September 9, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

SUBJECT: **CMS-1809-P, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities, (Vol 89, No 140), July 22, 2024**

Dear Administrator Brooks-LaSure:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule updating the Medicare outpatient prospective payment system (OPPS) for calendar year (CY) 2025.

California's hospitals continue to face unprecedented financial pressure resulting from uncontrollable input price inflation. From 2019 to 2023, costs per adjusted discharge rose 25%[1] (driven by increases in salary costs +22%, supply expenses +18%, and pharmaceuticals +19%). However, base payment rates for Medicare have failed to keep pace with input price inflation. Chronic underfunding by Medicare contributed to the closure of one hospital in California (Madera Community Hospital[2,3]), drove another into bankruptcy (Beverly Hospital[4]), and forced others to eliminate necessary but financially unsustainable services (like labor and delivery[5]) to ensure facilities can remain open. Unfortunately, more hospital closures are anticipated. Kaufman Hall, a nationally renowned consulting firm, estimates 70% of California's hospitals have unsustainable operating margins.

[1] Current State of California Hospital Finances, Kaufman Hall, May 2024
[2] https://calmatters.org/health/2023/01/hospital-closure/
[3] https://abc30.com/madera-commuity-hospital-remains-closed-emergency-services-residents/12922392/#:~:text=Ashraf.-,Madera%20Community%20Hospital%20closed%20its%20doors%20in%20December%20of%20last,Madera%20for%20over%20forty%20years.
[4] https://www.latimes.com/california/story/2023-04-20/beverly-hospital-in-montebello-files-for-bankruptcy-in-effort-to-avoid-closure
[5] https://calmatters.org/health/2023/11/california-hospitals-close-maternity-wards/

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The Medicare Payment Advisory Commission (MedPAC) recognizes the precarious nature of Inpatient Prospective Payment System (IPPS) hospitals' financial situation and the deleterious impact it is having on access — not just for Medicare beneficiaries. Nationally, at least 13 hospitals have closed in 2024 as of June[6] and many more hospitals have closed service lines[7,8,9,10]. It is worth noting that when hospitals are frequently forced to close service lines like labor and delivery and mental health, it is typically those that have a disproportionately larger governmental payer mix than other service lines due to inadequate payment rates relative to input costs. While Medicare does not pay for a large volume of labor and delivery services, the program's underpayment for services provided to its beneficiaries makes it more difficult for hospitals to sustain a service that is disproportionately used by Medicaid beneficiaries. For additional details, please see CHA's response to CMS' request for information related to access to maternal health services in the federal fiscal year (FFY) 2025 IPPS proposed rule[11].

Following hospital or service line closures, patients are forced to travel farther distances for care in already overcrowded hospitals, resulting in negative outcomes. Research shows that rural hospital closures increase inpatient mortality by 8.7%, with Medicaid patients (including those who are dually eligible) and racial minorities bearing the brunt of negative outcomes — 11.3% and 12.6% increases in mortality, respectively[12]. These are not abstract data points.

To prevent further loss of access to care in California and other states, the MedPAC took the unprecedented step of recommending Congress increase the market basket update (MBU) above current law. In its FY 2024 recommendation, MedPAC recommended an increase of one percentage point over market basket plus providing an additional $2 billion to hospitals[13]. For its 2025 recommendation, recognizing hospitals' rapidly deteriorating financial situation, the Commission recommended Congress increase the acute hospital market basket by 1.5 percentage points over current law and increase the additional funding for hospitals to $4 billion[14]. Regrettably, CMS continues to ignore the concerns expressed by MedPAC about hospital closure, service line termination, and Medicare beneficiary access to care.

California's hospitals are concerned that the CY 2025 OPPS proposed rule will exacerbate already dire circumstances for hospitals and the Medicare beneficiaries they serve. The proposed net OPPS MBU of +2.6%[15] is insufficient relative to the input price inflation faced by hospitals and continues CMS' historic trend of proposing inadequate payment updates. To ensure broad access to care for Medicare patients, the following comments on the CY 2025 OPPS proposed rule are offered:

- *Provide an Adequate Market Basket Update*: CMS is respectfully asked to use data better reflecting the input price inflation that hospitals have experienced and are projected to experience in 2025, and provide a forecast error adjustment for underestimating the update in prior years.

[6] https://www.beckershospitalreview.com/finance/5-hospital-closures-in-2024.html
[7] https://www.beckershospitalreview.com/finance/45-hospitals-closing-departments-or-ending-services.html
[8] https://www.beckershospitalreview.com/finance/10-hospitals-closing-departments-or-ending-services-4.html
[9] https://www.beckersasc.com/asc-news/what-services-are-hospitals-shuttering-2.html
[10] https://www.beckershospitalreview.com/finance/61-hospitals-closing-departments-or-ending-services.html
[11] https://calhospital.org/wp-content/uploads/2024/06/CHA-FFY-2025-IPPS-Proposed-Rule-Comment-Letter_FINAL-6.10.2024.pdf
[12] www.nber.org/system/files/working_papers/w26182/w26182.pdf
[13] https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf
[14] https://www.medpac.gov/recommendation/hospital-inpatient-and-outpatient-services-3/
[15] The 2.9% net MBU in the FY 2025 IPPS rule is also insufficient.

- *Expand Partial Hospitalization and Intensive Outpatient Programs*: CMS is respectfully asked to use all the measures at its disposal —including Section 1135 waivers available under the ongoing opioid public health emergency (PHE) to ensure that underserved beneficiaries have access to these services by allowing hospitals to expand partial hospitalization programs (PHPs) to off-campus, hospital-based locations that are paid appropriately.
- *Package Policies and Non-Opioid Treatment Alternatives:* CMS' proposals implementing Section 4135(a) and (b) of the Consolidated Appropriations Act (CAA), effective January 1, 2025, are supported. However, these provisions expire on December 31, 2027. While it is likely Congress will extend these provisions, CMS is asked to consider continuing separate payment for non-opioid pain treatment alternatives for services provided on or after January 1, 2028, by issuing a waiver under the opioid PHE which will likely still be ongoing.
- *Reconsider Changes to the Medicare and Medicaid Conditions of Participation (CoPs):* Hospitals are committed to improving maternal health outcomes and reducing disparities, but caution CMS against establishing new regulatory requirements that could threaten access to obstetrical services.

Our detailed comments on CMS' proposals follow.

Outpatient Market Basket Update

CMS proposes to increase the outpatient market basket update to the conversion factor, net of the total factor productivity (TFP), by 2.6%[16] in 2024. CMS finalized a net market basket update of 2.9%[17] in the Inpatient Prospective Payment System (IPPS). **Given that Section 1833(t)(3)(C)(iv) of the Act ties the OPPS market basket update to the IPPS update, it is anticipated the final rule OPPS market basket update will be the same as IPPS. A 2.9% net market basket update is wholly inadequate relative to the input cost inflation experienced by acute care hospitals.** Further, it is a continuation of a longstanding trend of market basket updates that have failed to keep pace with hospital input cost inflation.

