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June 21, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File code CMS-1716-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 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* on May 3, 2019. The rules revise the hospital inpatient prospective payment system, including payments for new technology in the inpatient and outpatient sectors, 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:

- Inpatient and outpatient drug- and device-related proposals
- Proposed changes to the hospital wage index
- Measuring uncompensated care on the hospital cost report's S-10 worksheet
- The LTCH prospective payment system

Inpatient and outpatient drug- and device-related proposals

The fiscal year (FY) 2020 proposed rule discusses multiple policies related to payment for new high-cost drugs and devices used in acute care hospitals. Specifically, the proposed rule discusses:

- alternative criteria for determining if a new drug or device results in “substantial clinical improvement” and qualifies for a new technology add-on payment (NTAP);

- the magnitude of the add-on payment for technologies meeting the criteria; and
- payment for chimeric antigen receptor T-cell (CAR-T) therapy in 2020 and the mechanics of creating a new Medicare severity–diagnosis related group (MS–DRG) in future rulemaking.

Alternative criteria for determining “substantial clinical improvement”

Medicare provides an add-on payment 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.*”¹ 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 some evidence that the new technology results in improved care for the beneficiary.

In response to the Administration’s concerns about administrative burden and stakeholders’ concerns regarding redundancy, CMS is now proposing two alternatives to the standing requirement of tying higher payments to evidence of substantial clinical improvement.

- ***Alternative 1: The FDA’s Breakthrough Device Program***—Under this alternative, CMS would deem a device as new and not substantially similar to an existing technology, therefore meriting higher payments, if it is part of the FDA’s Breakthrough Devices Program and received FDA marketing authorization. Such devices may not yet have demonstrated a substantial improvement in caring for Medicare beneficiaries, so under this alternative, that requirement would be waived.
- ***Alternative 2: Broad commercial use***—Under this alternative, CMS would allow the substantial clinical improvement criteria to be met if the applicant demonstrated that the new technology would be broadly adopted among applicable providers and patients.

¹ 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.

Comment

The Commission recognizes the need to promote beneficiary access to new technologies that improve outcomes while preserving the incentives within the inpatient prospective payment system (IPPS) for efficiency. The Commission also appreciates CMS's desire to eliminate perceived redundancies in bringing advances in technology to the Medicare population. However, the Commission does not support the use of the FDA's Breakthrough Device Program for qualification for NTAP unless the drug or device in question also meets the current substantial clinical improvement criterion—that is, unless there is some evidence that the new technology results in improved care for beneficiaries. The Commission maintains that the Medicare program, not the FDA, should adjudicate spending determinations based on the specific needs of the Medicare population.

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 device or pharmaceutical 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. Through the Breakthrough Device Program, the FDA considers whether a device is reasonably expected to provide more effective treatment or diagnosis relative to the current standard of care. The device manufacturer or sponsor could demonstrate this expectation through literature or preliminary bench, animal, or clinical data.² In its FY 2020 proposed rule, CMS acknowledges that "...*the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.*" Therefore, participation in the Breakthrough Device Program on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries. 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. Thus, the evaluation of the evidence of these outcomes should rest with CMS.

There have been many examples where devices approved through expedited FDA approval have not resulted in improvements in care relative to existing technologies. The proposed rule requested comments regarding balancing the risk of adverse events or negative outcomes with the use of the Breakthrough Device Program in qualifying for NTAP. The Breakthrough Device Program is available for devices subject to review under a premarket approval application (PMA), premarket notification (510(k)) clearance, or De Novo marketing authorization. In a July 2011 report, the Institute of Medicine of the National Academies concluded that the 510(k) process "is not a determination that the cleared device is safe or effective." Further, a review of several studies that presented clinical trial evidence of certain approved devices under the FDA's Priority Review

² Food and Drug Administration. 2018. Breakthrough Device Program: Guidance for industry and Food and Drug Administration staff. December 18.

