

September 9, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: File code CMS-1751-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled: "Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements," published in the *Federal Register*, vol. 86, no. 139, pp. 39104–39907 (July 23, 2021). We appreciate your staff's ongoing efforts to administer and improve Medicare's payment systems for physician and other health professional services (including implementing the Quality Payment Program and Medicare Shared Savings Program), particularly given the many competing demands on the agency's staff. We hope that our comments are helpful in those endeavors.

Our comments address the following provisions in the proposed rule:

- **Practice expense relative value units:** The Commission strongly supports CMS's proposal to update the prices for clinical labor that are used to determine practice expense relative value units.
- **Telehealth services:** The Commission supports CMS covering certain telehealth services on a temporary basis after the coronavirus public health emergency (PHE) to enable the agency to gather more evidence on these services to determine whether they should be added permanently to the Medicare telehealth services list. When Medicare expands telehealth for mental health services, CMS should adopt safeguards to protect the program and beneficiaries from inappropriate use.
- **Rural health clinics (RHCs) and federally qualified health centers (FQHCs):** The Commission supports continuing to allow FQHCs and RHCs to bill for mental health visits performed via telecommunications technology after the PHE expires but disagrees with

paying standard FQHC and RHC rates for such visits. Instead, the Commission believes that FQHC- and RHC-provided telehealth services should be paid at rates comparable to those under the physician fee schedule.

- **ASP reporting requirement:** We conclude that CMS’s proposal to require repackagers without a rebate agreement to report ASP data is reasonable.
- **Part B drug payment rates and self-administered products:** We support the proposal to utilize the lesser-of payment methodology for all self-administered national drug codes identified by the Office of Inspector General in future studies.
- **Medicare Part B drug payment for drugs approved through the pathway established under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act:** We reiterate our prior year’s comment, supporting CMS’s proposal to codify its longstanding process for assigning 505(b)(2) drugs into billing codes.
- **Medicare Shared Savings Program:** We express concerns with potential policies that would remove ACO beneficiaries from regional benchmark calculations and allow larger increases to benchmarks because of regional risk scores; we offer alternatives that better align with the program’s goal of improving the efficiencies of care delivery.
- **Medicare Ground Ambulance Services Data Collection System:** We support delaying data collection until after 2022 to increase the likelihood that information is collected during a post-pandemic period that is more reflective of a typical year.
- **Payment for specimen collection for COVID-19 laboratory tests:** The Commission supports CMS’s proposal to end the enhanced specimen collection fees for COVID-19 testing once the public health emergency expires.
- **Open Payments:** The Commission strongly supports CMS’s proposal to define physician-owned distributorships and require them to identify themselves when registering or recertifying with the Open Payments program.
- **CY 2022 updates to the Quality Payment Program:** We support transitioning “traditional” Merit-based Incentive Payment System (MIPS) to MIPS Value Pathways measure sets but share CMS’s concern that multi-specialty groups may use the new option of reporting at the subgroup level to avoid being assessed on cost measures; we suggest some ways to guard against this.

Practice expense relative value units

Practice expense relative value units (RVUs) are intended to cover the direct and indirect costs of operating a practice. Direct practice expenses include three components: medical equipment, medical supplies, and clinical staff. Indirect practice expenses include administrative labor, office expenses, and all other expenses. To determine the direct practice expense of each service, CMS periodically collects information on the types and quantities of equipment, supplies, and clinical staff used for each service and the price of each of these inputs. For example, in 2019, CMS began

updating the prices of equipment and supplies over a four-year period; the transition to practice expense RVUs based on this new price information will be complete in 2022.

However, CMS last updated the clinical labor prices used to calculate practice expense RVUs in 2002. Stakeholders have raised concerns that the RVUs thus do not reflect current wage rates. In addition, the transition to RVUs based on more recent equipment and supply prices may result in clinical labor becoming undervalued relative to equipment and supplies. CMS proposes to remedy this situation beginning in 2022 by updating the clinical labor prices underlying the practice expense RVUs using wage data from the Bureau of Labor Statistics and other sources. CMS estimates that using more recent wage data will result in payment increases for specialties with a higher share of direct practice expenses related to clinical labor (e.g., family practice) and payment decreases for specialties with a lower share of direct practice expenses related to clinical labor (e.g., interventional radiology). CMS is considering phasing in the updated clinical labor prices over a four-year period to smooth out any resulting payment changes.

Comment

The Commission strongly supports CMS's proposal to update the prices for clinical labor for 2022. As we stated in our June 2006 report to the Congress, the Commission contends that CMS needs recurring and accurate sources of data to keep practice expense RVUs up to date.¹ Such data sources should capture the prices of equipment and supplies, wage rates for clinical staff, the types and quantities of direct practice expense inputs, and specialties' practice costs. Inaccurate prices for practice expense inputs could lead to distortions in the practice expense RVUs. For example, updating prices for equipment and supplies but not clinical labor could lead to undervaluing of services that use a high share of clinical labor.

We urge CMS to update the prices for clinical labor during a shorter transition period than the proposed four-year transition because inaccurate payment rates distort the market for clinician services. By the time the four-year transition is over, the clinical labor prices may have become out of date again. Similarly, we supported a shorter transition period for the phase in of updated prices for equipment and supplies when CMS proposed a four-year transition for new prices in the proposed rule for 2019.² Going forward, CMS should set a reasonable schedule to periodically review and update prices for equipment, supplies, and clinical labor to maintain payment accuracy.

Telehealth services

Absent the current PHE, under the physician fee schedule (PFS), Medicare covers a limited set of telehealth services in rural locations. During the PHE, CMS has expanded Medicare's coverage of

¹ Medicare Payment Advisory Commission. 2006. *Report to the Congress: Increasing the value of Medicare*. Washington, DC. MedPAC.

² Medicare Payment Advisory Commission. 2018. MedPAC comment on the Centers for Medicare & Medicaid Services' proposed rule entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program." Letter to the Administrator. September 4.

telehealth services on a temporary and emergency basis under the Section 1135 waiver authority, as well as additional authority given by Congress under the Coronavirus Preparedness and Response Supplemental Appropriations Act and the Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES Act). CMS proposes in this rulemaking to extend the timeframe for covering some telehealth services, implement the expansion of mental health services provided by telehealth, and extend the flexibilities of virtual direct supervision.

Extend the timeframe for covering some telehealth services

CMS has established a regulatory process and criteria to review whether a service should be added to or deleted from the Medicare list of allowable telehealth services. The criteria include whether the service is similar to an existing telehealth service in authorizing legislation or whether it demonstrates clinical benefit. In response to the COVID-19 pandemic, CMS created a third category of services that are added to the allowable Medicare telehealth services list on a temporary basis through the end of the calendar year (CY) in which the PHE ends. This new category, known as Category 3, includes services that likely have a clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions.