As discussed in our comment letter[18] on the FFY 2025 proposed IPPS rule and reiterated here, the inadequate update is the result of methodological issues associated with the data CMS use to calculate the market basket update. **Further, given that Section 1833(t)(3)(C)(iv) of the Act ties the OPPS market basket update to the IPPS update, the agency is respectfully asked to re-calculate both the IPPS and OPPS final rule market basket update using data from the Medicare cost report or other more appropriate data source, and incorporate a forecast error adjustment. A more timely and accurate proxy for the cost increases that hospitals are facing and correcting CMS' previous market basket inaccuracies is necessary.** If CMS fails to provide an adequate payment update, inadequate payments will create access issues that negatively impact those who are already at risk for inequitable outcomes.

Given that the CY 2025 OPPS market basket update is tied to the IPPS final rule market basket update, CHA believes responding to CMS comments in the IPPS final rule is fully in the scope of comments submitted in response to the OPPS rule. In defining the outpatient department (OPD) fee schedule,

[16] This includes a market basket of 3.0% reduced 0.4 percentage points for total factor productivity.

[17] This includes a market basket of 3.4% reduced by 0.5 percentage points for total factor productivity.

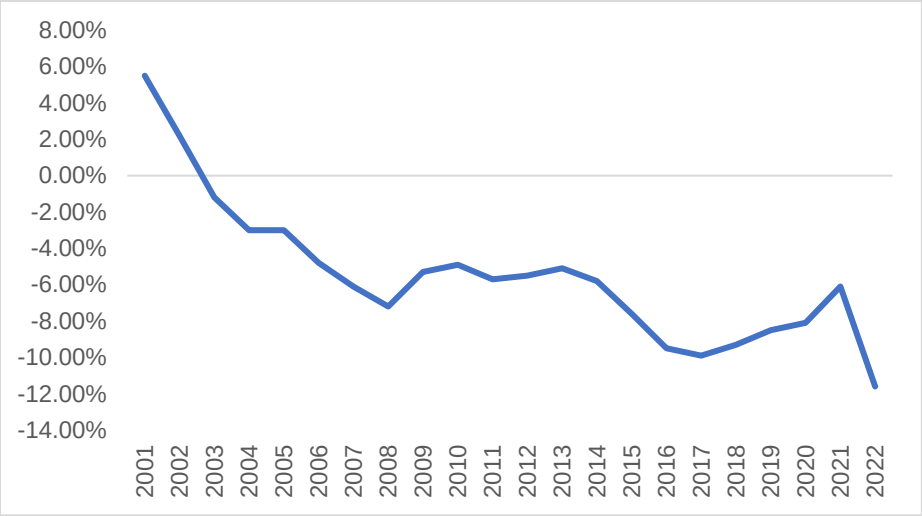
[18] https://calhospital.org/wp-content/uploads/2024/06/CHA-FFY-2025-IPPS-Proposed-Rule-Comment-Letter_FINAL-6.10.2024.pdf

Section 1833(t)(3)(C)(iv) specifically references "the market basket percentage increase applicable under section 1886(b)(3)(B)(iii)." Below, please find specific comments on the proposed market basket update.

Despite sustained cost reduction and efficiency efforts by hospitals, Medicare margins have declined over the last 20 years, as illustrated below. This is due to persistently inadequate Medicare MBUs. **Hospitals' financial situations are so precarious that MedPAC recommended to Congress that it increase IPPS and OPPS payments over current law to preserve access for the second year in a row (2024: MBU+1%; 2025: MBU+1.5%)[19,20].**

These were the only times in its history that MedPAC made such a recommendation for hospitals. Further, recognizing the precarious nature of safety net hospital finances, MedPAC again recommended that Congress increase payments to these anchor institutions (2024: $2B; 2025: $4B) to ensure access to care for Medicare beneficiaries who are most at risk for inequitable outcomes. It is not just Medicare beneficiaries' access to care and outcomes that are harmed when a hospital closes or is forced to cut unsustainable service lines. It is the entire community — particularly those at risk of inequitable outcomes — who suffer as a result of inadequate Medicare payment.

PPS Hospital Medicare Margin: 2001 to 2022[21,22,23,24]



This longstanding underpayment trend has been exacerbated by the labor dislocations and supply chain breakdowns that have continued since the COVID-19 pandemic. These challenges have increased baseline costs and are not offset by the limited increases in revenue hospitals have experienced. This has resulted in reduced margins that threaten hospitals' financial viability. As discussed above, California hospital expenses per adjusted discharge have increased 25% since 2019 (pre-pandemic). However, during this same period, Medicare base rates only increased 14.7%[25] to account for input price inflation.

[19] https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC.pdf
[20] https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf
[21] https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch3_SEC.pdf
[22] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch3_sec.pdf
[23] www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC.pdf
[24] https://www.medpac.gov/wp-content/uploads/2023/10/MedPAC-Hospital-payment-adequacy-Jan-2024.pdf
[25] CHA analysis of Medicare market basket update data

While CHA appreciates that CMS will refresh the market basket update in the final rule with more recent data, that refresh — as discussed above — is insufficient relative to input cost inflation. This is particularly true for clinical labor costs. CHA understands that the Bureau of Labor Statistics' Employment Cost Index (ECI) only captures the salary increases associated with employed staff, and thus does not capture extraordinary labor cost growth associated with hospitals' increased reliance on clinicians contracted through staffing agencies in response to labor shortages. While the COVID-19 PHE may be over, hospitals are still experiencing profound staffing shortages as a persistent aftereffect.

As employed nurses left the field due to burnout and early retirement, hospitals have been forced to use increased amounts of contract labor. Not only have the hours worked by contracted staff increased, the per-unit rate for these individuals has increased with demand for agency staff. California's hospitals, for example, spent more than double ($1.6 billion) on contract labor in 2023 than they did in 2019 even though patient days were only up 3%, ED visits were up 1%, and observation days were down 8% comparatively[26]. Additionally, the average length of stay is up 7%, which begins to explain the increased demand for clinical labor in light of flat utilization[27]. Further, while contract labor expense is declining relative to the peak of the COVID-19 pandemic, contract labor utilization will likely remain persistently elevated over 2019 levels for the foreseeable future due to a shortage of nurses and other clinicians. In a recent study, 610,388 nurses indicated their intent to leave the field by 2027[28].

Even before the application of the productivity adjustment, the MBU methodology — based on IGI data — failed to keep up with cost growth year over year as illustrated above. This is a direct result of the ECI exclusion of contract labor and explains much of the difference between hospitals' reported cost growth per discharge and the MBU. It is clear, based on rapidly rising labor costs, that CMS' current inputs for updating the MBU are ill-suited to the current environment. CMS itself acknowledges that setting payment updates during times of economic uncertainty can often result in large forecast errors[29]. While CMS believes forecast errors can go in either direction and will average close to zero over time, the most recent understatements of inflation have been large and to the disadvantage of hospitals at a time when many are facing insurmountable financial pressure, which is negatively impacting access to care[30,31,32,33]. **Therefore, CMS is again asked to identify more accurate data inputs and use its existing authority to calculate the final rule "base" (before additional adjustments) MBU with data that better reflect the rapidly increasing input prices facing hospitals.**

While acknowledging the considerable flaw in the ECI, CMS attempted to downplay concerns about it. In the FFY 2024 IPPS final rule the agency stated:

> *We note that the Medicare cost report data shows contract labor hours account for about 4 percent of total compensation hours (reflecting employed and contract labor staff) for IPPS hospitals in 2021. Therefore, while we acknowledge that the ECI measures only reflect price changes for employed staff, we believe that the ECI for hospital workers is accurately reflecting the price change*

[26] Current State of California Hospital Finances, Kaufman Hall, May 2024
[27] As CMS is aware, Medicare and most other payers do not pay for inpatient services using per diems or percent of charge payment models. Therefore, increased lengths of stay do not result in increased payments to compensate hospitals for the additional expense necessary to care for patients.
[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10074070/
[29] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/info.pdf
[30] https://www.beckershospitalreview.com/finance/10-hospitals-closing-departments-or-ending-services.html?
[31] https://www.beckershospitalreview.com/care-coordination/18-hospitals-scaling-back-care.html?
[32] https://www.beckershospitalreview.com/finance/19-hospital-closures-bankruptcies-in-2022.html?
[33] https://www.beckershospitalreview.com/finance/9-hospitals-have-closed-this-year-here-s-why.html

associated with the labor used to provide hospital care (as employed workers' hours account for 96 percent of hospital compensation hours).

