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Advancing Health in America

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September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–1772–P: 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 Proposed Rule (Vol. 87, No. 142), July 26, 2022.

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2023.

We support a number of the OPPS proposed rule's provisions, including CMS' decision to end its policy to significantly cut reimbursements to 340B hospitals following the Supreme Court's unanimous ruling in *American Hospital Association v. Becerra*. In restoring the payments for CY 2023, we urge the agency to apply the same budget neutrality adjustment it implemented when the policy was first put into place; doing so would ensure that CMS does not introduce permanent payment shortfalls related to this policy. In addition, we urge the agency to support a remedy that promptly reimburses those hospitals affected by these cuts for all years that it was in place (CYs 2018-2022). At the same time, no hospital should be penalized for the agency's implementation of an unlawful policy, including through unlawful attempts at

achieving retrospective budget neutrality. The end of this harmful policy and prompt repayment of funds without any retrospective claw backs will help ensure that both 340B and non-340B hospitals can continue to care for the patients and communities they serve.

In addition, we appreciate the opportunity to further comment and provide feedback on the establishment of the new Medicare provider type, the Rural Emergency Hospital (REH). **We thank the agency for its work on this program, as hospitals are eager to evaluate the feasibility of conversion. We support a number of proposals issued by CMS, including the use of Medicare claims data to calculate the monthly facility payment.** We ask that the agency continues to consider reimbursements and regulatory requirements that ensure the sustainability of REHs and look forward to working with the agency in implementing those guidelines.

However, we are very concerned that the proposed market basket update of 3.1% is woefully inadequate and does not capture the unprecedented inflationary environment hospitals and health systems are experiencing. Therefore, we urge CMS to take action to increase the market basket in the final rule to better account for these extraordinary circumstances in order to ensure that beneficiaries continue to have access to quality outpatient care. We also are concerned about the proposed reduction for productivity, and ask CMS to elaborate in the final rule on the specific productivity gains that are the basis for the proposed 0.4 productivity offset. Such a cut does not align with hospital and health systems' public health emergency (PHE) experiences related to actual losses in productivity during the COVID-19 pandemic.

Finally, we oppose CMS' proposal to add a service category, facet joint interventions, to its prior authorization process. The increased utilization of these services have other appropriate justifications, the current data reveals that utilization levels of these services have already recessed, and there are other oversight mechanisms available to CMS that do not inappropriately delay care that should be used, rather than prior authorization, to address improper Medicare payments.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director for policy, at rschulman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

American Hospital Association
Detailed Comments on the OPPS and ASC Payment System Proposed Rule for CY 2023

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CY 2023 PAYMENT UPDATE

For CY 2023, CMS proposes to apply the hospital inpatient market basket update of 3.1%, less a productivity adjustment of 0.4 percentage points, for a hospital outpatient update of 2.7%. **A 2.7% update is woefully inadequate and does not capture what hospitals and health systems need to continue to overcome the many challenges that threaten their ability to care for patients and provide essential services for their communities. This includes the extraordinary inflationary expenses hospitals are being forced to absorb, particularly related to supporting their workforce while experiencing severe staff shortages.** This is because the market basket is a time-lagged estimate that uses historical data to forecast into the future**.** When historical data vastly underestimate future inflation, the market basket becomes inadequate. Similarly, when data incorrectly predict gains in productivity, the productivity adjustment is substantially overstated. Indeed, using more recent data,[1] we see that the market basket for CY 2022 is trending toward 4.8%, well above the 2.7% OPPS update implemented in the CY 2022 final rule. Additionally, while CMS proposes a productivity cut of 0.4 percentage points, the latest data actually indicate *decreases* in productivity, not gains.[2]

Therefore, we ask that in the final rule CMS examine ways to account for these increased costs to ensure that beneficiaries continue to have access to quality outpatient care. We also urge the agency to reduce the productivity cut for CY 2023 as such a cut does not align with hospital and health systems' PHE experiences related to actual losses in productivity during the COVID-19 pandemic.

Context of the Inflationary Economy

The current inflationary economy combined with the COVID-19 crisis has put unprecedented pressure on America's hospitals and health systems. Health care providers remain on the front lines fighting this powerful virus, while at the same time struggling with persistently higher costs and additional downstream challenges that have emerged as a result of the lasting and durable impacts of high inflation and the pandemic. **We urge CMS to consider the changing health care system dynamics, including those described below, and their effects on hospitals. Taken together, these shifts in the health care environment are putting enormous strain on hospitals and health systems, which will continue in CY 2023 and beyond.**

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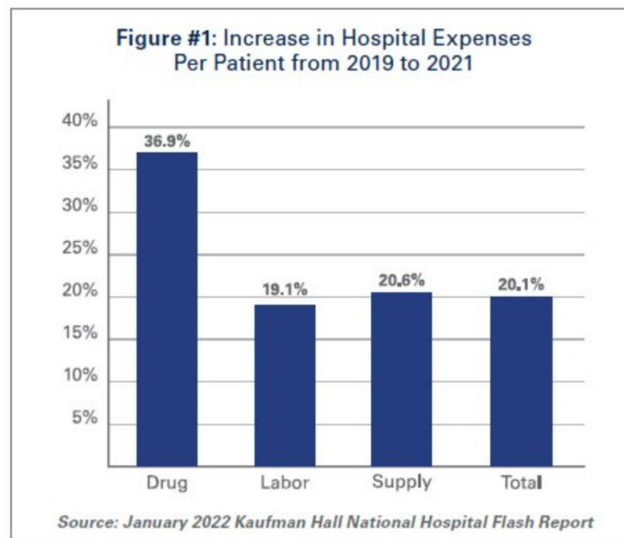
[1] IHS Global, Inc.'s (IGI's) forecast of the IPPS market basket increase, which uses historical data through fourth quarter 2021 and first quarter 2022 forecast. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData

[2] U.S. Bureau of Labor Statistics. (May 5, 2022). Productivity and Costs, First Quarter 2022, Preliminary - 2022 Q01 Results. https://www.bls.gov/news.release/pdf/prod2.pdf.

Historic inflation has continued and heightened the severe economic instability that the pandemic wrought on hospitals and health systems. Specifically, high inflation began to take hold in the second half of CY 2021, with the consumer price index (CPI), a measure of general inflation, ultimately hitting a 12-month high in June 2022 at 9.1%.[3] Fannie Mae forecasts that inflation will remain elevated through at least the end of 2022, averaging 5.5% in the fourth quarter.[4] Because this high rate of inflation is not projected to abate in the near term, it is critical to account for it when considering hospital and health system financial stability in CY 2023 and beyond. As described in a report by FTI Consulting (as attached to the AHA's FY 2023 inpatient prospective payment system (IPPS) comment letter), more recent inflationary pressures are also likely to work their way into wage expectations, particularly in industry sectors such as health care where labor is in short supply, thus driving up costs even further.

Indeed, the financial pressures providers are experiencing are massive. Expenses continue to rise across the board, from increasing costs for labor, drugs, purchased services, personal protective equipment (PPE), and other medical and safety supplies needed to care for patients. Specifically, an April 2022 report by the AHA highlights the significant cost growth in hospital expenses across labor, drugs and supplies (as shown in the reproduced chart below), as well as the impact that rising inflation is having on hospital prices. By the end of CY 2021, total hospital expenses per adjusted discharge were up 20.1% compared to pre-pandemic levels in 2019.



[3] U.S. Bureau of Labor Statistics. (June 10, 2022). Consumer Price Index Summary Results. https://www.bls.gov/news.release/cpi.nr0.htm; Statista. (June 13, 2022). Monthly 12-month Inflation Rate in the United States from May 2021 to May 2022. https://www.statista.com/statistics/273418/unadjusted-monthly-inflation-rate-in-the-us/

[4] Fannie Mae. April 19, 2022. Inflation Rate Signals Tighter Monetary Policy and Threatens 'Soft Landing'. https://www.fanniemae.com/research-and-insights/forecast/inflation-rate-signals-tighter-monetary-policy-and-threatens-soft-landing

Appropriately accounting for recent and future trends in inflationary pressures and cost increases in the final CY 2023 OPPS payment update is essential to ensure that Medicare payments for hospital outpatient services more accurately reflect the cost of providing hospital care. Indeed, Medicare already pays only 84% of hospital costs on average according to our latest analysis.[5] In 2020, two-thirds of hospitals received Medicare payments less than cost and Medicare margins fell to *negative* 12.6% without COVID-19 relief funds.[6] Moreover, hospitals' median change in operating margin dropped nearly 76% compared to April 2021 and gross operating revenue declined over 50% in the same time period.[7] Inadequate payment updates that do not account for inflation will cause this underpayment to be even more pronounced.

Market Basket

CMS proposes a market basket update of 3.1%, less a productivity adjustment of 0.4 percentage points, which would result in an OPPS update of 2.7% for CY 2023. These estimates were produced using historical data through the fourth quarter of CY 2021, forecast into the future. In a steady-state economy with small and stable changes in inflation and costs, it is possible to predict with some accuracy the anticipated rate of increase in the cost of goods and services to determine provider reimbursements. That is, the rationale for using historical data as the basis for a forecast is reasonable in a typical economic environment. However, we are not in a typical economic environment with inflation hitting decade highs in June 2022. **The end of CY 2021 into CY 2022 should not, in any sense, be considered a steady-state economic environment that is a continuance of past trends. Relying on this timeframe results in a woefully inadequate market basket update that will exacerbate Medicare underpayment if not corrected.** This is, in large part, because the market basket is a time-lagged estimate that cannot fully account for unexpected changes that occur, such as historic inflation and increased labor and supply costs faced by the health care industry that began in late 2021 but have continued at an increased pace in 2022.

Specifically, for CY 2022, CMS finalized a market basket update of 2.7%. To do so, it used estimates from historical data through the first quarter of CY 2021, forecast into the future.[8] Because this market basket was a forecast of what was *expected* to occur, it missed the *unexpected* trends that actually did occur. For example, the inflation rate in March 2021 was 2.6%, but by December 2021 it had skyrocketed to 7%.[9] Clearly, the

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[5] American Hospital Association (February 2022). Underpayment by Medicare and Medicaid Fact Sheet. https://www.aha.org/system/files/media/file/2022/02/medicare-medicaid-underpayment-fact-sheet-current.pdf

[6] MedPAC. (2022). March 2022 Report to the Congress: Medicare Payment Policy. Chapter 3 – Hospital inpatient and outpatient services. https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf

[7] Kaufman Hall (May 2022). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2022-05/KH-NHFR-05-2022-May.pdf

[8] 86 Fed. Reg. 45214 (August 13, 2021).

[9] Statista. (June 13, 2022). Monthly 12-month Inflation Rate in the United States from May 2021 to May 2022. https://www.statista.com/statistics/273418/unadjusted-monthly-inflation-rate-in-the-us/

CY 2022 market basket was unable to capture the extraordinarily high inflationary spikes that occurred towards the latter half of CY 2021.

The CY 2022 market basket was also unable to capture large increases in labor and wage costs, which also occurred towards the latter half of CY 2021. Indeed, when we examine preliminary labor costs reported on the Medicare cost report, we find that contract labor costs increased by 55% and total labor expenses increased by nearly 8% for those cost reports ending April 2021–December 2021 compared to the year prior (cost reports ending April 2020–March 2021).[10] Indeed, market basket forecast used for the CY 2022 OPPS final rule missed these unexpected turns reflected in the data. And, as more recent data becomes available beyond those used to forecast the CY 2022 market basket,[11] that market basket is trending toward 4.8%, well above the 2.7% CMS actually implemented.

In addition to the fact that the market basket, by nature, largely misses unexpected trends, its construction dulls the impact of any unexpected spikes that occur. For instance, the market basket uses three price proxies to measure price changes over time — the Employment Cost Index (ECI), which measures changes in compensation costs; the Consumer Price Index (CPI), which measures changes in prices paid by consumers; and the Producer Price Index (PPI), which measures changes in price experienced by producers. The figure below,[12] created by FTI, shows the three components that make up the market basket. In particular, CPI has a significantly steeper upward trend than is reflected in the market basket for hospital services. This suggests that when the market basket captures shocks, it is much more muted than what hospitals and health systems actually experience because it is a time-lagged rolling average estimate. Again, in a steady-state economy with small and stable changes in inflation and costs, this may be a reasonable approach. However, in an atypical environment, such as the one we are currently in, payment updates must adequately account for these dynamic changes. **We urge CMS to take action to increase the market basket in the final rule to better account for these extraordinary circumstances.**

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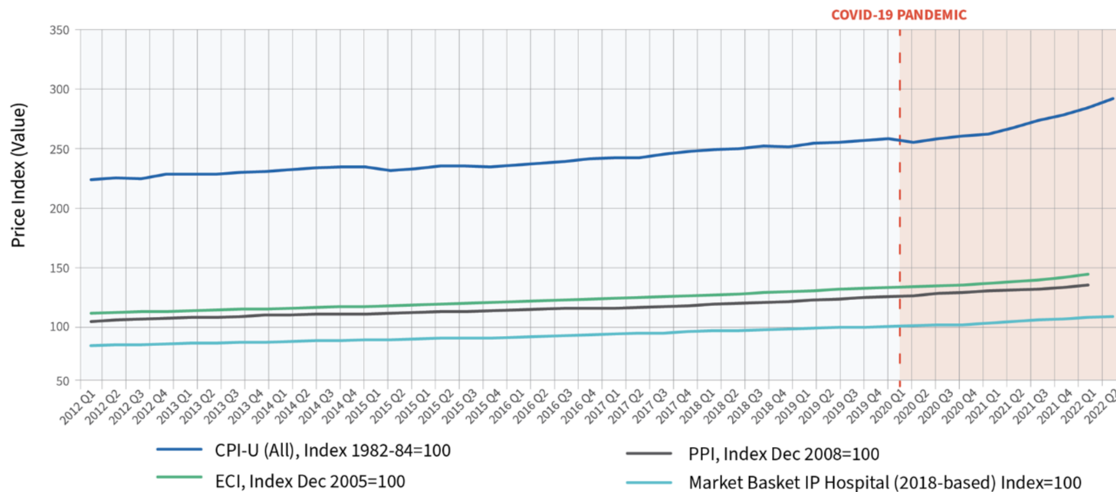
[10] AHA analysis of hospital Medicare cost reports reported to the Healthcare Cost Report Information System (HCRIS) March 31, 2022 Update.

[11] IHS Global, Inc.'s (IGI's) forecast of the IPPS market basket increase, which uses historical data through fourth quarter 2021 and first quarter 2022 forecast. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData

[12] Source: Consumer Price Index (CPI) Databases, U.S. Bureau of Labor Statistics; Employment Cost Index (ECI), FRED, Federal Reserve Bank of St. Louis; Producer Price Index (PPI), FRED, Federal Reserve Bank of St. Louis; CMS Market Basket Index Levels, IHS Global Inc. (IGI) 2021q4 Forecast by CMS, OACT, National Health Statistics Group.



Productivity

Under the Affordable Care Act (ACA), the OPPS payment update is reduced annually by a productivity factor, which is equal to the 10-year moving average of changes in the annual economy-wide, private nonfarm business total factor productivity (TFP).[13] This measure was intended to ensure payments more accurately reflect the true cost of providing patient care. For CY 2023, CMS proposes a productivity cut of 0.4 percentage points.

The use of the private nonfarm business TFP is meant to capture gains from new technologies, economies of scale, business acumen, managerial skills and changes in production. **Thus, this measure effectively assumes the hospital sector can mirror productivity gains across the private nonfarm business sector. However, in an economy marked by great uncertainty due to inflation, and demand and supply shocks, this assumption generates significant departures from economic reality.**

In fact, CMS itself has acknowledged that hospitals are unable to achieve the productivity gains assumed by the general economy over the long run. Specifically, research indicates that hospitals can only achieve a productivity gain that is one-third of the gains seen in the private nonfarm business sector.[14] Thus, using the private nonfarm business sector TFP to adjust the market basket exacerbates Medicare

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[13] Centers for Medicare and Medicaid Services. (February 2016). Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf
[14] Centers for Medicare and Medicaid Services. (February 2016). Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf

underpayments to hospitals, which is particularly burdensome when coupled with record inflation. Indeed, Medicare margins in 2020 were already *negative* 8.5% when COVID-19 relief funds are accounted for, and *negative* 12.6% without those funds.[15]

The use of an adjustment that is a 10-year moving average also negates year-to-year fluctuations. For example, over the last decade, there have been four quarters of productivity decreases. Two of these quarters occurred during the past 12 months — a 0.4% decline in the third quarter of 2021 and a 0.6% decline in the first quarter of 2022.[16] Two productivity declines in the last 12-month period is a material disruptor of the relative steady-state increases in private, nonfarm productivity gains. **Although the productivity adjustment uses a 10-year moving average, two quarter declines in 12 months in this metric is also noteworthy enough that it should be considered when deciding upon the appropriate productivity adjustment to implement for CY 2023.**

In addition, whereas the private nonfarm business economy experienced a rapid increase in output and productivity gains when communities began emerging from COVID-19 lockdowns in late 2021, the same has not been true for hospital services. Generally, hospital services have not recovered to pre-pandemic levels,[17] and it is highly unlikely that hospitals have achieved the significant productivity gains incorporated into the proposed CY 2023 payment update.

