapists; considering the role of other providers; or pursuing per beneficiary monthly payments for services associated with treating behavioral health conditions.

Our specific comments on CMS's proposals follow.

The proposal ties payment to a specific model of care. CMS proposes a suite of codes that strictly follow the CoCM services—involvement of a BH care manager and a consulting psychiatrist that works in arrangement with the care manager. But other models of integrating behavioral health services into clinician practices (particularly primary care practices) could also have value. Creating a set of codes around a specific model enshrines this specific type of care into the fee schedule. Structuring the payment this way could limit the model of care that clinician practices will adopt, resulting in some beneficiaries—particularly those who may need more intensive services—being referred outside of the practice, even though they might be able to be treated within the practice under a different BHI model. The Commission also notes that CMS reports that the CoCM model has shown efficacy for certain behavioral health conditions but does not limit the

coverage to only these diagnoses. Although this model has worked well as a structured intervention, like many innovations, dropping it into a fee-for-service environment with little restriction on coverage or payment raises program integrity concerns.

Commission staff recently visited primary care practices that have integrated BH in a variety of ways. Staff found that some primary care practices want to improve patient access to BH, but do not have a large enough patient population to hire a full-time prescribing BH provider (i.e., psychiatrist or psychiatric nurse practitioner). In order to offer integrated BH services, these practices have built a relationship with a local outpatient psychiatric clinic. The clinic sends their staff BH providers to see referred patients at the primary care practice for a portion of the week. The BH provider has access to and uses the primary care practice's electronic health record, and often discusses patient care with the primary care clinician both inside and outside of their specified office time.

Under CMS's proposed rules, a practice such as the one described could not bill the psychiatric CoCM codes because there is no explicit care manager involved in this integrated care. They could, however, bill the separate behavioral health integration code that CMS proposes in this rule. Another option for CMS is to roll-out the more general behavioral health integration code for use in 2017 and assess the utilization of that code, before adopting additional codes tied to a specific model of care. The Commission supports a more flexible, beneficiary-centered payment that allows clinicians to adopt the model of behavioral health integration that works best for their patients.

Payment for services should be limited to one provider that has an ongoing relationship with the patient. We continue to have concerns when non-face-to-face services can be billed by a provider without a preexisting relationship with the beneficiary. In the context of behavioral health, it may not be desirable to limit payment to a clinician with whom the patient has a pre-existing relationship (for example, a patient may have reservations about raising behavioral health issues with a doctor they know well). CMS should consider whether payment for behavioral health integration services should be halted if the clinician does not have a subsequent in-person service within a certain period of time, indicating that the clinician may no longer be providing ongoing care for that beneficiary.

We also suggest that billing for behavioral health integration services be restricted to certain types of clinicians (either by specialty or by billing patterns). We understand that this likely requires a legislative change, and so the Commission also plans to consider the details of such a policy. For example, billing for behavioral health integration services could be limited to primary care clinicians, or to additional specialties that bill predominantly evaluation and management services. In any case, we recommend that CMS restrict the behavioral health integration services to only one clinician per beneficiary per month. Allowing multiple clinicians to bill increases the likelihood of further fragmentation.

Primary care and care management services

In this NPRM, CMS proposes several related policies that would increase payment for certain care coordination and non-face-to-face services that are performed by clinicians and their staff. We discuss two proposals in detail:

- Modifying the service description, payment, and billing requirements for Chronic Care Management (CCM) services, including two new codes and an add-on code for a visit that initiates CCM services; and
- Establishing a code for prolonged evaluation and management (E&M) services.

Other policies in this section of the NPRM include the behavioral health integration codes (discussed above), a new code for assessment care planning for patients with cognitive impairment, and an add-on code for evaluation and management services for patients with physical impairments.

Chronic care management codes

CMS proposes to modify the service description, payment, and billing rules for the CCM codes. CCM codes were introduced into the fee schedule in 2015, and are designed to capture non-clinician, non-face-to-face time involved in managing the care of a patient—for example, creating or updating a care plan, communicating with other providers, and communicating with the patient.