Analysis of this issue using only hours worked and only focusing on the most recent data is incomplete. In 2019 — prior to the pandemic — clinical contract labor was 2.39% of total allowable hours worked[34]. Based on analysis of the 2022 data from the FFY 2026 preliminary wage index public use file, contract labor hours were 4.55% of total allowable hours worked. This implies that clinical contract labor as a percentage of total hours doubled during the pandemic. Further, CMS does not analyze the dollars associated with these hours. Analysis shows the average hourly wage for clinical contract labor in 2019 was $61.96 and increased 76% to $109.97 in 2022. In contrast, the fully loaded average hourly wage for employed staff in 2019 was $38.92 and is $46.07 in 2022, increasing just 18%. The spread between the average hourly rate for contract staff vs. employed staff in 2022 is $63. This is 2.74 times higher than it was pre-pandemic in 2019.

Nursing and other clinical staffing shortages have caused hospitals' reliance on contract labor to double, driving rates for clinical contract labor to increase by 76% prior to the pandemic. This has significantly increased expenditures on clinical contract labor when comparing 2019 (pre-pandemic) to 2022 (during the pandemic). In 2019, hospitals spent $12 billion on clinical contract labor, while in 2022 that amount grew to almost $42 billion. **As a percentage of total allowable salaries, contract labor increased from less than 4% in 2019 to over 11% in 2022. While contract labor only reflects 4% of allowable hours worked, it represents more than 11% of allowable salaries which is material to the calculation of the market basket update. Therefore, CMS is again asked to identify more accurate data inputs and use its existing authority to calculate the final rule "base" (before additional adjustments) MBU with data that better reflects the rapidly increasing input prices facing hospitals.**

A similar analysis was provided in comments to the CY 2024 OPPS and FFY 2025 IPPS proposed rules. Despite asserting that contract labor is immaterial in the 2024 IPPS final rule, and therefore this immateriality of hours absolves CMS of any need to make changes to the calculation of the MBU, the agency has not responded to this data in either the CY 2024 OPPS or FFY 2025 final rules. Contrary to CMS' position in the FFY 2024 IPPS final rule, this analysis shows that *contract labor is not an immaterial component of hospitals' cost structures* and must be accurately incorporated into any MBU. Therefore, CMS is again asked to use data that better incorporates changes in contract labor cost growth in the 2025 market basket update.

Specifically, CHA is again asking CMS to consider using the average growth rate in allowable Medicare costs per risk adjusted discharge for IPPS hospitals between FFY 2020 and FFY 2022 to calculate the FFY 2025 final rule market basket update (and therefore CY 2025 OPPS update). This growth rate will capture the increased cost of contract labor, unlike the ECI. Further, as discussed in CHA's FFY 2025 IPPS comment letter, using the growth rate in Medicare costs per risk adjusted discharge meets the statutory definition of "market basket percentage increase" as defined at section 1886(b)(3)(B)(iii) of the Act.

Given the unprecedented, continuing cost growth and the inadequate MBUs resulting from the use of the ECI, CMS is asked to use the weighted average growth rate in allowable Medicare costs per *risk adjusted discharge* for IPPS hospitals between FFY 2020 and FFY 2022 to calculate the FFY IPPS

[34] CHA analysis of Medicare cost report data

and CY OPPS 2025 final rule MBUs. This growth rate will capture the increased cost of contract labor, unlike the ECI. **The data for this calculation can be obtained from Worksheets D-1, Part II, Lines 48 and 49 and S-3, Part 1, Column 13 of Medicare cost report. Based on analysis, this would yield an unadjusted MBU of 4.91%[35]. A net MBU of 4.41%[36] for 2025 better reflects the actual input price inflation California's hospitals anticipate facing in the coming year, rather than the 2.6% net MBU proposed by CMS.** Further, this net market basket update is in line with MedPAC's recommendation to Congress of market basket update plus one percentage point (3.4%+1.5%-.5% = 4.4%).

Section 1833(t)(3)(C)(iv) of the Act defines OPD fee schedule increase to mean:

> *For purposes of this subparagraph, subject to paragraph (17)[37] and subparagraph (F)[38] of this paragraph the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii)[39] to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.*

By reference to section 1886(b)(3)(B)(iii), Congress aligned the outpatient market basket update with the inpatient market basket update. CHA believes that the Medicare cost report data described above meet the statutory requirement for the inpatient market basket update and, therefore by reference, the outpatient market basket update. These data capture all allowable costs, including employed and contract personnel costs and exclude non-operating costs that comprise inpatient and outpatient hospital services. Given that these data comprise all the costs necessary to deliver hospital care, they represent the "appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services …" as described in section 1886(b)(3)(B)(iii) necessary to provide hospital care to Medicare beneficiaries. CHA again believes these data are a more accurate projection of the cost inflation anticipated by hospitals during CY 2025 than the forecast IGI data used in the IPPS final rule, and the OPPS proposed rule. Therefore, CHA respectfully asks the agency to reconsider using the percentage risk adjusted growth in cost per discharge from the Medicare cost report as the market basket update for the FFY 2025 IPPS and, therefore by reference, the CY 2025 OPPS final rules.

[35] CHA analysis of Medicare cost report data
[36] 4.41% = (4.91% MBU - 0.5% ACA-mandated productivity factor)
[37] Section of the Act that adjusts the market-based update based on quality reporting requirements
[38] Section of the Act that implements the productivity adjustment
[39] Inpatient market basket update. Section 1886(b)(3)(B)(iii) of the Act defines the "market basket percentage increase" to mean "… with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year."

Market Basket Update – Forecast Error Adjustment

In prior comment letters, many stakeholders expressed concern that the market basket update proposed (and subsequently finalized) in a given year was inadequate relative to input price inflation[40,41,42,43,44]. Unfortunately, as discussed above, those concerns continue to be realized because of the impact that a unique event — the COVID-19 PHE — had on hospital labor, supply, and pharmaceutical expenses. In the FFY 2025 IPPS final rule, CMS again acknowledges this issue and fails to address it.

For the last three years for which data are available, CMS' finalized market basket was lower than what it should have been by 0.6% (FFY 2021), 3.0% (FFY2022), and 0.7% (FFY 2023).

