



Medicare Payment
Advisory Commission

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Chiquita Brooks-LaSure
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-1772-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating," *Federal Register* 87, no. 142, pp. 44502–44843 (July 26, 2022). We appreciate CMS's ongoing efforts to administer and improve Medicare's outpatient hospital payment policies, 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:

- **Payment for 340B drugs:** For calendar year (CY) 2023 and future years, the Commission continues to support reducing Medicare payment rates for 340B drugs to allow beneficiaries to share in the discounts 340B hospitals receive from drug companies and to use the Medicare program savings to support safety-net hospitals. Regarding CMS's question about back payments in light of the recent Supreme Court ruling, we contend that any changes in response to the ruling should be made in a budget-neutral manner.
- **Additional facility payments for rural emergency hospitals (REHs):** The Commission is concerned that the proposed \$3.2 million annual payments to REHs is excessive—especially given the minimal staffing requirements proposed in an earlier rule—and urges CMS to explore alternative methodologies for calculating the subsidy that would result in payments that better balance the goals of supporting access to care and being a fiscally responsible payer.

- **Separate payment for Software as a Service (SaaS):** The Commission opposes separate payment for expensive inputs that do not necessarily provide a substantial clinical improvement. We encourage CMS to seek ways to increase the amount of packaging and the extent to which services can be bundled with related services based on encounters or episodes of care.
- **Payment for domestic N95 respirators:** The Commission continues to oppose CMS's proposal to provide an additional payment for domestic N95 respirators, on the basis that Medicare is not the most appropriate mechanism to support domestic manufacturing of medical supplies.
- **Telehealth rehabilitation services:** The Commission supports allowing clinicians to provide direct supervision of certain rehabilitation services via telehealth for a limited period of time after the coronavirus public health emergency (PHE) ends to enable the agency to gather more evidence on these services.
- **Overarching principles for measuring equity and health care quality disparities:** The Commission continues to support CMS's overall efforts to measure and report health care disparities by stratifying quality measure results for different subgroups of beneficiaries and contends that these principles are applicable to the hospital outpatient quality reporting program.

Payment for 340B drugs

The 340B Drug Pricing Program allows some hospitals and other health care providers (covered entities) to purchase “covered outpatient drugs” at discounted prices from drug manufacturers. Covered outpatient drugs include prescribed drugs and biologics other than vaccines. The 340B discounts for these covered drugs are substantial. According to the Health Resources and Services Administration (HRSA)—which administers the 340B program—the intent of the 340B program is to allow the covered entities to stretch scarce federal resources as far as possible to provide more care to more patients.

Before CY 2018, CMS set the payment rate for most separately payable non-pass-through drugs—including drugs obtained through the 340B program—on the basis of each drug's average sales price plus six percent (ASP + 6 percent).¹

For CY 2018 through CY 2022, CMS established a policy of paying ASP – 22.5 percent for non-pass-through separately payable drugs that are obtained through the 340B Drug Pricing Program. Separately payable drugs that are not obtained through the 340B program continue to have payment rates set at ASP + 6 percent. CMS's rationale for this policy was to set drug payment rates that better align with 340B hospitals' acquisition costs.

¹ Pass-through drugs have always been paid ASP + 6 percent, as required by law.

The motivation for this 2018 policy change was concern about the growth in the number of providers participating in the 340B program and the high and growing prices of separately payable drugs under Part B. To make the 2018 policy change to reduce payments for separately payable 340B drugs budget neutral, CMS increased the outpatient prospective payment system (OPPS) payment rates for all nondrug services by 3.2 percent in 2018. CMS did not make budget neutrality adjustments related to the 340B payment policy in subsequent years because, as they explained in their final rule for CY 2022, “the adjusted percentage payment has remained at ASP minus 22.5 percent.”²

CMS asserted it is appropriate for the Medicare program to pay for drugs purchased through the 340B program at a rate that better represents what hospitals actually pay to acquire the drugs.³ CMS’s decision to pay for the separately payable drugs obtained through the 340B program at a rate of ASP – 22.5 percent was based on a Commission analysis that estimated a lower bound on the average discount on 340B drugs paid separately under the OPPS of 22.5 percent of ASP.⁴

However, the Supreme Court of the United States ruled on June 15, 2022, that CMS does not have authority to set separate reimbursement rates for outpatient prescription drugs by type of hospital unless it has first conducted a survey of hospitals’ acquisition costs for each covered outpatient drug, which CMS had not done prior to the policy change in 2018.⁵ The Court ruled that, if a survey is conducted, CMS may vary reimbursement rates by hospital group and such rates must be equal to hospitals’ average acquisition cost.

