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July 7, 2020

Seema Verma, MPH
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-1735-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Medicare proposed rule entitled, “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule” published in the *Federal Register* on May 29, 2020. The rule revises the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system. In view of the competing demands on their time, we especially appreciate your staff’s efforts to improve these hospital payment systems.

In this letter we comment on proposals to:

- use commercial insurer data to set Medicare severity–diagnosis related group (MS–DRG) relative weights
- create a new MS–DRG for chimeric antigen receptor T-cell (CAR-T) therapy
- add an additional alternative criterion for determining “substantial clinical improvement” for purposes of the new technology add-on payment
- adopt the Office of Management and Budget’s changes to geographic area delineations to establish hospital wage indexes for the IPPS and LTCH PPS and continue policies that began in fiscal year (FY) 2020 to address wage index disparities

Using commercial insurer data to set Medicare MS–DRG relative weights

The purpose of MS–DRG weights is to set the relative payment rate for each MS–DRG to be proportionate to each MS–DRG’s average cost of care. For example, if hospitals’ costs per discharge for patients with MS–DRG A are (on average) twice the costs for MS–DRG B, CMS will try to set the payment weight for MS–DRG A equal to twice the payment weight for MS–DRG B. MS–DRG weights that are too low or too high (relative to costs) are inequitable and create incentives for providers to expand service lines that are overpaid and contract services lines that are underpaid.

In this proposed rule, CMS asks for comments on whether MS–DRG weights could be improved by basing Medicare MS–DRG weights on the relative rates paid by Medicare Advantage (MA) plans or other commercial insurers. For example, if the median MA payment rate for cardiac bypass without complications or comorbidities (CC) was three times the median MA rate for pneumonia without CC, then the cardiac bypass weight could be set at three times the pneumonia weight. To support this potential change, this proposed rule states that some hospitals’ charges do not reflect market rates and therefore that payments based on these chargemaster rates (list prices) can be “*inherently unreasonable when judged against prevailing market rates.*” However, CMS has not used simple charges to set weights since 2008 when costs began to be estimated by multiplying department-level charges by department-level cost-to-charge ratios. The proposed rule also notes that adopting payment strategies that are more reflective of the commercial insurance market is consistent with recent executive orders that “*directed the Medicare program to adopt and implement market-based recommendations.*”¹ In addition, CMS also requested comments on alternatives to the current use of hospital charges multiplied by cost-to-charge ratios in determining other inpatient payments, including outlier and new technology payments.

Comment

In this comment, we discuss several policy concerns regarding CMS’s proposal to use negotiated commercial rates to set MS–DRG weights:

- First, we discuss the history of DRG weight refinement;
- Second, we discuss how using MA rates to set Medicare fee-for-service (FFS) MS–DRG relative weights would be circular;

¹ On October 3, 2019, President Trump issued Executive Order 13980, *Protecting and Improving Medicare for Our Nation’s Seniors*, which directed the Medicare program to adopt and implement market-based recommendations developed pursuant to the October 12, 2017, Executive Order 13813, *Promoting Health Care Choice and Competition Across the United States*.

- Third, we discuss how using commercial (non-MA) rates to set relative weights may cause Medicare to overpay for services that have high relative profits in the commercial sector and may cause weights to reflect pricing leverage instead of costs; and
- Fourth, we discuss how outlier and new technology payments would still depend on cost estimates and could be improved without market-based data.

We discuss these policy concerns about using MA or commercial rates to set weights without addressing the legal question of whether CMS has the authority to demand that hospitals disclose MA and commercial rates. This issue is currently in the courts with the American Hospital Association and other hospital groups challenging the CMS requirement that hospitals disclose their negotiated rates.

History of DRG weight refinement

Fifteen years ago, CMS used charges (list prices) as a proxy for costs, rather than estimating costs. At the time, cardiology departments tended to have high markups (high charges relative to costs), which resulted in high weights for cardiology admissions and cardiology cases being more profitable than the average admission. As we noted in our 2005 report on specialty hospitals, these inaccuracies in Medicare payments encouraged the formation of hospitals specializing in cardiology.²

MedPAC recommended CMS shift from using charges as a proxy for costs to actually estimating costs. In 2008, CMS started to estimate the relative costliness of MS-DRGs by multiplying department-level charges by department-level cost-to-charge ratios. The result was a better estimation of the relative costliness of cases—including a decline in weights for cardiac procedures and an increase in weights for some medical cases—and the reduction in the formation of hospitals specializing in cardiac care.