Medicare IPPS Market Basket Update Forecast Error 2021-2023

FFY	Final Rule Projected MBU	MBU Based on Actual Data	IPPS Under Reimbursement
2021	2.4	3.0	-0.6
2022	2.7	5.7	-3.0
2023	4.1	4.8	-0.7
Total	N/A	N/A	-4.3

In response requests for a one-time forecast error adjustment in the FFY 2025 IPPS final rule, CMS notes:

> *While the projected IPPS hospital market basket updates have been under forecast (actual increases less forecasted increases were positive) for this most recent period, over longer periods the forecasts have generally averaged close to the historical measures (for instance, from FY 2014 through FY 2023 the cumulative forecast error was 0.0 percentage point). CMS will continue to monitor the methods associated with the market basket forecasts to ensure there are not underlying systematic issues in the forecasting approach.*
>
> *We note that the under forecast of the IPPS market basket increase in the recent time period was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE. However, an analysis of the forecast error of the IPPS market basket over a longer period of time shows the forecast error has been both positive and negative. Only considering the forecast error for years when the final hospital market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error, in particular the numerous years that providers benefited from the forecast error.*

First, CMS' response in the FFY 2025 IPPS final rule (as in prior years) suggests that the MBU that was used during the prior 10 years was accurately calculated. As discussed above, this is a point hospitals

[40] https://calhospital.org/cha-issues-draft-comments-on-opps-proposed-rule/
[41] https://calhospital.org/wp-content/uploads/2023/06/FFY-2022-2023-IPPS-Comment-Letters-Combined.pdf
[42] https://calhospital.org/cha-issues-draft-comments-on-ipps-proposed-rule/
[43] https://calhospital.org/wp-content/uploads/2023/09/CHA-CY-2024-OPPS-Proposed-Rule-Comment-Letter-091123-Final.pdf
[44] https://calhospital.org/wp-content/uploads/2024/06/CHA-FFY-2025-IPPS-Proposed-Rule-Comment-Letter_FINAL-6.10.2024.pdf

continue to contest given the exclusion of a labor price proxy that accurately captures changes in contract labor utilization.

Second, CMS' analysis of the longer-term trend in the FY 2025 IPPS final rule does not incorporate the 0.5% threshold used for the SNF PPS forecast error adjustment as it did in its response in the FFY 2024 IPPS final rule. In looking over the most recent 10-year window and applying this threshold — to be consistent with CMS' previous comments and arguments on this subject —only seven years exceed the 0.5 percentage point threshold (three underestimated, four overestimated). While there are more years where an overestimation occurs, the cumulative impact for these seven years is a -0.8% underestimation of the MBU and there is a clear trend beginning in 2021 that poses a risk to Medicare beneficiary access to hospital services.

Finally, CMS notes in the FFY 2025 IPPS final rule that the recent trend is due to "unanticipated inflationary pressures." CHA fully agrees with the agency's analysis of the driver of the forecast errors. This analysis supports the argument for a one-time forecast error adjustment to correct for the "unanticipated inflationary pressures."

CMS is again asked to apply a *one-time* 4.3 percentage point "forecast error adjustment" to the FY and CY 2025 MBU. This update is necessary to account for the unprecedented hospital input price inflation — particularly for labor costs — stemming from the COVID-19 pandemic in the years 2021-2023. This inflation — as discussed above — was not captured in the MBUs from 2021 through 2023 as the input proxy used to account for labor costs does not include contract labor, which saw significant growth during these years. For these years, a unique convergence of factors resulted in hospitals being significantly underpaid for services provided to Medicare beneficiaries. If this underpayment is allowed to persist, it will harm access for Medicare beneficiaries and contribute to the further loss of labor and delivery services in communities most at risk for inequitable maternal outcomes.

In summary, CMS is requested to provide a net MBU of 8.71% in the final rule. This is based on an update of 4.91% that appropriately reflects hospital input price growth — including contract labor — and a forecast error adjustment of 4.3% to correct for prior years' gross underpayment, less the anticipated OPPS final rule 0.5% productivity reduction.

Partial Hospitalization and Intensive Outpatient Programs – Payment Rates in Non-Excepted Off-Campus Provider-Based Departments (PBDs)

For non-excepted partial hospitalization programs (PHPs) and intensive outpatient programs (IOPs), CMS uses the community mental health center (CMHC) rates for PHP and IOP as the payment rates for PHP and IOP services furnished by non-excepted off-campus hospital outpatient departments; it would use the 3-services rate or the 4-or-more-services rate based on how many services the non-exempted off-campus PBD furnished on that day.

Given the ongoing opioid public health emergency (PHE)[45], the need for increased access to mental health services and substance use disorder treatment programs has never been greater. A recent Office of Inspector General report confirms that a lack of access to care is preventing Medicare beneficiaries with substance use disorders from receiving medication to treat these disorders. Of the 1.1 million Medicare beneficiaries with opioid use disorder (OUD), just 210,771 — less than 20% — received

[45] https://aspr.hhs.gov/legal/PHE/Pages/Opioid-25June2024.aspx

medication for this disorder in 2022[46]. This is completely unacceptable given that addressing substance use disorder is a key priority for this administration. CMS' payment policies —as discussed below —are creating barriers to access OUD treatment.

A California hospital that evaluated starting new, off-campus PHPs to meet the growing need for intensive outpatient mental health services reports that doing so under the CMHC rate is not financially viable. However, if these off-campus, provider-based PHPs were paid as what they are — an off-campus, hospital outpatient department (HOPD) — they would be financially viable. This financial viability would allow hospitals to expand access to desperately needed outpatient intensive mental health services — including substance use disorder treatment — for Medicare beneficiaries. Further expanding outpatient capacity would allow for some individuals who are currently receiving inpatient treatment to receive care in a more appropriate setting. And it would allow more Medicare beneficiaries to have access to medication for opioid use disorder. This would also improve access to inpatient psychiatric services, which — as CMS is aware — are also in short supply.

CMS has previously used its Section 1135 authority to waive certain provider-based requirements in response to the COVID-19 PHE to allow for temporary expansions of provider-based locations[47]. Further, CMS has also used its 1135 waiver authority to allow a hospital-based PHP to relocate part of its exempted provider-based department to a new off-campus location while maintaining the original provider-based location[48]. CMS took these steps to improve access to care during the COVID-19 PHE. Given the ongoing opioid PHE and CMS' reiteration that PHP and IOP services can be used to treat substance use disorder, CHA believes there is a compelling argument to be made for using CMS' waiver authority under the opioid PHE to expand access to these desperately needed services.

Therefore, it is respectfully asked that CMS use its Section 1135 waiver authority to provide similar flexibilities to off-campus hospital-based PHP and IOP programs during the ongoing opioid PHE. Specifically, CMS is asked to continue waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 and the provider-based department requirements at 42 CFR §413.65 to allow provider-based PHP programs to establish and operate, as part of the hospital, any location meeting the conditions of participation that apply.

Further, CMS is asked to continue allowing excepted, provider-based PHPs to relocate part of their excepted provider-based PHP to a new off-campus location while maintaining the original location. CHA believes providing this flexibility under the opioid PHE is necessary to ensure there is sufficient access to provide outpatient substance use disorder treatment and intensive mental health care services to all Medicare beneficiaries who need them. As an example of the impact that a Section 1135 waiver of the site-neutral requirements would have, it would allow a California hospital to expand its outpatient behavioral health capacity by 30%. This health system anticipates that half of the new patients served through this PHP would be Medicare beneficiaries.