Specifically, the Bureau of Labor Statistics data show that hospital employment levels have decreased by approximately 100,000 from pre-pandemic levels.[18] Additionally, the combination of employee burnout and fewer available staff have forced hospitals to heavily rely on contract staff, especially contract nurses. The loss of established employees and the reliance on contract staffing firms to help address staffing shortages all echo our members' experiences related to declines in productivity during the pandemic, not gains. Indeed, an October 2021 survey conducted by Kaufman Hall found that many hospitals and health system leaders feel the COVID-19 pandemic made it significantly more difficult for them to improve their performance.[19]

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[15] MedPAC. (2022). March 2022 Report to the Congress: Medicare Payment Policy. Chapter 3 – Hospital inpatient and outpatient services. https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf
[16] U.S. Bureau of Labor Statistics. (May 5, 2022). Productivity and Costs, First Quarter 2022, Preliminary - 2022 Q01 Results. https://www.bls.gov/news.release/pdf/prod2.pdf, https://www.bls.gov/opub/ted/2022/nonfarm-business-labor-productivity-down-0-6-percent-from-first-quarter-2021-to-first-quarter-2022.htm.
[17] Kaufman Hall (May 2022). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2022-05/KH-NHFR-05-2022-May.pdf
[18] American Hospital Association. (April 2022). Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems. https://www.aha.org/costsofcaring
[19] Kaufman Hall. (October 18, 2021). 2021 State of Healthcare Performance Improvement Report: COVID Creates a Challenging Environment. https://www.kaufmanhall.com/insights/research-report/2021-state-healthcare-performance-improvement-report-covid-creates

The AHA has deep concerns about the proposed productivity cut of 0.4%, given the extreme and uncontrollable circumstances in which hospitals and health systems are currently operating. It is clear that significant uncertainty will continue to persist regarding the direction and magnitude of U.S. economic performance as inflationary pressures caused by multiple factors (such as fiscal and monetary policy, supply chain disruptions and the war in Ukraine) continue to affect productivity. **We urge CMS to reduce the productivity cut in the final rule given the declines in productivity in recent quarters due the COVID-19 PHE and other extraordinary circumstances.**

USE OF CLAIMS AND COST REPORT DATA FOR 2023 RATE SETTING

CMS proposes to use the CY 2021 claims data to set CY 2023 OPPS and ASC rates. However, cost report data usually lag the claims data by a year and CMS believes that the CY 2020 cost report data are not the best overall approximation of expected outpatient hospital services as the majority overlap with parts of the CY 2020 COVID-19 PHE. In order to mitigate the impact of some of the temporary changes in hospitals cost report data from CY 2020, the agency proposes to use cost reports from the June 2020 extract from Healthcare Cost Report Information System (HCRIS), which includes cost report data from prior to the COVID-19 PHE. This is the same cost report extract CMS used to set OPPS rates for CY 2022.

The AHA supports CMS' proposal to use CY 2021 claims and the cost report data from the June 2020 extract from HCRIS for CY 2023 rate setting. We appreciate the agency's recognition of the unusual nature of the CY 2020 cost data. That said, AHA's support of this methodology only pertains to the proposed CY 2023 rates and weights. The data used in future years' rulemaking should be revisited on a year-by-year basis.

Accordingly, the AHA also opposes the use of the alternative approach that CMS notes it is considering for rate setting. Under this approach the agency would continue with its standard process of using the most updated claims and cost report data available, including cost report data extracted from HCRIS in December 2021.

PAYMENTS FOR 340B DRUGS

The AHA appreciates CMS' decision to end their unlawful policy to significantly cut payments for separately payable drugs and biologicals purchased under the 340B drug pricing program for CY 2023. CMS correctly recognizes the significance of the Supreme Court's unanimous decision in *American Hospital Association v. Becerra*, 124 S. Ct. 1896 (2022). In that case, the Court held that "absent a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals" relative to other hospitals, and "HHS's 2018 and 2019 reimbursement rates for 340B hospitals were

therefore contrary to the statute and unlawful." As CMS acknowledges in its proposed rule, the Supreme Court's decision "obviously has implications for CY 2023 payment rates." (pg. 347, CY 2023 OPPS proposed rule). **To that end, the AHA supports the agency's position that it "fully anticipates" reverting to its prior policy of paying Average Sales Price (ASP) plus 6% for 340B-acquired drugs in CY 2023 and urge it to finalize this policy in the OPPS final rule.**

CMS also has requested comments on a remedy in *American Hospital Association v. Becerra*. As we explain below, the Supreme Court's decision dictates that the only possible remedy is to:

1. Revert to the prior lawful policy of paying ASP plus 6% for CY 2023, regardless of whether a drug was acquired through the 340B program;
2. Promptly repay any hospital the difference between ASP plus 6% and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018-2022; and
3. Hold the entire hospital field harmless for this illegal policy for CYs 2018-2022, which means no recoupment of funds received during this period.

We strongly encourage CMS to agree to this remedy in the ongoing *American Hospital Association v. Becerra* litigation and to ensure that payments to hospitals are appropriately restored in the agency's CY 2023 OPPS final rule.

Anticipated Restoration of 340B Drug Payment Policy for CY 2023

The proposed rule explains that "in light of the Supreme Court's recent decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying for drugs at ASP plus 6%, regardless of whether they were acquired through the 340B program for CY 2023." (pg. 16, CY 2023 OPPS proposed rule) **The AHA supports this policy.** Having failed to conduct the required cost acquisition survey, CMS is correct that, under *American Hospital Association v. Becerra*, it may not vary reimbursement rates for 340B hospitals for CY 2023 and therefore must pay 340B hospitals at the ASP plus 6% rate. **We urge CMS to follow through with this anticipated policy in its CY 2023 OPPS final rule.**[20]

[20] CMS stated in the proposed rule that "for CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. But again, in light of the Supreme Court's decision, we fully anticipate adopting, in the final rule, a policy of paying ASP+6 percent." **We believe that when CMS finalizes the policy to pay for 340B-acquired drugs at ASP plus 6% that policy will apply to both non-excepted and excepted off-campus PBDs.** Not doing so would be in direct violation of the Supreme Court's ruling as the agency cannot vary payment rates for 340B hospitals, which would include any sites where 340B drugs are furnished whether they be non-excepted or excepted PBDs, absent a legally sufficient survey of hospital acquisition costs.

Lack of Clarity around Continued Use of Modifiers

As CMS anticipates restoring the payment rate for 340B drugs to ASP plus 6%, the proposed rule is silent on whether the agency will continue requiring hospitals to bill separately-payable drug claims using either the “JG” or “TB” informational modifiers. **The AHA urges the agency to no longer require the use of these modifiers for separately-payable drug claims purchased under the 340B program for CY 2023.**

The use of these modifiers was finalized in the CY 2018 OPPS final rule in conjunction with the agency’s policy to pay for 340B drug claims at a reduced rate of ASP minus 22.5%. At that time, it was the CMS’ intent to use the modifiers to be able to identify 340B drug claims for which this reduced reimbursement should apply. However, in light of the Supreme Court’s decision invalidating this policy, as well as the agency’s intent to restore payments for 340B drug claims to ASP plus 6%, the need for these modifiers no longer exists.

Not only has the need for these modifiers been obviated, but the additional time and cost burden these modifiers pose to hospitals contravenes CMS’ longstanding policy to reduce provider burden. This is especially true at a time when many hospitals around the country are resource-strapped as they continue to deal with the effects of the COVID-19 pandemic and the rapid growth in expenses and inflation.

For these reasons, it would be imprudent for CMS to continue to require the use of these modifiers for CY 2023.

Proposed Budget Neutrality Adjustment to CY 2023 OPPS Conversion Factor Flawed

In restoring the payment rate for 340B drugs to ASP plus 6%, CMS stated its need to make a corresponding decrease to the OPPS conversion factor to ensure that the increase in payment from ASP minus 22.5% to ASP plus 6% remains budget neutral. The agency states that it calculated this budget neutrality adjustment based on separately paid line items with the ”JG” modifier in the CY 2021 claims available for OPPS rate setting, which represent all drug lines for which the 340B program payment policy applied. It found that the payment differential would be an increase of $1.96 billion in OPPS drug payments. Based on this calculation, CMS is proposing an adjustment of 0.9596 or -4.04% to the OPPS conversion factor.

However, when CMS first implemented the policy to pay 340B drugs at a reduced rate of ASP minus 22.5% in CY 2018, it estimated that the payment differential would be $1.6 billion in OPPS drug payments. Based on this calculation, CMS implemented a +3.19% budget neutrality adjustment to the OPPS conversion factor. Since 2018, CMS has not revised this adjustment, despite having updated data from the “JG” modifier for

CYs 2020-2022. By not recalculating this adjustment for CYs 2020-2022, as CMS does with other budget neutral policies such as the outlier adjustment and area wage index, the agency was underpaying all hospitals during those years. Specifically, our analysis of claims billed with the "JG" modifier show that CMS was taking out more money from 340B hospitals than the agency was putting back in to hospital payments for non-drug services through the +3.19% adjustment. In addition, it appears that CMS is now attempting to lock-in underpayments by recalculating the budget neutrality adjustment using updated data for CY 2023. The agency cannot choose to not update their budget neutrality adjustment in prior years and attempt to make up for it by updating it for CY 2023 and apply a steeper adjustment (-4.04%) than it originally applied (+3.19%).

If the agency's goal is to maintain budget neutrality as it restores payment for 340B drugs to ASP plus 6%, it should undo its prior adjustment by decreasing the OPPS conversion factor by the same 3.19% it had originally applied. If it were to instead apply a -4.04% adjustment, it would be dramatically overcorrecting, *resulting in an unacceptable permanent underpayment to hospitals, which would be in addition to the substantial underpayments hospitals already incur under Medicare.*

CMS indicates that by applying its proposed -4.04% proposed adjustment, the agency would reduce payments by $1.96 billion to all hospitals in CY 2023. If instead, CMS applied a -3.19% adjustment (i.e., reversing the original +3.19%), payments would be reduced by $1.55 billion, according to the AHA's calculation (i.e., backing out the -0.04% from $1.96 billion and applying a -3.19% adjustment instead). This results in an approximately $410 million underpayment to all hospitals ($1.96 billion vs. $1.55 billion). In other words, by applying the agency's proposed adjustment, hospitals stand to be permanently underpaid by approximately $410 million annually.

Indeed, CMS' proposed permanent underpayment finds no support in the law or past agency practice. In the AHA's comments to prior OPPS rules in which this issue was discussed, we urged CMS to recalculate the 340B budget neutrality adjustment annually based on the most recently available data, as it does for other budget neutral policies like the outlier adjustment, wage index, rural sole community hospital (SCH) adjustment and cancer hospital adjustments. In response, the agency indicated that "while some of the [340B] claims may change based on drug payment and billing, as indicated by the 'JG' modifier, these drugs, including their utilization and expected payments, would be included as part of the broader budget neutrality adjustments, but collectively they would not have a separate budget neutrality adjustment specifically for the 340B drug payment policy." But as the agency also noted, the OPPS budget neutrality is developed "on a prospective basis by isolating the effect of any changes in payment policy *or data* with all other factors held constant." (italics added). Therefore, the fact that the policy did not change does not obviate the need for CMS to fulfill its statutory obligation under section 1833(t)(9)(B) of the Act to apply a *new* prospective budget neutrality adjustment annually by taking into account any change in utilization data (in this case, based on 340B drug claims billed with the "JG" modifier) that affect the

magnitude of payments being affected by the 340B adjustment. *Cf. Cape Cod vs. Sebelius*, 630 F.3d 203, 213 (D.C. Cir. 2011) ("Having built the past into the cumulative methodology it chose for counteracting the budgetary impact of the rural floor, CMS may not now ignore past errors that have the effect of overly deflating current aggregate payments in violation of BBA section 4410(b)'s budget-neutrality mandate … Far from requiring CMS to carry over past adjustments that improperly deflate aggregate Medicare payments, BBA section 4410(b) seems to mandate precisely the opposite.")

This law and history directly undermines CMS' approach in the proposed rule. Having failed to meet their statutory obligations to annually recalculate the 340B budget neutrality adjustment in prior years, it cannot now apply a *steeper* downward adjustment for CY 2023 that would result in what amounts to a payment cut to hospitals going forward.

As such, the agency must revise its proposed adjustment to account for its prior errors. Doing so would avoid permanent shortfalls that would cause serious harm to hospitals and the patients and communities they serve. **Therefore, the AHA strongly urges the agency to finalize a -3.19% budget neutrality adjustment to the CY 2023 OPPS conversion factor, which would restore the original adjustment CMS applied when it first implemented its 340B payment policy.**

CMS Must Promptly Repay 340B Hospitals *without* Penalizing the Rest of the Hospital Field

CMS has sought public comment on "the best way to craft any potential remedies" for its unlawful reimbursement cuts from 2018 to 2022. (pg. 352, CY 2023 OPPS proposed rule) But, there is *only one* way for the defendants to fix the statutory violation that the Supreme Court identified: pay 340B hospitals the difference between the amounts previously paid for 340B drugs and ASP plus 6% (plus applicable interest) for *all* costs from years in which CMS acted unlawfully. What's more, CMS should repay 340B hospitals promptly. The Supreme Court recognized that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support" *Am. Hosp. Ass'n*, 142 S. Ct. 1896, at *13. Yet for five years, CMS deprived 340B hospitals of this limited funding. During that period, 340B hospitals struggled to care for patients amidst a once-in-a-century pandemic. Speedy repayment of 340B hospitals is crucial.

It is not entirely clear why the agency needs public comment to determine the remedy in *American Hospital Association v. Becerra*. That remedy, which will be decided in the context of the ongoing litigation and not in any separate rulemaking proceeding for CY 2023, is straightforwardly dictated by the reasoning of the Supreme Court's decision. As noted, the Supreme Court invalidated the rate reductions for CYs 2018 and 2019 because "the statute does not grant HHS authority to vary the reimbursement rates by hospital group." *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, at *12. The CYs 2018 and 2019 OPPS rules that were formally before the Supreme Court did just that: both varied

the payment rates for the same drugs depending on whether they were acquired by 340B hospitals without relying on a statutorily-required cost acquisition survey. The CYs 2020, 2021 and 2022 OPPS rules did the same thing.

The Supreme Court's decision therefore dictates what CMS must do to fix its violations. Under the Supreme Court's reasoning, there is no possibility for defendants to go back and readjust their rates downward from ASP plus 6% for 340B hospitals. Instead, having failed to conduct the required survey, **CMS must now reimburse 340B drugs each year at *the same* rate used for non-340B drugs that year. For every year from 2018 through 2022, CMS has already decided the payment rate for non-340B drugs: ASP plus 6%. CMS needs now to match that rate for 340B drugs, a proposition to which CMS appears to agree.**[21] It therefore must now craft a remedy that promptly repays 340B hospitals the difference between what they were previously paid and ASP plus 6% for CYs 2018 to 2022.

Because CMS "fully anticipates" reverting to its prior policy of ASP plus 6% for 340B-acquired drugs in CY 2023, and because the proposed rule nowhere mentions its 2020 survey in connection with CY 2023, the AHA assumes that CMS has come to recognize the fatal flaws in that survey. However, the proposed rule does briefly note that CMS once stated that "a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion." (pg. 351, CY 2023 OPPS proposed rule). The AHA reads this passage as merely recounting the history of this issue because the law is clear: **CMS may not rely on its defective 2020 survey in connection with the remedy for underpaying 340B hospitals.**

Reliance on CMS' 2020 survey in connection with any remedy would be unlawful. As the AHA has previously explained, CMS' survey did not comply with 42 U.S.C. 1395l(t)(14)(D)(iii).[22] We need not catalogue all of the survey's flaws again, but it is important to remind the new administration that the survey was issued during the height of the COVID-19 pandemic, while 340B hospitals were struggling to marshal critical resources to respond to the pandemic. Given that timing, CMS unsurprisingly received actual acquisition-cost data "for each individual" drug from only 7% of those surveyed, 85 Fed. Reg. at 86,044-86,045. Of the remaining hospitals surveyed, 38% did not respond and an additional 55% opted for a so-called "quick survey" whereby CMS used

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[21] *See* 2023 OPPS Proposed Rule at 347: "We fully anticipate applying a rate of ASP plus 6% to [340B drugs] in the final rule for CY 2023, in light of the Supreme Court's recent decision."; *Am. Hosp. Ass'n v. Hargan*, No. 17-2447, ECF No. 18 at 49 (D.D.C., filed Dec. 1, 2017) (if plaintiffs were to ultimately prevail, they could obtain "an order directing [CMS] to reinstate the ASP plus 6% OPPS payment rate for 340B drugs").