The underlying assumption in the proposed rule is that relative prices paid by either MA plans or other commercial insurers would be a better reflection of hospitals' true relative costs across DRGs than the current system of using cost report data to estimate relative costs. We believe that is an unfounded assumption.

Using MA rates to set Medicare FFS MS-DRG relative weights would be circular

The proposed rule discusses hospitals disclosing MA payment rates per MS-DRG and using those rates to set relative weights in the FFS system. At first glance, this may appear reasonable given that MA plans serve approximately one third of Medicare beneficiaries and have a mix of discharges that is similar to FFS. However, as CMS notes in the proposed rule, there is ample

² Medicare Payment Advisory Commission. 2005. *Report to the Congress: Physician-owned specialty hospitals*. Washington, DC: MedPAC.

health services research literature showing that MA plans set their rates based on Medicare FFS weights.^{3,4,5} For example, Berenson and colleagues report that MA rates are most commonly set at 100 percent of FFS rates.⁵ MedPAC's discussions with MA plans and hospital systems confirm that MA contracts are often based on Medicare FFS rates. This means that MA plans are explicitly using Medicare FFS relative weights to set their prices. Therefore, using MA rates to set FFS MS-DRG weights is circular and would do nothing to bring market-based payment rates into the Medicare hospital rate-setting process.

Using commercial (non-MA) rates to set relative weights may cause Medicare to overpay for services that have high relative profits in the commercial sector and may cause weights to reflect pricing leverage instead of costs

We also caution against using commercial (non-MA) rates to set Medicare MS-DRG weights. Commercial prices could fail to reflect hospitals' costs for several reasons. First, research on commercial payment rates has shown that negotiated commercial rates vary widely. Even within a single market, rates that insurers pay for the same service can vary by more than 100 percent depending on the insurer's market power.⁶ This suggests that markets are not competitive across all service lines. However, the question is whether relative median rates paid by commercial insurers accurately reflect providers' relative costs. One concern is that providers may have more pricing power over certain services rather than others. For example, hospitals may be less willing to discount highly specialized services such as neurosurgery or open-heart surgery if there are few competitors in the market for those services. In addition, a hospital may have more pricing leverage over emergency services (e.g., cardiac catheterization) than non-emergency services (e.g., behavioral health admission). Research by the RAND Corporation suggests that commercial payers tend to pay relatively high rates (more than twice Medicare on average) for orthopedic and circulatory discharges.⁷ By contrast, RAND finds that commercial rates for mental health and substance abuse on average are less than 150 percent of Medicare rates. To the extent the RAND data are representative of nationwide commercial rates, using relative commercial payment rates to set MS-DRG weights would increase Medicare's payment rates for cardiology and orthopedics and decrease weights for some non-procedural services such as mental health discharges. As we stated earlier, cardiac weights used to be higher when weights were set by charges rather than costs. If CMS shifted to using commercial prices rather than estimated costs to set weights, we may move back toward overpaying for cardiac procedures. Given the data on widely varying payment rates in the commercial sector and the high relative

³ Maeda J., and L. Nelson. 2018. How do the hospital prices paid by Medicare Advantage plans and commercial plans compare with Medicare fee-for-service prices? *The Journal of Health Care Organization, Provision, and Financing* 55: 1–8.

⁴ Baker, L.C., M.K. Bundorf, A. Devlin, et al. 2016. Medicare Advantage plans pay less than traditional Medicare pays. *Health Affairs* 35, no. 8 (August):1444–1451.

⁵ Berenson, R. A., J. H. Sunshine, D. Helms, et al. 2015. Why Medicare Advantage plans pay hospitals traditional Medicare prices. *Health Affairs* 34, no. 8 (August): 1289–1295.

⁶ Cooper, Z., S. V. Craig, M. Gaynor, et al., 2019. The price ain't right? Hospital prices and health spending on the privately insured. *The Quarterly Journal of Economics* 134 no.1: 51–107.

⁷ White, C., and C. Whaley. 2019. *Prices paid to hospitals by private health plans are high relative to Medicare and vary widely*. Santa Monica, CA: RAND Corporation.

rates paid for cardiology and orthopedic admissions compared to the commercial rates for other discharges, it does not appear that commercial rates are an appropriate metric for setting MS–DRG weights for the Medicare program.

Outlier and new technology payments would still depend on cost estimates and could be improved without market-based data

As CMS acknowledges, even if commercial rates were used to set MS–DRG weights, hospital charges and costs would still need to be collected to determine outlier and new technology payments. Because some cases (outliers) have very high costs and these outlier cases are not distributed equally across hospitals, CMS makes additional payments for cases with costs beyond the levels contemplated by standard MS–DRG rates. CMS generally sets outlier payments at 80 percent of costs above a fixed-loss threshold. CMS estimates each case’s costs by multiplying the case’s charges by a hospital-wide cost-to-charge ratio.