Because the ruling from the Supreme Court was issued just one month in advance of the publication of this proposed rule, CMS states there was insufficient time to adjust its proposal accordingly. As such, this proposed rule officially proposes to continue the current policy of paying for outpatient drugs obtained under the 340B program at a rate of ASP – 22.5 percent. The rule goes on to say, however, that, in light of the Supreme Court’s ruling, the agency anticipates finalizing a payment rate of ASP + 6 percent for separately covered outpatient drugs in CY 2023, thus eliminating the differential payment rates, and increasing payments for 340B drugs by an estimated \$1.96 billion. The agency also anticipates making a corresponding decrease to the OPPS conversion factor of 0.956, consistent with the statute and CMS’s longstanding policy that OPPS adjustments are made in a budget-neutral manner. CMS did not propose any specific remedies for historical payments—either for 340B drugs or other services—in years affected by the Supreme Court ruling.

² Centers for Medicare & Medicaid Services. 2022. Medicare program: hospital outpatient prospective payments and ambulatory surgical center payment systems and quality reporting programs; price transparency of hospital standard charges; radiation oncology model. *Federal Register* 86: 63458–63998.

³ Centers for Medicare & Medicaid Services. 2017. Medicare program: hospital outpatient prospective payments and ambulatory surgical center payment systems and quality reporting programs. *Federal Register* 82: 52356–52637.

⁴ Medicare Payment Advisory Commission. 2015. *Report to the Congress: Overview of the 340B Drug Pricing Program*. Washington, DC: MedPAC.

⁵ American Hospital Association v. Becerra, 596 U.S. ____ (2022).

CMS seeks comment on the propriety of maintaining differential payment for 340B drugs in the future, as well as how to craft potential remedies for 2018 to 2022 given the Supreme Court ruling.

Comment

The Commission continues to support differential payment rates for 340B drugs to allow beneficiaries to share in the discounts 340B hospitals receive from drug companies and to use the Medicare program savings to support safety-net hospitals. In March 2016, we recommended that the Congress direct the Secretary of HHS to (1) reduce OPPS payment rates for all separately payable drugs obtained through the 340B program by 10 percent of ASP and (2) direct the program savings from these reduced payment rates to safety-net providers through the uncompensated care pool.⁶ We recommended a reduction in the payment rate for 340B drugs to a level that reduced, but did not fully eliminate, hospitals' profit on these drugs. We continue to believe that this approach is appropriate, and the specific level of payment reduction could be considered further as newer data become available. In addition, MedPAC has recently begun to discuss alternative ways of identifying and supporting safety-net hospitals, including redistributing disproportionate share (DSH) and uncompensated care funds to support such hospitals.⁷ Under this construct, 340B savings from our 2016 recommendation would similarly be distributed to support these hospitals. We recognize that CMS would likely require additional statutory authority to set payment rates at slightly above hospitals' acquisition costs for 340B drugs and to target the savings to safety-net hospitals; we encourage CMS to request that Congress enact enabling legislation.

Most importantly, to the extent that any changes to historical payments must be made in response to the Supreme Court's ruling, the Commission contends adjustments should be made in a budget-neutral manner, consistent with OPPS statute and CMS's longstanding policy. Given scarce fiscal resources, it would be fiscally imprudent to increase Medicare spending by approximately \$2 billion in each year that CMS applied the overturned 340B policy (CY 2018 through CY 2022).

Additional facility payment for rural emergency hospitals (REHs)

In June of 2018, the Commission recommended that the Congress allow isolated rural stand-alone emergency facilities that would be open 24 hours a day, 7 days a week, to participate in Medicare.⁸ In making this recommendation, the Commission's goal was to have an emergency

⁶ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC. Specifically, MedPAC recommended reducing the existing payment rate of ASP + 6 percent by 10 percent of ASP.

⁷ Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC

⁸ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

facility that individuals in rural areas could go to and be assured that someone would be on site when they arrive to either treat or stabilize and transfer them to another facility. To facilitate this standby capacity, the Secretary would provide a subsidy to these emergency hospitals. We estimated that the seven CAHs that *closed* in 2014 (as opposed to *all* CAHs) received an average of about \$500,000 in Medicare *program* payments above the comparable prospective payment system (PPS) payments. Providing prospective payment rates and a fixed annual subsidy of \$500,000 in 2014 to these hospitals would have provided the hospitals with more financial flexibility without materially increasing federal spending.

In the Consolidated Appropriations Act (CAA) of 2021, the Congress created a new category of provider, the rural emergency hospital (REH). Hospitals that were critical access hospitals (CAHs) or rural acute care hospitals with fewer than 50 beds as of the date of enactment are eligible to convert to REHs. Regarding Medicare's payments to these hospitals, the legislation specifies that:

- Medicare payment for “rural hospital emergency services” will be the OPPS rate + 5%, and the otherwise applicable payment rate for other services
- REHs will also receive a Medicare subsidy amount, initially equal to
 - the excess of (i) the total amount the Secretary determines was paid to *all* CAHs in 2019 over (ii) the estimated total amount that the Secretary determines would have been paid to hospitals in 2019 if payment had been made under the standard inpatient hospital, outpatient hospital, and skilled nursing facility prospective payment systems [emphasis added];
 - divided by the total number of CAHs in 2019.
- The REH Medicare subsidy amount will be increased in future years by the market basket.