CMS proposes to extend the Category 3 telehealth code list from the end of CY 2021 until the end of CY 2023 to allow stakeholders more time to submit information to CMS about whether these telehealth services have contributed positively or negatively to the quality of care provided to beneficiaries during the PHE. CMS can then evaluate which services should be permanent additions to the Medicare telehealth services list.

Comment

The Commission supports CMS covering certain telehealth services on a temporary basis after the PHE to enable the agency to gather more evidence on these services before determining whether they should be added permanently to the Medicare telehealth services list. CMS's proposal is consistent with the Commission's recent policy option for expanding fee-for-service Medicare's coverage of telehealth services after the PHE.³ Under this policy option, Medicare should temporarily cover selected telehealth services for a limited duration after the PHE (e.g., one to two years) if there is potential for clinical benefit. This temporary expansion would allow policymakers to gather more evidence about the impact of telehealth outside of the PHE to inform any permanent changes. Policymakers should use the principles of access, quality, and cost to evaluate individual telehealth services before permanently covering them under Medicare.

Implement the expansion of mental health services provided by telehealth

The Consolidated Appropriations Act, 2021 (CAA) removed geographic restrictions and added a beneficiary's home as a permissible originating site for telehealth services when used for the

³ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

purposes of diagnosis, evaluation, or treatment of a mental health disorder. The CAA also requires that a non-telehealth service (i.e., an in-person visit) be provided by the clinician furnishing mental telehealth services within six months prior to the initial telehealth service. For subsequent mental telehealth services, the CAA requires that a clinician provide a non-telehealth service at intervals that the Secretary deems appropriate.

CMS proposes to implement the statutory requirement by requiring a non-telehealth service be provided by the clinician furnishing mental telehealth services within six months prior to the initial telehealth service, and at least once every six months thereafter by the same practitioner. CMS also proposes that a clinician of the same specialty or subspecialty in the same group can provide the in-person mental health service when a beneficiary's clinician is unavailable.

During the PHE, CMS has used emergency waiver authority to cover certain telehealth services when they are provided through an audio-only interaction. For example, CMS pays for most behavioral health services that are provided through an audio-only interaction, but not audio-only physical therapy or eye exams. After the PHE, CMS will return to paying only for telehealth furnished via "interactive telecommunications systems," which must include two-way, audio/video communication technology, unless the Congress gives CMS the authority to do otherwise.

CMS has found consistent and relatively high utilization for mental health services furnished via telephone during the PHE. To increase beneficiaries' access to mental health care beyond the PHE, CMS proposes to redefine "interactive telecommunications system" to include audio-only technology when used for mental health services for established patients when the originating site is the patient's home. CMS proposes to require that an in-person item or service must be furnished within six months of such an audio-only mental telehealth service by the same provider. CMS would also limit the provision of audio-only mental health services to clinicians who also have the capability to furnish two-way, audio/video communications. CMS proposes to create a service-level claims modifier that would identify a mental telehealth service furnished to a beneficiary in their home using audio-only communications. CMS requests comments on what, if any, additional guardrails or documentation requirements should be implemented to demonstrate clinical appropriateness and minimize program integrity and patient safety concerns.

Comment

The Commission has previously recommended that policymakers use the principles of access, quality, and cost to evaluate individual telehealth services before covering them under Medicare.^{4, 5} In our 2018 report to the Congress, we included examples of how these principles could be used to evaluate the value of individual telehealth services or conditions. We suggested that mental telehealth services could be candidates for policymakers to consider incorporating into the PFS.

⁴ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

⁵ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Tele-mental health coverage could expand access to mental health clinicians, a specialty that is in short supply. Quality of care could be improved for beneficiaries who did not receive this care previously (e.g., by making medication management more accessible). Therefore, the Commission supports removing the geographic restrictions around tele-mental health services because it would improve beneficiaries' access to mental health treatment and make it more convenient for them to receive these services.

When Medicare expands telehealth, CMS should adopt safeguards to protect the program and beneficiaries from inappropriate use. Telehealth companies have been involved in several large fraud cases involving durable medical equipment (DME) and cancer genetic tests, resulting in several billions of dollars in losses for Medicare.⁶ Based on these experiences, CMS should require clinicians to provide an in-person, face-to-face visit before they order a high-cost DME product or a high-cost clinical laboratory test. Although tele-mental health services present a lower risk for overuse and fraud than expensive DME items or genetic tests, we support CMS's proposed requirement that a non-telehealth service be provided by the clinician furnishing tele-mental health services within six months prior to the initial telehealth service and within a certain amount of time before follow-up telehealth services because this requirement could protect beneficiaries and limit inappropriate use. For example, it would prevent telehealth companies that lack a physical health care office from cold-calling beneficiaries and offering them mental health services that they may not need.

However, some contend that an in-person visit requirement may limit the potential improvements in access to tele-mental health services. For example, a disabled beneficiary without transportation may have difficulty seeing a mental health clinician in person every six months. Also, clinicians may choose to not provide tele-mental health services if they are required to comply with an in-person visit rule. Therefore, CMS should continue to gather evidence about the impact of the expansion of tele-mental health services and the accompanying restrictions on access, quality, and costs. If warranted, the Congress should consider revisiting the requirement that clinicians provide a non-telehealth visit within a certain period of time before a tele-mental health service.

The Commission also supports the creation of a new service-level claims modifier for audio-only mental health telehealth services furnished to beneficiaries in their homes. We agree with CMS that the addition of a service-level modifier is necessary to track utilization and compliance, such as certifying that clinicians providing audio-only telehealth visits have audio and video technology capability but used audio-only technology due to beneficiary choice or limitations. This modifier would also help researchers evaluate the quality of audio-only telehealth services for mental health conditions.

As we discussed in our March 2021 report to the Congress, CMS should establish the following safeguards to protect the program and beneficiaries from unnecessary spending and potential fraud related to telehealth:

⁶ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC

- CMS should apply additional scrutiny to outlier clinicians who bill many more telehealth services per beneficiary than other clinicians or who bill for a high number of services in a week or a month, and
- Prohibit “incident to” billing for telehealth services provided by any clinician who can bill Medicare directly.

Extend the flexibilities of virtual direct supervision

Although “incident to” services usually require the direct supervision of a clinician, meaning that the billing clinician must be present during the service and immediately available to furnish assistance/direction throughout the performance of the service, physical proximity of the clinician to the patient might present exposure risks to the clinician or patient during the PHE. Due to these concerns, CMS changed the definition of “direct supervision” during the PHE to allow clinicians to provide direct supervision virtually through real-time, interactive audio-video technology instead of in person. This temporary change was set to expire at the end of the calendar year in which the PHE ends, or December 31, 2021, whichever comes later. CMS is seeking comment on whether this flexibility should be made permanent or should be temporarily extended through a later date.