This proposed rule raises the issue that current methods of determining outlier payments (multiplying charges by a hospital-wide cost-to-charge ratio) could discourage hospitals from lowering their charges. One concern is hospitals’ charges (list prices) tend to be high and vary widely across hospitals with little correlation with costs. Hospitals have faced some pressure to reduce their charges to be more reflective of costs. However, hospitals may be reluctant to more closely align their charges with costs because the CCR used by CMS (usually based on historical data) does not automatically increase to reflect the lower charges. If CMS does not adjust the CCR to reflect the drop in a hospital’s charges, the hospital’s outlier payments may decline. However, there is a current solution to this problem. As CMS notes in the proposed rule, hospitals can request that CMS prospectively change the CCR used for outlier payments if they lower list prices on their chargemaster. Specifically, if a hospital is planning on lowering its charges, it can request that CMS use a new CCR that reflects the lower charges when calculating outlier payments. Therefore, we agree with CMS that the current system of using charges and cost-to-charge ratios will still work in a world of declining or increasing charges.

A second concern is that the current system uses a hospital-wide CCR to estimate outlier costs. As we have discussed in our March 2017 report to the Congress, hospitals could manipulate charges in certain departments to gain unwarranted outlier payments under this methodology.⁸ The hospital-wide CCR problem could be addressed by using department-specific CCRs (which are currently used to set DRG weights) and restricting outlier payments to cases with longer-than-average stays. Therefore, we conclude that CMS can continue to use charges and CCRs to set MS–DRG weights and to compute outlier payments for unusually expensive cases.

⁸ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Creating a new MS–DRG for CAR-T therapy

The FY 2021 IPPS proposed rule discusses proposals for Medicare payments to inpatient hospitals for chimeric antigen receptor T-cell (CAR-T) therapy. CAR-T is a type of immunotherapy used to treat certain types of cancer that involves collecting and genetically modifying the patient’s own T-cells. Patients receiving CAR-T therapy may be hospitalized during and after the treatment, as the treatment is associated with severe reactions in some patients. Currently, two CAR-T products—Kymriah and Yescarta—have been approved by the Food and Drug Administration (FDA). These products are extremely high-priced, with an average sales price of approximately \$411,000 and \$373,000, respectively, as of 2nd quarter 2020.⁹ In addition, there are two other CAR-T products that are currently under consideration for FDA approval. The manufacturers of these two new products have applied for an IPPS new technology add-on payment (NTAP) for FY 2021.

In FY 2020, Medicare paid IPPS hospitals for CAR-T under MS–DRG–016, which groups together patients receiving certain bone marrow transplants and patients receiving CAR-T. The relative weight for MS–DRG–016 was 6.8852, which equated to a base payment rate of about \$43,000. In addition, hospitals were eligible to receive an NTAP for CAR-T, which is set at 65 percent of the lesser of: the cost of the CAR-T product or the difference between the estimated cost of the case and Medicare’s payment for the case (maximum NTAP payment was \$242,450). Hospitals could also receive outlier payments for patients receiving CAR-T therapy, set at 80 percent of the amount by which the estimated cost of the case exceeds Medicare’s payment after a fixed -loss amount has been reached.

For FY 2021, CMS proposes establishing a new MS–DRG (MS–DRG–018) for inpatients receiving CAR-T treatment. The proposed relative weight for MS–DRG–018 is 37.1412, which equates to a base payment rate of about \$239,000. CMS calculated this relative weight by estimating the cost of a CAR-T case using the standard charges-reduced-to-cost approach. Because hospitals do not incur a cost for acquiring the CAR-T product when patients participate in a clinical trial, CMS calculated the proposed relative weight for the DRG using data only for patients who did not participate in a clinical trial. To address the lower cost to hospitals for clinical trial cases, CMS proposes to apply a clinical trial adjustment of 15 percent to the MS–DRG payment for patients participating in a CAR-T clinical trial, meaning the MS–DRG relative weight would be reduced by 85 percent for those cases. As with other MS–DRGs, hospitals would be eligible to receive outlier payments if the estimated cost of the case exceeds Medicare’s payment by more than a fixed-loss amount. With respect to NTAPs, CMS proposes to discontinue the NTAP for the two existing CAR-T products, Kymriah and Yescarta, in FY 2021. CMS states that these products do not meet the NTAP newness criterion for FY 2021 and, in light of the proposed new MS–DRG, also would not meet the NTAP cost criterion. CMS also discusses the NTAP

⁹ We inferred average sales price (ASP) for each product from Medicare’s public payment rates under the outpatient prospective payment system in second quarter of 2020. Under that payment system, Medicare pays for these products at a rate of 106 percent of ASP. Thus, we infer ASP by dividing that payment rate by 1.06.

applications made by the manufacturers of the two potentially new CAR-T products and raises a number of questions about whether they would meet the NTAP criteria.