Presently, CMS pays for CCM services using one code, which corresponds to 20 minutes of staff time in a calendar month. This code can be billed once per month per beneficiary. CCM services are covered for beneficiaries with two or more chronic conditions, who are at risk of functional decline or significant decompensation. A comprehensive care plan must also be in place.

In this NPRM, CMS proposes adopting two new CCM codes: a code for high complexity of decision making, and a code for each additional 30 minutes of CCM services in a month (Table 2).

Table 2. CMS is proposing to pay for additional chronic care management (CCM) codes for 2017

Code	Description	In use in 2016?	2017 estimated payment amount
99487	Complex chronic care management services, 60 minutes of staff time per month	No	\$92.67
99489	Each additional 30 minutes of clinical staff time per month	No	\$46.87
99490	Chronic care management services, 20 minutes of staff time per month	Yes	\$42.22

Note: In adopting the CPT code set, the code description for 99490 would change. Estimated payment amount based on proposed RVUs and a proposed conversion factor of \$35.7751.

CMS is also proposing changes in coverage and the scope of services for CCM. Under the current CCM code, clinicians must obtain beneficiary consent to the service at least once per year through an initiating visit where the clinician describes the service and obtains consent from the beneficiary. CMS proposes that initiating visits must only occur for new patients or patients not seen within one year. CMS is also removing the requirement for clinicians to obtain and record formal written consent to CCM services, and replacing it with a requirement for the clinician to document that the beneficiary accepted or declined the service. CMS is also proposing changes in the CCM scope of services (see Table 3).

Table 3. Selected changes in the CCM scope of services

Domain	Current	Proposed
24/7 access to care	Access to care management services 24/7 (timely contact with practitioners in the practice who have access to the patient’s electronic care plan)	24/7 access to clinicians including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or week
Electronic sharing of care plan	Care plan information must be captured electronically and must be available on a 24/7 basis to all practitioners within the practice whose time counts towards the CCM code	Must electronically capture care plan information and share care plan information electronically (can include fax) inside and outside the billing practice

CMS is also proposing to create an add-on payment for visits that count as CCM initiating visits. For example, an E&M visit in which the clinician discussed the CCM service and received beneficiary consent for this service would qualify for an additional payment on top of the standard payment for the E&M service.

Prolonged E&M services

CMS proposes to create two new add-on codes for E&M services that involve significant pre- or post-service work by the clinician: one for the first hour of pre- or post-service work by the clinician, and one for each additional 30 minutes beyond that first hour. These codes differ from CCM codes because they entail clinician time, whereas the CCM codes consist largely of work done by non-clinician staff (such as a care manager) instead of the clinician.

Comment

The fee schedule relatively underpays clinicians who are involved in providing continuous, comprehensive care for patients and truly managing their chronic conditions across multiple settings and providers. A comprehensive approach to improving payment accuracy and equity will entail both changes to the fee schedule as well as broader, patient-centered approaches such as

alternative payment models or per-beneficiary payments. For example, the Commission has recommended that the Congress establish a per-beneficiary payment for primary care.² We also plan to further consider how best to support these activities in clinician practices.

Within the context of fee schedule rulemaking, we agree with the intent to improve payment for the types of comprehensive, coordinated care that can improve beneficiary outcomes. However, in pursuing fee schedule modifications, CMS should establish guardrails that protect program integrity and ensure that higher spending results in meaningful value for the program and beneficiaries. Our specific comments follow.

CMS should not make duplicate CCM payments for the same beneficiary in the same month. Under the current CCM code, only one provider can bill per beneficiary per month. However, based on our review of final action claims from 2015, about 300 beneficiaries in any given month received CCM services from multiple providers. CMS should ensure that code edits are in place so that the Medicare program does not pay twice for the same service. This will become an even more acute problem if CCM volume increases.

CMS should limit CCM services to clinicians with a longstanding relationship with the patient. CCM services that are not made to a clinician with a longstanding relationship with the patient pose at least two problems. First, there is the risk for further fragmentation of care. A clinician with a new relationship to the patient could start billing CCM services, but is not required to communicate with the patient's longstanding provider, who can now not bill for CCM. Second, if CMS finalizes its proposal to modify the requirement for formal written consent, beneficiaries may not fully understand that the clinician has assumed responsibility for coordinating their care needs, and the resulting bill for cost-sharing could come as a surprise.