Program (also superseded by the Breakthrough Device Program) found that 4 out of 9 expert advisory panel reviews did not find the devices to be effective and, as of May 23, 2018, recalls had been issued for 6 of 14 devices.³ The Commission is concerned about inappropriate incentives (through increased payment) for providers to use new technology without proven safety or efficacy.

CMS's proposal for a broad adoption criterion would explicitly specify that the requirement for substantial clinical improvement could be met if the applicant demonstrates that the new technology would be broadly adopted by applicable providers and patients. The Commission does not support equating substantial clinical improvement with broad adoption and posits that it is not appropriate for the Medicare program to provide higher payment for services that have not been proven to have a clinical advantage over existing treatment options. The Commission has written extensively about services provided to Medicare beneficiaries that lack evidence of comparative clinical effectiveness, yet are broadly used.⁴ Therefore, the Commission reiterates that the clinical improvement standard is necessary to reduce incentives to use unproven technology, regardless of the degree of adoption.

Lastly, 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 thus the taxpayers, Medicare should not pay more for technologies that have not yet been proven to provide better outcomes for beneficiaries. Therefore, drugs or devices should not qualify for NTAP if there is no evidence that the drug or device is an improvement relative to existing care.

The magnitude of the new technology add-on payment

In addition to the alternative criteria for approving NTAPs, the Secretary proposes to change the share of the cost of the new technology covered by the NTAP. Medicare currently provides an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS-DRG payment. The NTAP represents additional Medicare spending that is not offset by other changes in the IPPS. In response to concerns regarding payment for new technology with "unprecedented" high costs, the Secretary proposes to increase the share of costs covered by the add-on payment to the lesser of: (1) 65 percent of the costs of the new medical service or technology or (2) 65 percent of the amount by which the costs of the case exceed the standard MS-DRG payment.

In making this proposal, the Secretary states that "we continue to believe it is important to preserve the incentives under an average-based prospective payment system... We do not believe it is

³ Jones, C. L., Dhruva, S. S., Redberg, R. 2018. Assessment of clinical trial evidence for high-risk cardiovascular devices approved under the Food and Drug Administration Priority Review Program. *JAMA Internal Medicine* 178, no. 10 (October): 1418–1419.

⁴ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

appropriate to pay an add-on amount equal to 100 percent of the cost of the new technology.” CMS seeks comment on the proposed increase to 65 percent in the NTAP formula. CMS also seeks comments on alternative policies such as adopting a higher percentage than the 65 percent or making a uniform add-on payment that equals 65 percent of the cost of the new technology.

The Secretary also requests comment regarding the timing of NTAP payment determinations as part of the annual updates and changes to the IPPS. The current process includes a New Technology Town Hall meeting open to the public to provide input prior to CMS announcing the proposed rule.

Comment

The NTAP policy seeks to facilitate beneficiary access to new technologies while preserving the incentives within the IPPS for efficiency. The Commission agrees with CMS that it would be inappropriate for the NTAP percentage to be 100 percent. Such a policy would amount to cost-based reimbursement and would be inflationary. In our view, although an NTAP percentage in the range of 50 percent to 65 percent is somewhat arbitrary, it achieves the goal of sharing the risk of the cost of a new technology between the program and providers in the context of an average-based payment system like the IPPS. However, we note that under the current policy of paying the lesser of 50 percent of the costs of the new technology or 50 percent of the amount by which costs exceed the standard MS–DRG payment rate, there have been a record number of NTAP applications for FY 2020. Indeed, the number of new applications for NTAP payments has increased steadily from 5 for FY 2010 to 17 for FY 2020. As CMS weighs whether to increase the share of the cost covered by the NTAP to 65 percent, the agency should consider whether quantitative evidence indicates that current payment is insufficient. The higher the NTAP percentage, the more the IPPS moves toward cost-based reimbursement, which is counter to the principles of the IPPS.