In this proposed rule, CMS proposes an annual subsidy (referred to as an additional facility payment) to each REH of \$3.22 million dollars, to be distributed in monthly payments of \$268,294. CMS arrived at this estimate by taking the difference between:

- \$12.08 billion: CMS's estimate of the amount paid to CAHs using claims for calendar year 2019, including both amounts paid to CAHs from the Medicare program and all required beneficiary copayment amounts, and
- \$7.68 billion: CMS's estimate of the amount CAHs would have received under the standard prospective payment systems using claims for calendar year 2019, again including cost-sharing amounts, and with some imputations for data that CAHs do not report.⁹

⁹ For both estimates of payments, CMS included not only items and services paid under the inpatient hospital (acute, rehabilitation, and psychiatric) PPSs, outpatient PPS, and skilled nursing facility (SNF) PPS, but also other services and items reported on inpatient, outpatient, and SNF claims that are paid under separate fee schedules or payment

The difference in these two estimates is \$4.40 billion dollars, which when divided by the number of CAHs with a claim in 2019 (1,368), yields an annual subsidy of \$3.22 million to each REH.

In calculating the annual REH subsidy, CMS also considered interpreting payments as just Medicare *program* payments (i.e., excluding beneficiary cost sharing). However, CMS stated that excluding beneficiary cost sharing to CAHs—which it estimated at 47 percent of the total spending for Medicare services—would result in a substantially smaller REH annual subsidy and could therefore discourage CAHs and small rural hospitals from converting to an REH.¹⁰ CMS concludes that “including both Medicare trust fund payments and beneficiary copayments in the calculation reflects the intent of the statute to provide incentives for CAHs and small rural hospitals that might otherwise cost to convert to REHs and continue to provide outpatient care in rural communities.”

CMS seeks comments on its methodology to calculate this additional facility payment to REHs.

Comment

While there is significant uncertainty in the exact level of annual subsidy that is needed to allow small rural hospitals that might otherwise close to be a financially viable REH, the Commission is concerned that CMS’s proposed additional facility payment to REHs is excessive. CMS’s current proposal of \$3.2 million dollars is higher than what industry groups suggested was needed (\$2 to \$3 million) and by itself constitutes about two-thirds of the estimated \$5 million-dollar total cost of operating a rural off-campus emergency department in 2015.¹¹ In 2019, the average CAH received less than \$9 million in Medicare revenue and about \$32 million in revenue from all sources. The proposed \$3.2 million annual fixed payment would be equal to over one-third of the average CAH’s current Medicare revenue and one-tenth of the average CAH’s total revenue. Furthermore, for over 10 percent of CAHs, the \$3.2 million supplemental payment would be more than 100 percent of their overall Medicare revenue in 2019. Because the shift to REH status is expected to reduce costs due to the elimination of inpatient services, small CAHs converting to REH status would receive an increase in Medicare revenue and a decrease in costs after converting to REH status. We believe the \$3.2 million subsidy amount could prove so large that it might convince some CAHs and small rural hospitals that can currently sustain

systems, such as lab services, physician services, ambulance services, durable medical equipment, and Part B drugs. CAHs benefit from cost-based lab services, but the statute does not include this difference in computing the supplement payment for converting to REHs.

¹⁰ CMS modeled excluding cost sharing amounts and estimated that under CMS’s assumptions, the annual REH subsidy would have been \$0.6 million ($\$6.4 \text{ billion in CAH Medicare program payments} - \$5.6 \text{ billion in alternative Medicare payments}$)/1,368.

¹¹ Tribble, S. J. and T. Leys. 2022. Rural hospital rescue program is met with skepticism from administrators. <https://khn.org/news/article/rural-hospital-rescue-program-medicare-skepticism/>.

Williams, J. D., P. H. Song and G. H. Pink. 2015. *Estimated costs of rural freestanding emergency departments*. Chapel Hill, NC: North Carolina Rural Health Research Program, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill

inpatient services to convert to an REH as a means to increase profitability rather than simply as a means to maintain financial viability.

