MEDPAC Medicare Payment Advisory Commission

425 I Street, NW • Suite 701
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Francis J. Crosson, M.D., Chairman
Jon B. Christianson, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

September 8, 2017

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: File code CMS-1676-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled "Revisions to Payment Policies Under Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program," published in the *Federal Register*, vol. 82, no. 139, pages 33950 to 34203. 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:

- Proposed valuation of specific codes
- Proposed payment rates under the Medicare fee schedule for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital
- Initial data collection and reporting periods for Clinical Laboratory Fee Schedule
- Part B drugs: Payment for biosimiliar biological products
- Medicare diabetes prevention program expanded model
- Medicare shared savings program

Proposed valuation of specific codes

CMS describes the importance of regularly revaluing services paid under the fee schedule for physician and other health professional services to ensure that payment rates reflect changing trends in the practice of medicine and changing input prices. The payment rates are based on the relative weights, or relative value units (RVUs), for three components: practitioner work, practice expenses (e.g., rent, utilities, and staff), and professional liability insurance. The statute defines practitioner work as consisting of time and intensity—the amount of time it takes to perform a

service and the relative intensity of work effort per unit of time. Each year, a committee formed by the American Medical Association (AMA) recommends work RVUs (including time and intensity) and practice expense inputs for new, revised, and potentially misvalued codes to CMS. This committee, which is primarily comprised of physicians, is called the AMA/Specialty Society Relative Value Scale Update Committee (RUC). CMS states that it uses a variety of information to review the work RVUs recommended by the RUC, such as information provided by the RUC, the medical literature, a comparison with other fee schedule codes, consultations with physicians employed by CMS, and Medicare claims data.

CMS is concerned that the work RVUs recommended by the RUC for many services do not appear to reflect changes in the work times recommended by the RUC. Because the amount of time it takes to perform a service is a key component of work RVUs, a decline in time should lead to a decline in work RVUs. In the past, when work RVUs recommended by the RUC did not appear to account for significant changes in time, CMS proposed alternative RVUs that better reflected changes in time.

Despite the concerns expressed by CMS about the work RVUs previously recommended by the RUC, the agency is proposing to adopt all of the work RVUs submitted by the RUC for services for 2018 without modifying them. This approach is a significant change from recent years, when CMS modified at least some of the work RVUs recommended by the RUC. CMS explains that this change is justified because the RUC generally considers CMS's concerns with regards to valuing work RVUs and because the majority of practitioners prefer that CMS rely more heavily on the RUC when setting payment rates.

Comment

We believe that CMS is moving in the wrong direction by proposing to accept all of the RUC's recommendations for work RVUs for 2018 without modification. This approach is inconsistent with the Commission's longstanding view that CMS relies too heavily on input from the RUC, which is made up of practitioners who have a financial stake in the payment rates for fee schedule services.[1,2] The executive branch and the Secretary have the responsibility and authority to manage the Medicare program on behalf of taxpayers and beneficiaries. The Secretary is responsible for establishing RVUs for fee schedule services, and this ultimate authority should not be delegated to a private entity. Therefore, CMS should independently evaluate the RUC's recommended RVUs based on objective data and revise them when they are inaccurate. In addition, as we have previously recommended, CMS should collect data from a set of efficient practices to validate the time estimates and establish more accurate RVUs.[3]

---

[1] Medicare Payment Advisory Commission. 2006. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[2] Medicare Payment Advisory Commission. 2011. Moving forward from the sustainable growth rate system. Letter to the Congress. October 14.
[3] Medicare Payment Advisory Commission. 2011. Moving forward from the sustainable growth rate system. Letter to the Congress. October 14.

The Commission believes that it is very important to pay accurately for fee schedule services. Because the fee schedule is budget neutral, when payment rates are inaccurately high for certain services, such as procedures, rates will be consequently low for other services, such as primary care. In addition, inaccurately overvalued services may experience unwarranted volume growth. We examined new work RVUs in this proposed rule that were recommended by the RUC for 188 potentially misvalued services and accepted by CMS without change (we did not examine services that received new code numbers for 2018). We looked at whether the RUC recommended that CMS increase, decrease, or maintain the work RVUs for these services. We found that work RVUs would stay the same for 52 percent of the services, increase for 19 percent, and decrease for 29 percent (Table 1). The RUC's recommendation to not change work RVUs for about half of the potentially misvalued services, and to increase RVUs for 19 percent of services, reinforces our position that CMS needs to apply greater scrutiny to the RVUs recommended by the RUC. As described below, there is evidence that certain procedures are overpriced, which leads to underpricing of other services such as primary care, and CMS is missing an opportunity to address this inequity.