Comment

In this comment, we discuss:

- Our support for CMS's proposal to develop a new MS-DRG for CAR-T, but that the standard approach to developing relative payment weight and applying IPPS adjustments may result in inappropriate pricing for CAR-T cases;
- Steps CMS should take to ensure appropriate use of CAR-T; and
- Medicare's lack of tools to influence drug launch prices and the need for approaches to ensure that Medicare is a prudent purchaser of high-cost drugs, such as CAR-T.

CMS's proposal to create a new CAR-T MS-DRG is appropriate, but the standard approach to developing relative weights and applying IPPS adjustments may result in inappropriate pricing for CAR-T cases

In FY 2021, CMS has proposed to move CAR-T cases from the MS-DRG where they are currently grouped with bone marrow transplant cases to a new MS-DRG specifically for CAR-T cases. Now that claims data are available for patients receiving CAR-T therapy, it is appropriate to consider creating a new MS-DRG. The cost of treating CAR-T patients—which includes the hospital's acquisition price for the CAR-T product as well as the cost of inpatient services furnished to CAR-T patients—is substantially higher than the costs of treating patients with bone marrow transplants. If CAR-T remains grouped with bone marrow transplants, the MS-DRG payment will remain relatively low, and hospitals would generally expect to receive a substantial amount of payments for CAR-T cases through outliers. Creating a new MS-DRG for CAR-T will increase the base payment rate for CAR-T cases, reduce the portion of payments for CAR-T cases made through outlier payments, and lessen the potential for the outlier pool to be skewed toward CAR-T cases. In addition, establishing a new MS-DRG for CAR-T will prevent Medicare's payment for bone marrow transplants from being distorted by grouping them with substantially higher cost CAR-T cases. For these reasons, we support CMS's proposal to establish a new MS-DRG, although we are concerned about the extraordinarily high cost of CAR-T products and the potential for further price growth.

The creation of a new MS-DRG for CAR-T also makes it possible for CMS to pay a substantially lower rate for CAR-T cases when the patient participates in a clinical trial where the hospital does not incur a cost to acquire the CAR-T product. CMS has proposed to reduce the payment rate for the CAR-T MS-DRG by 85 percent when the patient participates in a clinical trial. Given the high cost of CAR-T therapy, Medicare's payment for this MS-DRG should be reduced substantially

when a patient participates in a clinical trial and the hospital does not incur a cost to obtain the CAR-T product. Reducing the payment for CAR-T cases for clinical trial patients is consistent with Medicare's National Coverage Determination (NCD) for Routine Costs in Clinical Trials, which states that Medicare covers routine costs associated with a clinical trial, but does not cover the investigational item. We therefore support CMS's proposal to develop a clinical trial adjuster that would be applied to payment for MS-DRG-018.¹⁰ In addition, we note that it is possible there could be other circumstances besides a clinical trial where a hospital does not incur a cost for acquiring the CAR-T product from the manufacturer.¹¹ CMS should ensure that the Medicare program pays a hospital the full MS-DRG payment only in cases where the hospital has incurred the costs of acquiring the product.

If CMS establishes a new MS-DRG for CAR-T cases, an important issue is how to set the relative weight for the MS-DRG. While the standard approach of establishing a relative weight by estimating costs using charges and department-level cost-to-charge ratios is generally reasonable, the results may be inappropriate for CAR-T due to its very high cost and dominance in the overall cost of the DRG. Rather than use the standard charges-to-reduced-to-cost methodology to set the relative weight for the CAR-T MS-DRG, the Commission believes CMS should use a modified approach that would more accurately incorporate hospitals' acquisition cost for the CAR-T product. As we commented last year, we support using the average sales price (ASP) as an estimate of the CAR-T product's portion of the MS-DRG cost for purposes of developing a relative weight for a new MS-DRG. ASP reflects the average price earned by the manufacturer for sales to most purchasers net of rebates, discounts, and price concessions with certain exceptions. Using ASP would provide a better estimate of the hospital's acquisition cost of the CAR-T product, which would improve the accuracy of the MS-DRG relative weight and payment, and reduce the potential for the outlier pool to become skewed toward CAR-T cases. We also encourage CMS to use ASP as an estimate of the CAR-T product's acquisition costs in the outlier calculation. Using CAR-T's ASP in the outlier calculation would eliminate the possibility that a hospital could increase its charges on the CAR-T product to receive increased outlier payments. Therefore, we urge CMS to use ASP to estimate the cost of the CAR-T product (and use the standard charges-reduced-to-cost methodology to estimate the other costs associated with treating patients receiving CAR-T therapy) for the purposes of setting a DRG relative weight and determining whether an individual case qualify for outlier payments. Since two CAR-T products are currently on the market, CMS should use a weighted average of the ASP for the products as an estimate of the cost. Using a weighted average gives the hospital an incentive to use the lower cost product where clinically appropriate and can create incentives for price competition among manufacturers. CMS could also consider additional safeguards to ensure that Medicare does not face rising ASPs for CAR-T over time, such as capping the ASP amount included in the CAR-T