The statute states that CMS should pay REHs a fixed subsidy equal to the difference in the Secretary's estimated total amount that (1) was paid to all CAHs in 2019 and (2) would have been paid to hospitals in 2019 if payment had been made under the standard prospective payment systems. We believe a reasonable interpretation of this statute is to define "was paid" and "would have been paid" to refer to payments by CMS. We also believe that this methodology (which would exclude beneficiary cost sharing from the equation) would create a reasonable subsidy of approximately \$1.5 million per year per converting hospital, which is about 15 percent of the average CAH's Medicare revenue and more than half of all 2019 Medicare payments for the 10 percent of CAHs with the lowest Medicare revenue in 2019. Our \$1.5 million estimate differs from CMS's \$0.6 million estimate in the proposed rule because of an errant assumption in the proposed rule that CAH patients pay an average of 47 percent coinsurance on all CAH services. That 47 percent estimate was based on an Office of Inspector General report that found a 47 percent cost-sharing rate for 10 CAH outpatient services.¹² Commission analyses suggest that the 47 percent figure is approximately correct for outpatient services, but that cost sharing for inpatient and post-acute swing-bed services is much lower. (CAH and PPS cost sharing for these services (deductibles and daily copayments) do not differ based on whether the service is provided at a CAH or other hospital.) Therefore, we believe CMS erred in applying a 47 percent cost-sharing rate to all CAH services and that its resulting estimate of the annual REH subsidy if cost sharing were excluded (\$0.6 million) is artificially low. We estimate that the annual REH subsidy calculated exclusive of beneficiary cost sharing (i.e., the average difference between 2019 Medicare *program* payments using CAH payments rates versus the standard prospective payment systems) would be about \$1.5 million per CAH.¹³

As we noted in our comments on the CY 2022 OPPI proposed rule,¹⁴ the Commission continues to contend that CMS could reasonably interpret the statute in ways that would result in substantially higher or lower monthly facility payments for REHs, including whether to include beneficiary cost-sharing amounts. However, given the dual goals of setting the payment high enough to sustain REHs while ensuring Medicare is a prudent payer, the Commission contends that the subsidy should be computed by a more judicious calculation of the difference in CAH payments and what those payments would have been under the otherwise applicable payment systems. In particular, if CMS's General Counsel concurs that the agency has flexibility in interpreting the statute, the Commission contends that defining payments only as Medicare *program* spending (and not also beneficiary cost sharing) would be appropriate.

¹² Office of Inspector General. 2014. *Medicare beneficiaries paid nearly half of the costs for outpatient services at critical access hospitals*. Washington, DC, OIG.

¹³ The difference may be lower if CMS also made other minor methodological improvements that would increase the estimate of what inpatient PPS payments to CAHs would have been, such as accounting for how CAHs have fewer incentives to include all of a patient's diagnoses on claims and including estimated inpatient add-on payments before calculating outlier payments.

¹⁴ Medicare Payment Advisory Commission. 2021. MedPAC comment on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2022. September 10.

CMS's proposed \$3.2 million annual REH subsidy is especially troubling given the agency's prior proposal on REH conditions of participation that do not require a REH to have a clinician on-site 24/7.¹⁵ As we stated in our comment letter on that proposed rule, 24/7 staffing by a clinician should be a required REH condition of participation, meaning the REH should be held to a higher standard of emergency access than CAHs.¹⁶ Under current regulations, CAHs are not required have to have a clinician in the facility 24/7 and thus cannot always provide immediate emergency access. While the large monthly payments to REHs are expected to prevent almost all rural hospital closures, under CMS's proposed staffing requirements, emergency access will still not be guaranteed. To guarantee immediate emergency access, REH staffing requirements will have to be stronger than CAH requirements, and even the lower amount of the subsidy as calculated by MedPAC should be sufficient to ensure Medicare beneficiary access to emergency care in rural areas served by REHs. (At an average annual salary of approximately \$125,000 per nurse practitioner or physician assistant, a \$1.5 million subsidy should be more than enough to pay for 24/7 staffing of an REH emergency department.) Rural advocates point to the difficulty of staffing emergency rooms in rural areas. From MedPAC's perspective, that is precisely the reason for the additional fixed payment that REHs will receive. In contrast, CMS's current high proposed subsidy coupled with minimal staffing requirements placed on the REH could inadvertently reduce access to full hospital services by causing an excessive number of conversions.

As stated earlier, we acknowledge uncertainty around the appropriate subsidy amount. Therefore, regardless of how the REH subsidy is initially set for 2023, CMS should seek authority from Congress to adjust the subsidy for 2024 and future years based on CMS's monitoring of REH conversions.

Separate payment for Software as a Service (SaaS)

CMS states that the number of FDA-approved or -cleared "machine learning" or "AI" clinical software programs has rapidly increased in the past few years. CMS refers to these algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per use basis, as Software as a Service (SaaS).

Historically, the OPPS payment for analytics performed after the main diagnostic or imaging procedure was packaged into the payment for the primary diagnostic or imaging procedure. However, starting in CY 2018, CMS began making separate payments for a limited set of SaaS, generally only when provided as a standalone service (packaging the payment continued when SaaS was performed with another service).

¹⁵ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare and Medicaid programs; conditions of participation (CoPs) for rural emergency hospitals (REH) and critical access hospital CoP updates. *Federal Register* 87: 40350–40404.

¹⁶ Medicare Payment Advisory Commission. 2022. MedPAC comment on CMS's proposed rule on conditions of participation (CoPs) for rural emergency hospitals and critical access hospital CoP updates. July 27.