In addition, the relatively small share of potentially misvalued services that would receive lower work RVUs in 2018 (29 percent) represents a missed opportunity for CMS to address overpriced services. If CMS reduces RVUs for relatively few overpriced services, this results in a smaller pool of funds to redistribute to underpriced services. It also makes it more difficult for CMS to meet the annual statutory target for reductions in fee schedule spending resulting from adjustments to the RVUs of misvalued services. CMS estimates that the net reduction in spending resulting from adjustments to the RVUs of misvalued services will be 0.31 percent in 2018. Because this amount is lower than the statutory target of 0.5 percent, fee schedule payments must be reduced by the difference between the target and the estimated net reduction in spending. This would result in a reduction of 0.19 percent to all fee schedule payments in 2018 (0.5 – 0.31 = 0.19).[4] In other words, the inadequate review of misvalued services would lead to an across-the-board decrease in payment rates for all clinicians.

Table 1. Comparing proposed work RVUs for 2018 with actual work RVUs for 2017 for potentially misvalued codes

Proposed work RVUs for 2018 vs. actual work RVUs for 2017	Number of codes	Share of all codes
No change	97	52%
Increase	36	19
Decrease	55	29
Total	**188**	**100**

Note: RVU (relative value unit). Table includes codes defined as potentially misvalued in the proposed rule for 2018. Excludes new codes, codes that received a new code number, and codes that were deleted.

[4] This does not account for the 0.5 percent update specified in law.

The work RVUs are based on estimates of the amount of time it takes to perform a service and the relative intensity of the service. Depending on the type of service, the time estimates explain between 72 percent and 90 percent of the variation in work RVUs.[5] The time estimates are based on surveys conducted by physician specialty societies, which have a financial stake in the process. Research for CMS and the Assistant Secretary for Planning and Evaluation has found that time estimates for some services, such as certain procedures, are probably too high.[6] Therefore, the Commission recommended that CMS use a streamlined method to regularly collect data—including service volume and work time—from a cohort of efficient practices to establish more accurate RVUs.[7] To validate the time estimates, the Commission has explored a method that collects information on the amount of time that a physician worked over the course of a week or month and compares it with the time estimates in the fee schedule for all of the services that the physician billed over the same period. If the fee schedule's time estimates exceed the actual time worked, this could indicate that the time estimates are too high. If CMS used such an approach, it could identify groups of services that are likely overpriced, carefully review those services, and price them more accurately.

When time estimates are decreased during the review process, work RVUs should also decrease because time estimates explain most of the variation in work RVUs. However, we are concerned that the proposed decline in work RVUs for misvalued services for 2018 would be much less than the decline in time estimates for the same services. We examined 98 services from this proposed rule for which the RUC recommended a decrease in work RVUs, time estimates, or both for 2018 (Table 2). Although the proposed time estimates for these services decreased by an average of 22.4 percent between 2017 and 2018, the proposed work RVUs only declined by 6.4 percent, on average.[8] A likely explanation for this discrepancy is that decreases in time have been offset by significant increases in intensity values , which have a smaller effect on work RVUs. This strengthens our view that CMS should not accept the RUC's recommendations without rigorously scrutinizing them. One way that CMS could exercise its authority would be to identify services with high levels of intensity or substantial increases in intensity for additional review. In addition, CMS could consider reducing the work RVUs of such services so that the RVUs are more closely aligned with the time estimates.

[5] Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.
[6] Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.
[7] Medicare Payment Advisory Commission. 2011. Moving forward from the sustainable growth rate system. Letter to the Congress. October 14.
[8] The average reduction in time estimates between 2017 and 2018 does not mean that actual time decreased by 22.4 percent in one year. Rather, it reflects a decrease in estimated time from the last time these services were reviewed, which was likely prior to 2017.