¹⁰ <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&NCAId=186&bc=AiAAAAAAAgAAAA%3d%3d&>.

¹¹ For example, a hospital could have contractual arrangements with manufacturers under which a hospital does not pay for the CAR-T product unless the patient achieves a certain outcome.

MS–DRG relative weight in future years (e.g., to be no higher than the ASP in the first year of the new MS–DRG).¹²

We also reiterate our comments from the FY 2020 rule that creating a unique MS–DRG for an extraordinarily high-cost product like CAR-T therapy raises questions related to the appropriateness of payment adjustments under the IPPS, including the standard wage adjustment and IME and DSH payments. Because the price of the CAR-T product is extraordinarily high and dominates the costs in the MS–DRG, wage adjustment of the CAR-T MS–DRG payment using the standard approach would overpay hospitals in high wage index areas and underpay those in low wage index areas. For example, across IPPS hospitals, wage adjusted payment rates for MS–DRGs vary by more than two-fold across hospitals from the lowest to highest wage-index areas. Because the prices of drugs and biologics generally do not vary geographically, it would be inequitable to apply the standard wage adjustment to the payment for an MS–DRG that included CAR-T. Consequently, CMS should consider an alternate approach to wage adjusting the CAR-T MS–DRG, such as using a lower labor share for the CAR-T MS–DRG or applying the standard wage adjustment approach to only a portion of the CAR-T MS–DRG payment (e.g., the portion of the MS–DRG payment not associated with the cost of the CAR-T product). Parallel to our concerns with the wage adjustment, we contend that it would be inequitable to apply other IPPS payment adjustments, such as IME and DSH, to the CAR-T portion of the MS–DRG, and that CMS should consider applying these adjustments to only a portion of the CAR-T MS–DRG payment amount.

CMS should take steps to ensure appropriate use of CAR-T

Although some patients have experienced benefit from CAR-T therapy, given the high cost of currently available products and the potential for significant side effects, CMS should ensure that the use of these products are appropriate. To this end, the agency should consider implementing a claims monitoring system (as it has done for other services such as outpatient dialysis) to make certain that the use of these therapies is consistent with Medicare’s national coverage determination.¹³ If the Secretary’s monitoring system identifies inappropriate use or unusual billing practices, the Secretary should take immediate action to address such issues. Options that

¹² In our June 2017 report to the Congress, the Commission recommended that Congress establish an ASP inflation rebate, which would require manufacturers of Part B drugs to pay a rebate to Medicare when ASPs for Part B drugs increased faster than an inflation benchmark. While the Commission has not made a recommendation related to an ASP inflation rebate for drugs covered under Medicare Part A, this type of approach could also have merit in a situation where ASP is used to establish a portion of the relative weight. (Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.)

¹³ According to the NCD for CAR-T, “The Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.” <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=car-t&KeywordLookup=Doc&KeywordSearchType=Exact&kq=true&bc=EAAAABAAIAAA&>

the Secretary could consider include developing local coverage determinations, prepayment and post-payment reviews, provider outreach and education, and program integrity enforcement, as appropriate depending on the nature of any issues identified. In addition, CMS could reconsider its decision to not implement coverage with evidence development (CED) with a requirement for registry participation for CAR-T therapies in its national coverage determination (NCD).¹⁴ CED offers the agency an opportunity to generate clinical evidence specifically for Medicare beneficiaries who are older and often underrepresented in cancer clinical trials. CED enables the program to ultimately develop better, more evidence-based policies.¹⁵

Medicare lacks tools to influence drug launch prices to ensure that Medicare is a prudent purchaser of high-cost drugs, such as CAR-T