The American Medical Association has begun to establish two CPT codes for SaaS procedures: (1) a primary code that establishes the standalone clinical software service and (2) an add-on code that describes a clinical software service that is adjunctive to and billed concurrent with a primary diagnostic imaging service. However, applicants have informed CMS that the services described by the add-on codes should also be paid separately because the technologies are new and associated with significant costs.

For CY 2023, CMS proposes to not recognize the select CPT add-on codes that describe SaaS procedures under the OPDS and to instead establish Healthcare Common Procedure Coding System (HCPCS) C-codes to describe a standalone service that would be billed with the associated imaging service. CMS contends that the payment for these new C-codes, when billed concurrent with the acquisition of imaging services, should be equal to the payment for the SaaS procedures when performed as a standalone service without imaging, as the SaaS procedure is the same regardless of whether it is furnished with an imaging service.

In this proposed rule, CMS notes that SaaS procedures are a heterogeneous and evolving group of services, which presents challenges in adopting a uniform payment policy. CMS therefore solicits comments on a payment approach that could broadly apply to SaaS procedures, including specific payment approaches that might be used for the SaaS services that would provide equitable payment for SaaS procedures, while protecting the Medicare Trust Fund. CMS outlines potential options including:

- Packaging payments for the diagnostic image and the SaaS under a single HCPCS code, which would be assigned to a relevant clinical APC;
- Expand composite APCs, which provide a single payment for groups of services that are performed together—including the diagnostic imaging and SaaS procedure—during a single clinical encounter to result in the provision of a complete service; or
- Utilize a HCPCS code to describe both the diagnostic imaging and SaaS procedure and assign the code to a New Technology APC that would pay for both services.

Comment

The Commission's comments focus on CMS's request for information on a payment approach that would broadly apply to SaaS procedures, including payment strategies for these services across settings of care.

The Commission recognizes the need to ensure beneficiary access to new technologies that improve outcomes while preserving the incentives for efficiency that can be achieved within prospective payment systems (PPSs). Across all settings (inpatient hospital, outpatient hospital, post-acute care, etc.), this goal is best achieved by relying on broad payment bundles to the greatest extent possible when determining payment amounts. Bundled payment encourages judicious consideration of the items and services provided to beneficiaries. Combining a primary service and related ancillary items, including items and services with a similar function, into a

single payment unit encourages efficiency because the combination of inputs used to treat a beneficiary determines whether the provider experiences a financial gain or loss. Broader bundles also foster competition between similar items and services which generates pressure on manufacturers and suppliers to reduce prices.

In general, paying separately undermines the integrity of PPS payment bundles and can limit the competitive forces that generate price reductions among like services, lead to overuse (to the extent clinically possible), and shift financial pressure from providers to Medicare. Across all settings, paying separately for SaaS may have significant implications for Medicare. According to the agency, "... the number of FDA approved or cleared "machine learning" or "AI" clinical software programs has rapidly increased in the past few years."

With respect to the OPPI, MedPAC has long supported larger payment bundles because they provide hospitals with opportunities to find flexibilities in the provision of care and incentives to use the most cost-efficient methods. Consequently, for both SaaS and other items and services, we strongly encourage CMS to continue to seek ways to increase the amount of packaging and the extent to which services can be bundled based on encounters or episodes of care.¹⁷

However, if Medicare decides to pay separately, Medicare should not pay more for technologies that have not yet been proven to provide better outcomes than the standard of care. Limiting the additional payments to services that improve outcomes should help ensure good value for beneficiaries and taxpayers. However, the additional payments should only be made on a temporary basis until the cost of the new technology can be bundled in larger services. CMS could structure an SaaS clinical improvement criterion similar to the one the agency uses to pay for new technologies under the inpatient prospective payment systems (IPPS). Under that model, CMS initially pays for part of the cost of a new technology if there is evidence that the new technology improves outcomes. Then after the technology is widely adopted, the cost of the technology is packaged into the inpatient bundle. This creates a system where CMS initially reimburses providers for the additional cost of new technologies to allow dissemination of new technologies that improve outcomes. However, the eventual bundling of the technology into a larger service bundle (such as a DRG or outpatient bundle) creates long-term pressure to reduce the cost of the technology within the bundle.

Payment for domestic N95 respirators

CMS maintains that it is important to support domestic manufacturing of National Institute for Occupational Health and Safety (NIOSH)-approved N95 respirators to help prepare for future biological and pandemic threats. CMS therefore proposes increased IPPS and OPPI payments to hospitals to compensate them for the higher costs of purchasing domestically manufactured N95 respirators rather than those imported from other countries. This policy would be effective for

¹⁷ Packaging combines a primary, independent service and associated ancillary services into a single payment unit. Bundling collects multiple independent services that occur in an outpatient encounter or episode of care into a single payment unit.

hospital cost reporting periods beginning January 1, 2023, and result in biweekly interim payments to hospitals, with settlement on cost report reconciliation.