Invoice Drug Pricing Proposal for CY 2026

Beginning with CY 2026, CMS proposes to adopt an invoice pricing policy to establish payment rates for drugs and biologicals without pricing data. Specifically, CMS proposes that, for separately payable drugs

[46] https://oig.hhs.gov/oei/reports/OEI-02-23-00250.pdf
[47] https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf
[48] 85 FR 27561 https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf

or biologicals for which CMS does not provide a payment rate in Addendum B, Medicare Administrative Contractors would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions.

Hospitals are concerned that a process requiring providers to report a specific invoice amount would be inefficient and lead to providers forgoing reimbursement. Tracking a specific invoice amount for a drug, the price of which can change frequently, would be challenging and resource intensive for providers — particularly with the significantly growing number of drugs for which pricing information and claims data are not available. **CMS should instead require manufacturers to report additional pricing information that enables CMS to create an average sales price (ASP), thereby eliminating or substantially reducing the need for providers to report invoice amounts to receive appropriate reimbursement.**

Separate Payment for High-Cost Diagnostic Radiopharmaceuticals

CMS proposes paying separately for diagnostic radiopharmaceuticals with per-day costs above a threshold of $630. It also proposes to update the $630 threshold in CY 2026 and subsequent years by the Producer Price Index for Pharmaceutical Preparations. Finally, CMS proposes to pay for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost derived from OPPS claims. **California's hospitals thank CMS for this thoughtful proposal and encourage the agency to finalize it as proposed.**

Add-On Payment for Radiopharmaceutical Technetium-99m (Tc-99m)

For CY 2025, there is an add-on payment that applies to radiopharmaceuticals that use Tc-99m produced without use of highly enriched uranium (HEU). CMS proposes that for CY 2026 it would replace the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99. **California's hospitals thank CMS for this thoughtful proposal and encourage the agency to finalize it as proposed.**

Payment for HIV Pre-Exposure Prophylaxis (PrEP) in HOPDs

For CY 2025, CMS proposes to cover and pay for HIV PrEP drugs and related services under the OPPS, if covered by CMS through a National Coverage Determination. This proposed coverage would include coverage for the HIV PrEP drugs, drug administration, HIV and hepatitis B screening, and individual counseling performed by physicians or certain other health care practitioners. **California's hospitals thank CMS for this thoughtful proposal and support it. However, CHA encourages the agency to take the required step of issuing a national coverage determination immediately, as described in the proposed rule.**

Proposed Changes to the Inpatient Only (IPO) List

For CY 2025, CMS proposes to add three services (for which codes were newly created by the American Medical Association CPT Editorial Panel for CY 2025) to the IPO list. The agency does not propose to remove any services from the IPO list. **This is a thoughtful proposal and the agency should finalize it as proposed.**

Access to Non-Opioid Treatments for Pain Relief

As directed by the Consolidated Appropriations Act of 2023, CMS proposes to implement temporary additional payments for specific non-opioid treatments for pain relief dispensed in the HOPD and

ambulatory surgical center (ASC) settings from Jan. 1, 2025, through Dec. 31, 2027. CMS proposes a calculation methodology to determine the payment limitation as required by statute. The agency proposes seven drugs and one device that would qualify for these payments, which would be paid separately.

California's hospitals appreciate the agency's continued work on the negative impact packaging policies have on the use of non-opioid treatment alternatives in hospital outpatient settings. The current packaging of non-opioid alternatives continues to present a barrier to their broader use and, therefore, these treatments should be paid for separately. CMS' proposals are supported. While it is likely Congress will extend these policies beyond Dec. 31, 2027, there is concern the sunsetting of this provision without extension could further fuel the opioid epidemic. CMS should explore whether an extension of this policy could be achieved by issuing a waiver under the opioid public health emergency (PHE) declared on Oct. 26, 2017, and is likely to continue well beyond Dec. 31, 2027.

Comprehensive Ambulatory Payment Classifications (C-APC)

CMS proposes excluding specific gene therapies from the C-APC policy for 2025 only. If Healthcare Common Procedure Coding System (HCPCS) codes for these cell and gene therapies are on the same claim as an HCPCS code that is subject to the C-APC policy, CMS proposes paying separately for the cell and gene therapy. The rationale underlying CMS' proposal is that when these products are administered, they are the primary treatment for a patient and are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services. **CHA supports the proposal to exclude certain cell and gene therapies from packaging in C-APCs. It is likely this policy change will expand access to these high-cost therapies by ensuring Medicare payments more accurately reimburse providers. This proposal should be extended through 2027 to gather data to study the impact on access to these lifesaving therapies.**

Changes to the Review Timeframes for the Hospital Outpatient Department Prior Authorization Process

CMS proposes changing the current review timeframe for provisionally affirmed or non-affirmed standard review requests from 10 business days to seven calendar days, so it aligns with the recently finalized CMS Interoperability and Prior Authorization rule. **CHA supports aligning this process with the recently finalized CMS Interoperability and Prior Authorization Rule[49].**

CMS is still considering the impact of aligning the expedited review decision timeframe with the expedited review decision timeframe in the CMS Interoperability and Prior Authorization final rule because, depending on when the expedited request is submitted, it may take longer for an HOPD provider to receive a decision using the 72-hour timeframe than the current expedited timeframe of two business days. **CMS should adopt a "lesser of" standard that requires Medicare Administrative Contractors to review prior authorization requests under the timeframe that resulted in the fastest turnaround time, depending on when the request was submitted.**

[49] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP-Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program, CMS–0057–F

Also, CMS should revisit the timeframes finalized in the Interoperability and Prior Authorization rule. The finalized reductions in deadlines for payers to respond to standard requests are a small step in the right direction. However, even these reduced deadlines will continue to delay access to necessary services and transfers to more appropriate care settings.

CMS is again[50] urged to consider a more stringent deadline for payers to respond to urgent requests if a provider indicates that the standard time frame could jeopardize the patient's life, health, or ability to attain, maintain, or regain maximum function. Unnecessary delays in the prior authorization process have significant impacts on patient experience and outcomes. A major contributor to these delays is a lack of timely responses to prior authorization requests. **CMS should require plans (including Medicare Administrative Contractors) to deliver prior authorization responses within 72 hours for standard, non-urgent services, and 24 hours for urgent services. This will ensure patients are not forced to wait longer than necessary for care.**

Request for Information (RFI) Related to Separate Payment for Domestically Manufactured PPE

In the proposed rule, CMS notes that under the 2023 OPPS/ASC final rule, implemented payment adjustments under the OPPS and IPPS should offset the marginal costs hospitals face in obtaining domestically made National Institute for Occupational Safety and Health (NIOSH)-approved and FDA-certified surgical N95 respirators. The agency expresses concern that the use of the payment adjustments has been limited (cost reporting periods beginning on or after Jan. 1, 2023). Market data suggest that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made.

Payment adjustments have been limited as this policy suffers from many of the issues that were raised in the responses[51] to the RFI included in the FFY 2023 IPPS proposed rule.

CMS' efforts to provide payments to hospitals to compensate them for the additional, incremental cost of domestically produced surgical N95s are strongly supported. Hospitals' reliance on imported PPE — including N95s — and the resulting supply chain failures that occurred during the pandemic are a direct result of inadequate Medicare payment updates in both the IPPS and OPPS. The high-labor component of hospital care cannot be automated or offshored. Therefore, in the face of market basket updates that do not cover the increasing cost to deliver care to Medicare beneficiaries, hospitals have been forced to bind themselves to brittle supply chains for lower-cost products from non-domestic manufacturers to generate the savings necessary to ensure solvency and continue providing care in their communities.