[22] *See* American Hospital Association, Comment Letter on CMS–1736–P, Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals Proposed Rule (Vol. 85, No. 156) (Oct. 5, 2020), https://www.aha.org/lettercomment/2022-06-17-comments-cms-its-fy-2023-proposed-inpatient-prospective-payment-system .

340B ceiling prices maintained by the Health Resources and Service Administration (HRSA) as a proxy for actual drug acquisition costs. With such a low response rate, it is apparent that HHS was unable to gain enough data to yield a statistically significant estimate of average hospital acquisition cost for each specified covered outpatient drug, as is required under the statute in order for the agency to use the results of the survey to set prospective payment rates. In addition, the agency surveyed only 340B hospitals, but nowhere in the statute does Congress give HHS the authority to collect acquisition cost data from only a specific subset of all hospitals. Taken together, these design and execution flaws make clear that CMS did not, as the law requires, survey "a large sample of hospitals that is sufficient to generate a statistically significant estimate," 42 U.S.C. 1395l(t)(14)(D)(iii).

Perhaps for this reason, CMS has *never* relied on this survey to set payment rates — including in the current CY 2023 proposed rule. It would be both unfair and unlawful for the agency to rely on it now as part of any retrospective remedy. As an initial matter, the agency should not use a survey it explicitly chose not to rely on in CY 2021 and CY 2022. Giving CMS a second bite at the apple in these circumstances would prejudice the many 340B hospitals that were unlawfully forced to do more with less during the height of the COVID-19 pandemic.

More fundamentally, any attempt to rely on the 2020 survey to set reimbursement rates for prior OPPS years would violate the Administrative Procedure Act (APA), which limits "rules" to agency prescriptions of "future effect." 5 U.S.C. § 551(4); *see Bowen v. Georgetown University Hospital,* 488 U.S. 204, 216–25, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988) (Scalia, J., concurring); *Bergerco Canada v. U.S. Treasury Department,* 129 F.3d 189, 192–93 (D.C. Cir. 1997) (treating Justice Scalia's concurring opinion as substantially authoritative). Having lost in the Supreme Court without ever relying on the defective survey, any attempt to rely on it as part of a backwards-looking remedy would, as relevant case law makes clear, "make a mockery ... of the APA," since "agencies would be free to violate the rulemaking requirements of the APA with impunity if, upon invalidation of a rule, they were free to 'reissue' that rule on a retroactive basis." *Georgetown Univ. Hosp. v. Bowen*. 821 F.2d 750, 758 (D.C. Cir. 1987) quoted in *Bowen,* 488 U.S. at 225 (Scalia, J., concurring).

Accordingly, CMS must craft a remedy that fully and promptly repays 340B hospitals for all of the unlawful reimbursement cuts from CYs 2018 through 2022.

CMS Should Not Seek to Recoup Funds from the Rest of the Hospital Field as Part of Any Remedy for its Statutory Violations

CMS has previously invoked "budget neutrality" to argue that it may retrospectively recoup funds from hospitals as part of a remedy for its statutory violations. As a policy matter, CMS should not penalize other hospitals for its own mistakes. A wide variety of hospitals and health care facilities would be subject to recoupment if CMS insists on pursuing this ill-advised policy. Because they were exempted from CMS' prior unlawful

policy, these facilities include: 1) rural SCHs, 2) children's hospitals, and 3) certain cancer hospitals. E.g., 2018 OPPS Rule, 82 Fed. Reg. 59,216, 59,355, 59,366 (Dec. 14, 2017). Not only would it appear that these hospitals would be subject to claw backs, but it would be impossible to fairly implement a budget neutrality policy if these entities were not subject to the same recoupments as other hospitals. More generally, hospitals that would be subject to recoupment have struggled financially during the COVID-19 pandemic. Each one has long spent any money that CMS would seek to recoup. Clawing back funds would only further harm the patients and communities that they serve.

Importantly, moreover, recoupment in the name of budget neutrality would be unlawful. **Nothing in federal law requires — or even authorizes — CMS to claw back funds to achieve budget neutrality. CMS' prior legal arguments regarding budget neutrality are contrary to the text of the OPPS statute and contravene its own past practice.**

First, the text of the OPPS statute makes clear that budget neutrality applies prospectively — not retrospectively. Budget neutrality under the OPPS is an inherently prospective exercise; it avoids increases or decreases in "overall *projected* expenditures for *the next year*." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020) (emphasis added). Each year, the statute directs CMS to adjust the groups, relative payment weights, and wage indices in the OPPS *for the upcoming year*, taking into account changes in services, changes in technology, new cost data, and the like. 42 U.S.C. § 1395*l*(t)(9)(A). Any such changes must be budget-neutral — which means that they cannot cause any change in "the *estimated amount* of expenditures ... for the year" *Id.* § 1395*l*(t)(9)(B) (emphasis added); *see also* 2021 OPPS Rule, 85 Fed. Reg. at 86,054 ("OPPS budget neutrality is generally developed on a *prospective* basis by isolating the effect of any changes in payment policy or data under the OPPS with all other factors held constant." (emphasis added)). Thus, the plain text of the statute says nothing about past years or retrospective claw backs; instead, it only addresses future estimates and forward-looking periodic reviews.

The only provision of the OPPS statute that CMS previously cited in support of its budget-neutrality arguments is section 1395*l*(t)(14)(H). Defs' Opp. Brief on Remedy, *Am. Hosp. Ass'n v. Azar*, No. 18-2084, ECF No. 36 at 10 (D.D.C., filed Feb. 14, 2019). But that provision likewise relates to *prospective* budget neutrality and does not authorize the agency to retroactively recoup past payments as part of a remedy. Under sub-paragraph (14)(H), CMS must take paragraph (14) expenditures into account when annually adjusting the groups, relatively payment weights, and so on under paragraph (9) — including as affected by paragraph (9)'s budget-neutrality requirement — but because these adjustments are made under paragraph (9), they apply only to *the upcoming year*. Sub-paragraph (14)(H) does not authorize CMS to take any action in the name of budget neutrality in any context other than its annual, *prospective* adjustments under paragraph (9).

Nowhere does the OPPS statute speak of budget neutrality in connection with *retrospective* changes. During the many years it has litigated *American Hospital Association v. Becerra*, CMS has *never* identified a clear, expressed reference to retrospective recoupment in the statute's budget neutrality provisions. That is because CMS has no authority to recoup past payments to achieve budget neutrality. *See Bowen*, 488 U.S. at 208 ("Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect *unless their language requires this result*." (emphasis added)); *Claridge Apartments Co. v. Comm'r of Internal Revenue*, 323 U.S. 141, 164 (1944) ("Retroactivity, even where permissible, is not favored, *except upon the clearest mandate*" (emphasis added)).[23]

Second, although CMS frequently fixes prior errors in the OPPS, the AHA cannot identify a single relevant instance in which CMS offset the cost of doing so by retroactively recouping prior payments to providers. Here are a few examples of CMS fixing prior errors *without* recouping prior payments to achieve budget neutrality:

- In 2007 HHS retroactively adjusted payment rates to several rural hospitals without offsetting recoupments to achieve budget neutrality, an approach which the Court noted in *H. Lee Moffitt*, 324 F. Supp. 3d at 15; *see also* 2007 OPPS Rule, 71 Fed. Reg. 67960, 68010 (Nov. 24, 2006).

- In 2015, CMS realized that its OPPS payments in 2014 and 2015 was too high because it had inaccurately increased the conversion factor when it began packaging clinical diagnostic laboratory tests into its OPPS payments rather than paying for them separately using the Clinical Laboratory Fee Schedule. Upon recognizing its error, CMS reduced the conversion factor beginning in 2016 to prevent further overpayments going forward, but it did "not recoup 'overpayments' made for CYs 2014 and 2015." 2016 OPPS Rule, 80 Fed. Reg. 70,298, 70,354 (Nov. 13, 2015).

- For the IPPS, although annual area wage index adjustments must be budget-neutral, 42 C.F.R. § 412.64(e)(1)(ii), CMS can revise a wage index in response to an adverse judicial decision without any need for corresponding changes to achieve budget neutrality. *See id.* § 412.64(*l*).

Indeed, the AHA is aware of only a single instance when CMS recouped past overpayments caused by a policy change under a prospective payment system, but it did so only pursuant to *express authorization from Congress*. In that lone example,

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[23] Elsewhere, HHS has recognized that any agency authority to act retroactively must be set forth in the kind of exceedingly clear statutory language that does not exist here. *See* Gov't Memo., *H Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Price*, No. 1:16-cv-2337-TJK, ECF No. 16-1, at 25 (D.D.C., filed July 17, 2017) ("Generally, retroactive applications of a law are strongly disfavored, as they disrupt legitimate expectations and disturb settled transactions. … Indeed, cases where the Supreme Court has truly found retroactive effect adequately authorized by a statute have involved statutory language that was so clear that it could sustain only one interpretation" (cleaned up and citations omitted)).

CMS changed certain documentation and coding policies under the IPPS for 2008 and stated that those changes might lead to higher aggregate expenditures that did not reflect actual changes in services. 2008 IPPS Rule, 72 Fed. Reg. 47,130, 47186 (Aug. 22, 2007). After CMS announced the changes, Congress acted twice to give CMS narrow, specific authority to reduce payment rates in future years to offset past overpayments caused by the policy changes. *See* TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–97 (2007); American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013). Congress "knows exactly how" to give CMS express authority to offset past Medicare overpayments "when it wishes," but did not do so here. *Ysleta Del Sur Pueblo v. Texas*, 142 S.Ct. 1929, 1942 (June 15, 2022); *see generally Brimstone R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928) ("The power to require readjustments for the past is drastic. It ... ought not to be extended so as to permit unreasonably harsh action *without very plain words*." (emphasis added)).

Given this statutory text and regulatory history, CMS has no authority to retrospectively recoup funds from the hospital field as part of any remedy in *American Hospital Association v. Becerra*. Thus, not only would it be unfair and unwise to penalize hospitals for the agency's mistakes in this way, it would be unlawful for them to do. **We urge CMS to implement a fair, effective and lawful remedy promptly — without the cost, disruption and distraction of many more years of litigation to finally put the prior unlawful policy behind it.**

PAYMENT POLICY FOR OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

For CY 2019, citing "unnecessary" increases in the volume of outpatient clinic visits in hospital provider-based departments (PBDs) allegedly due to payment differentials driving the site-of-service decision, CMS finalized a policy to pay for clinic visits furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs.

For CY 2023, other than proposing to exempt rural SCHs from this site-neutral payment policy (discussed below), CMS would continue pay for all other hospital outpatient clinic visit services in excepted off-campus PBDs at 40% of the OPPS payment amount. **By continuing the cut, CMS has undermined clear congressional intent and exceeded its legal authority, despite the U.S. Supreme Court, on June 28, declining to review the unfavorable ruling by the appeals court that deferred to the government's inaccurate interpretation of the law. We continue to urge the agency to withdraw this policy.**

Outpatient Volume and Expenditures Growth is not "Unnecessary"

The implementation of this policy relied on the most cursory of analyses and policy rationales. Specifically, CMS finalized its phased-in policy implementing a 60% cut in payment for a clinic visit, an essential hospital outpatient service, *without* presenting any of its own data analysis on:

- Clinic visit volume;
- Clinic visit expenditures;
- The "unnecessary" nature of clinic visit volume or expenditures;
- The "shifting" volume of clinic visits from physician offices to excepted off-campus PBDs due to payment differentials; or
- How a reduction in payment for the hospital outpatient clinic visit is a "method" that would lead to a reduction in the volume of "unnecessary" services in excepted off-campus PBDs.

CMS also clearly failed to consider the many factors outside of hospitals' control that result in increases in OPPS volume and expenditures. This includes, for example: changes in patient demographics and clinical needs, technological advances, the impact of other Medicare policies that are intended to increase the volume of services in PBDs, drug price inflation, and the fact that physicians often refer Medicare beneficiaries to HOPDs for services they do not provide in their offices. We refer you to AHA's comments for the CY 2021 OPPS proposed rule for further description of the many factors that contribute to increases in OPPS volume and expenditures that are outside of hospitals' control.

Continued Cuts to Hospital Reimbursements for Clinic Visits are Excessive and Harmful, Especially at a Time of Tremendous Financial Challenges. Continuing these cuts in outpatient payment for clinic visits, particularly in light of the devastating impact that the COVID-19 pandemic and surging inflation has had on hospital and health system financial health, would be excessive and harmful to patients and communities. Indeed, for the past two and a half years, America's hospitals and health systems have gone above and beyond in the fight against COVID-19, taking extraordinary action to care for and save lives. They have worked around the clock, pioneered innovative treatment protocols, partnered with community organizations to address health disparities and inequities, and greatly expanded their capacity to provide care.

Hospitals have been on the front lines since the start of the pandemic and have endured historic financial challenges due to revenue losses from forced shutdowns and a slow resurgence of non-emergent care, as well as increased costs associated with preparing for the pandemic and treating COVID-19 patients. In the past year, hospitals have experienced a multitude of challenges, in part due to the fact that more than half of all COVID-19 hospitalizations have occurred in the past year, for which hospitals have

received no direct government support to date. Compounding this problem has been the skyrocketing growth in hospital expenses due to higher input prices and rising inflation, as well as generally increased patient acuity.

A recent AHA report[24] highlights the significant growth in expenses across labor, drugs and supplies, as well as the impact that rising inflation is having on hospital expenses. In fact, despite modest growth in revenues compared to pre-pandemic levels, median hospital operating margins were down 3.8% by the end of 2021 compared to pre-pandemic levels, according to a report by Kaufman Hall.[25] The median hospital operating margin has been consistently negative in 2022 through July, according to the Kaufman Hall Operating Margin Index.[26] These levels of increased expenses and declines in operating margins are expected to continue and are not sustainable.

Another important factor influencing the growth in expenses has been the rise in patient acuity. A recent report[27] by the AHA citing data from Kaufman Hall shows that patient acuity by the end of 2021 was nearly 10% higher than pre-pandemic levels in 2019. This means that hospitals across the country are now treating patients who are generally sicker and require more complex and intensive medical care than before the pandemic.

These challenges have also been echoed in the recent ratings released by credit rating agencies like Fitch and S&P. In one recent report[28] detailing the negative outlook for the nonprofit hospital sector, Fitch Ratings noted that “sector conditions will remain challenged for the remainder of 2022, as labor pressures and generationally elevated inflation compress margins for most providers.” Further, they come on top of already substantial Medicare underpayments.

According to FY 2020 Medicare cost report data, Medicare margins for outpatient services were negative 17.5% in 2020.[29] The Medicare Payment Advisory Commission (MedPAC) reports that overall Medicare margins were negative 8.5% in 2020, and would have been negative 12.6% without federal support dollars.[30] According to the latest data from Kaufman Hall for July 2022, median hospital operating margins are down 78.9% compared to July 2021, and have decreased 46.4% just compared to the prior month.[31]

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[24] https://www.aha.org/costsofcaring
[25] Kaufman Hall, National Hospital Flash Report, January 2022, https://www.kaufmanhall.com/sites/default/files/2022-01/National-Hospital-Flash-Report_Jan2022.pdf.
[26] https://www.kaufmanhall.com/sites/default/files/2022-08/KH_NHFR_2022-08.pdf
[27] https://www.aha.org/guidesreports/2022-08-15-pandemic-driven-deferred-care-has-led-increased-patient-acuity-americas
[28] : https://www.fitchratings.com/research/us-public-finance/fitch-ratings-2022-mid-year-outlook-us-not-for-profit-hospitals-health-systems-16-08-2022
[29] Medicare hospital cost reports, Healthcare Cost Report Information System (HCRIS), June 30, 2022 update.
[30] MedPAC Report to the Congress: Medicare Payment Policy. March 2022.
[31] https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-august-2022

Continuing to impose a 60% cut on most clinic visit services in 2023, on top of the dire financial situations U.S. hospitals and health systems find themselves in, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries.