CMS proposes basing the new hospital-specific payment on data from a new hospital cost report form where each hospital would:

- Record the aggregate quantity and costs of domestic and other respirators. To qualify as a domestic respirator, CMS proposes that the manufacturer would need to attest in writing that all components were grown, reprocessed, reused, or produced in the United States.
- Calculate the per unit additional marginal cost for domestic respirators (the per unit cost of domestic respirators minus the per unit cost of other respirators)
- Calculate the total additional cost for domestic respirators (the per unit additional cost multiplied by the aggregate quantity purchased)
- Calculate both IPPS and OPSS payments for domestic respirators. IPPS payments are calculated as the total additional cost multiplied by the IPPS share of total costs across all services. OPSS payments are calculated as the total additional cost multiplied by the OPSS share of total costs across all services.

The new payments would not be budget neutral for the IPPS, but would be for the OPSS, where CMS estimates the additional OPSS payments would be \$8.3 million (<0.01 percent of OPSS payments).

CMS notes that as the agency gains more experience with this payment policy, it may revisit its proposed approach, such as basing the payment adjustment on the national average cost differential between domestic and other respirators. CMS states it might also consider expanding this policy in future rulemaking to other forms of personal protective equipment (PPE) that are critical to responding to a public health emergency (PHE).

Comment

Although we agree with CMS that ensuring a robust supply chain of N95 respirators is vitally important for hospitals and the nation, as in our comments on the FY 2023 IPPS proposed rule,¹⁸ we do not support CMS's proposal. We contend that the best way to ensure a robust domestic supply of personal protective equipment likely involves solutions beyond the Medicare program (e.g., direct purchases and stockpiling of masks by the federal government).

CMS's proposal would undermine the prospective, bundled nature of Medicare's hospital payments by paying hospitals more as their costs increase. In addition, while N95 respirators are an essential supply—as CMS notes—other items, such as surgical gloves or pharmaceuticals,

¹⁸ Medicare Payment Advisory Commission. 2022. MedPAC comment on CMS's proposed rule on the hospital inpatient prospective payment system and the long-term care hospital prospective payment system for FY 2023. June 16.

might be equally important to combat future biological and pandemic threats. Similarly, hospitals are not the only type of providers to acquire N95s. Making higher Medicare hospital payments for domestically sourced N95 respirators would create a precedent, opening opportunities to establish separate cost-based payments for other domestically sourced supplies and other providers. The proposed options also would increase administrative costs for hospitals (e.g., hospitals would have to identify domestically made products and track their use), could be susceptible to misreporting of costs (e.g., hospitals' costs for N95 respirators could be artificially inflated to increase reimbursement), and are likely to have a minor effect on most hospitals' finances (e.g., the add-on of a few dollars to payment for a discharge for which Medicare now pays \$15,000).

Medicare payment policy is not the most appropriate mechanism to support domestic manufacturing of medical supplies. However, if CMS concludes that a change to Medicare payment policy is required for this purpose—a conclusion with which we strongly disagree—it should be done in way that minimizes administrative burden and effects on the integrity of Medicare's prospective payment systems. For example, setting the per respirator extra payment for purchasing a domestically made product at a national level (rather than on a hospital-by-hospital basis)—one of the alternatives CMS said it may use moving forward—would reduce the administrative burden on hospitals of tracking their expenditures on such products, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs (such as by getting discounts on other products in exchange for paying high prices on N95 masks).

Telehealth rehabilitation services

Starting in April 2020, CMS changed regulations to allow for direct supervision of certain rehabilitation services by clinicians by interactive communication technologies. Specifically:

- In an April 2020 rule, CMS changed regulations such that, during a PHE, the direct supervision requirement for pulmonary, cardiac, and intensive cardiac rehabilitation services could be met through audio/video real-time communications technology when its use would reduce exposure risks for the beneficiary or provider.
- In the CY 2021 OPSS final rule, CMS further amended its policy such that this flexibility would continue through the end of the calendar year in which the PHE ended.
- In the CY 2022 physician fee schedule final rule, CMS added CPT codes for certain rehabilitation services to the Medicare Telehealth Services List category, which enables these services to be paid when provided via telehealth to a beneficiary in a qualifying setting through the end of CY 2023.

In this proposed rule, CMS seeks comments on whether to continue to allow direct supervision of certain rehabilitation OPSS services via telehealth through the end of CY 2023. CMS also seeks comment on whether there are safety and/or quality of care concerns adopting this policy beyond the PHE and what policies CMS could adopt to address these concerns.

Comment

Consistent with our comment in the CY 2022 physician fee schedule proposed rule,¹⁹ the Commission supports temporarily extending the policy that would allow clinicians to provide direct supervision of OPSS rehabilitation services 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 three 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 OPSS 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. 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. Finally, this scenario could also lead to higher spending by allowing hospitals to bill for more services during a single day. It will be important going forward for CMS to develop approaches to maintain program integrity as access to virtual care expands.