CMS should adopt a broad payment policy that covers hospitals' cost of domestically produced PPE. Not only will this improve supply chain resilience and therefore national security but will also reduce carbon emissions by shortening the supply chain and shifting manufacturing from countries that have less stringent environmental protections to the United States.

[50] https://calhospital.org/wp-content/uploads/2023/03/CHA-Comment-Letter-Prior-Authorization-and-Interoperability-Proposed-Rule-031323-FINAL.pdf
[51] https://calhospital.org/wp-content/uploads/2022/06/CHA-Comments-FFY-2023-IPPS-Proposed-Rule-Comment-Letter-061722-Final.pdf

CMS should expand its existing policy to cover non-surgical N95 respirators. It is difficult for hospitals to determine whether N95s were used for surgical or non-surgical purposes. Second, California's hospitals report that during the pandemic, they experienced shortages of many types of PPE. Common shortages were of surgical masks, isolation gowns, surgical gowns, nitrile gloves, bouffant caps, shoe covers, and face shields. By focusing on only N95s, CMS is presuming that the next pandemic will be driven by a pathogen whose primary transmission mechanism is respiratory. This may not be the case and if the agency only focuses on N95s, hospitals could run short of other needed supplies to protect patients, caregivers, and the general population.

CMS should apply its policy of reimbursing hospitals for the incremental cost of domestically produced PPE to a broader set of items necessary to respond to any public health emergency. This will have the beneficial effect of reducing the carbon footprint of the health care supply chain.

As noted in the RFI discussion, one of the challenges hospitals face when attempting to claim reimbursement for domestically produced surgical N95s is determining which are "manufactured domestically." **For N95s and any other items CMS expands this policy to cover, CMS should provide a list of items that meet the domestic manufacturing requirements necessary for hospitals to claim the incremental reimbursement to offset the increased cost of purchasing domestically produced PPE.** For items that do not appear on this list, but those that hospitals believe are domestically manufactured, CMS should establish an ongoing means to enable manufacturers or hospitals to submit items for certification and addition.

CMS currently only pays for Medicare FFS' share of the domestically produced surgical N95s. Medicare FFS revenue only accounts for 28%[52] of California hospitals' total net revenue. Using this as a proxy for volume of surgical N95s consumed, CMS' payment for only the Medicare FFS share — in light of Medicare's ongoing underpayment issues — still leaves the incremental cost of 72% of consumed surgical N95s unreimbursed (assuming they are also domestically produced). Not only is it impractical for hospitals to attempt to use domestically produced surgical N95s (or any other PPE included in this policy at a future date) on only Medicare FFS patients, but it is also counterproductive to CMS' policy goals. Even if every hospital used domestically produced PPE for its Medicare FFS population (setting aside whether that is possible), demand for N95s (or other PPE) would not support a wholly domestic supply chain, let alone one whose prices are competitive with PPE produced offshore.

The incremental add-on payment will be based in some manner on the amount of PPE consumed by a hospital while providing care to Medicare beneficiaries in the current fiscal year. However, this is not what CMS is "buying" by making this payment. Instead, this payment is purchasing the option of having a secure, domestic supply of PPE available to protect Medicare beneficiaries (and members of the community served by the hospital) at a future date when the next PHE occurs. **CMS is again urged to expand the incremental payment to cover the cost of domestically produced PPE to care for all patients, not just Medicare patients, over the course of a hospital's fiscal year. This will create the demand necessary to sustain domestic manufacturing capability, ensuring that PPE will be available for caregivers to protect Medicare beneficiaries during a future pandemic.** If CMS does not have the statutory authority to do this, the agency should work with Congress to create this flexibility via Medicare statute.

[52] CHA analysis of 2020 California Department of Health Care Access and Information data

Finally, CMS asks if instead of calculating a hospital-specific payment adjustment, the agency should provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. CMS should explore how it would operationalize both providing a national standard unit cost differential and allowing a hospital to calculate its own differential. Some hospitals have the systems and resources to calculate a hospital-specific adjustment, while others may not have that capability. Allowing a hospital to choose the methodology will ensure that those unable to calculate a hospital-specific incremental cost are not precluded from being reimbursed for the incremental cost of using domestically manufactured surgical N95s (or other PPE).

Periodic In-Person Visits for Mental Health Visits Furnished by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPPS final rule, CMS established three HCPCS C-codes for mental health services provided by hospital staff to beneficiaries in their homes through communications technology. Consistent with statutory requirements that apply to the Medicare telehealth benefit under the physician fee schedule (PFS), CMS requires an in-person visit within six months prior to or after the remote mental health service, and subsequent in-person visits annually. Congress delayed requirements for periodic in-person visits though Dec. 31, 2024, in alignment with policies extending COVID-19 PHE telehealth flexibilities.

Absent additional Congressional action, CMS proposes to reinstate, beginning Jan. 1, 2025, the requirement that a patient have an in-person visit six months prior to the remote mental health service, and at least one in-person visit within 12 months of the remote visit. **Hospitals support CMS' intention to revise this proposal should Congress extend telehealth flexibilities in future legislation and support policies that would permanently expand access to telehealth services, including the removal of in-person visit requirements for remote mental health services.**

Telehealth is critical to overcoming longstanding obstacles to mental health treatment including stigma and transportation challenges. Telehealth also alleviates persistent workforce challenges, especially among prescribing professionals in underserved areas. As stated in the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA)[53] guidance on providing telehealth services for serious mental illness and substance use disorders, "requiring in-person visits can create a barrier to seeking or accessing care, so the decision to have in-person visits should be made in collaboration with the client." In-person requirements for remote mental health services result in unnecessary obstacles to care for the many individuals who demonstrate they do not need or prefer in-person services and are likely to restrict access to these critical services for the most vulnerable patients with unmet health-related social needs (HRSNs).

Hospitals appreciate that CMS has established exceptions to the in-person requirements if the patient and practitioner agree the risks and burdens associated with an in-person service outweigh the benefits and appropriately document these decisions in the medical record. **However, such a policy should be the rule, not the exception. Patients and their clinicians should make determinations about how, where, and when care is provided, rather than arbitrary regulatory requirements.**

[53] https://store.samhsa.gov/sites/default/files/pep21-06-02-001.pdf

Outpatient Therapy, Diabetes Self-Management Training, and Medical Nutrition Therapy

During the COVID-19 public health emergency, CMS allowed outpatient therapy services, diabetes self-management training (DSMT), and medical nutrition therapy (MNT) to be furnished by hospital staff to patients in their homes through the use of real-time interactive telecommunications technology. CMS also added outpatient therapy, DSMT, and MNT to the list of telehealth services that could be paid under the PFS when provided by an eligible practitioner or supplier. In addition, physical and occupational therapists and speech language pathologists were temporarily designated as "eligible telehealth distant site practitioners" under the PFS via COVID-19 waivers. CMS extended these flexibilities beyond the public health emergency through Dec. 31, 2024, under the Consolidated Appropriations Act (CAA) of 2023. CMS proposes that beginning Jan. 1, 2025, hospital-based therapists and staff will no longer be able to furnish these services remotely in a patient's home. Hospitals appreciate that CMS intends to revisit this policy should Congress act to extend telehealth flexibilities beyond 2024.