Comment

The Commission supports temporarily extending the policy that would allow clinicians to provide direct supervision virtually through interactive audio-video technology instead of in person for a limited period of time after the PHE ends. During this temporary extension, CMS should evaluate the impact of this policy on beneficiaries’ safety, quality of care, and Medicare spending. Although CMS’s temporary policy is justified during the PHE because it reduces the risk of exposure to COVID-19 and helps ensure access to care, we have two concerns about making it permanent after the PHE in the absence of evidence about its effects on safety, quality, and spending. First, allowing clinicians to supervise “incident to” services virtually could pose a safety risk to beneficiaries because the clinician would not be physically available to help the individual being supervised, if necessary, which is important if the service is a complex procedure. Second, allowing virtual supervision could potentially enable a clinician to supervise many individuals at multiple locations at the same time. It could be difficult for a clinician to address urgent clinical needs while virtually supervising many people at multiple locations simultaneously. This scenario could also lead to higher spending by allowing clinicians to bill for more “incident-to” services during a single day.

Rural health clinics (RHCs) and federally qualified health centers (FQHCs)

Medicare pays higher rates for physician and other health professional services provided by FQHCs and RHCs to help ensure access to care in medically underserved areas or areas with clinician shortages:

- Medicare pays FQHCs using a prospective payment system (PPS). In 2021, the FQHC PPS payment rate is \$176.45; the rate is updated annually based on the FQHC market basket and individual FQHC rates are adjusted based on geography.
- Medicare generally pays RHCs their costs, subject to a per visit limit. The per visit limit for provider-based RHCs that were enrolled in Medicare as of December 2020 and associated with a hospital with fewer than 50 beds is based on each RHC's cost-based payment rates in 2020, updated annually using the Medicare Economic Index (MEI). Because the per visit limit is based on each facility's costs, payment limits vary among this group of RHCs; among these RHCs, Medicare's average payment per visit in 2018 was more than \$200, and many RHCs had rates that far exceeded \$200. The per visit limit for all other RHCs is set statutorily and was recently increased by 117 percent, from \$87.52 to \$190. The higher limit will be fully phased in by 2028, after which the limit will increase annually by MEI.

FQHC and RHC visits are typically required to be face-to-face (that is, in person). However, the CARES Act allowed FQHCs and RHCs to bill for telehealth services (as the distant site) during the PHE. The CARES Act also directed CMS to establish a payment rate for telehealth services billed by FQHCs and RHCs that is similar to the payment rates for comparable telehealth services billed under the PFS, essentially establishing payment parity for telehealth services billed under the PFS and by FQHCs and RHCs. In 2021, Medicare's payment rate for telehealth services billed by FQHCs and RHCs is \$99.45.

CMS proposes to continue to allow FQHCs and RHCs to bill for mental health visits performed via telecommunications technology after the PHE expires and, correspondingly, proposes to revise the regulatory requirement that an FQHC or RHC mental health visit must be face-to-face. Instead, the agency proposes that an FQHC or RHC mental health visit may be face-to-face or performed via telecommunications technology, including audio-only technologies. As a result of this proposal, FQHCs and RHCs would be paid their standard payment rates for these telehealth services, which are higher than the \$99.45 rate FQHCs and RHCs have been receiving during the PHE for the same services.

CMS believes their proposal would reduce care fragmentation and provide beneficiaries who receive care at FQHCs and RHCs the same access to mental health care as those receiving care from clinicians paid under the PFS, as Congress recently expanded access to telehealth mental health visits under the PFS. CMS solicits comments on whether the agency should require an in-person visit with an FQHC or RHC before being able to receive a telehealth visit from an FQHC or RHC clinician.

Comment

The Commission supports continuing to allow FQHCs and RHCs to bill for mental health visits performed via telecommunications technology after the PHE expires. The Commission believes in equitable access to mental health care for all beneficiaries and applauds CMS for seeking to improve access.

However, the Commission disagrees with CMS's proposal to pay for telehealth services at standard, in-person FQHC and RHC rates (e.g., \$176.45 per visit for FQHCs and an average of more than \$200 per visit for certain provider-based RHCs). Unless compelling data emerges suggesting the need for such high payment rates for telehealth services, the Commission contends that allowing FQHCs and RHCs to bill for telehealth mental health visits at rates comparable to analogous telehealth services billed under the PFS is a preferable approach that balances the dual goals of ensuring beneficiary access and being a prudent fiscal steward of the Medicare program.⁷

Medicare's payment rates for in-person FQHC and RHC visits are higher than PFS rates. For example, for a midlevel office visit in 2021, Medicare's FQHC rate (\$176) is nearly double the PFS rate (\$92) and many provider-based RHCs are paid more than double the PFS rate.⁸ One justification for higher rates is to provide an incentive for clinicians to locate and practice in medically underserved areas, such as certain rural areas or areas with high poverty rates. However, clinicians who furnish telehealth services do not need to be physically located in those areas, so the higher rates for FQHC- and RHC-provided telehealth services might not be necessary to ensure access.

Paying standard FQHC and RHC rates for telehealth visits might also provide a disincentive to furnish in-person care, as furnishing a telehealth visit likely costs less than an in-person visit due to reduced facility costs. Moreover, paying standard FQHC and RHC rates for telehealth visits will result in paying substantially more for an FQHC- or RHC-provided telehealth service than if the same service were provided in-person by a clinician billing under the PFS. This again might disincentivize the provision of in-person care.

If CMS proceeds with this proposal, the Commission recommends requiring a beneficiary to have had an in-person visit with a given FQHC or RHC clinician within the past six months in order to qualify for a telehealth visit. Without such a requirement, FQHCs and RHCs would be able to bill telehealth visits—often at double PFS payment rates—for beneficiaries from non-medically underserved areas (i.e., outside their local service areas). Such activity would increase costs for the Medicare program and beneficiaries without improving access; undermine competition (as clinicians compete to bill under the highest paid facility as opposed to competing for patients based on quality and service); and could encourage the development of abusive billing practices that result in fragmented care (e.g., an RHC located in rural Virginia hiring a nurse practitioner who lives in Richmond, VA to bill telehealth visits for beneficiaries from across the state in order to get the facility's higher rates).

Implementing this restriction will help limit some of the potential negative consequences of paying telehealth mental health visits at standard FQHC and RHC rates. In addition, the Commission suggests CMS monitor how FQHCs and RHCs furnish telehealth visits. For example, if FQHCs and RHCs contract with firms solely to furnish telehealth visits, the justification for paying

⁷If CMS has determined it does not have the authority to cap telehealth visits billed through FQHCs and RHCs at PFS rates, the agency should seek additional legislative authority.