Overarching principles for measuring equity and health care quality disparities

In the FY 2023 IPPS proposed rule, CMS included a request for information on key considerations CMS might take into account across all CMS quality programs to address health care disparities and advance health equity.

In this proposed rule, CMS requests comments and feedback on the application of these overarching principles to the hospital outpatient quality reporting program.

Approaches for measures stratification

CMS identifies two approaches for reporting stratified measures: (1) "within-provider disparity method," which would compare a provider's performance results for a single measure between subgroups of their patients with and without a given factor (e.g., dual-eligible beneficiaries), and (2) "between-provider disparity methodology," which would report performance on measures for only the subgroup of patients with a particular social risk factor, allowing providers to compare their performance for the subgroup to state and national benchmarks.

¹⁹ Medicare Payment Advisory Commission. 2021. MedPAC comment on CMS's proposed rule on CY 2022 revisions to payment policies under the physician fee schedule and other changes to Part B payment policies. September 9.

Prioritizing measures for disparity reporting

CMS proposes a set of principles to prioritize measures for disparity reporting in quality reporting programs. These principles include prioritizing measures that: (1) meet industry standards for measure reliability and validity, (2) have evidence that the outcome being measured is affected by underlying health care disparities, (3) meet statistical reliability and representation standards, and (4) show differences in performance across subgroups.

Selecting social risk factors to use in stratification

Social risk factors are the wide array of nonclinical drivers of health known to negatively impact patient outcomes. These include factors such as socioeconomic status, housing availability, and nutrition (among others). CMS recognizes the limited availability of social risk data to use in stratification as a challenge. The agency names different sources of data that can be used to identify social risk, including patient-reported data, CMS administrative claims, area-based indicators of social risk, and imputed data sources.

Identifying meaningful performance differences

CMS proposes different approaches to identify differences in performance for stratified results. One potential approach is ordering health care providers in a ranked system based on their performance on disparity measures to quickly allow comparison of performance with that of similar health care providers. Another potential approach is benchmarking or comparing individual results to state or national averages.

Reporting disparity measures

CMS discusses different approaches by which stratified measure results can be reported. The agency cites that confidential reporting, or reporting results privately to health care providers, is generally used for new programs or new measures to give providers an opportunity to become more familiar with calculation methods and to improve before wider reporting is implemented. Measure results can also be publicly reported to provide all stakeholders with important information on provider quality. Public reporting also relies on market forces to incentivize providers to improve and become more competitive in their markets without directly influencing payment from Medicare.

Comment

The Commission continues to support CMS's overall efforts to measure and report health care disparities by stratifying quality measure results for different subgroups of beneficiaries, and believes these principles are applicable to the hospital outpatient quality reporting program.

As we stated in our comments on the FY 2023 IPPS proposed rule,²⁰ the Commission recognizes that optimal health outcomes can be adversely affected by social risk factors. MedPAC has traditionally focused on modifying payment systems to incentivize health care providers and payers (e.g., Medicare Advantage plans) to deliver high-quality care in the most efficient manner. While strong incentives for achieving value-based care objectives are critical, it is also important to apply such incentives fairly—that is, to recognize when these incentives can undermine access to care for beneficiaries. The Commission’s recent work to account for differences in patients’ social risk factors in quality payment programs and revisit payment for safety-net providers aims to improve incentives to deliver high-quality and efficient care. In the past, we have highlighted some disparities in care when we have identified them in our payment adequacy analysis. Moving forward, the Commission plans to more deliberately incorporate social risk factors into our analysis, in particular income and race/ethnicity, into our payment adequacy and other analyses.

Over the past several years, the Commission has recommended redesigned value incentive programs that incorporate peer grouping for hospitals, Medicare Advantage plans, and skilled nursing facilities.²¹ Rather than adjusting performance measures for patients’ social risk factors, which can mask disparities in performance, these programs would make adjustments to payments based on a provider’s performance compared with its peers. With peer grouping, each provider’s performance is compared with providers with similar mixes of patients (that is, its “peers”) to determine rewards or penalties based on performance. A provider would earn points based on its performance relative to national performance scales, but how those points are converted to incentive payments would vary by peer group, with larger multipliers (i.e., the payment adjustment per point) for peer groups with higher shares of beneficiaries at high social risk.

Selecting social risk factors to use in stratification

In our modeling of value incentive programs, we concluded that there is a need for better measures of patient social risk than are currently available.²² The National Academies of Sciences, Engineering, and Medicine (NASEM) outlined considerations to determine whether a social risk factor (measure) should be accounted for in a Medicare quality payment program.²³

²⁰ Medicare Payment Advisory Commission. 2022. MedPAC comment on CMS’s proposed rule on the hospital inpatient prospective payment system and the long-term care hospital prospective payment system for FY 2023. June 16.

²¹ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

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

Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

²² Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

²³ National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors*. Washington, DC: The National Academies Press.

