

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W. Room 445-G Washington, D.C. 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, July 26, 2022.

Dear Administrator Brooks-LaSure:

On behalf of our more than 200 member hospitals and health systems the Florida Hospital Association (FHA) appreciates the opportunity to offer comments 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 ("proposed rule").

II. Propose Update Affecting OPPS Payments

For two years hospitals have led their communities through the COVID-19 public health emergency (PHE). As the country continues to experience surges in COVID, and congressional allocations of financial aid for providers run dry, hospitals continue to respond to their mission to care. However, despite their resilience in the face of the pandemic, hospitals are not immune to the economic factors facing the country.

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An August 2022 Kaufman Hall report¹ on data from more than 900 hospitals paints a concerning picture of hospital finances:

- Hospitals have experienced negative operating margins every month of 2022.
- Hospitals saw a significant drop of revenue from June to July and are only up 0.6% yearto-day. The relative increase is offset by a 7.6% rise in expenses year-over-year.
- Inflation and labor shortages have contributed to total expenses rising 9.6% year to date. In-fact, Kauffman Hall's Labor Expense per Adjusted Discharge rose 3.5% from June and is up 13.9% YTD, a sign that the labor shortage is still going strong.
- In 2022 hospitals are treating fewer patients with a higher acuity Kaufman Hall also notes that hospital patients in 2022 are likely sicker, harder to discharge and more expensive to treat than hospital patients in 2021.

The PHE has required and continues to require hospitals to increase labor costs due to labor shortages that require increased compensation for full-time employees and increased use of more costly contract labor. These labor shortages are attributable to a number of factors, including quarantines, vaccine mandates, and apprehension and stress of healthcare staff resulting in their non-participation in the healthcare workforce (whether temporarily or permanently). Additionally, hospitals and other healthcare providers have incurred abnormally high costs associated with substantial additional paid time off for nurses and therapists suffering from COVID-19 or being quarantined due to potential exposure to this disease; increased operating costs related to purchases of additional PPE; increases in purchases of other supply costs; and increased costs of cleaning supplies, among other cost increases.

The national staffing issues are impacting Florida's hospitals more severely than hospitals nationwide. The RN vacancy rate is at 21% (compared to 17 nationally) and year-over-year turnover is nearly twice as high, at 32%, as pre-COVID (16.3%). Persistent vacancies and turnover have resulted in billions of additional spending to retain staff or hire temporary "travel nurses". Florida hospitals have reported an increase of nearly \$4 billion in additional staffing costs from 2019 (\$13.6B) to 2021 (\$17.6), and they anticipate they will spend an additional \$2 billion more year-over-year from 2021-2022.

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¹ https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-august-2022



The health care sector is not unique in its experience with inflation; however, providers are unable to adjust their rates to account for rising costs. Research commissioned by the American Hospital Association (AHA), show an increase in hospital costs by more than 20% from 2019-2021. This includes a 36.9% increase in drug costs and a 19.1% increase in labor costs. These inflated cost drivers have remained stubbornly high throughout the PHE regardless of actual rates of hospitalization for COVID-19.

Adding to these extraordinary stressors on hospital operations is a volatile stock market. A hospital's investment portfolio provides a financial cushion to absorb unforeseen operating challenges that may lead to potential shortfalls in operating margins. However, a confluence of world events, including inflation, have resulted in a stock market decline of more than 20% this year and the so-called bear market is not likely to end soon. As expenses climb, revenue decreases and margins are negative, hospitals will need to use their investment reserves to cover costs. Strong investment reserves have contributed to Florida's hospital's ability to weather health crises like the PHE. Reduced operating income resulting in depleted hospital investment reserves will create future vulnerabilities for hospitals.

Workforce challenges, inflated labor, drug, and supply costs, and a low volume high acuity patient population are ballooning hospital expenses. Those factors, coupled with a bleak U.S. economic outlook, are signposts of a looming crisis for hospitals. As you consider these policies and finalize the proposed rule, FHA urges you to not lose sight of the important role hospitals play in their communities and the importance of healthy margins to a hospital mission.

Proposed Conversion Factor Update

CMS proposes a market basket update of 3.1% less a productivity adjustment of 0.4%. FHA has significant concerns about this low payment update (2.7%), particularly given the inflationary environment and continued labor and supply cost pressures that hospitals and health systems face. Member hospitals across Florida are struggling to keep up with the increased inflationary pressures. The end of CY 2021 into CY 2022 should not, in any sense, be considered a steadystate 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

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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.

CMS uses the same market basket percentage update for the OPPS rate as in the Inpatient Prospective Payment System (IPPS) proposed rule, which CMS projected to be 3.1%. The final IPPS rule was published on August 10, 2022, and included an increase to the proposed market basket update by using second quarter 2022 forecast data. CMS finalized a market basket update of 4.1%, the largest update in 25 years. In the final OPPS rule, we ask that CMS continue to evaluate ways to ensure the market basket reflects inflationary pressures by increasing proposed payments.