⁸The PFS, FQHC, and RHC rates are not perfectly comparable because the payment for most professional services is bundled into FQHC and RHC rates, while such services are separately billable under the PFS. However, FQHCs and RHCs still receive substantially higher Medicare rates even after accounting for this enhanced bundling.

standard FQHC and RHC rates is likely limited, especially if such firms are actively contracting with other providers who are paid PFS rates. CMS should also seek to better understand how much it costs FQHCs and RHCs to furnish telehealth visits. CMS already requires FQHCs and RHCs to report their telehealth costs on their respective cost reports. CMS could use these or similar data to determine whether standard FQHC or RHC payment rates are necessary to ensure access or whether the lower, PFS rate is more appropriate. Over time, CMS should also consider incorporating the cost of telehealth visits into the rate setting process for FQHCs and RHCs.⁹

ASP reporting requirement

The Consolidated Appropriations Act, 2021 (CAA) requires manufacturers of Part B drugs without a Medicaid rebate agreement to report average sales price (ASP) data, similar to the existing requirement for manufacturers with a Medicaid rebate agreement. The CAA also gives the Secretary the discretion to exclude drug repackagers without a Medicaid rebate agreement from ASP data reporting, but it does not give CMS similar authority to exclude drug repackagers with a rebate agreement. CMS conducted an analysis of manufacturers that currently report ASP data and those that face a new requirement to report ASP data under the CAA and found that repackagers constitute a small portion of both groups. Based on that analysis, CMS proposes not to exercise its discretion to exempt repackagers from the new ASP reporting requirement, and thus require repackagers to report ASP data.

Comment

The Commission supports the implementation of the new ASP reporting requirement for manufacturers without a rebate agreement. This change is consistent with a MedPAC recommendation in June 2017 that all manufacturers of Part B drugs should be required to report ASP data.¹⁰ The Commission suggested in its June 2017 report that CMS be given the discretion to exclude repackagers from ASP reporting. We believe CMS's analysis and proposal to require repackagers without a rebate agreement to report ASP data is reasonable. Given that repackagers with a rebate agreement are required by statute to report ASP data, it is reasonable to require repackagers without a rebate agreement to also report ASP data. Having ASP data from repackagers with and without rebate agreements could also permit future analysis of the effect of repackagers' ASP submissions on Medicare Part B payment rates.

Part B drug payment rates and self-administered products

Medicare Part B covers provider-administered drugs and does not generally cover drugs that are considered usually self-administered. In a recent study, the Office of Inspector General found that for two Part B-covered biologics, the ASP payment rates for the billing codes were being inflated because non-covered self-administered versions of the product were included in the ASP payment

⁹Currently, FQHCs and RHCs are required to separately report their telehealth costs, but these data are not used in the rate setting process.

¹⁰ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

rate calculations.¹¹ The CAA, 2021 established a requirement that, for these two products, the Part B ASP payment rates be based on the lesser of the weighted average ASP calculated for (1) all national drug codes (NDCs) associated with the product or (2) all NDCs except those identified by OIG as self-administered. In addition, the CAA, 2021 directs the OIG to conduct additional periodic studies to identify whether there are additional NDCs for self-administered products covered by Part B that should be excluded from ASP payment rate calculations. The statute gives the Secretary authority, to the extent appropriate, to apply the “lesser of” payment methodology for additional self-administered NDCs identified by the OIG in the future. CMS proposes that the application of the “lesser of” methodology be deemed appropriate for all future self-administered NDCs identified by the OIG (with an exception for products that are in short supply).

Comment

We support CMS’s proposal to utilize the lesser-of payment methodology for all self-administered NDCs identified by the OIG in future studies. The “lesser of” approach eliminates the potential for non-covered self-administered forms of a product to inflate Medicare Part B payment rates and results in savings for beneficiaries and taxpayers.

Medicare Part B drug payment for drugs approved through the pathway established under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act

A 505(b)(2) application is a type of new drug application (NDA) that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In some cases, drugs approved under section 505(b)(2) share significant portions of labeling with generic drugs that are paid as multiple source drugs under section 1847A of the Social Security Act. The 505(b)(2) pathway is a hybrid between the generic approval process (under 505(b)(j)) and a full NDA under 505 (b)(1). According to Freije and colleagues, most 505(b)(2) applications consist of changes to a previously approved drug product (e.g., a new dosage form, new route of administration, etc.).¹²

In the CY 2021 rulemaking, CMS proposed to codify its longstanding process for determining whether a 505(b)(2) drug would be assigned to a multiple-source or single-source billing code. In the CY 2021 proposed rule, CMS stated that the agency determines whether to assign a 505(b)(2) drug to a multiple-source or single-source drug billing code by comparing the 505(b)(2) product with products in existing multiple-source billing codes. The comparison focuses on: active ingredients and labeling; whether the products could be ordered and used in the same way (e.g., based on dosage, administration, and pharmacokinetics); and, if necessary, additional sources such as the FDA’s Approval Summary Review, which is a part of the FDA’s application review files,

¹¹ Office of Inspector General. 2020. Loophole in drug payment rule continues to cost Medicare and beneficiaries hundreds of millions of dollars. <https://oig.hhs.gov/oei/reports/OEI-BL-20-00100.asp>.

¹² Freije, I., S. Lamouche, M. Tanguay. 2020. Review of drugs approved via the 505(b)(2) pathway: Uncovering drug development trends and regulatory requirements. *Therapeutic Innovation & Regulatory Science* 54, vol. 1 (January): 128–138.

and drug compendia. In response to commenters requesting more detail about the proposed approach, CMS did not finalize its proposal in the CY 2021 final rule.

In the CY 2022 proposed rule, CMS solicits comment on a more detailed two-part framework for determining when a section 505(b)(2) drug product would be considered a multiple source drug. The framework includes comparison of the: (1) active ingredient(s); (2) dosage form (if part of the drug product name); (3) salt form; and (4) other ingredients in the drug product formulation. For products that receive a match designation in the first portion of the framework, the second step would be to compare the pharmacokinetic and clinical studies of the 505(b)(2) drug product's FDA-approved labeling with those of the drug products already assigned to an existing multiple source code.

In making its proposal in the CY 2021 proposed rule, CMS expressed concern about high payments for some 505(b)(2) drugs that are assigned to unique separate HCPCS codes despite being described by existing multiple source drug billing codes. CMS also expressed concern about the effect of high payment amounts on beneficiaries' cost sharing for these products. In the FY 2022 proposed rule, the agency provides an example of a drug that was first approved as a lyophilized powder for reconstitution that was later approved via section 505(b)(2) as a ready-to-use intravenous bag. CMS indicates that the product in the ready-to-use intravenous bag approved via 505(b)(2), which has its own billing code, has a payment rate that is 17 times higher than the payment rate for the lyophilized form of the product paid through a multisource billing code as of July 2021.

Comment

We reiterate our comment from last year, supporting CMS's proposal to codify its longstanding process for assigning 505(b)(2) drugs into billing codes. Paying 505(b)(2) approved products that are similar to existing multiple source drugs the same rate should spur price competition among these products with similar health effects and reduce prices. In the Commission's June 2017 report to the Congress, we recommended policies to improve the ASP payment system by promoting price competition among groups of drugs with similar health effects.