The social risk factor should have a conceptual relationship with the outcome of interest (that is, there should be a reasonable hypothesis positing how the social risk factors could affect a Medicare beneficiary's health outcome) and empirical association with outcome measures (that is, there should be verifiable evidence of an association between the social risk factor and the outcome of interest). Medicare beneficiaries who are disabled or low income are eligible to concurrently enroll in Medicaid. In our various value incentive program models, we tested a share of a provider's patients who were fully dually eligible for Medicare and Medicaid as a measure of social risk because there is a conceptual relationship between dual eligibility and our outcomes of interest.

Although there are many reasons to use dual eligibility as proxy for beneficiary social risk, we recognize it is an imperfect measure. One drawback is that Medicaid eligibility requirements and benefits vary across states. Also, dual eligibility may be too narrow because it reflects a beneficiary's income but does not directly reflect other social risks, like food insecurity and limited access to transportation.

In the Commission's recent work to identify safety-net hospitals we expanded our definition of "low income" as a proxy for beneficiary social risk.²⁴ In this work, we defined "low-income" beneficiaries as those who are eligible for full or partial Medicaid benefits or receive the Part D low-income subsidy (LIS). This expanded definition includes beneficiaries who do not qualify for Medicaid benefits in their states but who do qualify for the LIS based on having limited assets and an income below 150 percent of the federal poverty level. Collectively, we referred to this population as "LIS beneficiaries" because those who receive full or partial Medicaid benefits automatically receive the LIS. Compared to the non-LIS population, LIS beneficiaries have relatively low incomes and differ in other regards, including being twice as likely to be Black and three times as likely to be disabled. In addition, expanding the definition of "low income" to include all LIS beneficiaries helped to reduce impact of variation in state Medicaid policies. The Commission intends to continue to explore improvements to our definition of "low income" as a proxy for beneficiary social risk.

The Commission also recognizes that another approach to capture beneficiary social risk would be to use area-level measures of social risk.²⁵ We encourage CMS to test various area-level measures for their potential to account for differences accurately across providers in the social risk of their patient populations. More research is needed to understand the accuracy of any area-level measure for Medicare beneficiaries compared with the gold standard of person-reported information.

²⁴ Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

²⁵ Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Identifying meaningful performance differences

The Commission encourages CMS to report stratified quality measure results that are reliable, meaning that they reflect true differences in performance and not be attributable to random variation. Key decisions for CMS include defining the reliability standard for measure results and selecting the strategies to ensure reliable measure results for as many providers as possible.

A high reliability standard should be used to determine the minimum number of observations required for a provider's performance to be stratified and reported. For providers with low patient volume, establishing reliable measure results is problematic because they do not have enough observations to ensure that the measure detects signal (actual performance) rather than noise (random variation). Unreliable measure results can lead to erroneous conclusions about a provider's performance; a low-volume provider can appear to have unusually good or poor performance when in fact its performance is not statistically different from the average.²⁶ In our illustrative modeling of a value incentive program for skilled nursing facilities, we used a reliability standard of 0.7, meaning that 70 percent of the variance in a measure's results was attributable to actual performance differences and that providers can be differentiated.²⁷

Setting a minimum case count to ensure reliability inevitably means excluding some providers from the quality measurement program. One way to include as many providers as possible is to pool data across years, allowing a performance measure to be calculated for many small providers that would otherwise be excluded. Such pooling is consistent with other quality payment program designs and measures. For example, Medicare's Hospital Readmissions Reduction Program uses three years of performance data to calculate readmission results. Blending performance across years also encourages sustained high quality. However, pooling data across years could dampen a provider's drive to improve if their recent better results are blended with older, poorer performance. In such a case, the provider's improved performance would not be fully recognized in its payment incentive payment for several years. To counter this disincentive, CMS could consider weighting the more recent years more heavily. CMS could also pool data across years only for low-volume providers, while reporting just the most recent year's performance for providers that meet a minimum count in a single year.

Reporting disparity measures

The Commission supports moving to publicly reporting stratified measure results. Publicly reporting Medicare quality information has two main objectives. The first is to increase the accountability of health care providers by offering patients, payers, and purchasers a more informed basis on which to hold providers accountable (e.g., directly through purchasing and treatment decisions). The second objective is to maintain standards and stimulate improvements in the quality of care through economic competition (reputation and increased market share) and

²⁶ Garrett, B., C. Carter, and D. Wissoker. 2021. Evaluation of the reliability of Medicare spending per beneficiary for post-acute care. *Medical Care* 59, no. 8 (August 1): 721–726.

²⁷ Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

by appeals to health care professionals' desire to do a good job.²⁸ The Commission also contends that public reporting should enable comparisons of individual providers with state and national averages to give consumers meaningful reference points.

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 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

²⁸ Marshall, M. N., P. G. Shekelle, H. T. Davies, et al. 2003. Public reporting on quality in the United States and the United Kingdom. *Health Affairs* 22, no. 3 (May–June): 134–148.