Table 2. Proposed work RVUs would decrease less than time estimates, 2017-2018

	Number of services with a proposed decrease in work RVUs, time estimates, or both	Average change, 2017-2018
Work RVUs	98	–6.4%
Time estimates	98	–22.4

Note: RVU (relative value unit). Table includes services with work RVUs and times estimates in 2017 and proposed work RVUs and time estimates for 2018. A time estimate is the estimated amount of time it takes practitioners to perform a service.

Proposed payment rates under the Medicare fee schedule for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital

Section 603 of the Bipartisan Budget Act of 2015 prohibits certain provider-based departments (PBDs) that are located off a hospital campus (off-campus PBDs) from billing under the hospital outpatient prospective payment system (OPPS). This provision applies to off-campus PBDs that began providing OPPS services on or after November 2, 2015 (the date of passage of the Act). Instead of billing under the OPPS, these off-campus PBDs must bill under "the applicable payment system," which CMS established as the fee schedule for physicians and other health professionals, also known as the physician fee schedule (PFS).

The Congress passed this legislation in response to hospitals acquiring freestanding physician offices, establishing these offices as PBDs, and billing for their services under the OPPS. Medicare makes separate payments for the professional services of the practitioner under the PFS and for the facility services under the OPPS. In many cases, a physician's practice that is purchased by a hospital stays in the same off-campus location and treats the same patients. The acquisition of freestanding offices led to a shift of billing of ambulatory services from offices to PBDs.[9] Because these services are paid under both the OPPS and PFS, they result in increased Medicare spending, which leads to higher costs for taxpayers and higher cost sharing for beneficiaries, without any changes in the services provided.

For 2017, CMS determined that the payment rate for services provided at these PBDs would generally equal 50 percent of the OPPS rate. CMS applies this 50 percent adjustment to all services except for drugs that are separately paid under the OPPS and services that are currently paid using PFS rates in hospital outpatient departments, such as physical therapy. CMS determined the 50 percent adjustment by comparing the OPPS rate with the PFS rate for 22 frequently billed codes in off-campus PBDs. However, this analysis did not include the most frequently billed code in off-campus PBDs: hospital outpatient clinic visit.

[9] Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

For 2018, CMS proposes to reduce the payment rate for services provided at certain off-campus PBDs from 50 percent of the OPPS rate to 25 percent of the OPPS rate. CMS determined this adjustment by comparing the OPPS rate with the PFS rate for the most frequently billed code in off-campus PBDs: hospital outpatient clinic visit.

CMS proposes to apply a standard, across-the-board 25 percent adjustment factor to all services provided at certain off-campus PBDs for 2018 (excluding separately-payable drugs and services currently paid at PFS rates). However, CMS recognizes that the difference between the OPPS rate and the PFS rate varies for many services, and that other factors (e.g., policies related to paying for multiple procedures on the same day) contribute to differences in payment amounts between settings. Although the 25 percent adjustment factor is an imprecise proxy for the difference between OPPS and PFS payment rates, CMS believes it is a better proxy than the current 50 percent adjustment factor. CMS asks for comment on its analysis and the proposed adjustment factor.

Comment

In 2012 and 2014, the Commission recommended a different approach to address the issue of the higher Medicare payments that result from hospitals converting freestanding offices to off-campus PBDs. [10,11] Our approach would identify services that meet a certain set of criteria. For services that meet these criteria, the OPPS payment rates would be adjusted so that total Medicare payments are the same whether the service is provided in a freestanding office or a hospital outpatient department. The adjustments should apply at the level of ambulatory payment classifications (APCs), which are groups of services with clinical and cost similarity that are used in the OPPS. This policy would generally lead to reductions in OPPS rates. Because our recommended approach does not distinguish between on-campus and off-campus PBDs, it would be less complex to implement than the policy in Section 603. However, we recognize that the Congress took a different approach than ours based on whether an off-campus PBD began billing after a certain date.

To ensure that total Medicare payments for a service are the same regardless of setting, CMS should calculate separate adjustment factors for each APC instead of applying an across-the-board adjustment for all services furnished in off-campus PBDs. This method is consistent with Section 603 and consistent with the method we recommended in 2012 and 2014. Because differences in payment rates across settings often vary from service to service, applying a single adjustment factor would lead to payment rates that are too high for certain services and too low for others. In addition, the adjustment factors for APCs should account for differences in payment policies between settings. For example, the OPPS is more likely to package ancillary services with the primary service than the PFS.