Given the increasing number of drugs approved under the 505(b)(2) pathway, CMS's proposal should yield savings for both beneficiaries and taxpayers in the future, without compromising beneficiary access to needed medications. According to CMS, the number of drugs approved through the 505(b)(2) pathway established has been growing, from about 40 per year from 2011 to 2016, to about 60 to 70 per year from 2017 to 2020. According to Darrow and colleagues, applications submitted under the 505(b)(2) pathway were the majority of new drug approvals in 2017.¹³ Its increasing use over time may be driven by a number of factors, including exclusivity

¹³ Darrow, J. J., M. He, K. Stefanini. 2019. The 505(b)(2) drug approval pathway. *Food and Drug Law Journal* 74, no. 3: 403–438.

incentives that generally do not apply to generic drugs and lower research and development costs compared to drugs approved under the FDA's 505(b)(1) pathway.¹⁴

Medicare Shared Savings Program

Calculation of the regional adjustment and blended national–regional growth rates for trending and updating the benchmark

Shared savings and losses for accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP) are determined by comparing per capita Part A and Part B expenditures of beneficiaries assigned to an ACO with the ACO's financial benchmark. CMS estimates a benchmark for each ACO in each agreement period, which are five years in length as of July 2019 (the initial period of MSSP *Pathways*). Benchmarks use the three years prior to an ACO's agreement period as the baseline years. CMS computes the Part A and Part B expenditures for the beneficiaries who would have been assigned to the ACO during the baseline years. For ACOs that either started a second agreement period as of 2017 or started an agreement period as of July 2019, baseline expenditures are a blend of the ACO's historical spending and *all* the fee-for-service spending in an ACO's region (including spending attributable to the ACO's assigned population). The effect of regional spending (i.e., the regional adjustment) on the baseline calculation is capped at (plus or minus) 5 percent of national per capita expenditures. After the end of a performance year, CMS trends forward baseline expenditures to an ACO's performance year by blending the actual growth rates in the ACO's regional per capita expenditures and national per capita expenditures. The weight of the national component is equivalent to the ACO's share of assignable beneficiaries in its service area. Thus, as the ACO's share of assignable beneficiaries in its region increases, CMS places a higher weight on the national component of the blend and a lower weight on the regional component.

In the calculations of the regional adjustment and regional portion of the growth rate for trending the benchmark forward, CMS includes an ACO's beneficiaries' spending in the calculations of regional expenditures to mitigate patient selection and maintain benchmark stability when ACOs have a high regional market share. Including ACO beneficiaries also reduces the effect of differential coding between ACO and non-ACO physicians when computing an area's risk-adjusted spending. ACO stakeholders have expressed concerns that including an ACO's performance in the calculation of its regional FFS expenditures penalizes an ACO for reducing spending, particularly in rural areas.

Using MSSP *Pathways* participants in 2019, CMS's simulations found that relatively few ACOs had high market shares and found that removing each ACO's spending from its benchmark would slightly increase the average MSSP benchmark—even for ACOs with low regional market share and those in urban areas. CMS found that the median ACO regional market share was about 16 percent, and 90 percent of ACOs had a regional market share of less than 38 percent. When

¹⁴ Chandanais, R. 2017. 505 (b)(2) Regulatory pathway for new drug approvals. *Pharmacy Times*. November 1. <https://www.pharmacytimes.com/view/505-b2-regulatory-pathway-for-new-drug-approvals->

removing each ACO's spending from benchmarks, CMS found that average benchmarks would increase across all quintiles of ACO regional market share and rural status (ranging from 0.1 to 1.5 percent). However, changes to benchmarks varied by individual ACO. Those with higher market shares and in rural areas would have slightly higher average benchmark increases than ACOs with relatively lower market shares, and some ACOs would experience decreases to benchmark amounts.

To inform future rulemaking, CMS seeks comment on potential alternatives to determining regional FFS expenditures that would reduce the influence of an ACO's assigned beneficiaries on regional expenditure benchmark calculations. Specifically, CMS seeks comment on:

- what would constitute heavy penetration in the ACO's regional service area and how removing the ACO's assigned beneficiaries from regional calculations, dependent on the level of penetration, could either increase or decrease the ACO's benchmark;
- approaches that could strike a balance between adjusting program policies to address impacts on potentially few ACOs that are heavily penetrated in their regional service area while maintaining stability for most ACOs that have relatively low penetration in their regional service area;
- approaches that do not introduce an inordinate amount of administrative burden for the agency or ACOs;
- possible unintended consequences, including incentives for patient selection, market consolidation, participation of large ACOs at the expense of smaller ACOs, and penalizing ACOs for serving larger proportions of medically complex beneficiaries.

Comment

The Commission recognizes the difficulty in setting benchmarks that appropriately reward performance, including balancing incentives for ACOs that are already efficient within their region (i.e., historically low-spending ACOs) with those that are higher spending within their region (i.e., historically high-spending ACOs). In seeking to reduce the influence of an ACO's assigned beneficiaries on benchmark regional expenditure calculations, we appreciate that CMS is seeking solutions that mitigate potential imbalances of ACO incentives in the MSSP. Removing an ACO's expenditures from its benchmarks would further penalize physician practices that historically serve high-spending beneficiaries and potentially reduce incentives for most MSSP ACOs to improve care efficiencies. However, other alternatives—such as increasing the size of an ACO's region—could reduce the influence of an ACO's performance on its benchmarks while also mitigating potential threats to the program's goal of improving the efficiency of Medicare.

The balance of overall MSSP benchmark incentives currently favors historically low-spending ACOs at the expense of participation from historically high-spending ACOs. The overwhelming majority (87 percent) of the 205 ACOs that entered MSSP *Pathways* in 2019 historically had low

risk-adjusted spending and received a positive regional adjustment to benchmarks. In 2019, the Pathways ACOs with a positive regional adjustment had higher average savings relative to benchmarks (3 percent compared with 1 percent for historically high-spending ACOs) and consequently had a far higher share of ACOs that were rewarded shared savings (61 percent compared with 30 percent of historically high-spending ACOs). The incentives that seem to favor historically low-spending ACOs have coincided with record levels of shared savings in recent years. However, it is unclear whether the levels of shared savings rewarded to historically low-spending ACOs have come at the expense of overall net savings for the Medicare program. In addition, overall MSSP participation has leveled off in recent years, and incentives that seem to be unfavorable toward historically high-spending ACOs may have contributed to this trend.

The imbalance of current program incentives would likely be exacerbated through any potential change to benchmarks that removed an ACO's expenditures from its baseline or its benchmark trend factor.