In addition, we are concerned that continued Medicare site-neutral payment reductions, together with the devastating impacts of COVID-19 and surging inflation, will undermine the ability of hospitals to adequately fund their 24/7 emergency standby capacity and threaten beneficiary access to critical hospital-based "safety-net" services. **For better or worse, the hospital safety-net and emergency stand-by role are funded through the provision of outpatient services. If CMS continues to erode this funding, so too will these critical services be eroded.**

In fact, this erosion is already occurring, due in no small part to CMS' policies. As spurred by the steady decline in Medicare margins over the past two decades, and as documented by the North Carolina Rural Health Research Program, 139 rural hospitals have closed since 2010, 24 of them since 2020.[32] While MedPAC and others dismiss these closures by noting that the hospitals were "small" or "near other facilities," the concern remains that these very vulnerable rural hospitals are the "canaries in the coal mine." They serve as the initial indicators that we are beginning to reach a tipping point where private payers are no longer willing to fund, and hospitals can no longer sustain, operations on the cost-shift that such considerable Medicare underpayments, particularly those under OPPS, necessitate.

And, the availability of these services is perhaps more critical for the sickest Medicare beneficiaries, and those are more likely to come from historically marginalized demographics. That is, such Medicare beneficiaries tend to be cared for in HOPDs disproportionate to independent physician offices (IPOs). For example, an AHA analysis comparing beneficiaries treated in IPOs to those in HOPDs shows that patients who are more medically complex (as measured by patient risk scores and prior medical care use) and require more intensive services are more likely to be seen at HOPDs.[33] This analysis also provides evidence that compared IPOs, HOPDs treat more beneficiaries from areas with lower socioeconomic status, including beneficiaries who are dually eligible for Medicare and Medicaid.

Specifically, among all Medicare beneficiaries, relative to patients treated in IPOs, patients treated in HOPDs:

- Are more likely to have severe chronic conditions and more chronic conditions;

[32] https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/
[33] Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices, KNG Health Consulting, LLC, April 2021.

- Are more likely to have a prior hospitalization and have higher prior emergency department (ED) use;
- Are more likely to come from communities with lower income;
- Are 73% more likely to be dually eligible for Medicare and Medicaid;
- Are 52% more likely to be enrolled in Medicare through disability or end-stage renal disease (ESRD);
- Are 62% more likely to be eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis (under age 65); and,
- Are 11% more likely to be 85 years old or older.[34]

Site-neutral Policies are based on Flawed Assumptions. Finally, the entire premise of CMS' site-neutral policies is based on the flawed assumption that Medicare physician fee schedule (PFS) payment rates are sustainable rates for physicians. However, the truth is much different. AHA members tell us that when they acquire independent physician practices, it occurs because the physicians have reached a point where their practices are no longer financially viable — they are failing due to poor payer mix, increasing Medicare and Medicaid regulatory burden and declines in Medicare and Medicaid reimbursement. Instead of allowing these physician services to be lost to the community, or in communities where there are already health care deserts, hospitals purchase the practices in order to ensure continued access to these services.

For all the reasons above, we urge CMS to reverse entirely its harmful policy of reducing payment for outpatient clinic visits in excepted off-campus PBDs.

PROPOSED EXEMPTION OF RURAL SCHS FROM SITE-NEUTRAL PAYMENT REDUCTIONS FOR OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PBDS

In the rule, CMS indicates that it has continued to assess how the site-neutral clinic visit policy has been implemented, and how it affects both the Medicare program itself and the beneficiaries it serves. **Therefore, for CY 2023, it proposes to pay the full OPPS payment rate, rather than 40% of the OPPS rate, when a clinic visit is furnished in an excepted off-campus PBD of a rural SCH.** In its rationale, CMS notes that it already provides these providers with a number of special payment provisions to account for their higher costs and the disproportionately harmful impact that payment reductions could have on their ability to maintain access to care in their rural communities. Further, CMS indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities, which means that it is unlikely that financial incentives are driving the site of care decisions. In particular, CMS notes the closure of hospital inpatient departments and the shortage of primary care

[34] Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices, KNG Health Consulting, LLC, April 2021.

providers in rural areas as a driver of utilization to off-campus PBDs in areas where rural SCHs are located.

As we discuss above, the AHA continues to urge CMS to reverse entirely its harmful policy of reducing payment for clinic visits in excepted off-campus PBDs of *all* hospitals. **However, if despite these concerns, CMS nevertheless declines to do so, the AHA strongly supports CMS' proposal to exempt excepted off-campus PBDs of rural SCHs from the site-neutral payment reductions outpatient clinic visit services.** We agree that by paying rural SCHs the full OPPS rate for the clinic visit service, the most commonly furnished services furnished in HOPDs, CMS would be supporting the ability of these critical providers to continue to maintain access to care in their rural communities.

CMS also requests comments on whether it would be appropriate to exempt other rural hospitals, such as those with fewer than 100 beds, from this policy. **And indeed, to more fully support vulnerable rural providers, the AHA also urges CMS to exempt other rural hospitals from the clinic visit cuts, such as rural hospitals with fewer than 100 beds, and all Medicare-dependent Hospitals (MDHs), Low-volume Adjustment (LVA) program hospitals and rural referral centers.** The network of providers that serve rural Americans is financially fragile and more dependent on Medicare revenue due to the high percentage of Medicare beneficiaries who live in rural areas. Rural residents also on average tend to be older, have lower incomes and higher rates of chronic illness than urban counterparts. This greater dependence on Medicare may make certain hospitals more financially vulnerable. Indeed, Medicare only pays 84% of hospital costs on average according to our latest analysis.[35] Extending the exemption for the site-neutral clinic visit cuts to these facilities would protect the financial viability of small, rural hospitals to ensure they can continue serving as a, and often only, point of care in their communities.

PROPOSED ADDITION TO THE PRIOR AUTHORIZATION PROGRAM

Citing authority under section 1833(t)(2)(F) of the Social Security Act to control "unnecessary increases in the volume of covered OPD services," CMS in the CY 2020 OPPS/ASC final rule established a prior authorization process as a condition of payment for certain HOPD services. In the CY 2023 proposed rule, CMS proposes to add one new service category, facet joint interventions, to the prior authorization program, effective for dates of services on or after March 1, 2023. The facet joint interventions service category would consist of facet joint injections, medial branch nerve blocks and facet joint nerve destruction.

[35] American Hospital Association (February 2022). Underpayment by Medicare and Medicaid Fact Sheet. https://www.aha.org/system/files/media/file/2022/02/medicare-medicaid-underpayment-fact-sheet-current.pdf.

The AHA appreciates that CMS has, for the first time, provided a more researched justification for adding a new service category to its prior authorization process; in this case, audit reports from the OIG demonstrating improper Medicare payments.[36] **However, we oppose the application of prior authorization for facet joint intervention services, as:**

- **the increased utilization of these services have other appropriate, yet underexplored, justifications;**
- **data reveal that utilization levels of these services have already recessed; and**
- **there are other oversight mechanisms available to CMS that do not inappropriately delay care.**

The AHA urges CMS not to finalize this policy. If the agency continues to believe that additional controls are necessary, we recommend that it instead improve its existing oversight mechanisms and enhance its education on Medicare payment policy for providers, physicians, and billing and coding teams. Doing so would be a more appropriate way to help ensure that medically necessary care is provided, without introducing avoidable delays in patient care.

Increased Utilization of Facet Joint Intervention Procedures May Have Appropriate, Underexplored Justifications

Although CMS highlights data showing that utilization of facet joint interventions has grown faster than other OPPS services, the agency fails to consider whether this increase could have resulted from appropriate medical care decision-making rather than inappropriate utilization.

Facet joint injections are a type of non-opioid interventional pain management technique used to diagnose or treat back pain, including chronic back pain. Amidst the opioid PHE, providers and patients have been *encouraged* to pursue such alternatives to prescribing and using opioids, with the Centers for Disease Control and Prevention (CDC) particularly highlighting interventional injection therapies as effective alternatives.[37] To further emphasize this point, chronic pain management is a focus in the CY 2023 physician fee schedule (PFS) proposed rule. That is, CMS proposes to create separate codes and payment for chronic pain management services, citing "Federal efforts for more than a decade to effectively address pain management as a response to the nation's overdose crisis, such as the National Pain Strategy and the HHS Pain Management Best Practices Inter-Agency Task Force (PMTF) Report."[38] Also, elsewhere in the CY 2023 OPPS/ASC proposed rule, the agency proposes

[36] https://oig.hhs.gov/oas/reports/region9/92003003.asp and https://oig.hhs.gov/oas/reports/region9/92103002.asp
[37] https://www.cdc.gov/opioids/patients/options.html
[38] CY 2023 PFS proposed rule, Federal Register Vol. 87, No. 145, July 29, 2022, page 45932

another policy to address the opioid PHE — the un-packaging of certain non-opioid pain management drugs in the ASC setting. In doing so, CMS cites the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) provision requiring the secretary to “review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, *nerve blocks, surgical injections*, and neuromodulation), with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives” (emphasis added).

Moreover, in one of the OIG reports[39] which the agency cites to support its rationale that facet joint intervention services demonstrate an “unnecessary increase in the volume of OPD services,” CMS’ own words indicate that the OIG’s findings do not necessarily rule out that these services could have been “medically necessary.” That is, while the OIG audit does demonstrate improper billing for facet joint denervation services, the agency states that this was due to the MACs not enforcing their own local coverage determinations (LCDs) regarding the number of services per beneficiary per rolling year. However, in CMS’ response to the OIG report, the agency notes that the “OIG relied solely on claims information for this study. OIG did not conduct medical review to determine whether services were medically necessary. OIG also did not contact any of the physicians who administered the facet-joint denervation sessions. *Without conducting medical record review, it is unclear whether the potential overpayments that the OIG identified were the result of medically necessary procedures.* Through the administrative appeals process, a medical necessity review may be conducted and the denied services may be subsequently deemed medically necessary”[40] (emphasis added).

As a result of the comprehensive efforts of the provider community to reconsider how pain is treated and to move away from opioid prescriptions, increases in the utilization of safe non-opioid chronic pain management therapies, such as facet joint interventions, should not be deemed inappropriate. Rather, they should be expected. In addition, CMS itself has disputed some of the evidence it cites in the proposed rule to justify the use of prior authorization.

Data Reveal That Utilization Levels Have Already Recessed

CMS states that both the facet joint injections/medial branch block CPT codes and nerve destruction CPT codes showed significant increases in volume from 2012 through 2021. In its analysis, the agency specifically notes that it accounts for the 2020 drop in service utilization due to the COVID-19 PHE. While this explains the precipitous drop in utilization during 2020, the data show that since hospital and health care systems have resumed widespread patient care, utilization of facet joint interventions has continued to

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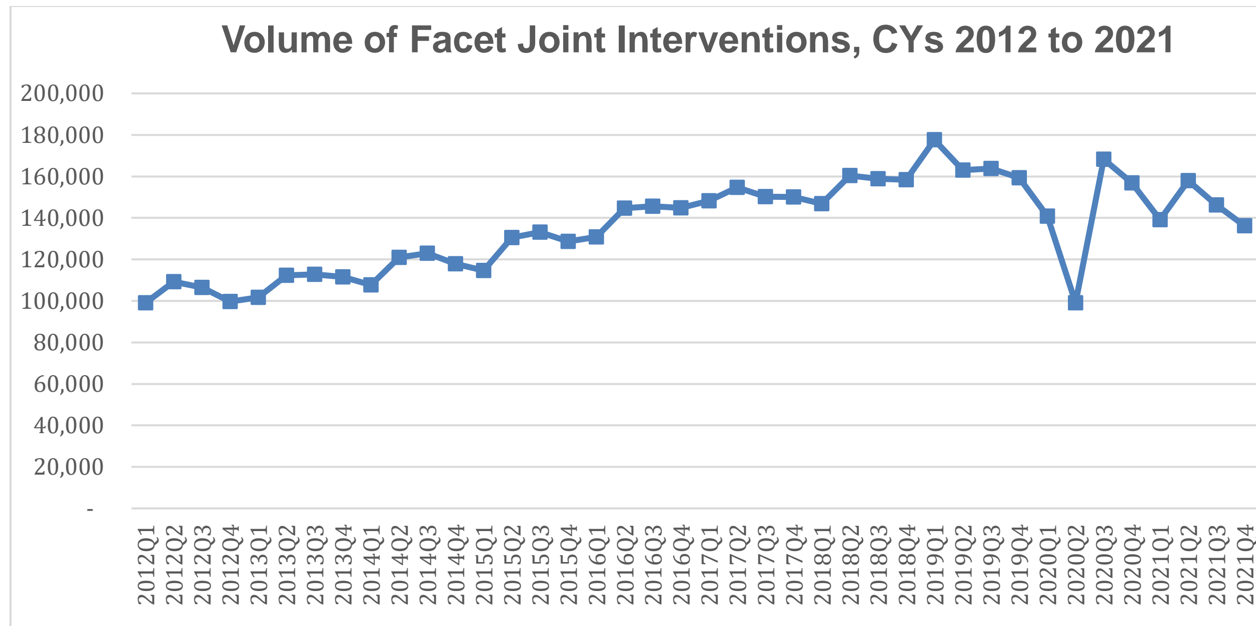
[39] “Medicare Improperly Paid Physicians for Spinal Facet-joint Denervation Sessions”, Report No. A-09-21-03002, Department of Health and Human Services, Office of the Inspector General, Dec. 2021.
[40] Ibid, page 18.

recess (see figure below). **This again demonstrates the imprudence of imposing a prior authorization policy on this services.**



Source: AHA analysis of annual SAF 2012-2020, quarterly for 2021, 2020 data estimated to be 93% complete.

CMS Should Adopt Other Oversight Mechanisms Which Do Not Inappropriately Delay Care, Rather Than Prior Authorization

As discussed above, CMS supports its proposal by discussing two audit reports published by the OIG indicating improper Medicare payments for facet joint interventions in certain Medicare Administrative Contractor (MAC) regions. **However, although the OIG made a number of recommendations to improve CMS' oversight for preventing and detecting improper payments, in neither of these reports was prior authorization invoked as a reasonable solution.** Instead, the OIG recommended that CMS assess the effectiveness of oversight mechanisms specific to preventing or detecting improper payments to physicians for facet joint interventions, and modify the oversight mechanisms based on that assessment — a recommendation with which CMS agreed. OIG also recommended that CMS work with its MACs to educate physicians on Medicare payment policies, in particular the LCDs that apply to facet joint intervention services, so that physicians can exercise reasonable diligence to identify, report and return any overpayments in accordance with Medicare policies. CMS agreed that it will continue to educate health care providers on "proper billing through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters when appropriate."

The AHA agrees that more education on Medicare payment policy is key — for providers, physicians, as well as for billing and coding teams. Given the number of LCDs and national coverage determinations (NCDs), it can be challenging to reach all those individuals who need education so as to bill correctly. While it is critical to ensure the entire medical record documentation supports the complexity and continuity of care, education along with implementing documentation worksheets or templates to help meet NCD/LCD requirements from the providers could be helpful.

In contrast, the consideration of prior authorization as a solution for facet joint interventions raises substantial concerns. Prior authorization can, *when utilized appropriately and administered efficiently*, reduce unnecessary costs and inappropriate care. However, it is all too frequently utilized in ways that interfere with the timely delivery of patient care. Indeed, CMS has failed to establish an efficient process that would prevent such delays in care while authorizations are being considered. As a result, patients who have been recommended for facet joint interventions would need to wait for treatment until the submission, receipt, review, analysis and decision-making occur, a process that can take days or even weeks — and they would endure prolonged pain as these inefficient processes occur. This is inappropriate and harmful to patients who receive medically indicated facet joint intervention.

Prior authorization also adds substantial administrative costs for providers, and significantly contributes to clinician burnout.[41] One of the most frustrating aspects for providers and patients is the lack of a standard, efficient prior authorization submission process across plans. The non-standardized process, which is detailed in a recently published AHA report, requires providers to complete a number of steps that vary across each insurer and plan. Even more alarming is that this lack of standardization creates extremely long processing times that often lead to care delays or treatment abandonment. According to a 2021 American Medical Association survey, 93% of physicians report that prior authorization leads to care delays, with over 82% reporting that it has led to treatment abandonment.[42] Providers, patients and plans are in desperate need of a streamlined approach to prior authorizations to prevent much of the collateral damage associated with current implementations; CMS and health plans should be extremely cautious about applying prior authorization to situations where care could be delayed and health outcomes could be negatively impacted.