The Commission does not support the use of a uniform NTAP. CMS should not make an NTAP payment unless the total cost of the case exceeds the Medicare payment in the absence of NTAP. The current NTAP approach that compares the cost of the case involving the new technology with the DRG payment amount strikes the right balance between innovation and incentives for efficiency. If a hospital’s cost for a case involving a new technology is less than the DRG payment amount, no NTAP is needed. Therefore, the NTAP should continue to be capped at a fraction (e.g., 50 percent or 65 percent) of the hospital’s loss on the case or the cost of the new technology, whichever is less.

In terms of the NTAP review process, the Commission supports transparent and predictable processes with established routines for the agency, stakeholders, and the public. The current annual process of review for NTAP qualification provides manufacturers a forum for feedback and questions, and it provides other stakeholders with opportunities to participate in the process. We do not see any reason at this time to alter the current process, given its predictability and transparency.

Payment rates for services using CAR-T therapy

The FY 2020 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. Both products are approved for adult patients with certain advanced lymphomas who have already tried two other kinds of treatment. CAR-T products have an extremely high list price, with Yescarta listed at \$373,000 and Kymriah's listed at \$475,000 for leukemia.⁵

For FY 2020, CMS proposes to continue to assign patients treated with CAR-T products to an existing MS-DRG (MS-DRG-016) that currently includes certain bone marrow transplants. CMS notes that, although the 2018 claims data do include some cases that involve CAR-T, the number is limited, so it would be premature to use these data to establish a separate DRG for CAR-T.

CMS seeks comment on whether the agency should change its approach in determining the cost of CAR-T therapy and requests feedback regarding whether a cost-to-charge ratio (CCR) of 1.0 in estimating the costs of the CAR-T product for the potential NTAP and outlier payment calculations and for IPPS-exempt cancer hospitals' payment formula would be appropriate. As a rationale, CMS indicates that it has received a number of public comments suggesting that hospitals would not inflate their charges for the CAR-T product given its high price and that consequently a CCR of 1.0 could be warranted.

In addition, CMS requested feedback on whether CAR-T therapy meets the criteria for its own MS-DRG in the future, and if so, whether alternate methodologies should be used to establish a relative weight for CAR-T therapy, given its extraordinarily high costs. For example, instead of using the average costs of cases that include CAR-T, CMS suggested the use of the average sales price of the drugs to reflect the costs involved in treating patients receiving CAR-T therapies.

CMS is soliciting comment regarding how such a payment should be determined if CAR-T therapy is assigned to a new MS-DRG in the future, given that CAR-T costs are not present on claims for cases involved in clinical trials. The absence of these costs could have a significant impact on the calculation of a relative weight for a new MS-DRG. CMS also requested input regarding the extent to which a new MS-DRG for CAR-T should be geographically adjusted or increased for

⁵ Press reports suggest that the manufacturer of Kymriah has matched Yescarta's list price of \$373,000 when used for lymphoma patients. See Beasley, D. 2018. U.S. approves Novartis cell therapy for lymphoma. *Reuters*, May 1. <https://www.reuters.com/article/us-novartis-pharmaceuticals/u-s-approves-novartis-cell-therapy-for-lymphoma-idUSKBN1I24GP>.

indirect medical education (IME) or for the Medicare disproportionate share (DSH) hospital adjustment.

Comment

We support CMS's proposal to pay for inpatients receiving CAR-T therapy in FY 2020 through an existing MS-DRG, with a new technology add-on payment (if CMS determines CAR-T continues to meet the criteria) and outlier payments. Over the years, this approach has provided a mechanism for CMS to incorporate payment for new technologies into the IPPS while creating incentives for efficiency and sharing risk between providers and the Medicare program. This approach would cover most (but not all) of any losses hospitals realized on inpatients receiving CAR-T therapy.