- Removing each ACO's expenditures from its benchmark likely would reward historically low-spending ACOs without improving their efficiency of care while at the same time reducing incentives for participation of high-spending ACOs that likely give Medicare the greatest opportunities for efficiency improvements. CMS's simulations show that such a policy would raise benchmarks for most ACOs but decrease benchmarks for others; ACOs with historically high spending likely represent a large share of ACOs that would experience decreases to benchmarks.
- In addition, benchmarks that penalize ACOs serving historically high-spending beneficiaries in a region would inadvertently increase incentives for patient selection and market consolidation. As an ACO's regional market share increases, its assigned population would likely become less comparable with its region—even after risk adjustment. CMS's 2009 evaluation of the Physician Group Practice (PGP) demonstration (a predecessor to MSSP) cited comparability concerns between an ACO and non-ACO assigned beneficiaries when ACOs had a high market share.¹⁵
- Moreover, there are relatively few ACOs with enough market share to warrant a change in policy of this magnitude. CMS's simulations show that relatively few MSSP ACOs had high market share in 2019, which is consistent with our analysis of 2018 MSSP data where the median ACO market share was only 17 percent, and 90 percent of ACOs had regional market shares of less than 39 percent.

Medicare's current policy for calculating ACO benchmarks reasonably attempts to address high ACO market share by placing a higher weight on the national component of the blended trend factor, but the influence of an ACO's performance on its benchmark could be better addressed without explicit increases to stakeholder benchmarks. Current policy reasonably avoids policy thresholds or "cliffs," and any changes in policy should attempt to avoid any market share threshold. Instead, consistent with the Commission's recommendations on establishing geographic

¹⁵ <https://innovation.cms.gov/files/reports/pgp-rtc-sept.pdf>.

areas for payment, CMS should consider altering the calculation of regional spending in the trend factor by extending the ACO service area to a larger market area (e.g., core-based statistical areas, health service areas, or hospital referral regions).^{16,17,18,19} Using 2018 MSSP data, we simulated the change in ACO regional market share when using markets (core-based statistical areas within a state and counties in the same health service area for other areas) instead of counties. The median ACO regional market share would decrease from 17 percent under current policy to 13 percent under a larger geographic area alternative. Additionally, the number of ACOs with over 50 percent regional market share would decrease from 16 to 11, and 90 percent of ACOs would have less than one-third regional market share under a geographic area alternative. Therefore, expanding the service area of an ACO to regional markets would help reduce an ACO's influence on its regional benchmark calculation without explicitly favoring certain stakeholders (e.g., historically low-spending ACOs).

In addition to establishing geographic areas as ACO regions, CMS could consider additional modifications that reduce the influence of an ACO's performance on its benchmarks without explicit increases to benchmarks. For example, the national portion of the trend factor could either be standardized for average wages or adjusted to reflect local wage and geographic practice indices. Administrative burden under this option would be minimized by publishing these adjustments on annual basis at the county level (similar to annual estimates currently published by CMS's Office of the Actuary and CMS's Office of Enterprise Data and Analytics). For ACOs that choose prospective assignment, CMS could consider offering a prospectively set trend factor prior to the start of the performance year. This trend factor could utilize the local and national estimates in the rate book recently developed for the Direct Contracting demonstration. Any changes that CMS considers to benchmarks should enhance incentives for care improvement and avoid penalizing populations that are more complex and costly than the ACO's regional average.

Risk adjustment methodology

The risk adjustment model (known as the CMS-hierarchical condition category (CMS-HCC) model) uses beneficiary demographic information along with diagnostic information from certain fee-for-service claims from the prior calendar year to calculate a coefficient for each demographic characteristic and medical condition in the model. Demographic characteristics and medical conditions with larger coefficients are associated with higher expected medical expenditures and vice versa. A risk score is the sum of the coefficients identified for a given beneficiary. CMS currently uses one year of diagnostic data to estimate the size of the coefficients and to identify diagnoses for risk scores. The 21st Century Cures Act permits the Secretary to use at least two years of diagnostic data in the calculation of the risk adjustment model.

¹⁶ Medicare Payment Advisory Commission. 2005. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

¹⁷ Medicare Payment Advisory Commission. 2010. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹⁸ Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

¹⁹ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

CMS adjusts baseline expenditures in MSSP benchmarks to account for changes in health status using prospective HCC risk scores and then further adjusts baseline expenditures to account for changes in assigned beneficiary health status between the baseline and performance years. CMS makes separate adjustments for assigned beneficiaries in each enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). Changes to baseline expenditures in MSSP benchmarks due to risk score changes are subject to a cap of positive three percent for each performance year in each enrollment type. ACOs stakeholders have expressed concerns that this three percent risk score cap on MSSP benchmark adjustments does not account for risk score growth in the ACO's regional service area.

CMS seeks comment on potential approaches to improve risk adjustment in MSSP. Specifically, CMS seeks approaches to improve risk adjustment for medically complex beneficiaries while protecting against coding intensity. In addition, CMS seeks comment on methods that would increase the current 3 percent cap, including applying the cap after accounting for an ACO's regional area increase in risk scores.

Comment

The Commission commends CMS for the considerable caution it is taking in increasing coding incentives. More complete coding can result in higher shared savings payments without any improvement in the delivery of care to beneficiaries. Population-based models can be highly susceptible to coding incentives, and MSSP does not offset these incentives with a retrospective coding adjustment. Thus, shared savings payments will likely be at least partially influenced by enhanced coding initiatives.

Prior to any consideration of a policy that would increase MSSP coding incentives (e.g., allowing more than a 3 percent increase in benchmarks due to risk score changes), CMS should address the underlying incentives for coding intensity and the accuracy of risk adjustment. Consistent with the Commission's 2016 recommendation, CMS should use two years of diagnostic data for risk adjustment.²⁰ This would both improve the accuracy of coefficients estimated with FFS data and reduce year-to-year variation in beneficiary risk scores, as shown by the Commission's finding that beneficiaries in traditional Medicare are more likely to have a chronic condition coded in one year and not in the subsequent year.²¹ Using two years of diagnostic data for both the HCC model calibration and risk score calculation would also allow CMS to better discern whether risk score differences between an ACO's baseline and performance year were explained by health status changes. In addition, using at least two years of diagnostic data would relieve ACOs of much of the administrative burden they bear related to annual diagnostic documentation. ACOs would be more appropriately rewarded for improving the efficiency of care delivery rather than identifying and documenting HCCs.