Although we believe the approach we have suggested for payment to inpatient hospitals for CAR-T therapy in FY 2021 would improve payment accuracy and equity across hospitals, it does not address our concerns about launch prices for drugs and biologicals. With the launch of extraordinarily high-cost products like CAR-T, Medicare faces challenges as the program acts as a price taker and lacks tools to arrive at payment rates for new drugs that balance an appropriate reward for innovation with value and affordability for beneficiaries and taxpayers. As we stated in last year's comment letter to the Secretary,¹⁶ with respect to Medicare payment policy for drugs more broadly, if manufacturers continue to launch drugs at extraordinarily high prices, there may be merit in considering whether new approaches for handling payment for these services are warranted. For example, in the Commission's June 2019 report to the Congress,¹⁷ we discussed potential approaches to increase price competition and value for drugs covered by Medicare Part B, and potentially by Medicare Part A. In that report, we explored a potential policy that would permit the Secretary, under certain circumstances, to enter into baseball-style binding arbitration with drug manufacturers for high-cost Part B drugs with limited competition. The report discusses the possibility of extending the prices arrived at through arbitration to Part A providers like acute care hospitals, as a way to assist these providers with their costs for expensive drugs with limited

¹⁴ In its proposed NCD for CAR-T therapies, CMS said that, "We believe the current evidence base, which has significant gaps but demonstrates that CAR T-cell therapy is a promising type of cancer immunotherapy, supports coverage through the CED paradigm for further study in patients with cancer. Accordingly, we believe that patient, product, practitioner, and provider limitations are appropriate at this time in order to maximize the likelihood that Medicare beneficiaries experience a health benefit during and from treatment of their cancer with a CAR T-cell product." (<https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=291>.) CMS discussed several factors in its final NCD for CAR-T therapies for eliminating the use of CED and registry participation including the requirement by the Food and Drug Administration for post-marketing studies and the ongoing research by scientists and manufacturers.

¹⁵ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

¹⁶ Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed rule entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule published in the Federal Register." June 21.

¹⁷ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

competition. Although the Commission has not made a recommendation on this policy option, we continue to explore approaches to incorporate value into Medicare's payment for drugs. As policymakers consider alternative approaches to address payment for high-cost drugs, it is important to recognize that the establishment of special payment methods for high-cost products could create incentives for manufacturers to set high prices as a way to circumvent the normal payment systems. Care will need to be taken in devising any special approaches to ensure that they are structured in ways that ensure Medicare is a prudent purchaser.

Adding an alternative pathway for antimicrobials to meet the new technology add-on payment's 'substantial clinical improvement' requirement

Medicare provides an add-on payment (NTAP) to hospitals for the use of new medical services or technologies, including certain drugs and devices that are not substantially similar to an existing technology. In CMS's final rule for FY 2002, the Secretary concluded that a new service or technology would be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries "*such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology.*" However, in the FY 2002 rule, the Secretary raised concerns regarding new technologies that turn out to be less effective than initially thought, or in some cases even potentially harmful. The Secretary stated that "*...it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.*"¹⁸ The result has been that physicians and hospitals can choose to use new technologies, but under current rules, Medicare pays more for those new technologies only if there is evidence that the new technology results in improved care for the beneficiary.

In response to the Administration's concerns related to antimicrobial resistance and its impact on Medicare beneficiaries, in the FY 2020 rule CMS created an alternative pathway for NTAP applications received for FY 2021 and subsequent fiscal years. Under this new pathway, if a drug is designated by the FDA as a Qualified Infectious Disease Product (QIDP) and receives FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of NTAP and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this pathway, a drug that has received FDA marketing authorization and is designated by the FDA as a QIDP will only need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(d)(3) (84 FR 42292 through 42297) in order to be eligible for a NTAP. In addition, applications that qualify for a NTAP through the QIDP pathway will receive a higher add-on payment: the lesser of 75 percent of the costs of the new technology or of the amount by which the costs of the case exceed the standard DRG payment (while other new technologies will only receive 65 percent). In the first year of the alternative pathway for NTAP payment (FY 2021), CMS is proposing to approve 6 products designated by the FDA as

¹⁸ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2001. Medicare program; payment for new medical services and new technologies under the acute care hospital inpatient prospective payment system; final rule. *Federal Register* 66, no. 174 (September 7): 46901–46925.

QIDPs, in addition to 3 applicants under the Breakthrough Device Program and 15 applicants under the traditional NTAP criteria.