The Commission contends it is important to maintain the structure of the IPPS and not create policies that would unbundle services included in an MS-DRG or create incentives that encourage high launch prices for new technologies. The IPPS has an established process for incorporating payment for new technologies, including drugs and devices, into the payment system. New technologies are paid through existing MS-DRGs. Since the cost of a new technology may not be reflected in the data that is used to establish the MS-DRG payment rates, a manufacturer can apply for an NTAP for the first three years a product is on the market. CMS should continue to work through its established process to determine payment for CAR-T therapy. We support CMS paying for CAR-T in FY 2020 through an existing MS-DRG, an NTAP (if CMS determines CAR-T continues to meet the criteria for such a payment), and outlier payments.

We agree that efforts should be made to accurately estimate the costs of the CAR-T product for the purposes of calculating a potential NTAP, outlier payments, and cancer hospital cost calculations, but we are concerned about a policy that would set the CCR for CAR-T equal to 1.0. Generally, hospitals inflate charges for services above their incurred costs. The Commission recently estimated that, on average, hospitals' charges are more than three times their actual costs.⁶ An industry-sponsored report found that, on average, hospitals charge 479 percent of their costs for drugs nationwide.⁷ A CCR of 1.0 for CAR-T would presume hospitals charged their actual costs, despite the clear financial incentive to increase charges. Under both the current and proposed outlier rules, hospitals that inflate charges for CAR-T more would extract a larger share of the fixed outlier pool than hospitals that inflate charges less. Furthermore, we are concerned that presuming charges equal costs could set a precedent for other items or services going forward.

Rather than using a CCR of 1.0, we support using the average sales price (ASP) with a two-quarter lag as an estimate of the cost of CAR-T products. ASP reflects the average manufacturers' price to all purchasers net of rebates and discounts, with certain exceptions. The two-quarter lag in ASP

⁶ Medicare Payment Advisory Commission. 2017. *A data book: Health care spending and the Medicare program*. Washington, DC: MedPAC.

⁷ The Moran Company. 2018. *Hospital charges and reimbursement for medicines: Analysis of cost-to-charge ratios*. <http://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf>

could create incentives for price reductions. If the price of CAR-T declined, that decline would not be immediately reflected in ASP and thus hospitals would benefit for two quarters from the use of the higher ASP in the cost calculations (even if the hospital received the price reduction). The ASP for the two CAR-T products could be averaged to permit use of a single average ASP for the cost of CAR-T in these calculations. Such averaging would put the products on a level playing field and could create incentives for price reductions. It is important to note that hospitals will incur other costs in treating patients receiving CAR-T therapy besides the cost of the CAR-T product itself. 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.⁸

We support CMS's consideration of establishing a new MS-DRG, consistent with its established process for doing so under the IPPS, once sufficient claims and cost report data for CAR-T therapy become available. Similar to our comments regarding calculating an NTAP for CAR-T therapy for FY 2020, we also support using the average sales price (ASP) with a two-quarter lag as an estimate of the cost of CAR-T products for purposes of developing a relative weight in a new MS-DRG. The cost of CAR-T therapy is high; therefore, we are concerned about the risk associated with using an inaccurate cost-to-charge ratio, whereas ASP data would provide a reasonable estimate of the cost of the drug to the hospital. 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 if CMS moves forward with a new MS-DRG.

A material share of cases receiving CAR-T therapy is associated with clinical trials, resulting in no hospital drug costs for either Kymriah and Yescarta.⁹ In cases where the hospital incurs the cost of acquiring the CAR-T therapy, we expect such costs to account for a large share of the total cost of the claim. In cases where the hospital does not incur the cost of acquiring the CAR-T therapy, we expect the total costs of the claim to be substantially lower. Thus, if claims related to clinical trials are included in calculating the relative weight for a CAR-T therapy MS-DRG, the relative weight will not accurately reflect the true costs of providing CAR-T therapy. Indeed, averaging the cost of the claims with and without the cost of acquiring the CAR-T therapy would result in a substantial overpayment of claims for beneficiaries enrolled in a clinical trial and a substantial underpayment for beneficiaries not enrolled in a clinical trial. Although this issue exists throughout the development of relative weights, it is significantly amplified with regards to CAR-T because of: (1) the high costs associated with CAR-T, (2) the relatively low volume of cases, and (3) the high