At a minimum, CMS should consider whether to require that a clinician and a beneficiary have a prior relationship (evidenced by claims) before paying for the CCM service. CMS should also ensure that it is clear that the removal of formal beneficiary consent does not remove the requirement for providers to explain the CCM services to their beneficiaries.

CMS should retain requirements for seamless exchange of care plans. Providers involved in delivering the CCM service should be able to electronically view the beneficiary's medical record and update the care plan; we are concerned that the proposal to allow sharing of plan information via fax would weaken providers' ability to seamlessly do so. In the absence of these requirements, there is the potential for fragmentation of care. For example, if the beneficiary needs to recap their medical history every time they seek care outside of the practice's office hours, there is little benefit to having CCM services in the clinician's office versus using another setting (e.g., urgent care). Many third-party administrators offer CCM services for clinicians, which, particularly if there is no requirement for clinical integration between the CCM provider and the clinician, could further fragment the care the patient receives.

² Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Multiple codes for care plan services could create confusion for beneficiaries. A further consideration is the potential for proliferation of care plans through various codes throughout the fee schedule. In this rule, CMS proposes a care plan code for beneficiaries with mental impairments, care plans in the CCM code, and a care plan in the CoCM codes. This is in addition to existing care plan oversight codes for home health and SNF services. CMS proposes that certain combinations of codes could not be billed together for the same patient, but the potential for multiple, conflicting care plans remains. The CCM code, in particular, requires that beneficiaries be provided a copy of their care plan. Some beneficiaries could receive multiple care plans that each address a separate condition, containing potentially conflicting instructions, without a single comprehensive care plan that addresses all of their needs.

Prolonged E&M codes raise concerns about unbundling and valuation of E&M services. Adding a new set of codes for pre- and post-service time for E&M codes unbundles the E&M service into multiple components. If there is concern that E&M services are not appropriately valued for pre- and post-service activities, then ideally the E&M code set should be revalued in its entirety. CMS has also not specified limits to billing this code, in terms of the number of providers who can bill, the types of patients for whom it may be medically necessary, and how frequently the code can be billed. If CMS pursues this policy, they should clarify the circumstances for which this code is appropriate beyond the average pre and post-service time included in the current E&M visit.

Value-based payment modifier and physician feedback program

CMS is required by statute to establish a value-based payment modifier (VM) and apply it to all physicians and groups of physicians by January 1, 2017. The law also requires CMS to provide confidential feedback reports to physicians that assess their performance relative to their peers on resource use measures and that may also include comparisons on quality measures. While the VM will be replaced by the Merit-based Incentive Payment System (MIPS) on January 1, 2019, many VM measures and policies will carry over to the new program.

Beginning with the 2016 payment adjustment year, CMS finalized a timeline for collecting data from physicians and calculating measure results based on performance in 2014, providing feedback to physicians through Quality Resource Use Reports (QRURs) in the fall of 2015, followed by a 60-day period during which physicians can request an “informal review” if they believe that their report includes errors. In prior rulemaking, CMS stated their intention of correcting errors identified by the informal review and adjusting physicians’ quality tier designation (i.e., average, low, or high) to reflect corrected results when possible and setting the designation to “average” when not.

In this proposed rule, CMS notes three sets of errors that affected physician performance scores and VM in the most recent year:

- the agency was unable to determine the accuracy of PQRS data that physicians submitted via electronic health record (EHR) and qualified clinical data registry (QCDR) so these data (if they were the sole means of submission) were excluded from VM calculations,
- two weeks of claims data were initially excluded from resource use measures, and

- the program used to adjust resource use measures for physician specialty was defective.

Based on this experience and in anticipation of the possibility of future errors, CMS proposes that when errors affect physicians' VM, rather than attempting to correct the errors, their "high" or "low" quality or cost designation be reset to "average." The agency notes the need to complete all tier designations in a timely manner to allow calculation of the high and low VM dollar amounts before the beginning of the calendar year.