---

[10] Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.
[11] Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Initial data collection and reporting periods for Clinical Laboratory Fee Schedule

The Protecting Access to Medicare Act of 2014 required certain laboratories to report private payer rate and volume data to CMS. That data are then to be used to set payment rates for the Clinical Laboratory Fee Schedule. The first data reporting period ended May 30, 2017, and CMS is soliciting feedback from laboratories on their experience with the data reporting process.

Comment

We commend CMS's efforts to improve the process by which laboratories report their private payer data. However, any improvements CMS may make to the reporting process should not delay the implementation of the new Clinical Laboratory Fee Schedule rates on January 1, 2018. Delaying implementation would increase costs for both the Medicare program and beneficiaries (through higher Part B premiums), as Medicare's current payment rates for laboratory services are often far in excess of private payer rates.

Part B drugs: Payment for biosimilar biological products

In the CY 2016 PFS final rule, CMS finalized its policy on paying for biosimilar products that rely on a common reference product's biologics license application under the Food and Drug Administration's approval process. Under this policy, all biosimilars associated with a given reference biologic are assigned to a common billing code and receive a payment equal to 100 percent of the weighted average of the average sales prices (ASPs) for the biosimilar products plus a constant dollar add-on equal to 6 percent of the reference product's ASP.

The NPRM is seeking comments about the effects of this payment policy on the U.S. biosimilar product marketplace since the regulation went into effect on January 1, 2016. CMS is also seeking information about other novel payment policies that would foster competition, increase access, and drive cost savings in the biologic marketplace. The NPRM does not make a proposal to change Medicare's current biosimilar payment policy.

Comment

The Commission supports Medicare expanding its common billing code policy to group biosimilars together with their reference product in one billing code. Such a policy would spur even more price competition than current policy. In our June 2017 report to the Congress, we recommended that the Congress require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.[12] CMS should pursue statutory authority to use a common billing code for the reference biologic and its biosimilars if the agency does not believe it has such authority. Beyond grouping a reference biologic with its biosimilars, we also are interested in the use of a broader common billing code within the current ASP payment system to maximize

[12] 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, calculated from the combined sales for both the reference and biosimilar products

competition among products with similar health effects that have separate billing codes (e.g., grouping all erythropoiesis-stimulating products in one billing code).

The Commission is against separate billing codes for each biosimilar because we believe that the reference product and its biosimilars should all be included in the same billing code. Therefore, we support Medicare's continued use of a common billing code to pay for biosimilars associated with a specific reference product. This policy is consistent with the Commission's belief that Medicare should pay similar rates for similar care. Within the current ASP payment system, competition is maximized when products that result in similar health effects are assigned to the same billing code and paid according to the volume-weighted ASP of all products assigned to the code. Medicare would be moving in the wrong direction by assigning each biosimilar to its own code; such a policy would decrease price competition between the biosimilars and result in higher spending for beneficiaries and taxpayers.

Separate billing codes do not maximize price competition, as demonstrated by the pricing behavior of the manufacturers of currently available reference biologics (Neupogen and Remicade). The expectation is that the price of each reference product would decline after the introduction of their biosimilars. Instead, since the launch of their respective biosimilars, Neupogen's ASP has increased by 1 percent (over eight quarters) while Remicade's ASP has increased by 4 percent (over 3 quarters). In addition, our analysis of the changes in ASP between April 2012 and April 2017 for eight groups of competing products that have separate billing codes found that the ASPs for nearly all of the products have either remained the same or increased.[13]