Prior Authorization Considerations for Other Health Plans

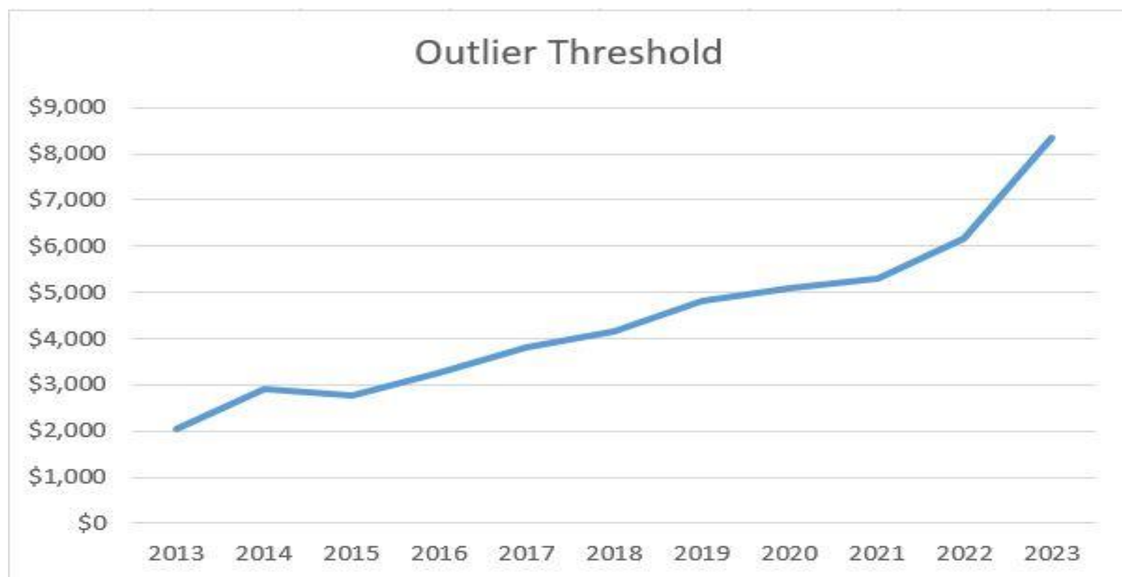
As noted above, although the AHA does not support the proposal to require prior authorization for an additional category of services, we appreciate that CMS has used a multi-factor justification as its foundation. The provision of such a rationale

[41] Addressing Health Worker Burnout: The U.S. Surgeon General's Advisory on Building a Thriving Health Workforce. 2022. https://www.hhs.gov/sites/default/files/health-worker-wellbeing-advisory.pdf
[42] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

was not provided in previous additions to the OPPS prior authorization process. Moreover, it is all-too-often not provided or discussed when other health insurers expand the utilization of prior authorization, which often happens mid-year, without sufficient warning or clinical/administrative justification. Such unfounded expansion creates unnecessary barriers to care, erodes any notion of collaboration between plans and providers, and leaves patients questioning the system. **We urge CMS to require the clear delineation of data-driven justifications by health plans over which it has oversight authority, including Medicare Advantage and plans on the Federal Exchange.**

HOSPITAL OUTPATIENT OUTLIER PAYMENTS

CMS proposes to adopt an outpatient outlier threshold for CY 2023 of $8,350. **The AHA is concerned about the dramatic scale of the proposed increase in the threshold — a 35% increase from the CY 2022 amount of $6,175.** The chart below details the increase proposed for the outlier threshold for CY 2023 compared to the past decade.



CY 2013–2022 outlier thresholds in the published final rule.
Source: AHA analysis of outlier threshold published in final and proposed rules.

The proposed rule notes that to calculate the outpatient outlier threshold, CMS inflated the charges on the CY 2021 claims using the same proposed charge inflation factor that it used to estimate the IPPS fixed loss cost threshold for the FY 2023 IPPS proposed rule. CMS also used the same cost-to-charge ratio (CCR) adjustment factors used to determine the FY 2023 IPPS fixed loss threshold.

For the IPPS rule, CMS used the one-year charge inflation factor between FY 2018 and FY 2019 to inflate FY 2021 charges to determine the FY 2023 outlier threshold. Normally, CMS would compute the charge inflation factor using data for FYs 2020 and 2021. However, CMS' analysis indicated that the one-year increase in charges between FY 2020 and FY 2021 is 10% compared to 6% between FY 2018 and FY 2019. Similarly, CMS used the changes in CCRs between the March 2019 and March 2020 updates to the provider-specific file to adjust the CCRs to determine the proposed 2023 outlier threshold.

Both of these special interventions lowered the FY 2023 inpatient fixed loss threshold and the proposed CY 2023 outpatient outlier threshold. **The AHA appreciates CMS making these interventions to avoid using charge inflation and CCR adjustments that would be affected by the COVID-19 pandemic and, if used, would have inappropriately increased the inpatient fixed loss threshold and the outpatient outlier threshold.**

In addition, in the FY 2023 IPPS final rule, CMS calculated two fixed-loss thresholds — one including COVID-19 cases and one excluding COVID-19 cases — and then averaged these two fixed-loss thresholds to determine the final fixed-loss threshold for FY 2023. Based on AHA's analysis, we do not believe this option would be appropriate to apply to the CY 2023 outpatient outlier threshold. **Nevertheless, given the large increase in the 2023 outpatient outlier threshold, the AHA requests that CMS consider any other factors that could be applied in order to lower the 2023 outpatient outlier threshold.**

PAYMENT FOR THE BLOOD NOT OTHERWISE CLASSIFIED (NOC) CODE

Starting Jan. 1, 2020, CMS established a new HCPCS code, P9099 (Blood component or product not otherwise classified (NOC)), which allows providers to report unclassified blood products before blood product-specific HCPCS codes are available. For CY 2023, CMS proposes a new payment rate of $56.58 per unit for any blood product billed with HCPCS code P9099. However, this rate is tied to a low-priced plasma product rarely supplied in the U.S. (HCPCS code P9060 Fresh Frozen plasma, donor retested), and CMS does not provide an explanation for the change. **While this proposed CY 2023 rate is a marked improvement over the CY 2022 rate of $7.79 per unit, it is still an unacceptably low for new NOC blood and blood products assigned to HCPCS P9099.** As evidence of this, CMS' "NPRM Drug Blood and Brachy Cost Statistics File CY 2021" displays a geometric mean unit cost of $419.48 for the 87 units of blood products coded using the HCPCS code P9099.

In addition, there are several new types of blood products currently in development that are expected to be approved over the next several years. These new products would be grossly underpaid if they were placed into HCPCS code P9099 at the proposed $56.58 rate. These products include Cerus-developed pathogen-reduced red blood cells

(RBCs) in phase 3 clinical testing, Cellfire-developed freeze-dried platelets in phase 2 clinical testing, and Teleflex-developed freeze-dried plasma submitted for Food and Drug Administration approval. Appropriate payment for these critical new blood products is necessary to help ensure patient access.

The AHA urges CMS to allow HCPCS code P9099 to be paid by the MACs at reasonable cost, as recommended by the HOP Panel in 2021.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS does not propose to adopt or remove any quality measures from the OQR, but does propose to modify one previously adopted measure and requests feedback on potential changes to the OQR.

Proposal to Change Cataracts Measure from Mandatory to Voluntary. CMS proposes to allow for voluntary rather than mandatory reporting of the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31/ASC-11) beginning with the CY 2027 payment determination (CY 2025 reporting period). The measure was initially adopted for voluntary reporting in the CY 2015 OPPS/ASC final rule, then finalized for mandatory reporting beginning with the CY 2025 reporting period in last year's final rule despite the measure's significant shortcomings.

The AHA supports CMS' proposal to no longer require reporting of this measure. While the agency suggests that it makes this proposal due to ongoing concerns about the reporting burden of this measure in light of national staffing and medical supply shortages as well as changes in patient case volumes — which are legitimate challenges — the measure continues to suffer from the same deficiencies as when it was first proposed for adoption that significantly limit its utility. The rationale for initially adopting the measure for voluntary reporting only was based on several concerns, including:

- The measure is operationally difficult for hospitals to collect and report.
- The results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery.
- Clinicians used inconsistent surveys to assess visual function, as the measure allows the use of any validated survey.

The measure's specifications remain unchanged, and CMS has not adequately addressed these concerns. In this proposed rule, CMS notes that it plans to continue to evaluate this policy moving forward and consider mandatory reporting after the end of the COVID-19 PHE. But unless and until CMS can demonstrate that the problems with

this measure have been ameliorated, the AHA does not support the required reporting of this measure in any future year.

Request for Comment: Measure for Outpatient Volume. CMS seeks comment on whether it should consider adopting a measure assessing procedure volume for the OQR and ASC Quality Reporting (ASCQR) program. The agency explains that surgical procedures are increasingly moving into the outpatient space, and thus believes it is important to track the volume of outpatient procedures. One way to do this would be to re-implement the previously removed measures from the OQR and ASCQR that assessed surgical volumes; another would be to create a novel measure related to procedure volume.

CMS acknowledges in the proposed rule that "quality measurement efforts moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes," and that while larger facility surgical volume may be associated with better outcomes, these outcomes are likely attributable to other characteristics that are proven to improve care (such as effective care teams and robust surveillance). However, the agency also reasons that a volume measure would provide information to Medicare beneficiaries and other interested parties on numbers and proportions of procedures by category performed by individual facilities.

The AHA does not support the re-implementation of existing volume measures or the development of new volume measures for the OQR or ASCQR as methods to assess quality of care. We would be especially concerned by using volume measures for performance comparison purposes — including hospital star ratings — for a variety of reasons.

Volume measures are inconsistent with the important and strategic goals of CMS' own Meaningful Measures 2.0 framework, and we are concerned that the agency would consider moving forward with an idea that is so incongruous with the significant work it has undertaken to streamline and focus its quality reporting programs on the most important and useful measures. According to CMS, "Meaningful Measures 2.0 will promote innovation and modernization of all aspects of quality." It would be diametrically contrary to this goal to pursue a measure that was removed years ago due to a lack of evidence linking the measure to improved clinical quality, and which was initially adopted before the National Quality Forum began reviewing measures for usefulness in CMS programs. In that intervening time, no definitive information has emerged about the exact volumes of procedures at which patient outcomes will improve significantly. As a result, any prescribed number of procedures against which a hospital is measured has a significant chance of being arbitrary. Performance comparisons based on those volumes also could mislead, rather than inform, the choice of facilities for patients.

Furthermore, much more sophisticated and meaningful measures of quality and safety of care have emerged, and we believe a modernized approach to measurement should

look forward to these new approaches, rather than backwards at measures the agency already has concluded do not meaningfully advance quality and safety.

In addition, CMS also notes that its framework "will further shape the entire ecosystem of quality measures that drive value-based care." By definition, value-based care replaces the traditional fee-for-service approach in which providers are paid based on the volume of services they deliver by instead focusing on health outcomes on a larger scale. Thus it is again inconsistent to consider measuring volume to inform a system seeking to improve outcomes.

Finally, it is unclear how such a measure of volume would fit into CMS' streamlined priorities in its 2.0 framework. We support the agency's efforts to use only high-value quality measures that impact key quality domains and align measures across programs; no other CMS quality reporting program utilizes a measure regarding procedure volume. We urge CMS to continue to support the priorities in its Meaningful Measures framework by focusing on high-value measures and avoid undoing the progress it has made to date by considering re-implementing measures without evidence linking them to improved outcomes.

ASC PAYMENT UPDATE

For CYs 2019 through 2023, CMS adopted a policy to update the ASC payment system using the hospital market-basket update rather than the CPI for all urban consumers (CPI-U). As such, for CY 2023, the agency proposes to increase payment rates under the ASC payment system by 2.7% for ASCs that meet the quality reporting requirements under the ASCQR program.

Medicare payment should reflect providers' underlying costs and patients served. However, hospitals and ASCs obviously have different costs and serve different patients. As such, it is inappropriate to continue to use the hospital market-basket to update payments for ASCs. **Therefore, the AHA recommends that CMS end this policy after CY 2023 and instead work expeditiously with ASC stakeholders to develop and implement a minimally burdensome way to collect ASC costs that could then be used to propose an appropriate update mechanism for CY 2024**.

Indeed, MedPAC has, since 2010, consistently recommended a similar approach. In fact, in its March 2022 report, it recommended that the secretary "require ambulatory surgical centers to report cost data." It further states, "Beginning with the Commission's March 2010 report to the Congress, the Commission has stated in comment letters and in published reports that the CPI–U likely does not reflect the current input costs of ASCs. However, the Commission does not support using the hospital market basket index as an interim method for updating the ASC conversion factor because this index also does not accurately reflect ASCs' costs (Medicare Payment Advisory Commission 2018a) ... We are concerned that neither the CPI–U nor the hospital market basket

index reflects ASCs' cost structure … The Commission asserts, however, that all other institutional providers submit at least abbreviated versions of cost reports to CMS, including small entities such as hospices and home health agencies. Moreover, ASCs in Pennsylvania submit revenue and cost data each year to the Pennsylvania Health Care Cost Containment Council, so it is clear that submission of cost data is feasible for ASCs. Nevertheless, CMS has not acted on this issue." MedPAC has suggested several streamlined cost-collection processes that could be used to determine an appropriate input price index for ASCs.

UN-PACKAGING OF NON-OPIOID PAIN MANAGEMENT DRUGS UNDER THE ASC PAYMENT SYSTEM

Under a policy adopted in 2019, non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are un-packaged and paid separately at ASP plus 6%. The goal of the policy is to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. In this rule, CMS proposes to add HCPCS codes C9290 (Exparel), J1097 (Omidria), C9089 (Xaracoll) and J1096 (Dextenza) to this policy, meaning these drugs would receive separate payment in the ASC setting as non-opioid pain management drugs that function as a surgical supply.

The AHA appreciates that CMS is engaging stakeholders to investigate novel strategies to address the opioid crisis. We continue to agree that stemming the tide of this epidemic must involve changes to how services are reimbursed so that financial incentives promote a full range of approaches to treating pain. However, packaging payments for non-opioid alternatives not only presents barriers to care in ASCs, but also in HOPDs. **Therefore, we recommend that CMS un-package non-opioid pain management treatments in HOPDs as well.** Based on feedback from our members, the AHA believes that this strategy has the potential to incentivize use of non-opioid pain management drugs in *all* settings in which outpatient surgery and other outpatient services involving pain management are furnished (such as in the ED). While certainly not a comprehensive solution to the opioid epidemic, un-packaging appropriate non-opioid therapies is a low-cost tactic that could change long-standing practice patterns without major negative consequences.

Similarly, AHA continues to support un-packaging other non-opioid treatments including drugs, devices and therapy services that are not currently separately payable in either the ASC or HOPD setting. Specifically, we support separate payment for continuous infusion pumps, as our members suggest that this would be a helpful approach to increase the usage of these non-opioid therapies. For example, the "On-Q" pain relief system is a portable pain system that provides non-opioid local anesthetic medication to the site of the pain. Its purpose is the same as Exparel's: to deliver relief at the site of the pain rather than by a systemic pain reliever. It also prevents the side effects that many people experience from oral medications. Other

drugs that should be considered for separate payment are intravenous (IV) Ibuprofen and Ofirmev (IV Acetaminophen). Our members also have suggested that CMS consider separate payment for Polar ice devices that use ice and water for post-operative pain relief after knee procedures. In addition, therapeutic massage, THC oil applied topically, acupuncture and dry needling procedures are very effective therapies for relief of both post-operative pain and long-term and chronic pain.

Criteria for Eligibility for Separate Payment in ASCs for Non-Opioid Drugs that Function as Surgical Supplies. In CY 2022, CMS finalized two criteria intended to identify non-opioid pain management drugs that function as supplies for which separate payment under the ASC payment system would be appropriate. These include:

Criterion 1: FDA Approval and Indication for Pain Management or Analgesia. The drug must be approved by the FDA under a new drug application, a generic drug application or, in the case of a biological product, licensed under provisions in the Public Health Service Act. Also, the drug or biological must have an FDA-approved indication for pain management or analgesia.

Criterion 2: Cost of the Product. A drug or biological only would be eligible for a payment revision under the ASC payment system if its per-day cost exceeds the drug packaging threshold under the OPPS, which for CY 2023 is proposed to be a per-day cost of $135.