Comment

We applaud CMS's commitment to delivering detailed, actionable feedback to physicians on their relative performance via the QRURs and to conveying clear information about VM payment amounts prior to their implementation each year. We recognize the coordinated data analytic and information presentation work that underlies fulfilling this effort within time constraints. Well-designed QRURs that clearly convey how VM is determined along with actionable details on performance are an essential element to physician acceptance of and engagement with Medicare's performance measurement system. We are concerned that adopting a policy of defaulting to "average-quality" designation in lieu of correcting errors will undermine this goal.

We urge CMS to seek opportunities to compress or move up steps in the timeline to allow completion of the VM calculation before the end of the year. Specifically, two suggestions that we made in our comment letter on the MIPS and Alternative Payment Model (APM) proposed rule, if adopted, would serve to avoid or ameliorate two of the errors that CMS encountered and expedite calculation of measures.³ First, rather than relying on physicians selecting and reporting quality measures, CMS could establish a common measure set that the agency would calculate on behalf of physicians using available data. Second, once measures are adjusted for geographic payment rate differences and beneficiary risk factors, there is no need to apply an adjustment for physician specialty. In addition, to allow for the six weeks needed to correct errors and communicate new results to physicians, CMS could also consider shortening the 60-day physician review of QRURs to 30 or 45 days and scheduling it to start sooner. If additional measure calculation time is still needed after moving to CMS-calculated quality measures and removing specialty adjustment, CMS could consider ending the mid-year QRURs. While these are valuable in that they serve as a preview of possible QRUR results, they include only a subset of measures used to determine the VM and are provided for informational purpose only. If cancelling production of the mid-year QRURs would free up sufficient resources to prevent and correct errors identified by informal review of the QRURs and VM, that would be a worthwhile tradeoff.

³ Medicare Payment Advisory Commission. 2016. Comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled "Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models." Letter to the Acting Administrator. June 15. Washington, DC: MedPAC.
<http://medpac.gov/documents/comment-letters/medpac-comment-on-cms's-proposed-rule-on-the-merit-based-incentive-payment-system-and-alternative-payment-models.pdf?sfvrsn=0>.

Proposed expansion of the Diabetes Prevention Program (DPP) model

CMS is proposing in this rule to create a new benefit: the Diabetes Prevention Program (DPP). The DPP is a lifestyle change program that consists of a structured set of counseling sessions with the goal of averting Type II diabetes in individuals who are pre-diabetic or at risk of developing diabetes. Currently, the Centers for Disease Control and Prevention (CDC) recognizes and certifies organizations to deliver the Diabetes Prevention Program, which means that organizations must cover a specific curriculum for the sessions and the lifestyle coaches delivering the DPP services must meet certain criteria.

The DPP was tested in the Medicare population through a Center for Medicare and Medicaid Innovation (CMMI) Innovation Award, made to the YMCA of the USA. On the basis of the test and resulting evaluation, CMS's Office of the Actuary certified the DPP for expansion.⁴

CMS proposes to start coverage for the DPP on January 1, 2018, and CMS will issue subsequent rulemaking over the next year to set further guidance for the benefit (including coverage, the benefit and payment parameters, and requirements for suppliers). CMS is proposing that DPP will be an additional preventative service under FFS Medicare and will be available to beneficiaries meeting three criteria:

- Are covered under Part B of Medicare;
- Have a body mass index (BMI) of 25.0 or over (or a BMI of 23 or above for beneficiaries of Asian ancestry); and
- Have certain laboratory values that indicate that the beneficiary has pre-diabetes or is at risk for developing diabetes.

Beneficiaries who are already diagnosed with diabetes or end-stage renal disease would not be eligible for the benefit.