For FY 2022, CMS is proposing to expand the NTAP alternative pathway for antimicrobials to also include drugs approved under the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). Under this proposal, drugs designated as LPADs will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that they represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

Created through Section 3042 of the 21st Century Cures Act, the LPAD pathway is intended for a "*limited population of patients with unmet needs.*" This pathway provides the FDA with more flexibility in assessing the risks and benefits of a drug given the "*severity, rarity, or prevalence of the infection the drug is intended to treat and the lack of alternatives available for the patient population.*" Drugs considered under the LPAD pathway may receive FDA approval without evidence of a favorable benefit-risk profile for a broader population. Currently, there are two drugs approved for use under this pathway, neither of which had applied for FY 2021 NTAP:

- Pretomanid tablets in combination with bedaquiline and linezolid for the treatment of a specific type of highly treatment-resistant tuberculosis (TB) of the lungs; and
- Arikayce (amikacin liposome inhalation suspension), for the treatment of lung disease caused by a group of bacteria, Mycobacterium avium complex (MAC), in a limited population of patients with the disease who do not respond to conventional treatment (refractory disease).

As part of the expansion of the alternative pathway, similar to the QIDPs, CMS is proposing to apply an NTAP payment percentage of 75 percent for LPADs, compared with 65 percent for other drugs and devices receiving NTAP.

In FY 2021, CMS received 24 new NTAP applications, up from 17 for FY 2020 and 5 for FY 2010.

Comment

The Commission recognizes the need to promote beneficiary access to new technologies that improve outcomes while preserving the incentives within the IPPS for efficiency. The Commission also appreciates CMS's desire to address concerns related to antimicrobial resistance in the Medicare population. However, the Commission does not support the use of the FDA's LPAD for qualification for NTAP unless the drug in question also meets the current substantial clinical improvement criterion—that is, unless there is some evidence that the new drug results in

improved care for beneficiaries. As we have discussed in prior comment letters, the evaluation of the evidence of these outcomes should rest with CMS.^{19,20}

The Commission recognizes the importance of the unique roles across federal agencies with different standards for approval. The FDA's role in the drug and device development process as a regulator is distinct and separate from the role of CMS as a payer. The FDA regulates whether a product is "safe and effective" for its intended use by consumers. The FDA approval process may or may not include the new device or pharmaceutical's safety or effectiveness with regard to the Medicare population. As specified in regulation, CMS's evidence base for an NTAP decision should rely on the drug or device's ability to specifically address the needs (diagnosis and treatment) of Medicare beneficiaries. CMS should not pay more for a new technology without evidence that it improves outcomes for Medicare beneficiaries. The Commission maintains that the Medicare program, not the FDA, should adjudicate spending determinations based on the specific needs of the Medicare population.

As with all products that receive an increase in payment through an NTAP, the Commission is concerned that, if this proposal is adopted, the additional payment would also provide an incentive for increased use (including off-label use) of drugs approved under the LPAD pathway. The drugs approved under the LPAD pathway are for a limited population, based on a more flexible risk-benefit assessment, and prescribing these products outside of the targeted approved indication could endanger patients unnecessarily.²¹ Further, the practice of prescribing antimicrobials in populations that are not indicated could also lead to more resistance to antibiotics, contrary to CMS's stated policy goals. If CMS finalizes its proposal to expand the alternative NTAP pathway to include products approved under the LPAD pathway, CMS could attempt to mitigate incentives for off-label use by limiting NTAP to cases that meet the FDA's approved and targeted indications.

In addition, the Commission has long held that Medicare should pay similar rates for similar care. To protect the well-being of beneficiaries and ensure good value for the Medicare program and taxpayers, Medicare should not pay more for technological advances that have not yet been proven

¹⁹ Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed notice entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Hospital Prospective Payment System, and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule." June 21.

²⁰ Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, and DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements." September 20.

²¹ Gingery, D. 2018. Pink Sheet- LPAD approval pathway is not saving antimicrobial development. November 28. <https://www.focr.org/news/pink-sheet-lpad-approval-pathway-not-saving-antimicrobial-development>.

to provide better outcomes for beneficiaries. Therefore, new products should not qualify for NTAP if there is no evidence that the drug or device is an improvement relative to existing care.

As we stated last year, as the NTAP percentage increases (from 50 percent in 2019 to 65 percent (for non-QIDPs) and 75 percent (for QIDPs) in 2020), Medicare's payments move further toward cost-based reimbursement, which is counter to the principles of the IPPS. As CMS weighs whether to expand the alternative pathway for LPADs to qualify for NTAP payment to 75 percent, the agency should consider whether quantitative evidence indicates that current payment of 65 percent is insufficient especially given that NTAP represents additional Medicare spending that is not offset by other changes in the IPPS.