As we noted in our CY 2022 comment letter, the AHA generally supports these criteria. **However, we continue to believe that the first criterion is too narrow and that non-opioid anesthesia drugs also should qualify for separate payment, in both the ASC and HOPD settings.** For instance, we are aware of four common options for non-opioid anesthesia that can be used during and after surgery. Dexmedetomidine is a fast-acting sedative that is only given intravenously and can be easily titrated during surgery. Two non-opioid options that are typically used at the end of surgery are IV acetaminophen and ketorolac. Ketorolac is a non-steroidal anti-inflammatory drug that can be quite useful for controlling severe pain following surgery, as well. Finally, ketamine is a type of sedative and hypnotic agent that works quickly during surgery and that can significantly improve post-operative pain. Unlike its opioid counterparts, ketamine actually opens up the airways to improve respiration. There are several clear benefits to using non-opioid anesthesia along with, or instead of, its traditional counterparts. For example, these drugs work better for patients who may have a long history of opioid use for chronic pain and who may have a high tolerance for these traditional drugs. In addition, non-opioid agents tend to result in fewer post-operative complications with breathing and decreased consciousness and can allow patients to get back to their baselines as quickly as possible.

RURAL EMERGENCY HOSPITAL PROPOSALS

Many rural hospitals struggle with their remote location, limited workforce and constrained resources, yet the nation's nearly 2,000 rural community hospitals frequently serve as the anchor for their area's health-related services. They provide essential acute services, prevention and wellness services, as well as community outreach and employment opportunities. Many of these hospitals are currently fighting to survive — especially in the high inflationary and workforce shortage environment hospitals have been operating under — potentially leaving their communities at risk for losing access to local health care services. To support rural communities, Congress established a new Medicare provider type, the Rural Emergency Hospital (REH), which would allow a facility to provide emergency hospital services for Medicare payment without the need to furnish acute care inpatient services. After seeking a request for information to help establish the model, CMS issued several specific proposals in this year's OPPS rule and under separate rulemaking. **We thank the agency for issuing these proposals, as hospitals are eager to evaluate the feasibility of conversion. Going forward, we urge the agency to provide further guidance on key issues in a timely manner so that rural hospitals have timely and necessary information to enable informed decision making.**

Below, we offer comments on specific proposals related to payment, covered outpatient services, and the Physician Self-Referral law and provide additional recommendations for the agency to consider. The AHA's feedback on conditions of participation for REHs are in a separate comment letter.

Monthly REH Facility Payment

As part of its reimbursement, REHs will receive a monthly facility payment. By statute, the additional facility payment for 2023 is calculated as the excess of the *actual* total amount paid to all critical access hospitals (CAHs) in 2019 that exceeds what would have been paid had payments been made under the applicable prospective payment systems (i.e. the *projected* Medicare payment), divided by the total number of such hospitals in 2019. For 2024 and subsequent years, the facility payment would be increased by the hospital market basket percentage. In this proposed rule, CMS provides the details on how the additional facility payment would be calculated.

However, CMS has not included Medicare Advantage (MA) payments in its calculations, although these may be included, and we encourage the agency to evaluate the inclusion of MA.

We also agree with the agency's proposal to include amounts paid to CAHs from Medicare and beneficiary copayments and to calculate amounts using CY 2019 claims and not fiscal year 2019 claims. Under this proposed methodology, CMS is estimating that the actual amount of Medicare spending for CAHs in CY 2019 was $12.08 billion and that the projected amount of Medicare spending is $7.68 billion, resulting in a

monthly facility payment of $268,294. **We support the agency's use of Medicare claims data to determine the facility payment. Going forward, we ask that CMS continue to carefully consider the ongoing financial challenges for rural hospitals and monitor the adequacy of the facility payment given rising costs in labor and supply.**

With that said, we strongly urge CMS to publish a more detailed methodology of its additional facility payment calculations. Without this information, stakeholders are not fully able to replicate and evaluate the agency's methodology. Specifically, we urge CMS to publish its calculations of CAH actual and projected Medicare spending for CY 2019 broken down by provider category (inpatient hospital, inpatient rehabilitation, inpatient psychiatric, outpatient hospital, and skilled nursing (hospital-based and swing bed)). While the agency provided the aggregate figures across all payment systems, stakeholders need to understand the role each payment system plays in the calculation of actual and projected spending in order to properly evaluate and comment on the agency's proposed methodology.

Similarly, we urge the agency to clarify how it handled spending for clinical lab, physician services, ambulance services, parenteral and enteral nutrition, durable medical equipment, prosthetics/orthotics, and supplies, and vaccines and Medicare Part B drugs. Specifically, it is unclear from the proposed rule language whether these services were included in the *actual* CAH Medicare spending for CY 2019. Payments for these services should absolutely be included in the actual costs of CAH Medicare spending for CY 2019 so as to avoid underestimating the additional monthly facility payment.

Additionally, we ask that CMS clarify and publish its calculations for projecting supplemental payments under the IPPS and OPPS. Specifically, because CAHs are paid based on costs, their claims do not include supplemental payments that are normally paid under IPPS and OPPS, such as indirect medical education (GME), disproportionate share hospital (DSH), and uncompensated care payments. To capture these supplemental payments, CMS would estimate payments for IME, DSH payments and uncompensated care payments for CAHs had they been paid under IPPS and OPPS. CMS proposes a methodology that identifies all IPPS rural hospitals and the closest IPPS hospital to each CAH, even if the closest IPPS hospital is an urban hospital. It then averages the applicable percentage for each supplemental payment between these two groups. For example, the agency would average the IME percentage of rural IPPS hospitals and closest IPPS hospitals to determine overall IME supplemental payments. While this methodology assumes that CAHs serve in communities that are similar to other IPPS hospitals, they and other small rural hospitals often have challenges recruiting residents to train in their communities or operate in

communities with varying uninsured rates.[43] Therefore, we also urge CMS to publish in detail the estimated payments for each supplemental payment type and to provide, as applicable, estimates separately for IPPS rural hospital and closest IPPS hospital categories.

Separately, we agree with CMS' methodology to determine what CAHs would have been paid under the IPPS as it relates to patient comorbidities. Some stakeholders expressed concerns that because CAHs are paid on cost, they have less incentive to fully document patient's comorbidities. This is in contrast to IPPS payments, where documented diagnoses determine payment amounts. Stakeholders expressed concern that without accounting for this incentive, the monthly facility payment could be larger than what it should be since what would have been paid prospectively would be underestimated (i.e. the projected Medicare spending). However, we agree with the agency's assessment that there is not immediately available data that definitively demonstrates whether CAH patients are healthier or less healthy compared to IPPS patients. Additionally, we agree with the agency that it would not be feasible to gather data before implementing the provider type and that it should not adjust the distribution of reported diagnosis in CAH to reflect the distribution in IPPS.

We also appreciate that the agency is not requiring CAHs to submit additional information in order to help CMS project payments for skilled nursing facilities (SNFs). Specifically, CAHs are not required to submit Minimum Data Set (MDS) 3.0 assessments for their SNF swing bed patients; these assessments are the primary basis for determining case mix groupings under the SNF PPS. **Instead, we support the agency's proposal to predict per diem-rates of claims through modeling.**

Finally, REHs are required by statute to maintain information on how they have used their additional facility payments. CMS is proposing that this requirement be met using existing cost report requirements on outpatient services. We agree with this proposal and believe that REHs should not be required to report new data and information to meet this requirement.

REH and Covered Outpatient Department Services

The statute defines "REH services" as ED and observation services as well as, at the election of the REH, other medical and health services furnished on an outpatient basis as specified through rulemaking. In this rule, CMS is proposing to define REH services as all covered outpatient department services that would be paid under the OPPS; the agency would pay the applicable OPPS payment plus an additional 5% payments for these services. **We support this proposal. The specific care needs in rural communities are diverse and the current proposal gives an opportunity for REHs**

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[43] Department of Health and Human Services: Assistant Secretary for Planning and Evaluation. Access to Affordable Care in Rural America: Current Tends and Key Challenges. https://aspe.hhs.gov/sites/default/files/2021-07/rural-health-rr.pdf

to best serve the needs of their communities, allowing all services under the OPPS to be furnished, as well as to be paid for under the statutory rate.

In addition, we strongly agree with the agency's proposal to not apply Section 603 site-neutral rates to REHs. Under this policy, certain non-excepted off-campus PBDs are reimbursed a PFS-equivalent rate of 40% of the OPPS rate. CMS appropriately recognizes that if a CAH becomes an REH and as a result becomes subject to the Section 603 amendments, it would experience a significant decrease in payment for items and services furnished by its off-campus PBDs. This would create a financial disincentive for CAHs to convert to REHs and would therefore be contrary to the congressional intent for creating this new provider type. **We strongly agree the site-neutral policy would disincentivize many otherwise eligible facilities from choosing to convert to REHs. As such, we strongly oppose the alternative CMS outlines in the rule that considers whether application of this policy to an off-campus PBD of an REH should depend on whether that provision applied to the entity before it converted to an REH.** This alternative proposal is contrary to congressional intent to help financially struggling rural hospitals to stay as an access point for their communities.

CMS proposes that outpatient services not covered under the OPPS could still be furnished by REHs, but they would not receive payment at the OPPS plus 5% rate. These include services such as laboratory services and outpatient rehabilitation therapy services, among others. Specifically, CMS proposes that any outpatient service furnished by an REH that is not under covered OPPS would be paid under the same, applicable payment system as if it was performed in a hospital outpatient department (HOPD). For example, laboratory services provided at a REH would be paid under the Clinical Laboratory Fee Schedule, and ambulance services provided by REHs would be paid under the ambulance fee schedule.

Since the core intent of REHs is to provide emergency services and to transfer patients, we urge CMS to consider that these functions must be paid appropriately in order to be sustainable for the community. We have heard from rural members that ambulance services are particularly challenging to provide and to sustain in communities where long distance and low volume often create difficulties in maintaining financially viable models. **Therefore, we ask that CMS work with Congress to help improve reimbursements for these services, thereby helping to ensure the financial sustainability of REHs.**

Finally, we urge CMS to provide more clarity around provider-based rural health clinics (RHCs). Specifically, we ask CMS to explicitly state and allow for REHs to operate provider-based RHCs. We also urge CMS to definitively state that provider-based RHCs that meet the requirements under Section 130 of the Consolidated Appropriations Act of 2021 would retain their grandfathered status after the hospital converts to a REH provider type and to continue to operate under the payment rules grandfathered as of April 1, 2021.

REH Provider Enrollment

CMS proposes that conversions to an REH be accomplished via change of information applications rather than applications for initial enrollment. **We support this proposal.** We also urge the agency to establish a simple process for any conversions from REHs back to a previously designated status. In particular, we urge CMS to ensure that necessary provider status CAHs are able to revert back to their necessary provider status if they so choose.

Medicare Outpatient Observation Notice

Hospitals are required to provide the Medicare Outpatient Observation Notice (MOON) when a patient receives observation services for more than 24 hours. The notification explains the individual is an outpatient, not an inpatient, and the implications of that classification. CMS propose that REHs not be required to provide the MOON since REHs are excluded from the definition of "hospital." **We support this proposal.**

Physician Self-Referral Law

For decades, the Stark Law has protected federal health care programs from the inherent conflict of interest created when physicians self-refer their patients to facilities and services in which they have an ownership interest. In 2010, based on a decade of research on the adverse impacts of physician-owned hospitals (POHs), Congress strengthened that protection by imposing a prospective ban on self-referral to new physician-owned hospitals and by imposing limitations on the growth of POHs that were "grandfathered in" to the exception. In effect, the Affordable Care Act allowed then-in-place POHs to continue to operate in their then-current form, but physicians could not invest or own non-grandfathered hospitals and the grandfathered hospitals had to either meet limitations on expansion or divest of their physician owners.

In this rule, CMS proposes to create a new regulatory "REH exception" to the Stark Law that would permit physician ownership or investment in REHs. The proposed REH exception is modeled after existing exceptions for other specific providers (e.g., the rural provider exception), and would protect all referrals from physician owners for designated health services furnished by an REH, as well as all billing for those referred services, if the conditions of the exception were met.

Critically, the REH exception would create an avenue for *new* physician ownership of or investment in hospitals. This is in contrast to existing exceptions, where the rural provider and the whole hospital are "grandfathering" exceptions available only to hospitals that met their requirements as of 2010. The proposed REH exception also imposes less of a burden on investors than earlier exceptions, exceptions no longer available for new investment. For example, REHs would not be subject to requirements that relate to disclosure of conflicts of interest, prohibition on facility expansion, and prohibition on increasing aggregate physician ownership or investment levels, each of

which are program integrity policies that were passed as part of the Affordable Care Act and that otherwise limit physician-owned rural providers and whole hospitals.

CMS' stated rationale for creating new, more relaxed standards for REH ownership is "that limitations on facility expansion or the amount of physician investment or ownership in an REH could negatively impact access to needed services in rural and other underserved areas" and thereby thwart the underlying goal of Section 125 of the Consolidated Appropriations Act of 2020 to safeguard of expand such access. **We disagree with this rationale and strongly oppose the proposed new Stark exception that would allow *new* physician ownership of or investment in REHs. While we support allowing existing POHs that convert to REHs to maintain their POH status, we oppose any other attempts to loosen the current restrictions so as to allow for *new* POHs.**

The growth of physician-owned hospitals was restricted for good reasons, and those reasons remain valid today. The initial moratorium on new physician ownership of hospitals came about after decades of analysis from several administrations, the Medicare Payment Advisory Commission and the Congressional Budget Office. Their studies highlighted the adverse effects of this practice, the most important of which was that physician referrals to their own hospital risked undermining the nation's health care safety-net by too often prioritizing the most profitable patients over those who are underinsured and uninsured. They also found that such referrals consistently lead to costly overuse of medical services and to higher costs for the Medicare program.

Recent studies reinforce the need to retain restrictions on new and expanded physician-owned hospitals. An analysis conducted by the health care economics consulting firm Dobson | DaVanzo confirmed previous findings that these facilities cherry-pick patients by avoiding Medicaid and uninsured patients, treat fewer medically-complex patients, and are penalized for unnecessary readmissions at 10 times the rate of non-physician owned hospitals. Another analysis from DeBrunner & Associates conducted in August 2020 found that, on average, patients treated at full-service community hospitals are 36% more likely to have one or more chronic conditions than those treated at physician-owned hospitals. At the same time, community hospitals provide 25% more in uncompensated care as a share of total expenses. Both of these trends contribute to the fact that POH hospitals have, on average, an operating margin that is *57 times higher* than non-POH hospitals.

Hospitals rely on a balance of patient mix to cover the costs for providing necessary care. Because POHs tend to cherry-pick the most profitable patients, these actions jeopardize communities' access to full-service care. This trend creates a destabilizing environment that leaves sicker and less affluent patients to community hospitals, threatening the health care safety net. The proposed "REH exception" would occur in already challenged rural communities where patient and payer mix often play an outsized role in determining the financial sustainability of a facility. For example, a physician-owned REH that tends to see healthier and more profitable patients would

negatively impact the utilization and case mix of patients in rural community hospitals serving the same communities, creating a cascading effect of financial instability. The impact of a new POH on the larger rural ecosystem would be detrimental and undermine the purpose behind the creation of the REH entity in the first place.

The proposals in this rule run counter to the sum total of the research in that they would pave the way for the creation of new POHs and allow certain POHs to expand, putting high-quality, reliable care at risk. **We believe that with thoughtful inputs from stakeholders during this process, CMS can, without the need of an "REH exception," establish a model that provides sufficient access to services in rural communities without relying on investment from individuals whose financial interests would run contrary to the goal of expanding access for Medicare beneficiaries and other underserved constituencies. We urge CMS to consider and adopt the myriad other recommendations detailed in this letter that provide REHs the flexibility for conditions of participation and appropriate reimbursements so that access to needed services remain intact for these rural and underserved communities.[44] By adopting these proposals to give REHs greater flexibility, CMS can support the financial incentives for the creation and operation of REHs without undermining important Stark law protections.**

REH Quality Reporting Program

According to the proposed rule, CMS seeks to adopt a concise set of important, impactful, reliable, accurate and clinically relevant measures for REHs that would inform consumer decision-making and promote quality improvement efforts. We appreciate the considerations the agency describes that will inform this work, and acknowledge the challenges CMS will face in determining measures that meaningfully assess quality of care in facilities offering such limited services. For example, the AHA strongly urges CMS to use only measures that have been endorsed by the National Quality Forum (NQF) in its quality reporting programs (QRPs). The NQF endorsement process identifies measures that meet baseline standards of validity, reliability, and usefulness; the iterative review process incorporates feedback from a variety of stakeholders, including NQF's Rural Workgroup which reviews measures under consideration for use in other CMS programs for applicability in rural settings. Without NQF endorsement and ongoing review, measures are less likely to achieve the objectives of CMS QRPs; however, using only NQF-endorsed measures limits the universe of available measures for consideration in the REHQR.