Assigning each biosimilar to its own billing code could result in higher launch prices than under the current policy because each product would initially be priced using its wholesale acquisition cost (WAC) (for two to three calendar quarters to permit time for manufacturers to report sales data to CMS and for the agency to calculate an ASP). Putting a product in its own billing code and basing its initial payment rate on WAC gives manufacturers an incentive to set a high WAC at launch and then discount the price to create a large spread between the Medicare payment amount and the provider's acquisition cost. (Because the ASP payment rate is set based on transaction prices from two quarters prior, when prices go down, purchasers may buy products at prices significantly below the payment rate until the ASP catches up.) In fact, we observed this phenomenon with the first biosimilar to Remicade, Inflectra. Because Inflectra was the first biosimilar to Remicade, it was initially in its own billing code and paid based on WAC for the first two quarters it was on the market. Inflectra's manufacturer set its WAC at a level that resulted in Medicare paying a higher price for the biosimilar Inflectra than the reference biologic Remicade, 22 percent and 17 percent higher, respectively, during the first two quarters that Inflectra was on the market. Because Medicare's current biosimilar payment policy groups all subsequent biosimilars together in the same billing code, subsequent biosimilar manufacturers will not have the same incentive to set a high WAC. If CMS were to reverse its biosimilar payment policy and

[13] The eight groups included in this analysis are: erythropoiesis-stimulating agents, anti-vascular endothelial growth factors, targeted immune modulators, leukocyte growth factors, immune globulins, luteinizing hormone-releasing hormone agonists, viscosupplements, and botulinum toxins. See Chapter 2 of the Commission's report to the Congress located at http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0 for additional details of this analysis.

give all biosimilar products their own billing code, the manufacturer of each biosimilar product would have an incentive to set a high WAC and discount off of that WAC, which would lead to higher Medicare payment rates for beneficiaries and taxpayers.

Some stakeholders contend that there are benefits to being able to track which biosimilar was given to a particular beneficiary through separate Healthcare Common Procedure Coding System codes in administrative claims data for the purposes of monitoring adverse events. However, under CMS's current coding policy, clinicians are required to report a modifier that distinguishes these products on claims, which eliminates the need for separate billing codes for this purpose.

Most stakeholders acknowledge that using common billing codes will result in lower drug prices, but they contend that the lower prices paid will reduce the profit potential and return on investment for new products, which will result in the loss of investment capital from venture capitalists. According to the industry's assumptions, the loss of investment capital would, in turn, decrease the number of manufacturers choosing to enter (or remain in) the biosimilar market, which would decrease the uptake of biosimilars. Ultimately, critics contend, there would be fewer products available, thus leading to less competition and higher prices.

Available objective, transparent data are insufficient regarding the research and development costs of biosimilars, although recent research by Yu and colleagues suggests that the additional revenue generated by the difference in prices between the United States and other countries substantially exceeds global research and development spending.[14] Given the large market for Part B drugs, it could be argued that development of biologics is likely to continue, even in the presence of a common billing code policy. In 2014, we estimate that Medicare spending for biologics accounted for roughly one-quarter of total biologic spending in the U.S.[15] With the enormous market that biologics command, biosimilar manufacturers have the opportunity for substantial revenue gains, even with the expected biosimilar discounts that studies estimate range from 10 percent to 50 percent of reference biologics.[16] In Europe, the biosimilar market has grown (with, in some instances, multiple biosimilars in a given therapeutic class) even with much stricter price policies. As of March 2017, there were 28 biosimilars available in Europe.[17]

In summary, the Commission supports Medicare's continued use of common billing codes to pay for biosimilars associated with a given reference product. This policy is consistent with the Commission's belief that Medicare should pay similar rates for similar care. Assigning each

---

[14] Yu, N., Z. Helms, and P. B. Bach. 2017. R&D costs for pharmaceutical companies do not explain elevated US drug prices. *Health Affairs* blog. July 28.

[15] We estimated Medicare's share of U.S. biologic spending based on: 1) QuintilesIMS estimates for total biologic spending; and 2) our conservative spending estimates for Parts B and D biologics. Because we do not have access to Part D rebate data, we estimated Part D spending net of rebates by applying the following estimates: a 50 percent discount to spending for insulin products and a 15 percent discount to spending for all other biologics. Part B biologic spending only includes the leading eight biologics (as measured by spending). Total spending for biologics is based on data reported in: QuintilesIMS Institute Medicines. 2017. *Use and Spending in the U.S.* Parsippany, NJ: QuintilesIMS Institute.

[16] Mulcahy, A., Z. Predmore, and S. Mattke. 2014. *Perspective: The cost saving potential of biosimilars in the United States.* Santa Monica, CA: RAND Corporation.