CMS is proposing that DPP would adopt many of the processes and requirements set up through the CDC certification process for DPP suppliers, and that CMS would waive the national coverage determination process that generally governs the process of adding new benefits under Medicare. The DPP benefit would consist of a program using CDC-approved DPP curriculum. CMS states that the agency is considering whether to allow the benefit to be delivered remotely (versus in-person). The benefit is available to beneficiaries only one time (for a six-month period). Any payment after the initial six months is contingent on the beneficiary attaining the required weight loss. The benefit would be delivered by organizations certified under a new Medicare supplier category. Any supplier currently certified or provisionally certified through the CDC program

⁴ PPACA establishes a process for national expansion of a model tested under the Center for Medicare and Medicaid Innovation (CMMI). The Secretary may, through rulemaking, expand the duration and the scope of a model that is being tested if CMS's Office of the Actuary certifies that "the expansion is expected to reduce spending without reducing the quality of care; or improve the quality of patient care without increasing spending." OACT's certification of the DPP is here: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf>

would be eligible to enroll in Medicare as a supplier, and the DPP lifestyle coaches would have to enroll in Medicare and get a national provider number (NPI).

CMS proposes that DPP suppliers would receive payment based on the payment schedules in Tables 4 and 5. The payment schedule creates incentives for suppliers to have beneficiaries attend more sessions, and makes payment after the first six months contingent on sustained weight loss of 5 percent. The total maximum payment for core sessions and maintenance sessions, if the beneficiary attended the maximum sessions and met the maximum weight loss goals (attained at least 9 percent weight loss and maintained at least 5 percent weight loss), would be \$630 per beneficiary.

Table 4. Diabetes Prevention Program: Payment for core sessions, first six months of Year 1

Beneficiary attends 1 session	\$25
Beneficiary attends an additional 3 sessions	+\$50
Beneficiary attends an additional 5 sessions	+\$100
Total base payment for core sessions	=\$175
<i>Incentive payment (5% weight loss)</i>	<i>\$160</i>
<i>Incentive payment (9% weight loss)</i>	<i>\$185</i>
Maximum payment for core sessions (9% weight loss)	\$360

Table 5. Diabetes Prevention Program: Payment for maintenance sessions, starting month 7 of Year 1

	<i>Did beneficiary achieve and maintain 5% weight loss?</i>	
	<i>Yes</i>	<i>No</i>
<i>Months 7-12 of Year 1</i>		No further payment
--Beneficiary attends fewer than 3 sessions	\$0	
--Beneficiary attends 3 sessions	+\$45	
--Beneficiary attends an additional 3 sessions	+\$45	
Total maintenance payment, Year 1	=\$90	
<i>Year 2 and subsequent years</i>		
--Beneficiary attends fewer than 3 sessions	\$0	
--Beneficiary attends 3 sessions	+\$45	
--Beneficiary attends an additional 3 sessions	+\$45	
--Beneficiary attends an additional 3 sessions	+\$45	
--Beneficiary attends an additional 3 (or more) sessions	+\$45	
Total maintenance payment, Year 2 and later years	=\$180	
Total maintenance payment, all years	\$270	

Comment

Reducing Medicare beneficiaries' risk of developing diabetes is a laudable goal, given the significant morbidity and cost caused by diabetes and end-stage renal disease. The fact that DPP

has shown such efficacy in reducing risk through a lifestyle intervention makes it an attractive approach. However, introducing the model as-is into unconstrained FFS poses a risk of expansion of the benefit beyond patients for whom it is appropriate, and fraudulent overuse of the benefit. As proposed, the Commission is concerned that the potential risks of creating the DPP program within FFS Medicare may outweigh the benefit.

We recommend CMS take two steps, outlined below. First, CMS should seek expert advice regarding the appropriateness of the DPP as a supplier-determined benefit under FFS Medicare (appropriate for all FFS beneficiaries—e.g., older beneficiaries or beneficiaries with dementia). Second, CMS should roll out the DPP deliberately, and expand the benefit only after it has been tested in a smaller group of providers with strict edits for program integrity and clinical appropriateness.

CMS should seek clinical input in designing the DPP program in FFS Medicare—in particular, whether weight loss targets are an appropriate goal for the pre-diabetic elderly population. In proposing the DPP as an unlimited fee-for-service benefit under Medicare, the population that could receive this benefit could expand far beyond the structured intervention tested in CMMI and through the randomized clinical trial that launched the CDC certification process for DPP programs.⁵ The benefits of DPP for some beneficiaries should be weighed against the risk of creating a payment system based on weight loss for other beneficiaries (for example, an 85-year old beneficiary with dementia). This is of particular concern when the benefit is widely available and the supplier can initiate services directly.