²⁰ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

²¹ Medicare Payment Advisory Commission 2012. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Without addressing the underlying differences in coding, increasing the current MSSP cap beyond 3 percent may reward coding intensity without any improvement to risk adjustment for medically complex beneficiaries. CMS should not reward ACOs for greater coding in their region. Allowing larger benchmark increases when an ACO's region increases its coding effectively permits ACOs to be rewarded for more coding—particularly for those with higher market share. In general, we would expect changes in an ACO's population to be accounted for by the HCC model, and the current 3 percent potential increase to benchmarks—in addition to being susceptible to rewarding ACOs for coding—would likely cover anomalies when ACO populations have outlying deteriorating health status. The current model has some protections for ACOs that experience a disproportionate increase in the medical complexity of their population. For example, the current risk adjustment method makes separate adjustments for assigned beneficiaries in each enrollment type, which allows ACOs to increase the proportion of their ESRD, dual-eligible, and disabled populations without being affected by the 3 percent cap. In addition, CMS is phasing in the Alternative Payment Condition Count (APCC) CMS–HCC risk adjustment model from 2020 to 2022, which is designed to improve the accuracy of risk adjustment for high-spending beneficiaries—including those with four or more health conditions. CMS should only consider changes to the 3 percent cap after observing the effect of phasing in the APCC model and using at least two years of diagnostic data (as mentioned in the preceding paragraph).

Medicare Ground Ambulance Services Data Collection System

The Bipartisan Budget Act of 2018 directs the Secretary to begin collecting cost, revenue, utilization, and other information from ground ambulance providers and suppliers. In the initial years of data collection, the Secretary is directed to collect information from a rotating sample of ambulance providers and suppliers. By the end of CY 2019, the Secretary is required to identify the first representative sample of ambulance organizations that would be asked to report these data. The Secretary is also required to impose a 10 percent pay cut for one year on ambulance organizations that are asked to report data but fail to do so, with pay cuts taking effect starting in CY 2022. After 2024 data are collected, the law requires providers and suppliers to report data at a frequency to be determined by the Secretary (but, at a minimum, at least every three years).

The law directs MedPAC to use the data collected to assess the adequacy of Medicare's payments for ground ambulance services, and to assess the geographic variation in ambulance organizations' costs. MedPAC is also directed to analyze the burden on ambulance organizations of reporting the collected data, and to recommend whether to revise CMS's data collection system. MedPAC's initial report to the Congress on these topics is due March 15, 2023, and subsequent reports may be submitted thereafter as determined necessary by MedPAC.

Originally, CMS planned for 25 percent of ambulance organizations to report 2020 data, 25 percent to report 2021 data, 25 percent to report 2022 data, and 25 percent to report 2023 data, according to the CY 2020 physician fee schedule final rule. However, in two subsequent waivers issued during the COVID-19 pandemic (in May and November of 2020), CMS canceled plans to collect 2020 and 2021 data because costs and utilization rates would be atypical in these years.

Instead, CMS planned to ask 75 percent of ambulance organizations to report 2022 data, and 25 percent to report 2023 data.

In this proposed rule, CMS would now cancel the 2022 data collection, and instead ask 50 percent of ambulance organizations to report 2023 data, and 50 percent to report 2024 data. CMS explains that a delay in its data collection timeline would allow “more distance from the peak of the COVID-19 pandemic.” CMS believes 2023 will be “even more reflective of a typical year ... than 2022.”

Comment

The Commission supports delaying data collection as proposed. It is important that assessments of the adequacy of ground ambulance payments not be based on data that reflect anomalous, temporary trends in utilization and costs caused by a global pandemic. Trends in ambulance utilization and costs have changed substantially during the pandemic. According to data collected through the National Emergency Medical Services (EMS) Information System (NEMSIS), the number of EMS activations prompted by 911 calls dropped by a third in the early months of the pandemic, then rebounded, and then dropped by about two-thirds in the pandemic’s 2020 winter months.²² The mix of types of transports performed has also changed during the pandemic. According to NEMSIS data, 2020 saw lower-than-expected numbers of EMS activations for injuries and vehicle crashes in 2020, and higher-than-expected activations involving influenza-like illness and deaths at the scene. (These unusual trends could alter costs per transport, since different amounts and types of staff and equipment may be needed for different types of transports.) NEMSIS data also indicate that ambulance staff responding to activations for influenza-like illness in 2020 have been spending more time per transport when responding to such activations. The pandemic thus could have affected the number and mix of transports that ambulance organizations performed and their costs per transport in different parts of the country. To the extent that these anomalous trends might still be occurring in 2022, the Commission concurs with CMS’s caution about using 2022 data, since it could bias analyses of the geographic variation in costs and the adequacy of Medicare’s ground ambulance payments.

Payment for specimen collection for COVID-19 laboratory tests

In addition to paying for the performance of a laboratory test under the clinical laboratory fee schedule, Medicare pays a nominal fee for specimen collection and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). The specimen collection fee is set at \$3 or \$5 (for a sample collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency). During the PHE, CMS increased those fees to \$23.46 and \$25.46, respectively, for specimen collection associated with COVID-19 testing to account for higher costs (e.g., increased

²² Mann, N. C. 2020. EMS by the numbers: Impact of COVID-19. https://nemsis.org/wp-content/uploads/2020/12/NEMSIS-TAC-Update-to-COVID-19-Trends-12_23_2020-Pre-Findings-V1-1.pdf.

costs for personal protective equipment). CMS proposes to end those higher rates at the end of the PHE and seeks comment.

Comment

The Commission agrees with CMS's decision to end the enhanced specimen collection fees once the PHE has ended. In our June 2021 report to the Congress, we noted that many laboratories, especially those who performed a high volume of COVID-19 tests, had improved financial performance during the PHE. For example, the operating profits for the two largest laboratory companies in the country increased by 143 percent and 60 percent, respectively, from 2019 to 2020.²³ The fact that COVID-19 testing is relatively profitable for laboratories suggests that laboratories will still have an incentive to perform COVID-19 testing (including obtaining the specimen) when specimen collection fees return to pre-pandemic levels.

Open Payments

Open Payments is a program mandated by statute that requires manufacturers of drugs, devices, biologics, or medical supplies, as well as group purchasing organizations (GPOs), to annually report to the Secretary certain payments or other transfers of value provided to covered recipients. Covered recipients include physicians, teaching hospitals, nurse practitioners, physician assistants, and other clinicians. In addition, Open Payments 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 proposes to add several provisions to the Open Payments program to improve the quality of the data. Among these new provisions, CMS would define a physician-owned distributorship (POD) and require PODs to self-identify when registering or recertifying with the Open Payments program. CMS proposes to define a POD as an entity that meets the definition of an applicable manufacturer or GPO and meets at least one of the following two conditions: (1) a physician (or physician's immediate family member) holds at least a 5 percent direct or indirect ownership or investment interest in the manufacturer or GPO, or (2) a physician (or physician's immediate family member) receives compensation from the applicable manufacturer or GPO derived from the sale or distribution of devices by the manufacturer or GPO in which the physician (or physician's immediate family member) has ownership. CMS believes that requiring PODs to disclose themselves will improve transparency and will help clarify that PODs are required to report ownership and investment interests under the program.