Adopting the Office of Management and Budget's changes to geographic area delineations to establish hospital wage indexes for the IPPS and LTCH PPS and continuing policies that began in FY 2020 to address wage index disparities

The payment rates for both short-term and long-term acute care hospitals are adjusted to reflect the relative differences in area wage levels using geographic areas (called core-based statistical areas, or CBSAs) delineated by the Office of Management and Budget (OMB). Periodically, OMB revises the delineations and CMS adopts them in establishing the wage index values. In 2018, OMB published an updated set of delineations that included the creation of new CBSAs, the splitting of some existing CBSAs, and changes in the designation of some areas from rural to urban and from urban to rural.²²

For FY 2021, CMS proposes to adopt the 2018 OMB delineations of geographic areas and to continue policies begun in FY 2020 to address index disparities.²³ Consistent with the wage index transition policy implemented in the FY 2020 rule, CMS proposes a 5 percent limit on wage index reductions (regardless of the circumstance causing the reduction), thus mitigating the impact on hospitals whose wage index values will decrease. The adoption of the new wage index values would be done in a budget-neutral manner.

Under the IPPS, hospitals may also receive numerous adjustments to their wage index. For example, in FY 2021, 435 hospitals applied for and were granted geographic reclassifications from

²² On April 10, 2018, OMB issued OMB Bulletin No. 18-03, which superseded the August 15, 2017, OMB Bulletin No. 17-01. On September 14, 2018, OMB issued OMB Bulletin No. 18-04, which superseded the April 10, 2018, OMB Bulletin No. 18-03. CMS was unable to complete an exhaustive review of the changes in these 2018 OMB bulletins prior to the issuance of the FY 2019 IPPS/LTCH rule. OMB issued another interim bulletin on March 6, 2020, which CMS stated was not issued in time for inclusion in the development of the FY 2021 proposed rule.

²³ For more information on the technical changes to the hospital wage index that CMS implemented in FY 2020 and proposes to continue, see MedPAC's comment letter at http://medpac.gov/docs/default-source/comment-letters/06212019_medpac_2020_ipps_ltch_comment_v3_sec.pdf?sfvrsn=0.

the Medicare Geographic Classification Review Board, an increase from 279 reclassifications in FY 2020.

Comment

The Commission supports the adoption of the new delineations of the geographic areas, the continuation of policies to reduce wage index disparities and data circularity, and the use of transition policies to mitigate the impact of changes to the wage index values. Regarding the limit on decreases to the wage index values, the Commission supports eliminating wage index changes of more than 5 percent in one year. However, the Commission believes the limit should apply to both increases and decreases in the wage index, not just decreases. As a result, no provider would have its wage index value increase or decrease by more than 5 percent for FY 2021. Consistent with CMS's proposed approach and statute, the implementation of the revised relative wage index values (where changes are limited to plus or minus 5 percent) should be done in a budget-neutral manner.

The Commission also reiterates its June 2007 recommendations on wage index reform.²⁴ We recommended that the Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across the inpatient prospective payment system and other prospective payment systems, including certain post-acute care providers. Specifically, our recommended wage index system would:

- use wage data from all employers and industry-specific occupational weights,
- adjust for geographic differences in the ratio of benefits to wages,
- adjust at the county level and smooth large differences between counties, and
- include a transition period to mitigate large changes in wage index values.

The wage index system we proposed would more fully reflect input prices, automatically adjust for occupational mix, reduce circularity, and reduce large differences between adjoining areas compared with the current system. Two significant research evaluations commissioned by the Secretary concluded that MedPAC's proposed wage index system would be an improvement over Medicare's current hospital wage index system.^{25,26} We understand that eliminating the current wage index system and the associated apparatus (such as the rural floors and reclassifications)

²⁴ Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.

²⁵ Institute of Medicine. 2011. *Geographic adjustment in Medicare payment, Phase I: Improving accuracy. Second edition*. Washington, DC: The National Academies Press.

²⁶ MaCurdy, T, T. DeLeire, K. Lopez de Nava. et al. 2009. *Revision of Medicare Wage Index. Final Report, Part I*. MaCurdy, T, T. DeLeire, K. Lopez de Nava. et al. 2010. *Revision of Medicare Wage Index. Final Report, Part II*. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/CMS1237065.html>.

would require Congressional action, but we urge the agency to consider our recommendations and make adjustments to the current system where it has the authority to do so. In particular, the continued increase in the number of IPPS hospitals applying for and being granted geographic reclassifications underscores the need to fix flaws in current wage index policy in a more uniform and consistent manner.

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 long horizontal line extending to the right from the end of the signature.

Michael E. Chernew, Ph.D.
Chair