Similarly, we understand that CMS is working to transform quality measurement and reporting into a fully digital enterprise in order to improve accuracy and reduce burden associated with chart-abstraction. However, many rural facilities, including those eligible

[44] Also see generally AHA's comments in the REH request for information in CY 2022 OPPS proposed rule comment letter. https://www.aha.org/lettercomment/2021-09-17-aha-comments-cms-hospital-opps-and-ambulatory-surgical-center-payment

to convert to an REH, lack the technical and logistical resources needed to report digital quality measures.

CMS requests comment on a selection of measures recommended by the National Advisory Committee on Rural Health and Human Services. It is challenging to advise CMS on the appropriateness of these OQR and other measures, past and present, because the precise mix of services that REHs will provide is still under development. In the June 2022 proposed rule seeking comment on potential Conditions of Participation for REHs, CMS requests feedback on several aspects of potential REH services including low-risk childbirth-related labor and delivery, outpatient surgical services, and use of certain advance practice providers for on-call coverage. Because we have not yet established what care will be provided in an REH, it is difficult to opine on the best metrics to assess this care.

Further, we anticipate the mix of services provided will differ greatly by facility. For example, some REHs may see a high volume of acute coronary interventions, so the OQR measures evaluating time to application of fibrinolytic therapy or transfer would be relevant; for other facilities that see high volumes of other types of procedures, such as orthopedic or respiratory, these measures would hold little value. Even if CMS were to develop a broad set of measures, the variation in volumes — not just by procedure, but by year — would likely result in REHs across the nation reporting disparate combinations of these measures over time.

This leads to the larger question of the goals of the REHQR. Other QRPs have dual purposes: one, to evaluate performance in order to set benchmarks, hold providers accountable and help providers improve quality; and two, to inform people in their decisions on where to seek care. Patients served by an REH are likely not going to be using quality information to choose a location for care; REHs were established as a new provider type to allow rural hospitals that are not able to sustain full hospital operations to instead provide a limited set of essential health care services to the communities they serve. Like any health care provider, REHs will be responsible for delivering the best possible care, but given their unique nature it is difficult to apply the goals of a QRP for general acute care or other traditional provider type to an REH.

Thus, the AHA is unable at this time to support or oppose any of the individual measures listed in the proposed rule. We will better be able to respond to discrete proposals once more specific expectations for REHs and the services they are to provide are established.

REMOTE OUTPATIENT MENTAL HEALTH SERVICES

CMS proposes to designate certain mental health services performed remotely by clinical hospital staff using telecommunications technology to beneficiaries in their homes as “covered OPD services” for which payment is made under the OPPS; to do so, CMS would create three new HCPCS codes for diagnosis, evaluation or treatment

of a mental health or substance use disorder. CMS would price these codes based on the PFS facility payment rates for similar CPT codes.

The AHA appreciates and supports CMS' efforts to maintain the expanded accessibility of remote mental health services granted via waiver during the COVID-19 PHE by permanently allowing hospital staff to provide these services to patients in their homes. These services have not only been vital to ensure access to mental health care during the past two-plus years, but also have demonstrated that it is helpful and necessary to allow HOPDs to bill for outpatient mental health services in general. In particular, these services have been especially helpful for rural communities where small rural hospitals have leveraged virtual care to meet the surging demand of behavioral health needs in the communities they serve. Given geographic and transportation challenges in rural settings, the ability of CAHs and other rural hospitals to furnish outpatient behavioral therapy via telehealth has improved continuity of care and removed barriers to access mental health care in these isolated and underserved communities. We strongly support permanently allowing hospitals staff to continue to provide these services for patients in their homes.

That said, we encourage CMS to reconsider the proposal to create three new C-codes to describe these services. In the rule, CMS reasons that it believes that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resemble the PFS payment amount for similar services when performed in a facility; based on this reasoning, the agency would create new HCPCS C-codes to describe diagnosis, evaluation or treatment of a mental health or substance use disorder and price them based on comparable payments under the PFS. The AHA is concerned that these three generic codes would not appropriately account for the vast range of services and staff comprising remote mental health offerings from an HOPD. First, while providers might not incur the same direct patient-related costs when providing virtual services as they would if the patient were physically present in the HOPD, these codes may fail to account for the other expenses to a hospital of supporting employed staff who cannot bill professionally, including licensed professional counselors and administrative or technical staff necessary to maintain remote service offerings.

Second, C-codes were initially activated to pay appropriately for items, services and surgical procedures not described by existing Level II HCPCS codes, like drugs, biologicals, magnetic resonance angiography, devices, new technology procedures and radiopharmaceuticals. There are dozens of existing HCPCS codes that represent outpatient behavioral health services that have been billable under the OPPS for services rendered remotely during the PHE, so it is doubtful that these services would be better represented by novel C-codes. In fact, this approach would introduce additional confusion and burden into the hospital billing process.

CMS does not provide sufficient background to demonstrate that the proposed creation of new codes priced using PFS proxies is a superior approach, so it is unclear whether

the agency has considered an alternative path. **Thus, we encourage the agency to consider a far simpler approach — to continue to allow these codes to be billed beyond the end of the PHE and attach a modifier indicating that the services were rendered remotely.** In addition, we request that CMS provide a more thorough explanation of how it arrived at its proposal in order to ensure that HOPDs are being appropriately remunerated for their services without introducing unnecessary administrative burden. If it is able to demonstrate that its proposal to create new codes would more appropriately cover the cost of providing care while maintaining access to these vital services than using existing codes to represent outpatient behavioral health services provided remotely (rather than justifying its proposal by noting that they "believe" it does), we would urge the agency to closely monitor the use of these codes to ensure that reimbursement is sufficient to cover the variety of outpatient, non-partial hospitalization mental health services offered by HOPDs.

We also encourage CMS to closely monitor the use of these codes for patients receiving partial-hospitalization program (PHP) services. Under PHP plan of care requirements, patients must receive a minimum of 20 hours per week of therapeutic services. The proposed remote mental health services are not to be recognized as PHP services, but CMS acknowledges that it is reasonable for a patient receiving PHP services to also receive non-PHP remote mental health services from a HOPD. In the rule, CMS notes that it expects a clinician caring for such a patient to update the medical documentation to support the patient's eligibility for participation in a PHP; we encourage the agency to provide more specific instructions on this documentation, and to carefully monitor whether clinicians are under the impression that these remote services may count toward the required care for PHP patients and provide leeway so as to not penalize providers and patients trying to keep up with changing rules and treatment modalities. The services described by the codes are so broad that this misconception is reasonable.

Finally, the AHA once again objects to the in-person service requirements associated with these codes. The Consolidated Appropriations Act of 2021 initially established the requirement for patients to receive an in-person service within six months prior to the first remote mental health service and subsequently thereafter each remote mental health service; CMS implemented these requirements for services billed under the PFS in the CY 2022 PFS final rule as well as for RHC and FQHC services. CMS proposes to apply these same requirements to the newly established code "in the interest of maintaining similar requirements." However, these in-person service requirements are arbitrary and not based upon any clinical guidelines or evidence. While some patients certainly should receive in-person services complementary to their remote interactions, the decision to do so should be made by that patient and their clinician rather than mandated by a regulatory body. While CMS allows for this requirement to be waived if the patient and their physician determine that the risks and burdens outweigh the benefits, providers must include clear justification documented in the beneficiary's medical record including the clinician's professional judgment behind the decision. It is incongruous that providers must provide clinical evidence that the in-

person visit is unnecessary while CMS cannot provide clinical evidence that the in-person visit is necessary.

RFI ON USE OF CMS DATA TO DRIVE COMPETITION IN HEALTHCARE MARKETPLACES

CMS has requested feedback on a proposal to supply additional data for researchers on topics that it asserts would be useful to promote competition in the healthcare field. There are at least three key reasons that the agency should not dedicate its resources, which it not infrequently describes as "limited," to aid researchers on a topic that is already one of the most frequently studied in the healthcare field and is closely scrutinized by two federal agencies actually charged with protecting competition. Those reasons are:

> (1) The Executive Order (EO) on which this proposal is based failed to focus on the main source of increased cost and harm to consumers — the commercial health insurance industry. This agency should not compound that oversight;[45]
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> (2) By focusing almost entirely on hospital mergers, the request for comment itself is entirely one-sided. In addition, its discussion of hospital mergers is factually unsupported. The sources on which the agency's proposal relies are out-of-date, seriously flawed, or otherwise unreliable; and
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> (3) There are two federal antitrust agencies (the Federal Trade Commission and the Department of Justice' Antitrust Division) capable of producing studies and data on competition in the health care field, and they regularly do. These agencies are much more likely than CMS to aid in any serious effort to understand the impact of mergers, acquisition and conduct by entities in the health care field and how the interaction among those entities impacts consumers.

A Primary Source of Increased Cost and Harm to Consumers Comes From Consolidation in the *Commercial Health Insurance Industry*. Presumably, the agency's principal concerns as it relates to competition would be the impacts on consumers who are Medicare or Medicaid beneficiaries or purchase health insurance through the Health Insurance Marketplace® (Exchange) or the Medicare Advantage (MA) program. The latter two programs rely heavily on competition among commercial health insurance companies (insurers). Yet competition among those insurers is scarce at best — a fact seemingly overlooked in the EO. That oversight should not be compounded by this agency.

[45] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/

Numerous studies and yearly reports demonstrate that the commercial insurance industry is concentrated to the detriment of consumers. In a 2019 study, for example, the Government Accountability Office (GAO) concluded that three or fewer companies held 80% or more of the private insurance market in at least 37 states, and an even higher proportion of ACA individual exchanges (46 of 49) and small employer exchanges (42 of 46).[46] The American Medical Association (AMA) also has documented the steady progression of consolidation among commercial health insurers. According to their 2021 update, 73% (280) of MSA-level markets were highly concentrated (HHI>2,500) in 2020, up from 71% in 2014 with corresponding concentration in the Exchanges.[47] Consolidation like this among insurers drives the cost of premiums up for consumers according to a study in Health Affairs.[48]

This unprecedented degree of concentration also enables conduct that harms consumers in other ways that should concern the agency. That includes:

- denying medically necessary care and delaying authorizations for patient care;[49]
- failing to pass on savings in hospital or other medical costs to consumers, e.g., *United States v Anthem Inc.* Feb. 8, 2017;
- intimidating hospitals to suppress competition from integrated hospital systems with health insurance offerings, e.g., *Federal Trade Commission v. Thomas Jefferson University et al.*; and
- systematic unjustified denials of care to consumers who rely on the MA program, which were well documented by the agency's own OIG. These denials were enabled or worse by the lack of competition among commercial health insurers offering MA products.[50]

If CMS is *serious* about aiding in efforts to assure that competition benefits the consumers that purchase, use, and rely on the Medicare, Medicaid, Exchange and MA products it oversees, it should use its limited resources to police anticompetitive conduct by *commercial* insurers. If to do so it requires more data that is where its efforts and limited resources should be directed.

The Executive Order's Discussion of Hospital Mergers Rests on Flawed Studies. The EO does not cite any studies for its broad assertions about competition among hospitals or hospital mergers. The fact sheet accompanying it cites *only* four studies. That dearth of support would be troubling enough, but is made worse by the fact that the studies it does cite are poorly designed or rely on defective data.

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[46] https://www.gao.gov/products/gao-19-306
[47] https://www.ama-assn.org/delivering-care/patient-support-advocacy/competition-health-insurance-research
[48] "ACA Marketplace Premiums Grew More Rapidly In Areas With Monopoly Insurers Than In Areas With More Competition" HEALTH AFFAIRS 37, NO. 8 (2018): 1243–125.
[49] https://www.aha.org/white-papers/2022-07-28-commercial-health-plans-policies-compromise-patient-safety-and-raise-costs
[50] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp

Much of the "academic" research on hospital mergers, including the limited research cited in the fact sheet, is flawed in ways that seriously limit the reliability of the results. For example, many of the studies measure hospital competition based on core based statistical areas (CBSAs), a small geographic area defined by the Office of Management and Budget. CBSAs rarely align with where and how patients seek care because it does not define a relevant geographic market. In addition, some hospitals and health systems compete based on specialties or certain services, *not* based on proximity to a person's home or workplace. And, rural hospitals are not located in a CBSA, calling into question the reliability of any research that uses this geographical designation for rural hospitals and health systems.

Research cited on hospital competition is also flawed because it relies on incomplete or biased samples. For instance, RAND's hospital price report (one of the four sources cited in the EO's accompanying fact sheet) is often cited without acknowledging its sample limitations. The RAND report relies on data from a small number of handpicked and self-selected sample of employers and insurers and fails to differentiate between in- and out-of-network claims. Tellingly, in the fourth version of the report, when RAND collected more claims compared to previous versions, the average price for hospital services actually *declined*. This alone demonstrates that it is not possible to draw credible conclusions from such a limited and biased set of claims.

Likewise, another oft-cited report is "The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured." But in this report, which is also cited in the fact sheet, the authors rely on old claims data comprised of employer-sponsored health insurance (ESI) claims for three large payors: Aetna, Humana and United, and represent 27.6% of individuals with ESI coverage. Notably, the HCCI sample represents just 13.5% of covered lives and does not include *any* data from Blue Cross Blue Shield (BCBS) plans. Those plans dominate virtually every insurance market in the U.S. making it impossible to draw reliable conclusions when those data are excluded. It should be of great concern to this agency and others that BCBS recently has been forced to settle a class action lawsuit challenging its anticompetitive conduct and forcing it to make changes to some of the anticompetitive practices determined to be particularly harmful to competition and consumers.[51] That fact alone should be sufficient to warrant this agency devoting its limited resources to better understand and police those insurers' conduct not pursuing yet another study of the hospital field.

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[51] The plaintiffs alleged that the defendants (Blue Cross Blue Shield Association and individual Blue Plans) violated antitrust laws by entering into an agreement not to compete with each other and to limit competition among themselves in selling health insurance and administrative services for health insurance. [T]he plaintiffs and defendants have agreed to a Settlement to avoid the risk and cost of further litigation. If approved by the Court, the settlement will establish a $2.67 billion Settlement Fund. The defendants will also agree to make changes in the way they do business, which the plaintiffs believe will increase the opportunities for competition in the market for health insurance. https://www.hr.utah.edu/benefits/bcbssettlement.php

In contrast to these flawed studies, more reliable research has found that recent hospital acquisitions *reduce* costs and *improve* performance on important quality indicators without an increase in revenue that may signal enhanced market power. For example, a leading study by Charles River Associates (CRA) found that hospital acquisitions can generate substantial benefits and reduce costs through several mechanisms, including by increasing hospital scale, standardizing clinical practices, reducing hospitals' cost of capital and allowing hospitals to avoid duplicative capital expenditures. Drs. Sean May, Monica Noether, and Ben Sterns, *Hospital Merger Benefits: An Econometric Analysis Revisited* at 1 (Aug. 2021), https://www.aha.org/system/files/media/file/2021/08/cra-merger-benefits-revisited-0821.pdf.[52]

Mergers also enable hospitals to potentially realize substantial benefits in clinical quality attributable to the standardization of clinical protocols, investments to upgrade services at acquired hospitals and deployment of additional staff where needed. *Id*. In particular, the study found that acquisitions were associated with a statistically significant 3.3% reduction in annual operating expense per adjusted admission at the acquired hospitals. *Id*. And rather than using flawed samples like the studies discussed above, this CRA study uses cost and revenue data from CMS' *own* Healthcare Cost Report Information System. Importantly, these data are publicly available and completed by *all* hospitals. The availability of this data raises questions about the need to solicit new data from hospitals and health systems, which would add additional administrative burden to health care providers and the agency. Put simply, CMS has all the information it needs to learn that hospital mergers are not the problem.

Finally, the request for feedback puts a particular emphasis on rural hospitals. It highlights a sentence from the EO stating that "[h]ospital consolidation has left many areas, especially rural communities, without good options for convenient and affordable healthcare service." But that is simply untrue. The best available research linking rural hospital closures to merger and acquisition activity tells a different story. Researchers have recently found that acquisitions significantly help rural hospitals that are financially distressed, reducing their risk of bankruptcy or closure.[53] And measuring closures alone over simplifies what happens in many communities. Some health systems have restructured inpatient rural hospitals, repurposing them as an outpatient facility such as an urgent care center, community health center or other outpatient clinic.

The EO (and consequently this RFI) does not consider that integration and consolidation may be a key component in preserving access to care, particularly in rural areas. For example, the agency repeats the inaccurate statement that consolidation has

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[52] CRA is the same economics consulting firm used by the past three California Attorney Generals (AGs) in antitrust cases. Two of those AGs now hold prominent position in this administration and even this agency.