Comment

The Commission strongly supports CMS's proposal to define PODs and require them to identify themselves when registering or recertifying with the Open Payments program. PODs are

²³ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

physician-owned entities that derive revenue from selling, or arranging for the sale of, medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients.²⁴ PODs may distort the supply chain for medical devices—potentially resulting in a higher volume of surgeries, higher costs for hospitals and Medicare, and inappropriate care.²⁵ PODs have been the subject of investigations by OIG and the Senate Finance Committee.^{26,27} Although CMS has stated that PODs are subject to Open Payments reporting requirements, a Senate Finance Committee report found evidence that many PODs do not report their physician ownership interests to CMS. Based on the Commission’s prior research, very few PODs appear in Open Payments data. Using data from 2015, we found that only 16 PODs reported physician ownership.²⁸ OIG warned that PODs are inherently suspect under the anti-kickback statute because they offer financial incentives to their physician-owners that may induce the physicians to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices sold by the PODs instead of other devices.²⁹ In prior reports, the Commission has supported requiring all PODs to report under the Open Payments program.^{30,31}

In addition to facilitating the identification of PODs in the Open Payments data, CMS should take other steps to improve the transparency and usability of the data. Although the Open Payments records list the name of each manufacturer or GPO that made a 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. Therefore, CMS should require each entity that reports data under Open Payments to indicate:

- whether it is a manufacturer or GPO; and
- whether, if a manufacturer, it produces drugs, biologics, devices, supplies, or a combination of products.

Including more information on the types of companies that have financial relationships with clinicians and teaching hospitals would enable researchers, oversight agencies, and the public to better understand these relationships.

²⁴ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

²⁵ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

²⁶ Office of Inspector General, Department of Health and Human Services. 2013. *Spinal devices supplied by physician-owned distributors: Overview of prevalence and use*. Washington, DC: OIG.

²⁷ U.S. Senate Committee on Finance. 2016. *Physician owned distributorships: An update on key issues and areas of congressional concern*. A Senate Finance Committee majority staff report. Washington, DC: Government Printing Office.

²⁸ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

²⁹ Office of Inspector General, Department of Health and Human Services. 2013. Special fraud alert: Physician-owned entities. March 26. https://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

³⁰ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

³¹ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

CY 2022 updates to the Quality Payment Program

Under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Congress created two new policies: an annual 5 percent incentive payment for clinicians with a sufficient share of patients or payments in advanced alternative payment models (A-APMs); and the Merit-based Incentive Payment System (MIPS). CMS refers to these two programs collectively as the Quality Payment Program. Most clinicians are in MIPS, which means they receive annual increases or decreases to their Medicare physician fee schedule payments based on their performance on measures of quality, cost, improvement activities, and promoting interoperability.

In the proposed rule's section on MIPS, CMS reiterates its plan to move away from the hundreds of performance measures it currently permits clinicians to choose from (in what it now calls "traditional" MIPS) to small measure sets designed for particular specialties or conditions. CMS refers to this shift as the "MIPS Value Pathways" (MVP) framework. In this proposed rule, CMS proposes the first seven MVP measure sets—for clinicians who manage chronic diseases, heart disease, and strokes; clinicians who practice emergency medicine; clinicians who do lower-extremity joint repairs; and rheumatologists and anesthesiologists. Clinicians can begin to report MVP measure sets starting in 2023, and MVP measure sets would be the only option for participating in MIPS starting in 2028.

CMS proposes allowing multi-specialty groups to split into multiple subgroups that could separately report on MVP measure sets. For example, clinicians of a given specialty, or clinicians who work at a given office location, could be scored as a subgroup separate from the rest of their group. MVP reporting by subgroups would be allowed starting in 2023, then required of multi-specialty groups wishing to participate in MIPS starting in 2025. CMS cautions that there is a risk that multi-specialty groups may strategically split into smaller subgroups to avoid being measured on cost, since cost measures are not scored if a subgroup is small enough that it fails to meet case minimums.

Comment

The Commission continues to be concerned about many aspects of MIPS—including, for example, its burdensome complexity. This complexity is evident in the proposed rule itself: CMS devotes 750 pages to describing this year's proposed changes to the program. The clinician who searches for instructions on how to participate in MIPS in the 2021 performance year will find 77 manuals and guidance documents on CMS's Quality Payment Program website. For the clinician who sifts through these documents to figure out what to do and what to report on to achieve a positive MIPS adjustment, the reward is small: the largest adjustment any clinician will receive in 2021 is a 1.79 percent positive adjustment to the payments they receive for the subset of their patients in original Medicare.

Problems with MIPS led the Commission to recommend that the Congress eliminate the program in our March 2018 report.³² We were concerned that MIPS is inequitable, because clinicians are evaluated and compared on dissimilar, self-chosen measures. In addition, many clinicians are exempt from MIPS, because they don't treat a sufficient number of cases to produce statistically reliable scores on performance measures. For these two reasons, MIPS is unlikely to help beneficiaries choose clinicians, and is unlikely to prompt clinicians to change practice patterns to improve value. MIPS also imposes a significant reporting burden on clinicians and is complex—with different rules for clinicians depending on location, practice size, and other factors. And finally, MIPS-based payment adjustments have been very small in the early years of the program but have the potential to become very large and arbitrary in future years—which could create significant financial uncertainty for clinicians.

In MIPS's place, we recommended a Voluntary Value Program, through which groups of clinicians would receive increases or decreases to their physician fee schedule payment rates based on their performance on a uniform set of measures assessing outcomes, patient experience, and value. These measures would be calculated by CMS from claims and surveys—eliminating clinician reporting requirements.

Many of the Commission's concerns with MIPS have also been conveyed to CMS by clinicians. In the proposed rule, CMS acknowledges hearing from them that MIPS is "confusing" and "burdensome," and that it "does not allow for sufficient differentiation of performance across practices due in part to clinician quality measure selection bias." CMS acknowledges that these aspects of MIPS "detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality."

To its credit, CMS has attempted to address concerns with MIPS while working within its statutory constraints. Since CMS must abide by the language in MACRA that created MIPS, the agency is precluded from engaging in the type of program overhaul proposed in MedPAC's 2018 recommendation. But we appreciate the fact that CMS has nevertheless taken steps through rulemaking to modify MIPS to address issues we and others have raised. In particular, the Commission continues to support CMS's shift to their MVP framework—which should reduce complexity and burden, better promote apples-to-apples comparison of clinicians' performance, and ultimately reduce opportunities for clinicians to strategically select measures to maximize MIPS scores.

That said, we are concerned that multi-specialty groups may take advantage of the option to report at the subgroup level to avoid being assessed on cost measures. We suggest that CMS monitor the share of subgroups formed within larger practices that end up not being assessed on cost due to case minimums and consider requiring such subgroups to include a sufficient number of clinicians to allow case minimums to be met.

³² Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Chiquita Brooks-LaSure

Administrator

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Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please do not hesitate to contact James E. Mathews, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink, appearing to read "m. chernew", with a horizontal line extending to the right from the end of the signature.

Michael E. Chernew, Ph.D.
Chair