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.

FHA 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, FHA'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.

Proposed Wage Index Changes

FHA is pleased to see that CMS has proposed a 5% cap on any decrease to a hospital's wage index. External factors outside of a hospital's control, such as COVID-19 labor demands, can contribute to significant fluctuations in the wage index, and a cap on any decrease will mitigate those factors. However, we urge CMS to apply this cap in a non-budget-neutral manner for rural hospitals. There is substantial variation in the hospital wage index adjustment of rural and urban hospitals. Given that all hospitals are affected by the budget neutrality to offset changes in the wage index, hospitals

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receiving a cap will receive a benefit, but non-protected hospitals may receive a detriment if not implemented in an appropriate manner.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

OPPS Payment Methodology for 340B Purchased Drugs

As you are aware, earlier this summer, the U.S. Supreme Court unanimously struck down CMS' policy of varying reimbursement rates for 340B hospitals. As such, we support 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.

Complete and Prompt Repayment Is Necessary

To correct the unlawful policy that the Supreme Court struck down, the agency should promptly repay 340B hospitals the difference between ASP plus 6% and the amount actually paid to hospitals for 340B drugs (plus applicable interest) for all the years in which the agency acted unlawfully. 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." Yet for five years, CMS' unlawful policy has deprived 340B hospitals of payment, even as hospitals

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across the country struggled to care for their patients and communities amidst a once-in-acentury pandemic.

The survey of 340B acquisition costs initiated in CY 2020 was defective and as such, cannot be used to set future payment rates or to delay or deny repayment for CYs 2021 or 2022. That survey does not comport with the law and was never relied upon by the agency as the basis for continuation of its unlawful policy. It is not a fair, proper, or legal basis for the agency to delay or deny repayment.

Retrospective Recoupment Would Be Unfair, Unlawful and Unprecedented

In the past, CMS has raised the specter of invoking "budget neutrality" to retrospectively recoup funds from hospitals that received them because of its unlawful policy. However, the agency should not penalize any hospital for the agency's own past mistakes in implementing an unlawful policy. Not only would retrospective recoupment be illegal, it would be impossible to implement as a practical matter. Most of the funds that hospitals received were already spent during the pandemic, a crisis that even today is causing hospitals to struggle financially. Clawing back those funds would only further put patients and communities at risk.

Moreover, nothing in federal law requires - or even permits - CMS to claw back funds to achieve budget neutrality. The law governing the OPPS makes it clear that budget neutrality applies prospectively --- not retrospectively --- as it addresses only future estimates and forward-looking periodic reviews. Therefore, CMS lacks the legal authority to recoup past payments to achieve budget neutrality and, to the best of our knowledge, there is no relevant instance where CMS has even tried to recoup prior OPPS payments.

Finally, it is important to keep in mind that the agency exempted a number of 340B hospitals from its unlawful policy, including rural sole community hospitals, free-standing children's hospitals and free-standing cancer hospitals. 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. Neither these exempted hospitals nor any others should be subject to claw backs based on an illegal policy that has already disrupted the entire hospital field during arguably the most vulnerable period in its history.

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Concerns Regarding CY 2023 Conversion Factor Adjustment and Reporting of Claims Modifiers

For CY 2023, CMS states that it "fully anticipates" restoring payment to 340B hospitals at a rate of ASP plus 6% for separately-payable drugs. In undoing the agency's unlawful policy, CMS is proposing a new budget neutrality adjustment to the OPPS conversion factor to account for this increase in payment. We have concerns, however, that the agency's calculation of this adjustment is incorrect and will result in further underpayment to all hospitals. These payments are critical for us to cover the costs associated with caring for Medicare patients. In fact, according to the most recent report by the Medicare Payment Advisory Commission (MedPAC), hospitals' Medicare margins were *negative* 8.5% in 2020, even after accounting for federal relief during the pandemic. Hospitals simply cannot afford to endure further underpayments. **Therefore, we urge CMS to correct the proposed adjustment to ensure that the appropriate amount is added back into the CY 2023 OPPS conversion factor and no hospital is underpaid.**

On a related matter, we also ask the agency to abandon its policy of requiring certain hospitals to report the informational "JG" and "TB" modifiers to identify separately-payable drug claims. When the agency first proposed its unlawful 340B payment policy in the CY 2018 OPPS proposed rule, it required certain hospitals to report these modifiers on drug claims. But given that the agency fully anticipates abandoning its current 340B payment policy, there is no need for the agency to continue to collect such information from hospitals. In fact, abandoning the use of these modifiers would be consistent with CMS' ongoing commitment to reducing the regulatory burden for providers. Therefore, we urge the agency to no longer require hospitals to report these modifiers for CY 2023 and subsequent years.