Our second set of suggestions center on program integrity concerns. CMS should set up the program from the beginning to ensure that beneficiaries are protected and that Medicare does not make excess payments. There is a history of supplier-driven benefits being subject to fraud and overuse. The Secretary has been given new statutory authority to improve program integrity and reduce fraud, and she should use those authorities to ensure the integrity of the DPP.

CMS should strongly consider introducing the DPP program through a small, targeted set of providers, and then only expanding it more broadly once it can be shown that the benefit can operate with a low risk of fraud, overuse, or inappropriate use. For example, CMS could limit initial DPP supplier enrollment to Area Agencies on Aging or other organizations where the risk of fraud or overuse is low. CMS should also include all material information on the claim, including the weight loss targets and progress, and the lab values certifying eligibility for the benefit. Once the model has been rolled out, CMS could assess the potential program integrity implications and only then relax the supplier criteria.

CMS should also apply additional criteria beyond the CDC certification. Specifically, if a supplier has ever been excluded from participation in Medicare or Medicaid (or if their coaches have ever been excluded from participation), they should not be allowed to enroll in the DPP. CMS should apply a set of edits to ensure that usage complies with the design of the program. CMS should

⁵ The certification of the DPP for expansion consisted of one year of results from the evaluation of the YMCA DPP. OACT also cited other studies of the DPP in other settings, including the clinical trial of patients age 25 and over. The CMMI evaluation stated that the majority of the YMCA DPP participants were between the ages of 65 and 75.

consider whether to impose a surety bond requirement for new suppliers, and whether other program integrity tools are appropriate for DPP suppliers. Finally, CMS should require that the lab values required for coverage come from a clinician not affiliated with the DPP supplier.

CMS should also consider the role of beneficiary incentives in the DPP. First, CMS should clarify whether cost-sharing will apply. In our benefit design work, we have supported giving the Secretary the authority to alter or eliminate cost sharing based on the evidence of the value of the services.⁶ However, there is significant risk in the context of DPP for overexpansion of the service to beneficiaries for whom it is inappropriate, as well as a high risk of outright fraud. Cost-sharing can both make beneficiaries sensitive to the value of the care they receive, and act as an additional check to ensure appropriate utilization. Weighing these factors against each other, the Secretary should consider using copayments for the DPP services.

Second, CMS should consider whether some of the incentive payment for weight loss should go to the beneficiary (instead of the supplier). This could engender more buy-in from the beneficiary and allow them to share in the potential financial benefit (e.g., their copayments could be rebated upon successful completion of the program). We understand that anti-kickback provisions could apply if the supplier gave the beneficiary the payment, but it may be possible for the Medicare program to provide the payment directly to the beneficiary.

Incorporating beneficiary preference into ACO assignment

Background

Currently, beneficiaries are assigned to Medicare shared savings program (MSSP) ACOs based on the beneficiaries' claims history. That is, if an ACO's providers account for the plurality of a beneficiary's claims for specified kinds of services, that beneficiary is assigned to the ACO. For MSSP ACOs in Track 1 and Track 2, a "claims-based hybrid approach" is used. This approach gives ACOs an idea of who their beneficiaries might be at the start of the year according to claims data from the previous year, but their official list of beneficiaries is finalized retrospectively after incorporating beneficiary service utilization in the performance year. For Track 3 MSSP ACOs, the same methodology is used to assign beneficiaries prospectively, but assignment is not adjusted at the end of the period.

Pioneer ACOs in the last few years were allowed to incorporate beneficiary attestation in addition to the claims-based system. The concept was that asking beneficiaries to specify their "main doctor" would increase beneficiary engagement, encourage beneficiaries to seek the majority of their services from their chosen provider, and thus reduce "churn;" the problem of beneficiaries drifting in and out of assignment to an ACO. Beneficiary attestation was collected manually by the ACOs, physicians' offices, and CMS. If a beneficiary specified a main doctor as one within an ACO and met the additional ACO requirements, the beneficiary was prospectively assigned to that ACO for the following year. However, only beneficiaries who had been assigned to the ACO in

⁶ Medicare Payment Advisory Commission. 2012. Report to the Congress: Medicare and the Health Care Delivery System. June. Washington, DC: MedPAC.

the previous year had the opportunity to attest. The attestation process increased the number of beneficiaries assigned to Pioneer ACOs by between 0.2 and 2.7 percent more than would have been expected in the absence of the process. While the attestation program followed principles of primary-focused care that CMS supports, the manual collection of information was time and resource intensive.