⁸This suggestion to use ASP as the estimated cost of the CAR-T product in the potential NTAP, outlier, and cancer hospital cost calculations would apply to situations in which the hospital had to pay the manufacturer for the CAR-T product administered to its patient. Some hospitals may have contractual arrangements with manufacturers under which a hospital does not pay for the CAR-T product unless the patient achieves a certain outcome. CMS should ensure that the Medicare program pays hospitals for CAR-T only in cases where the hospital has incurred the costs in acquiring the product.

⁹ Kite Pharma. 2019. Medicare and CAR T Therapy. Presentation at EO 12866 Meeting 0938-AT73. March 22. <https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0938-AT73&meetingId=3867&acronym=0938-HHS/CMS>

share of cases enrolled in clinical trials. CMS could consider assigning CAR-T cases with no CAR-T therapy costs due to being in a clinical trial to a different MS-DRG. The estimated cost (and thus relative weight) for that alternative MS-DRG housing the clinical trial cases should be computed without including any CAR-T drug costs.

We appreciate that, in future years, if CMS does consider creating a unique MS-DRG for an extraordinarily high-cost product like CAR-T therapy, it will be important to contemplate issues related to payment adjustments under the IPPS, including the standard wage adjustment and IME and DSH payments. 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 a MS-DRG that included CAR-T. (Initially assigning CAR-T to an existing MS-DRG with a potential NTAP and outlier payments would mitigate this concern in the short run because NTAP and outlier payments are not wage adjusted.) Similarly, we contend that it would also be inequitable to apply adjustments for IME and DSH to the CAR-T portion of the MS-DRG.

In the longer run, 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, 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 inpatient hospitals, as a way to assist these providers with their costs for expensive drugs with limited competition. Although the Commission has not made a recommendation on this policy option, we continue to explore its potential.

More generally, 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 incorporate strong incentives to constrain drug prices.

Proposed changes to the hospital wage index

The FY 2020 proposed rule discusses several technical changes to the current hospital wage index system to help address wage index disparities and invites comment on reforming this system more broadly. The three technical changes are:

- ***Narrowing the range of wage indexes.*** For FY 2020 through at least FY 2023, CMS proposes for hospitals with a wage index value below the 25th percentile to increase the wage index by half the difference between the otherwise applicable wage index for that hospital and the 25th percentile wage index value across all hospitals. To maintain budget neutrality, CMS would offset these increases with decreases in the wage index among

hospitals with a wage index value above the 75th percentile. CMS is attempting to break a circularity issue where hospitals in low-wage-index areas receive lower Medicare rates and thus may have difficulty raising wages.

- ***Removing reclassifications from calculation of the rural floor.*** Beginning in FY 2020, CMS proposes that the rural floor be calculated without including the wage index data of hospitals that have been reclassified as rural.
- ***Cap on decrease in wage index.*** For FY 2020, CMS proposes to place a 5 percent cap on any decrease in a hospital's wage index relative to FY 2019. To maintain budget neutrality, CMS would apply an adjustment to the national standardized amount.

Comment

In response to CMS's request for comments on revising the current wage index system more broadly, we wish to reiterate our June 2007 recommendations on wage index.¹⁰ We recommended that the Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across the IPPS 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. As summarized in the FY 2019 IPPS proposed rule, 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.^{11,12} We hope this invitation for additional feedback initiates action on this critical element of Medicare's prospective payment systems.

¹⁰ Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.

¹¹ Institute of Medicine. 2011. *Geographic adjustment in Medicare payment, Phase I: Improving accuracy. Second edition*. Washington, DC: The National Academies Press.