[17] http://www.ema.europa.eu/.

biosimilar to its own billing code would decrease price competition between the biosimilars and result in higher spending for beneficiaries and taxpayers. The Commission believes that using a common billing code for the reference product and its biosimilars would spur even more price competition than current policy and recently recommended that the Congress require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

In response to CMS's request for information about other novel payment policies that would foster competition, increase access, and lead to cost savings in the biologic marketplace, the Commission's June 2017 report recommended the following approaches to improve payment for Part B drugs and biologics:

- *Improving ASP data reporting.* CMS relies on manufacturer reported ASP data to calculate payment rates for Part B drugs, but not all manufacturers are required to report ASP data. The Commission recommended that all Part B drug manufacturers be required to report ASP data, with civil monetary penalties for failure to report. Requiring ASP data from all manufacturers would improve the accuracy of CMS's drug prices and help prevent CMS from relying on other, less appropriate prices, such as WACs.

- *Modifying payment rates for drugs and biologicals paid at 106 percent of WAC.* New single source drugs, biologics, and the first biosimilar to a reference biologic are paid 106 percent of WAC for the first two to three quarters on the market. WAC is an undiscounted price that does not reflect prompt pay discounts or other discounts. The Commission recommended reducing the WAC add-on from 6 percent to 3 percent, which would reduce the current excessive payment rates for WAC-priced products and better align the WAC-based and ASP-based payment rates for the same product.

- *Establishing an ASP inflation rebate.* Medicare's ASP + 6 percent payment rates are driven by manufacturers' pricing decisions. In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for a drug can increase over time. The Commission recommended establishing an ASP inflation rebate as a way to protect the Medicare program and beneficiaries from rapid price increases for individual products.

- *Establishing a drug value program.* Over the longer term, the Commission recommended Medicare develop an alternative program—which we refer to as the Part B Drug Value Program (DVP)—that would allow providers to voluntarily enroll and would use private vendors to negotiate drug prices with manufacturers. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers. To encourage provider enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing) and with DVP vendors and Medicare.

Medicare Diabetes Prevention Program expanded model

In this NPRM, CMS continues to develop proposals for a benefit in FFS Medicare based on the Diabetes Prevention Program (DPP). This benefit would consist of a lifestyle change intervention based on a structured set of counseling sessions for individuals at risk of developing diabetes. In 2013, the Centers for Medicare and Medicaid Innovation funded the YMCA of the United States to test the Diabetes Prevention Program through a Health Care Innovation Award grant. Based on the evaluation of that grant coupled with external studies of the DPP in other settings, in 2016 the CMS Office of the Actuary certified that the DPP met the criteria for expansion (which is that it would reduce spending without reducing the quality of care, or improve patient care without increasing spending).[18]

In the 2017 fee schedule rule, CMS established initial guidelines for the benefit and proposed that it would begin on January 1, 2018, including a process to start enrolling DPP suppliers under a new enrollment category. In this NPRM, CMS continues to develop policies for the DPP benefit. CMS proposes to: delay the implementation date from January 1, 2018 to April 1, 2018, refine the period of performance, modify the payment amount and schedule; and that the DPP benefit could be delivered only in-person (with virtual visits only allowed for make-up visits). CMS also proposes modest changes to the eligibility criteria. CMS has also provided more detail on eligibility for ongoing maintenance sessions, and proposed policies for individuals who switch suppliers during their period of eligibility.

The Diabetes Prevention Program consists of a set of structured group sessions led by a lifestyle coach and following a standard curriculum from the Centers for Disease Control and Prevention (CDC). The CDC certifies organizations to deliver the DPP benefit. Presently the CDC lists 1,367 organizations that have applied to offer the DPP benefit, of which 123 have full certification and 1,244 have pending certification.[19] Organizations can receive pending certification immediately, if they comply with certain CDC requirements. After 24 months, provided the organization has been submitting required information and met certain criteria for session attendance and weight loss, the organization can receive full CDC certification.

CMS is also proposing to change the payment amount and structure for the DPP. In the 2017 proposed and final rule, CMS established a payment schedule that would total, at maximum, $630 per individual (individuals are eligible only once in their lifetime for the benefit). In the 2018 NPRM, CMS is proposing to modify the payment amount and schedule to total, at maximum, $810 in payments per individual. CMS has proposed that the DPP would be considered to be a preventive service under Medicare, and as such, beneficiaries receiving the service would not be required to pay coinsurance.