Proposal

CMS proposes to collect voluntary attestations from beneficiaries and use them for assignment to all MSSP ACOs via an automatic system that is run solely by CMS—ACOs and physicians would not be responsible for collecting the information. Automatic means that all beneficiaries (not just those who may have been previously attributed to an ACO) will be asked by CMS to designate their “main doctor.” An education campaign would have to be undertaken to explain to beneficiaries why it is important to make this designation and a mechanism to make the designation would need to be developed. Options proposed for collecting this data could be via MyMedicare.gov and having beneficiaries select their main doctor, or by having beneficiaries provide the information via 1-800-Medicare. This automatic program would begin early in 2017 and information would be collected from the beneficiaries at their convenience. For Tracks 1 and 2, beneficiaries would be added retrospectively throughout the year as they selected providers within those ACOs, while ACOs in Track 3 would still have beneficiaries assigned to them prospectively.

If an automated system is not available by 2017, CMS proposes to continue with the manual collection of beneficiary attestations (that is via letters or forms provided by some combination of CMS and ACOs only to beneficiaries that have been attributed to the ACO in the past), but this would only apply for Track 3 ACOs. Because the manual system was created for prospective assignment, it is believed that it would be too complicated to incorporate it into retrospective systems (Tracks 1 and 2). This manual system would follow similar principles as the system used for Pioneer ACOs

Under the manual system, beneficiaries would have to designate their main doctor each year, whereas the automatic system would rely on beneficiaries to update their information when appropriate, with encouragement during their care visits to keep this information up to date. The attestation system as proposed by CMS does not limit beneficiaries to only seeking care from the provider they designate as their main doctor or from the ACO that doctor participates in—they are still free to seek care from any provider in FFS Medicare. Attestation as proposed would override assignment based on claims. Providers would be prohibited from providing incentives to beneficiaries to enroll but would be encouraged to explain the benefits of belonging to an ACO and the importance of designating a main doctor.

Comment

The Commission supports the direction CMS is taking in its proposal for incorporating beneficiary preference for ACO assignment. The Commission maintains that beneficiaries should have a more active role in ACOs (and alternative payment models in general) and that attestation would be a

useful first step. Further, the concept of an automated method wherein all beneficiaries—not just those who were at one time attributed to an ACO—could choose a “main doctor” is very attractive for several reasons. First, it could lead to more accurate assignment to ACOs. Second, it would be useful in FFS Medicare because attribution will be required for some measures in the new MIPS program and could inform other aspects of the program. We comment below on specific aspects of the proposal about which CMS asked for comment.

Is voluntary alignment an appropriate mechanism for assigning beneficiaries retrospectively to an ACO? The Commission continues to support prospective assignment for ACO beneficiaries as opposed to retrospective assignment. Voluntary alignment fits better with prospective assignment because at the beginning of the year the ACO would know which beneficiaries had been attributed on claims and which beneficiaries had voluntarily chosen an ACO participating clinician as their “main doctor.” This would give the ACO more certainty about the population for which they are accountable and increase their incentive to keep those patients happy with the services of the ACO. In addition, beneficiaries would be free to switch designation to a “main doctor” outside of the ACO in the course of the year but ACO attribution should not change if they do so.

Voluntary alignment might work under retrospective assignment but may increase the problem of selection. There is an incentive under retrospective assignment for ACO providers to systematically encourage some beneficiaries to stay aligned to the ACO and others to leave it. For example, a beneficiary who is likely to have a hip replacement in the next few months might be encouraged to voluntarily align with a provider outside the ACO to avoid having the high cost of a hip replacement included in the ACOs expenditures. It is not clear that the benefits of voluntary alignment would outweigh the concern about selection in a retrospective system.