CHA understands the statutory limitations of Medicare telehealth policies and encourages CMS to consider policies to expand access to hospital-based remote therapy services in the future. While telehealth will never be a replacement for all in-person therapy services, the flexibilities available for the duration of the COVID-19 PHE demonstrated that remote services could expand access to physical, occupational, and speech therapies, and — in some cases — enhanced these services. For example, telehealth can improve an assessment of a patient's functional status in their home environment. **CMS should work with Congress to permanently expand access to remote hospital-based therapy services.**

Virtual Supervision of Cardiac and Pulmonary Rehabilitation Services

Under current OPPS policy, cardiac (CR), intensive cardiac (ICR), and pulmonary rehabilitation (PR) services must be provided under the direct supervision of a physician. The CAA of 2023 extended the authority for virtual supervision of these services furnished by physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists beginning Jan. 1, 2024. For the duration of the COVID-19 PHE, CMS adopted that — for the purposes of direct supervision — a physician can be present *virtually* through audio/video real-time communications technology for PR, CR, and ICR services when the use of technology reduces exposure risks for the patient or the provider; this flexibility was extended through CY 2024 by the CAA of 2023.

CMS proposes to extend this flexibility and would allow direct supervision of CR, ICR, and PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) under the OPPS through Dec. 31, 2025. In the CY 2025 PFS proposed rule, CMS proposes to align this policy to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through Dec. 31, 2025. **CHA supports these proposals and urges CMS to consider making these flexibilities permanent.**

Hospital Outpatient Quality Reporting Program

Proposed Hospital Commitment to Health Equity Measure

CMS proposes to add an attestation-based structural measure — the Hospital Commitment to Health Equity (HCHE) — beginning with the CY 2025 reporting period/CY 2027 payment determination. The HCHE measure requires a hospital to attest to its commitment to health equity across five domains (equity in a strategic priority, data collection, data analysis, quality improvement, and leadership

engagement), with multiple attestation statements under each domain. Hospitals must attest affirmatively to each statement under a domain to receive credit, and scores of 0 to 5 are publicly reported.

Hospitals are already reporting this measure under the hospital inpatient quality reporting (IQR) program. Because a hospital outpatient department is part of the hospital, it is unclear what value there is in reporting this measure for both the IQR and outpatient quality reporting (OQR) programs. For example, an outpatient hospital site must have the same governing body as the main hospital, so any attestations made under the leadership engagement domain would be the same under IQR and OQR reporting. Hospital outpatient departments must demonstrate clinical and financial integration with the inpatient hospital services and a hospital's overall strategic plans — including those to address health equity — will be aligned under both settings. **CMS should reconsider its proposal to include the HCHE separately as a measure in the OQR program and instead only require reporting under the IQR program.**

Proposed Screening for Social Drivers of Health (SDOH) and Screen Positive Rate for SDOH Measures

CMS proposes to add two measures — Screening for SDOH and Screen Positive Rate for SDOH — as a voluntary OQR measure beginning with CY 2025 and as a mandatory measure beginning CY 2026. The measures require hospitals to report on the percentage of patients assessed for health-related social needs across five domains (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety), and then report on the percentage of patients in each domain who screened positive for an HRSN. While the Screening for SDOH measure enables identification of individuals with HRSNs, the Screen Positive Rate for SDOH measure captures the extent of such needs and estimates the impact of individual-level HRSNs on health care utilization.

Both of these measures are now required as part of the IQR program, and because there may be differences in the inpatient and outpatient patient populations, hospitals support adding these measures to the OQR program. The collection of comprehensive and accurate data on HRSNs is essential to understanding how the social needs of patients contribute to disparities in our health care system. Screening patients for this information is an important step that has assisted hospitals in shaping their strategic health equity goals.

It is appreciated that CMS will allow for one year of voluntary reporting to support implementation in the outpatient setting and continues to give hospitals the flexibility in utilizing a screening tool of choice. Hospitals also appreciate the clarification that hospital outpatient department staff could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, instead of re-screening a patient within the reporting period. CHA also supports CMS' proposal to allow hospitals to use SDOH screening information that is recorded in the electronic health record (EHR) in another health setting during the same reporting period to report data on the measures.

Proposed Information Transfer Patient Reported Outcome-Based Performance Measure (PRO-PM)

CMS proposes to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM) beginning with voluntary reporting for the CY 2026 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period. The measure is intended to assess the level of clear, personalized recovery information provided to patients 18 years of

age or older who had surgery or a procedure in a hospital outpatient setting. Data would be collected via a web-based survey administered to patients two to seven days after the surgery or procedure and would consist of nine items across three domains.

Hospitals and health systems value the patient perspective on their care and are increasingly utilizing patient experience data to improve quality and make care safer and more equitable. PRO-PMs are a newer measure type with important potential to capture whether patients are regaining function and activities that matter in their daily lives. It is appreciated that CMS proposes an initial voluntary reporting period, as hospitals and patients adapt to the processes associated with successful reporting on these measures. **CMS should use voluntary reporting periods to evaluate patient and provider perspectives on survey administration and analyze voluntarily reported data prior to finalizing a mandatory reporting period.**

CMS should also consider significant concerns about the impacts of survey fatigue on patient response rates and the data that are reported. The proposed Information Transfer PRO-PM does not exclude patients who receive other surveys. Patients undergoing a joint procedure could be asked to respond to multiple PRO-PM surveys with the recent adoption of Patient-Reported Outcome-based Performance Measure Following an Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in both the inpatient and outpatient settings. The same patient could also conceivably receive multiple Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, both for the facility participating voluntarily in the Outpatient and Ambulatory CAHPS and individual CAHPS surveys for clinicians involved in the procedure. Multiple surveys administered across multiple timelines for the same procedure will lead to confusion about what aspect of care is being assessed, and could cause frustration for patients, impacting the quality of the data that is provided.

Proposed Removal of Measures

CMS proposes to remove two measures beginning with the CY 2025 reporting period: the MRI Lumbar Spine for Low Back Pain Measure and Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure. CHA appreciates that CMS continually assesses its quality measures and is proposing to remove these measures that demonstrate limited ability to improve the quality of care for patients. **CHA supports the removal of these measures.**

Hospital IQR Program Hospital-Wide Hybrid All-Cause Readmission and Standardized Mortality Measures

CMS previously finalized two hybrid measures in the hospital IQR program, with mandatory reporting beginning with the FFY 2026 payment determination — based on performance data from July 1, 2023, through June 30, 2024 — and data submission required by Sept. 30, 2024. These measures are hybrid because they use data from multiple sources — including hospital EHR data and Medicare claims data — and linking variables must be reported to connect those sources for accurate reporting and measurement. In response to hospital concerns raised during the voluntary reporting periods and among hospitals working in good faith to report for the FFY 2026 payment determination, CMS proposes to extend voluntary submission of the required core clinical data elements (CCDEs) and linking variables for an additional year. CMS proposes that reporting of this data would be required for the FFY 2027 payment determination.

California hospitals support this proposal and urge CMS to quickly issue guidance — prior to the final rule — to clarify that hospitals are not required to submit this data for FFY 2026. The final rule will not

be issued until on or around Nov. 1, 2024, beyond the current data reporting deadline. CMS should also improve the technical assistance available to hospitals to ensure successful reporting and linkage of the CCDEs with claims data in future reporting periods.