¹² MaCurdy, T, T. DeLeire, K. Lopez de Nava. et al. 2009. Revision of Medicare Wage Index. Final Report, Part I. and 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>

In the proposed rule, the most significant proposed wage index change is to increase the wage index of those areas in the bottom 25 percent and reduce the wage index in areas with high wages to create budget neutrality. The 2007 MedPAC recommendations would also have resulted in reduced variance in the wage index across markets and greater equity across neighboring hospitals. But the magnitude of our recommended wage index would be empirically derived from Bureau of Labor Statistics data and would result in less compression relative to the CMS proposal. We are concerned that the proposed increase in wage indexes for those at the bottom of the distribution is one more ad-hoc adjustment to the wage index, which already has many exceptions. A better long-term direction is for a more data-driven adjustment to wage indexes.

Regarding removing reclassifications from calculation of the rural floor, the Commission supports removing hospitals that reclassified from urban to rural areas when computing the rural floor. The calculation of the rural floor has allowed a limited number of states to manipulate the wage index system to achieve higher wages for many urban hospitals in those states at the expense of hospitals in other states.

Regarding the limit on wage index decreases, the Commission supports eliminating wage index movements of more than 5 percent in one year. However, the limit should apply to both increases and decreases in the wage index, not just decreases. It should be done in a budget-neutral manner.

Measuring uncompensated care on the hospital cost report's S-10 worksheet

Medicare adjusts inpatient payment rates to increase payments to hospitals with a “disproportionate share” (DSH) of low-income patients, as measured by the disproportionate patient percentage (DPP). The DPP is computed as the sum of two fractions: the “Medicare SSI fraction” and the “Medicaid fraction.” The “Medicare SSI fraction” is the hospital’s share of Medicare patients that are low-income; it is computed as the share of Medicare inpatient days attributable to patients entitled to Supplemental Security Income (SSI). The Medicaid fraction is the hospital’s share of total inpatient days attributable to Medicaid patients. The policy pays higher inpatient rates for hospitals with a high DPP.

In 2010, Congress enacted several changes to DSH payment policy in the Patient Protection and Affordable Care Act (PPACA). Under the updated DSH policy, CMS determines the amount of Medicare dollars that are potentially available for distribution as DSH and uncompensated care payments using the traditional DSH formula that is based on the DPP. However, rather than distribute the whole pool as traditional DSH payments, a portion of the pool is made available to hospitals as uncompensated care payments, and a portion is returned to the Medicare Part A trust fund as savings, assuming the rate of uninsurance remains below the rate of uninsurance in 2013 (presumably reducing the need for uncompensated care payments below the 2013 level). For FY 2020, CMS calculated the size of the pool of potential DSH and uncompensated care dollars to be \$16.3 billion. CMS proposes to allocate this pool of dollars as follows:

- 1) CMS will pay 25 percent of the pool (\$4.2 billion) based on the traditional DSH formula.

- 2) The remaining 75 percent of the pool (\$12.7 billion) will be further divided into two parts: savings for the trust fund and payments for uncompensated care.
 - a) For every 1 percent decline in the rate of uninsurance, the share of the remaining pool allocated to trust fund savings increases by 1 percentage point. CMS estimates that the rate of uninsurance in FY 2020 will be 33 percent lower than in 2013. This means that 33 percent of the \$12.7 billion (\$4.2 billion) will be savings for the Medicare Part A trust fund.
 - b) The remaining \$8.5 billion (67 percent of \$12.7 billion) will be distributed to partially pay for uncompensated care costs at hospitals in 2020. The distribution of these payments depends on each hospital's estimated share of uncompensated care.

Each DSH hospital's share of the \$8.5 billion will equal its estimated share of historical uncompensated care costs. CMS has proposed to distribute the funds using 2015 S-10 cost report data.

For FY 2020, CMS is proposing to use the FY 2015 cost report data, instead of a more recent version of the data, to allocate the fixed pool of uncompensated care dollars to DSH hospitals. CMS suggests using 2015 data because: "Given that we have conducted audits of the FY 2015 Worksheet S-10 data and have previously used the FY 2015 data to determine uncompensated care payments, and the fact that the FY 2015 data are the most recent data that we have allowed to be resubmitted to date, we believe that, on balance, the FY 2015 Worksheet S-10 data are the best available data..."