In conclusion, we appreciate CMS' decision to restore payment to 340B hospitals for CY 2023 in light of the Supreme Court's decision in *American Hospital Association v. Becerra*. However, we urge the agency to ensure no further harm is done to any hospital by promptly paying 340B hospitals the funds they are rightfully owed and not unfairly, unlawfully, and unprecedentedly recouping any funds from hospitals who were paid as part of the agency's own unlawful policy.

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XVIII. Rural Emergency Hospitals (REH): Payment Policies, Conditions of Participation, Provider Enrollment, Use of the Medicare Outpatient Observation Notice, and Physician **Self-Referral Updates**

In the wake of years of unprecedented rural hospital closures, Congress, in the Consolidated Appropriations Act of 2021 (CAA), created a new designation for small rural and critical access hospitals who may not have otherwise been able to sustain operations given compounding financial, workforce and other challenges. The designation, intended to be a lifeline for hospitals on the brink of closing, would maintain medical services in communities that are already healthcare underserved.

FHA generally supports the efforts of Congress and CMS to implement the REH designation. However, regulatory compliance and the cessation of inpatient services are likely to produce limited adoption by hospitals. Indeed, very few of FHA's eligible members are considering conversion to an REH designation. With our general support in mind, we offer the following on the payment and quality provisions included in the proposed rule:

Payment for Services Performed by REHs and Monthly Facility Payment

FHA is pleased with CMS' proposal to include all outpatient department services otherwise paid under OPPS as REH services payable under the REH payment policy. We also applaud CMS for the monthly payments proposed for CY 2023. Robust payments for REHs will ensure that facilities are financially feasible and can continue to provide essential services to the surrounding rural communities.

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.

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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 the 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.

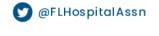
With that said, we strongly urge CMS to publish a more detailed methodology of its additional facility payment calculations. Without this information, stakeholders are not fully able to replicate and evaluate the agency's methodology. Specifically, we urge CMS to publish its calculations of CAH actual 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 to properly evaluate and comment on the agency's proposed methodology.

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. 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. FHA urges CMS to add the additional 5% to non-OPPS services provided at REHs. For example, outpatient therapy services should be paid under the respective fee schedule plus the additional 5%. In its proposed Conditions of Participation for REHs, CMS notes that REHs may be interested in becoming opioid treatment providers (OTP). To encourage REHs to do so, CMS should also consider applying the additional 5% to OTP services paid under the Physician Fee Schedule. Should CMS determine this is beyond the scope of the law authorizing REH's, CMS should work with Congress to improve reimbursements for non-OPPS services.

FHA also requests clarification from CMS on payment for provider-based rural health clinics (RHCs). Consistent with legislative intent, CMS must provide guidelines for payment to REH provider-based RHCs. CMS must allow REHs to maintain operation of existing provider-based

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RHCs grandfathered by April 1, 2021, that meet the qualifications in section 1833(f)(3)(B) of the Social Security Act for the special payment rules that establish non-capped rates instead of the national statutory payment limit. This must be explicitly stated in the REH payment regulations.

Finally, we would like to see REHs become eligible to participate in the 340B program. We recognize that CMS does not have the regulatory authority to allow REHs to participate in 340B, however, we ask that the CMS and the Administration work alongside Congress to ensure that a statutory change is made to include REHs as eligible participants.

VIII. Proposed Payment for Partial Hospitalization Services

Outpatient Non-PHP Mental Health Services Furnished Remotely

FHA 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 hospital staff to continue to provide these services for patients in their homes.

With 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 the diagnosis, evaluation or treatment of a mental health or substance use disorder and price them based on comparable payments under the PFS. FHA 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. Instead, we

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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.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR Program

Hospital OQR Program Quality Measures

Proposal to Change Cataracts Measure from Mandatory to Voluntary

FHA supports the proposal to no longer require reporting of the measure, Cataract Improvement in Patient's Visual Function within 90 days Following Cataract Surgery. Our member hospitals have shared concerns about the difficulties in collecting and reporting this measure, especially given the ability to obtain valid, consistent data from clinicians.

Request for Comment: Measure for Outpatient Volume

FHA does not support re-implementing the procedure volume measures for the OQR and the ASCOR program as a method to assess quality. Volume is a poor proxy for quality as noted by the lack of evidence linking it to better outcomes. CMS removed it in the past for cause and nothing has changed to indicate it is now a valid measure. Reporting volume does not provide the type of comparative data that is actionable for consumers. Additionally, consumers could be misled in interpreting the data without understandable guidelines on how to use the data in health care decisions.

Sincerely,

Mary C. Maylien

Mary C. Mayhew President and CEO Florida Hospital Association

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