Health and Safety Standards for Obstetrical Services

California hospitals are dedicated to providing high quality and equitable care to pregnant and birthing patients. In 2021, 98% of the approximately 420,000 births in California occurred in a hospital, accounting for about 1 in 10 births nationally[54] . In many communities, hospitals are the only provider of labor and delivery services and in all communities serve as the only option for emergency obstetrical services. Maintaining access to hospital-based maternal health care is essential to improving maternal health outcomes. However, a combination of factors including declining birth rates, shortages of physicians, nurses, and other clinical professionals, and low Medi-Cal reimbursements are converging to create a predicament where some hospitals have no choice but to close maternity care services. Since 2012, at least 46 labor and delivery units have been closed in California (approximately 60% of the closures have taken place in just the last three years, consistent with nationwide trends).

There are concerns that if faced with the costs associated with increasing regulatory compliance — such as with the new conditions of participation (CoPs) proposed by CMS in this rule — access to these services will further be reduced, as hospitals on the brink could be forced to shutter labor and delivery units. While the CoPs are important regulatory tools establishing baseline standards for quality and safety, they will not address the complex factors contributing to poor maternal outcomes, most of which occur outside of hospital walls. **Hospitals stand ready to work with CMS and other health care stakeholders to improve maternal health and urge CMS to focus its resources on a comprehensive approach that addresses the main drivers of maternal morbidity and mortality in the periods before, during, and after pregnancy.**

For hospitals and critical access hospitals (CAHs) that offer obstetric services, CMS proposes new CoPs that encompass organization, staffing, delivery of care and staff training, as well as updates to the CoPs for quality assessment and performance improvement (QAPI) requirements. CMS also proposes to update CoPs for hospitals and CAHs that offer emergency services, and further proposes updates to the discharge planning CoPs for all hospitals. These substantial changes will require hospitals to dedicate significant resources to compliance, including documentation, purchasing new equipment, and staff education and training, diverting resources from direct patient care and potentially reducing access to labor and delivery services.

Hospitals urge CMS to clarify a timeline for expected compliance with the proposed changes. If it is CMS' intent that hospitals comply with finalized changes to the CoPs by Jan. 1, 2025, a significant period of enforcement discretion would be necessary for hospitals to develop the written protocols and procedures, purchase new equipment, and educate and train staff. Similarly, CMS will need considerable time to develop guidance and train surveyors on new requirements. While hospitals urge CMS to reconsider its approach of creating new regulatory requirements, CMS should consider the following comments and questions should it finalize any of its proposals.

Organization, Staffing, and Delivery of Services

CMS proposes to add two new sections (§§482.59 and 485.649) to its CoPs regulations for hospitals and

[54] https://www.chcf.org/wp-content/uploads/2023/11/MaternityCareAlmanac2023.pdf

CAHs offering obstetrical services outside of an emergency department. This includes a proposal to establish minimum standards for equipment. Specifically, labor and delivery room suites would be required to have a call-in system, cardiac monitor, and fetal doppler or monitor. CMS further proposes to require additional equipment, supplies, and medication necessary to treat emergency cases, which would have to be kept on the premises and be readily available to treat emergencies. While not prescriptive, CMS provides examples including resuscitators, defibrillators, oxygen, intravenous therapy supplies, suction machines, analgesics, local anesthetics, anti-arrhythmics, antihypertensives, antiepileptics, and anticoagulants.

In considering the proposed rule, hospitals raised several questions about the equipment that a hospital would be required to maintain as "available" to labor and delivery suites. For example, a "call-in system" could mean any number of communications-based systems that are used throughout the hospital to call for assistance when needed. Hospitals also raised concerns about requiring certain equipment in each labor and delivery room. One rural hospital reported that it has several beds designated as available for labor and delivery services, however, it has only three fetal monitors, one of which is on a cart and can be wheeled to a room if necessary. If required to meet a CoP that requires one fetal monitor for each labor and delivery room, the hospital would have to limit the number of available beds, arbitrarily reducing access to these services in that community.

QAPI Program

CMS proposes to require a hospital or CAH that offers obstetrical services to use its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. Hospitals would be required to analyze data and quality indicators collected for the QAPI program to improve patient health outcomes and disparities for obstetric patients, conducting at least one quality performance project on this population annually. Hospitals in states like California would also be required to incorporate data and recommendations from the state's maternal mortality review committee (MMRC) into the hospital's QAPI program.

Absent these regulatory requirements, California's hospitals have led the way in working with the state MMRC and perinatal collaborative — the California Maternal Quality Care Collaborative (CMQCC) — to improve maternal health outcomes in the state. Since CMQCC's inception, California saw maternal mortality decline by 65 percent between 2006 and 2016, while the national maternal mortality rate continued to rise. Despite these improvements, there is much more work to be done, as maternal mortality rates increased in 2020 during the COVID-19 PHE, and disparities by race/ethnicity, insurance type, and social determinants of health remain persistent.[55] While nearly all birthing hospitals in California are active CMQCC participants — and many report that maternal health outcomes are already integrated into QAPI programs — it is clear that hospitals cannot be held *solely responsible* for implementing much needed improvements and solutions to improve maternal health outcomes and reduce disparities. **CMS should consider policies to improve the health of pregnant, birthing, and postpartum patients that incorporate the broader health care continuum, rather than placing additional regulations on hospitals only.**

[55] https://www.cdph.ca.gov/Programs/CFH/DMCAH/CDPH%20Document%20Library/Communications/CA-PMSS-Factsheet-2018-2020_2023.pdf

Emergency Services Readiness

CMS proposes to establish a new standard for readiness that would apply to all hospitals and CAHs offering emergency services without regard to whether they also offer obstetric services. Facilities would be required to have adequate provisions and protocols to meet emergency needs of patients — including, but not limited to, those of pregnant, birthing, and postpartum patients — that would vary depending on the complexity and scope of services offered. This would also include a requirement that hospitals have a call-in system for each patient in an emergency treatment area. Similar to concerns already raised for the obstetric services CoPs, hospitals raised questions about the definition of a call-in system and concerns that patient access to emergency services could be limited by equipment availability at any given time. CMS should ensure that any finalized policies are flexible enough to safeguard a hospital's ability to care for emergent patients during a surge beyond typical volume, and not be limited to a specific number of physical equipment.

Transfer Protocols

CMS proposes to amend its discharge planning CoPs regulation to impose requirements for transfer protocols. Specifically, hospitals and CAHs would be required to have written policies and procedures for the transfer of patients under their care, including transfers from the emergency department to inpatient admission or transfers between inpatient units in the same hospital as well as transfers between inpatient units at different hospitals. Hospitals and CAHs would also be required to train relevant staff on hospital policies and procedures for transferring patients.

While CMS proposes these changes in the context of the proposed health and safety standards for obstetrical services, it does not provide evidence to show why additional regulation in this space is necessary to improve maternal health outcomes. Under existing policies, California hospitals broadly reported that written transfer protocols and procedures are already used. **Given the significant consequences for failure to comply with a CoP, CMS should provide more evidence to support the need for additional regulatory requirements.**

CHA appreciates the opportunity to comment on the CY 2025 OPPS proposed rule. If you have any questions, please contact me at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Megan Howard
Vice President, Federal Policy