Comment

In FY 2018, CMS started to use Worksheet S-10 from the Medicare hospital cost reports to estimate hospitals' share of uncompensated care costs. Using the S-10 computation is an improvement over the prior policy of using Medicaid days as a proxy for uncompensated care costs. The 2015 S-10 cost report data are appropriate for two reasons. First, CMS has had time to conduct some audits of the data. Second, as we mentioned last year, the Commission is concerned that Worksheet S-10 was changed for fiscal year 2017 in a way that created an incentive for hospitals to inflate charges. The instructions in effect in 2015 should produce more accurate estimates of uncompensated care costs. Therefore, the Commission supports the proposal to use FY 2015 cost report data to allocate the fixed pool of uncompensated care dollars to DSH hospitals. The Commission also encourages CMS to amend the instructions to the form S-10 to decrease the incentive for hospitals to inflate charges and thus more accurately reflect these costs in the future.

The LTCH PPS

CMS requested input on the continued use of the acute care hospital unadjusted wage index values for purposes of LTCH payment and has proposed a revision to the discharge-to-community measure used in the LTCH quality reporting program (QRP).

Use of the hospital wage index

Historically, CMS has calculated the LTCH PPS wage index values using unadjusted wage index values (pre-reclassification, unadjusted for occupational mix and the rural floor) from acute care hospitals. In response to stakeholder comments on certain aspects of the wage index values and their impact on payments, the FY 2020 proposed rule requested feedback regarding the wage index used to adjust LTCH payments and suggestions for possible updates and improvements to the geographic adjustment of payments to LTCHs.

Comment

In response to CMS's request for feedback on the current wage index system, we wish to reiterate our recommendations on wage index reform included in the Commission's 2007 report to the Congress and discussed earlier in this comment letter.¹³ As summarized in the FY 2019 proposed rule, 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.^{14,15} Although the wage index system we proposed did not evaluate the use of the calculated index for LTCHs specifically, since the LTCH payment system uses the unadjusted wage index values from acute care hospitals, we contend this change 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.

Revisions to the discharge-to-community quality measure

As part of the LTCH QRP, CMS calculates a risk-adjusted rate of fee-for-service beneficiaries discharged to the community from an LTCH stay who do not have a subsequent hospital readmission and remain alive during the following 31 days. CMS proposes to exclude patients who

¹³ Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.

¹⁴ Institute of Medicine. 2011. *Geographic adjustment in Medicare payment, Phase I: Improving accuracy. Second edition*. Washington, DC: The National Academies Press.

¹⁵ MaCurdy, T, T. DeLeire, K. Lopez de Nava. et al. 2009. Revision of Medicare Wage Index. Final Report, Part I. and 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>

were nursing facility residents before an LTCH stay from the measure calculation because they are not expected to return to the community following their stay.

Comment

The Commission maintains that Medicare quality measures should be patient oriented, encourage coordination across providers and time, and promote improvement in the delivery system. Medicare quality programs should include population-based outcome measures that are not unduly burdensome for providers. For example, measures that can be calculated by CMS using claims data represent a low level of provider burden. In principle, therefore, the Commission supports the inclusion of the discharge-to-community measure in the QRP. However, the Commission does not support CMS's proposal to remove nursing home residents from the measure sample. Rather, the Commission supports the expansion of the definition of "return to the community" to include nursing home residents returning to their residence—that is, the nursing home where they live. The home of a nursing home resident is the nursing home; thus, a nursing home resident who returns to the nursing home following discharge from an LTCH is returning to their community. Further, providers should be held accountable for the quality of care they provide for as much of their Medicare patient population as feasible.

If you have questions about any of the issues raised in our comments, please contact James E. Mathews, MedPAC's Executive Director, at (202) 220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." in a cursive style.

Francis J. Crosson, M.D.
Chairman