[53] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9250050/

left rural areas in particular without good "options" for care. This conclusion entirely ignores that even prior to the pandemic "about one in five hospital partnership transactions involved a financially distressed hospital, many at risk of imminent closure."[54] The extreme financial pressure exerted by the pandemic both then and now would have closed off even more "options" had many of those rural hospitals not been part of an integrated hospital system.

CMS Should Not Devote Its Limited Resource to a Subject That Two Federal Agencies are Already Charged with Addressing. It is rare that two separate federal agencies have the very same charge. But for competition, including in the healthcare sector, two do – the Department of Justice's Antitrust Division (DOJ) and the Federal Trade Commission (FTC). The FTC and DOJ share jurisdiction over federal civil antitrust enforcement. These agencies routinely study, report on and take action to protect competition in the healthcare sector for the benefit of consumers.

The FTC, in particular, touts its efforts to oversee, study, and provide advice to other agencies in health care matters that implicate competition or consumer protection: "The Commission and its staff undertake a variety of other activities to promote competition in health care. One key area is research and reports on competition issues in health care and, in the past, has included such matters as…economic analyses of the effects of mergers involving non-profit hospitals and of state 'any willing provider' laws; and a series of public hearings in 2003 on a wide range of issues in health care."

"Another broad area of activity is competition advocacy. Aside from speeches to market participants, the FTC and its staff advise federal and state governmental bodies on competition issues in health care, in an effort to provide policymakers with a sound basis for assessing the implications for competition and consumers of proposed legislative or regulatory actions"[55] (emphasis supplied).

By contrast, this agency is not charged with protecting competition, much less aiding independent researchers that are well able to purchase data or obtain it elsewhere. The EO's directive does not alter that fundamental fact. That is particularly true when at least two other federal agencies are charged with, and regularly do collect, report, investigate, and otherwise obtain whatever information or data they determine is necessary and useful to protect competition in the health care and other sectors. We urge the agency to reconsider this effort to expand its mission and expend resources outside its remit. Instead, the public will be best served if CMS focuses its efforts elsewhere, where its expertise and resources can actually benefit the consumers that rely on the programs it oversees.

[54] https://www.fiercehealthcare.com/hospitals/industry-voices-a-time-need-hospitals-must-be-able-to-transform
[55] https://www.ftc.gov/advice-guidance/competition-guidance/industry-guidance/competition-health-care-marketplace

REQUIREMENT TO REPORT DISCARDED AMOUNTS OF CERTAIN SINGLE-DOSE OR SINGLE-USE PACKAGE DRUGS

Currently, when a provider discards an unused portion of a drug from a single-dose container or single-use package, Medicare provides payment for the discarded amount as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier is used to report the amount of a drug that is discarded and eligible for payment.

The Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. CMS proposes to implement this provision, including requiring physician offices, HOPDs and ASCs to report the JW modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the PFS, OPPS or ASC payment system. The agency also proposes that physician offices, HOPDs and ASCs use a new modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts. The proposed JZ modifier is intended to address purported inconsistent compliance with the use of the JW modifier.

The AHA opposes the new JZ modifier; it is repetitive of the JW modifier and would unnecessarily increase reporting burden for providers. Instead, we recommend that CMS undertake an education campaign, directed to physician offices and hospital and ASC pharmacies and coding experts to reinforce the requirements related to the use of the JW modifier, which has been in place since 2017.

Furthermore, the AHA also urges CMS to take steps to address some confusion around its existing policy regarding the appropriate use of the JW modifier. Specifically, a special edition MLN Matters article SE1316, issued Aug. 1, 2013, reminded providers that the billed amount for administered dosage plus waste "*must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient."* That is, some drugs are purchased in several different dose strengths, resulting in multiple national drug codes (NDCs) being in inventory for the same drug. Some drugs also come in different vial types (single-dose and multi-dose). Hospitals, ASCs and physician offices have had difficulty identifying what is the smallest dose (vial) available for purchase for which they are required to report wastage and have sought the help of CMS in the past. CMS, in turn, directed providers to look to their MACs to interpret this matter. However, different MACs have responded to the same question with different answers. **Therefore, the AHA urges CMS to clarify at a national level which vial size represents the smallest dose vial for each of the drugs for which reporting of wastage is required.**

ORGAN ACQUISITION PAYMENTS

The Medicare program reimburses transplant hospitals (THs) for organ acquisition costs, the transplant surgery and post-transplant costs for Medicare recipients. Currently, Medicare reimburses transplant hospitals for organ acquisition costs under a reasonable cost-based method using the hospital's ratio of Medicare usable organs to total usable organs. In the FY 2022 IPPS proposed rule, CMS proposed a number of policies to change, clarify, and codify Medicare's organ acquisition payment. However, due to the nature and volume of comments received by the agency, it did not finalize any of its proposed policies.

In this year's OPPS proposed rule, CMS proposed additional revisions and policies related to Medicare's organ acquisition payment policies. Specifically, the agency proposed to change how organs procured for research are counted for the purposes of calculating Medicare's share, requiring that THs and organ procurement organizations (OPOs) exclude organs used for research. The agency also clarified that organ acquisition costs would include certain hospital costs incurred for services provided to deceased donors. Additionally, CMS solicited a request of information (RFI) on an alternative methodology for counting organs used in the calculation of Medicare's share of organ acquisition costs.

The AHA remains concerned with CMS' proposals related to Medicare usable organs and organ acquisition payments to THs. Excluding research organs from the count of Medicare's share of organ acquisition costs would disincentivize innovative scientific organ research. In addition, CMS' alternative methodology for counting organs in the calculation of Medicare's share would jeopardize hospital transplant programs, which of course rely on these funds. Taken together, these proposals would entail payment cuts endangering transplant programs' ability to provide care and, subsequently, access to organ transplantations for vulnerable patients. We strongly urge CMS to withdraw these proposals.

Specifically, CMS is proposing that THs exclude organs that are furnished to other THs or OPOs from its count of organs in Medicare's share. That is, the agency would exclude organs furnished to other THs or OPOs from the Medicare usable organs (numerator) and total usable organs (denominator). Additionally, THs would only include organs transplanted into Medicare beneficiaries within their TH in the Medicare usable organ count (numerator). CMS states that this would not require TH/HOPOs to track organs they furnish to other THs and OPOs and would result in apportionment of costs to only organs transplanted into Medicare beneficiaries within the recipient TH.

In proposing these policies, CMS states that its rationale is to ensure that Medicare does not share in the cost of procuring organs that are not transplanted into Medicare beneficiaries. However, the proposals go too far in that they could actually result in

Medicare not reimbursing for organ procurement costs that ultimately are transplanted into Medicare beneficiaries. Indeed, the proposed alternative methodology would no longer consider *any* organs sent to another TH or OPO in the count of Medicare's share of acquisition costs because the agency presumes that *none* of these excised organs that are sent outside of the excising TH are transplanted into Medicare beneficiaries. Because of this presumption, Medicare would then be in danger of failing to provide the "necessary costs of efficiently delivering covered services" to Medicare beneficiaries, which could result in inducing cross-subsidization and relying on such costs being covered by other payors, contrary to its statutory requirement.[56] **CMS would be financially penalizing THs based on an incorrect presumption that *no* organs sent outside of a TH are transplanted into Medicare beneficiaries. This would be extremely detrimental to the financial sustainability of transplant programs writ large across the country. Thus, not only would this proposal reduce access to organ transplantation, it would also decrease health equity and negatively impact organ access and distribution for low income, minority, and pediatric populations.**

Furthermore, reducing Medicare's role in supporting organ transplantation and research stands in stark contrast to the 2019 Executive Order "Advancing American Kidney Health" that directed HHS to increase utilization of available organs, specifically aiming to "double the number of kidneys available for transplant by 2030." Potential decreases in the number of transplant programs in the future would, of course, be detrimental to the Medicare program and beneficiaries, including end stage renal disease patients who would have to stay on dialysis rather than undergo a kidney transplant. CMS' proposal to exclude research organs from THs count of Medicare's share of organ acquisition costs in particular is at odds with Medicare's commitment to cover routine costs in clinical trials as part of its national coverage policy.[57] Doing so would negatively impact the affordability and availability of research organs and hinder the advancement of clinical research.

DIRECT SUPERVISION OF CARDIAC AND PULMONARY REHABILITATION SERVICES BY INTERACTIVE COMMUNICATIONS TECHNOLOGY

During the COVID-19 PHE, cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR) and pulmonary rehabilitation (PR) services may be provided via telehealth with the services originating from a patient's home, and the physician supervision of these services permitted to take place virtually using audio/video real-time communications technology (excluding audio-only). However, once the PHE ends, CR, ICR and PR services must originate from a health care setting in a rural area to be paid via telehealth under the PFS, but this only applies until December 31, 2023. After that date, CR, ICR and PR services will no longer qualify as Medicare telehealth services.

[56] Social Security Act Sec. 1861(v)(1)(A)
[57] CMS. "Medicare Coverage Database: Routine Costs in Clinical Trials." https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1

Under current OPPS policy, during the COVID-19 PHE, these services may be furnished in the HOPD with the virtual physician's direct supervision, but this policy will no longer apply when the COVID-19 PHE ends. After that date, the physician will be required to be immediately available in a physical way for the direct supervision requirement to be met and for the hospital to be paid for these services.

In the CY 2023 OPPS proposed rule, CMS requests comments on whether it should extend its deadline for allowing physician direct supervision to be provided virtually for CR, ICR and PR services in the HOPD setting through the end of CY 2023, to be consistent with the policy under the PFS.

The AHA appreciates and supports CMS' proposal. We believe it will improve access to these important hospital outpatient services for patients and reduce burden on providers as the impact of the pandemic gradually recedes and as CMS unwinds its waivers and flexibilities. Permitting this additional flexibility will be particularly valuable in rural and other communities where workforce shortages remain acute and resolving them will take time.

In addition, we urge the agency to consider making this policy permanent, which we believe would do far more to improve access to these highly effective, yet underutilized services. Allowing for virtual supervision could help improve access for beneficiaries, particularly those who face barriers to participation in these programs. In the CY 2023 PFS proposed rule, CMS identified CR as a potentially underutilized service that may "provide the best possible health outcomes at the lowest possible cost".[58] In fact, the Million Hearts 2027 initiative created by CMS and CDC aimed to prevent one million heart attacks and strokes within five years, in part by increasing cardiac rehabilitation participation to 70% in eligible patients.[59] However, data show that only 24.4% of Medicare beneficiaries eligible for CR participated and that participation was lower among women (18.9%) compared with men (28.6%) and was lower among Hispanic Americans (13.2%) and non-Hispanic Black Americans (13.6%) compared with non-Hispanic white Americans (25.8%).[60,61] Making virtual direct supervision a permanent policy would help to close these gaps, including those related to health equity, by providing access to patients who face barriers to participation. Finally, direct supervision by a physician is just as safe and effective in a virtual setting as in a HOPD-based setting. The physician is still immediately available to join a two-

[58] 87 FR 45942, https://www.federalregister.gov/d/2022-14562
[59] CMS. "Million Hearts, Cardiac Rehabilitation." https://millionhearts.hhs.gov/about-million-hearts/optimizing-care/cardiac-rehabilitation.html
[60] "Tracking Cardiac Rehabilitation Participation and Completion Among Medicare Beneficiaries to Inform the Efforts of a National Initiative," ahajournals.org, American Heart Association, 14 January 2020, https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.119.005902.
[61] "Racial and Ethnic Disparities in Heart and Cerebrovascular Disease Deaths During the COVID-19 Pandemic in the United States," ahajournals.org, American Heart Association, 18 May 2020, https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.054378.

way audio/video conference with the patient and the other on-site clinical staff monitoring the exercise session and has immediate access to real-time patient data and can intervene as effectively as they would in an in-person service. Adverse events are very rare, particularly as only clinically appropriate patients receive virtual CR.

SUPERVISION BY NON-PHYSICIAN PRACTITIONERS OF HOSPITAL AND CAH DIAGNOSTIC SERVICES FURNISHED TO OUTPATIENTS

Prior to 2020, as a condition of Medicare Part B payment for diagnostic services under the PFS, Medicare only allowed physicians to supervise diagnostic services. However, in a COVID-19 related interim final rule issued in May 2020, CMS allowed, for the duration of the PHE, for diagnostic tests to be supervised by NPPs — nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwifes and certified registered nurse anesthetists — to the extent they are authorized under their scope of practice and applicable state law. While the interim final rule only provided for a temporary change to the supervision rules, in the CY 2021 PFS final rule, CMS made the changes permanent.

CMS noted that the basis for making these revisions was to both ensure that an adequate number of health care professionals were available to support critical COVID-related and other diagnostic testing during the PHE as well as to implement policy consistent the President's executive order on ''Protecting and Improving Medicare for Our Nation's Seniors," which directed the Secretary to identify and modify Medicare regulations that contained more restrictive supervision requirements than existing scope of practice laws, or that limited healthcare professionals from practicing at the top of their license.

In this rule, CMS proposes to clarify that the same NPPs that can provide supervision of diagnostic services payable under the PFS can provide supervision of diagnostic services furnished to outpatients by hospitals or CAHs, to the extent they are authorized to do so under their scope of practice and applicable State law. **The AHA supports this proposal and believes that it will improve access to these services in rural hospitals and in other areas in which there are shortages of physicians. Furthermore, we support the notion of allowing NPPs to practice at the top of their license.**

PROPOSED IPPS AND OPPS PAYMENT ADJUSTMENTS FOR DOMESTIC NIOSH-APPROVED SURGICAL N95 RESPIRATORS

CMS proposes to make a payment adjustment under the OPPS and IPPS for the additional costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. The AHA appreciates CMS' recognition of the significant and costly supply challenges America's

hospitals and health systems have been forced to navigate throughout the course of the pandemic. **We also appreciate the agency's novel approach to incentivizing domestic manufacturing of N95 respirator masks, but have several concerns over the proposed payment adjustment. In addition, as we have stated previously, while we agree with the agency that increased domestic manufacturing of medical supplies is vital to reforming the medical supply chain, we also continue to believe that much more must be done beyond CMS' control.**

Specifically, the agency proposes to base the payment adjustment on the estimated difference in the reasonable costs of purchasing domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators, provided as a biweekly interim lump-sum payment. The agency recognizes that hospitals cannot fully independently determine if respirators are manufactured domestically, and therefore, proposes that they rely on written statement from the manufacturer that the respirator is domestically made. In order to determine the payment adjustment, CMS proposes that a hospital would need to separately report on its cost report the aggregate cost and total quantity of domestic and non-domestic respirators.

We are concerned that these proposals would increase reporting burden on hospital staff and frontline workers, and that this would come at a time when workforce shortages have already created challenges to hospitals and health systems. First, hospitals must differentiate domestically made respirators from non-domestically made. As such, hospitals must obtain a written statement as to manufacturing origin, as proposed by CMS, which has been certified by the manufacturer's Chief Executive Officer (CEO); the manufacturer's Chief Operating Officer (COO); or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. It is unclear how hospitals would be able to obtain such a document or if the manufacturer would provide one for the purposes of Medicare reimbursement. Certainly, requiring manufacturers to meet new labeling and reporting requirements that would be more efficient and less burdensome.

Additionally, hospitals and health systems would be required to separately report on a new supplemental cost report form the aggregate cost and quantity of domestically made and non-domestically respirators. To do this, hospitals must devote critical staff to track, report and maintain these requirements and cost report records. For example, if a hospital were to obtain a manufacturer's written statement attesting to domestically made status, hospitals would also be required to maintain these records to be included on the supplemental cost reporting form, presumably until cost reports have been settled. **Therefore, we urge CMS to work with stakeholders to determine a less burdensome method of attestation and reporting for these payment adjustments.**

Furthermore, the agency proposes to make the payment adjustment budget neutral under the OPPS but *not* budget neutral under the IPPS. CMS estimates that OPPS payments would total $8.3M for CY 2023, which would entail a budget neutrality adjustment. **While we support CMS' proposal to increase Medicare reimbursement**

for those hospitals that purchase domestically manufactured N95 respirators, we urge CMS to make any additional payments non-budget neutral. Redistributing payments from an already underfunded system will not be of benefit to providers or to patients.

Finally, we also continue to have concerns over several potential unintended consequence of the proposal related to equity, as we have previously written. These include, but not limited whether CMS has considered the disadvantages this proposal may pose for hospitals and health systems that serve a significant number of Medicaid patients, as this proposal only would apply to Medicare fee-for-service beneficiaries. We also urge CMS to consider that Medicare fee-for-service utilization varies state-by-state across the country, which could put providers at a disadvantage depending on the state(s) in which they operate.