Should ACOs be permitted to opt into or out of voluntary alignment? Track 3 ACOs under a manual system should be allowed to choose whether or not to participate in voluntary alignment because it is a resource intensive process for them. This should be a one-time choice. Once an automated system is in place for all beneficiaries, all ACOs should have to participate. This would encourage all ACOs to communicate with their beneficiaries and create a level playing field across ACOs.

Should CMS continue to use a beneficiary’s designation of the healthcare provider responsible for coordinating their overall care until it is changed under the automated system? As the system matures and CMS continues to communicate with beneficiaries about the importance of making a choice of “main doctor,” the default should be to continue using the beneficiary’s designation. This is analogous to the way that beneficiaries who choose an MA plan remain enrolled until they otherwise designate. However, it would be worthwhile to remind beneficiaries to make that designation on enrollment and each year thereafter when the *Medicare and You* brochure is sent out. Providers in ACOs should also be able to remind beneficiaries to make the designation with appropriate safeguards as discussed in the proposed rule.

Reports of payments or other transfers of value to covered recipients: Solicitation of public comments

Section 6002 of the Patient Protection and Affordable Care Act of 2010 (PPACA) requires manufacturers of drugs, devices, biologics, or medical supplies to annually report to the Secretary certain payments or transfers of value provided to covered recipients, or to an entity or individual at the request of or designated on behalf of a covered recipient. Covered recipients include physicians and teaching hospitals. In addition, PPACA requires manufacturers and group purchasing organizations (GPOs) to report on physician ownership or investment interests. CMS publishes the information submitted by manufacturers and GPOs on a public website. CMS calls this section of PPACA the “Open Payments (Sunshine Act)” program.

In this proposed rule, CMS solicits comments about the Open Payments program to inform future rulemaking. CMS is interested in receiving comments on several issues, such as: whether the nature of payment categories are inclusive enough, whether there should be additional categories for research payments, whether manufacturers and GPOs should be required to pre-vet payment information with covered recipients before reporting it to CMS, and how to define physician-owned distributors for data reporting purposes.

Comment

We support CMS’s efforts to implement and improve the Open Payments program. Although the Open Payments records list the name of each manufacturer or GPO that made the payment or transfer of value, they do not indicate whether the company was a GPO or a manufacturer, nor do they indicate whether the manufacturer produces drugs, biologics, devices, or supplies. Although some manufacturers are well-known and the general public may recognize whether they produce drugs, devices, or another product, some manufacturers are less well-known. In addition, some manufacturers report payments in the name of their subsidiaries. Including more information on the type of manufacturer or GPO that provided each payment would enable patients and researchers to better understand the relationships between industry and covered recipients. CMS should require each manufacturer or GPO that reports payment data to indicate whether it is a manufacturer or GPO and, if it is a manufacturer, whether it produces drugs, biologics, devices, supplies, or a combination of products. CMS should include this information on the public website.

The Open Payments system includes information about financial relationships between manufacturers and physicians, which includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. Based on statute, however, Open Payments does not include other health professionals, such as advance-practice registered nurses (APRNs) and physician assistants (PAs), or institutional organizations other than teaching hospitals. The number of APRNs and PAs has been growing, and they play an increasingly important role in the health care system, such as coordinating care and managing medications. A literature review found that nonphysician health professionals (such as APRNs and PAs) reported frequent interactions with manufacturers of drugs and other products.⁷ For example, 64 percent reported receiving industry-sponsored meals during

⁷ Grundy, Q., L. Bero, R. Malone. Interactions between non-physician clinicians and industry: A systematic review. *PLOS Medicine* 10, no.11: e1001561.

the prior six months and 96 percent attended an industry-sponsored educational event during the past five years.

In 2009, the Commission recommended that manufacturers be required to report financial ties with many types of health professionals, including APRNs and PAs.⁸ We recognize that, absent a statutory change, CMS cannot require manufacturers and GPOs to report payments to APRNs and PAs. However, we urge CMS to seek legislative authority to include these clinicians in Open Payments.

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 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 cursive script that reads "Francis J. Crosson M.D.".

Francis J. Crosson, M.D.
Chairman

FJC/mm/kb

⁸ Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.