All Medicare FFS beneficiaries would be eligible for the DPP benefit if they: are covered under Part B of Medicare; have a BMI of 25 or over (or a lower BMI if they have Asian ancestry); and have certain lab values indicating pre-diabetes. In this NPRM, CMS also clarifies that individuals

[18] Spitalnic, P. Certification of Medicare Diabetes Prevention Program. March 14, 2016.
[19] Centers for Disease Control and Prevention. 2017. Registry of all recognized organizations. https://nccd.cdc.gov/DDT_DPRP/Registry.aspx

with diabetes (or who have had diabetes in the past) are not eligible for the benefit, but that previous diagnoses of gestational diabetes does not disqualify an individual from being eligible for DPP.

Comment

We reiterate the Commission's comments responding to CMS' proposals in the 2017 NPRM.[20] Specifically, we are concerned about the design of the DPP benefit in two ways: 1) that the benefit could be expanded more widely than is appropriate or cost-effective; and 2) that the design of the DPP benefit poses a high risk of fraud and overuse.

We agree with CMS that the evaluations of the DPP show it to be highly effective in promoting weight loss. But this does not mean that the model should be imported, whole cloth, into FFS Medicare without appropriate limitations. For example, the DPP evaluations cited in CDC's research largely focused on commercial-age populations, and the CMMI demonstration did not have a significant number of enrollees over the age of 75. All of the evaluations to date have focused on much smaller interventions than those contemplated for FFS Medicare (the CMMI demonstration included fewer than 7,000 beneficiaries), and fewer than 10 percent of DPP organizations have reached full certification—the vast majority are only preliminary (in large part because of a significant number of recent entrants).

Based on the experience of other supplier-driven benefits in FFS Medicare, we are concerned that there will be a broad expansion of the benefit and take-up, far beyond the population for which it is appropriate. For example, CMS has proposed no limit on the number of individuals that can attend a DPP session, and there is no requirement that a clinician order the service for the beneficiary, which would help ensure clinical appropriateness or integration with other medical services and health maintenance goals. So, for example, one could envision a DPP supplier conducting a session for a large group of beneficiaries at a nursing home, for example, without consideration of whether a general weight loss target is clinically appropriate for each beneficiary in that group.

Furthermore, the Office of the Actuary certified the DPP for expansion into the FFS program based on the payment schedule CMS initially proposed—with a maximum amount per beneficiary of $630. CMS has not provided detail regarding whether the newly proposed higher payment amount and schedule (with a maximum of $810 per beneficiary) would still meet the Actuary's certification.

Finally, CMS should use all program integrity tools at its disposal, including significant oversight from the OIG and limitations on supplier enrollment (particularly for organizations that have not yet received CDC full certification). CMS should also consider requiring that a clinician order the service—to ensure that the DPP benefit is clinically indicated and appropriate for the beneficiary.

[20] Medicare Payment Advisory Commission. 2016. Comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule on the physician fee schedule and other revisions to Part B for CY 2017.

Medicare Shared Savings Program

As originally enacted, the Affordable Care Act required assigning beneficiaries to ACOs in the Medicare Shared Savings Program (MSSP) based on the beneficiaries' use of primary care services provided by a primary care physician. This created an issue for ACOs that included Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs) because those entities' claims did not routinely record the practitioner who provided the service or, in some cases, the specific service performed. Section 17007 of the 21st Century Cures Act, amended section 1899(c) of the Act to require the Secretary to assign beneficiaries to ACOs participating in the MSSP based not only on their utilization of primary care services furnished by physicians but also on their utilization of services furnished by RHCs and FQHCs. This change is effective for performance years beginning on or after January 1, 2019. The proposed rule implements the change by treating all RHC and FQHC claims as primary care services provided by primary care physicians for beneficiary assignment purposes.

Comment

We support the steps outlined in the proposed rule to treat all RHC and FQHC claims as primary care services provided by primary care physicians for beneficiary assignment purposes. In fact, we made a similar proposal in our June 6, 2011 comment letter, and welcome this innovation.

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, at 202-220-3700.

Sincerely,

Francis J. Crosson, M.D.
Chairman