September 11, 2023

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

SUBJECT: CMS-1786-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction, Federal Register (Vol. 88, No. 145), July 31, 2023

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) 2024.

California's hospitals continue to face unprecedented financial pressure resulting from the COVID-19 pandemic's impact on the labor market and the health care supply chain. From 2019 to 2022, 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 recent closure of one hospital in California (Madera Community Hospital[2,3]), drove another into bankruptcy (Beverly Hospital[4]), and has forced others to eliminate financially unsustainable services[5] to ensure they can remain open. Frequently, the service lines that hospitals are forced to close are those that treat a disproportionate number of

[1] https://www.kaufmanhall.com/insights/research-report/california-hospital-financial-impact-report-april-2023-update
[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://www.beckershospitalreview.com/finance/we-can-do-anything-but-we-cant-do-everything-tough-decisions-loom-for-hospital-c-suites.html

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individuals (e.g., labor and delivery,[6,7] inpatient psychiatric care[8]) covered by government payers,[9] which further exacerbates access issues and the likelihood of inequitable outcomes for underserved populations. Unfortunately, more closures of service lines and hospitals are anticipated. Kaufman Hall, a nationally renowned consulting firm, estimates 20% of California's hospitals are currently on the financial brink. This is in line with national trends — recently, three hospitals closed in just one week.[10]

The financial challenges facing hospitals — which were recognized in the Medicare Payment Advisory Commission's (MedPAC) recent hospital payment update recommendations to Congress[11] — threaten access to care for not just Medicare beneficiaries, but all members of the affected community. 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. These are not abstract data points. Sadly, two individuals' deaths have already been attributed[12] to Madera Community Hospital's closing.

CHA is concerned that the 2024 OPPS proposed rule will only exacerbate these already dire circumstances for hospitals and the Medicare beneficiaries they serve. The proposed net market basket update of +2.8% is inadequate relative to the input price inflation faced by hospitals and continues CMS' historic trend of proposing woefully inadequate payment updates. To ensure broad access to outpatient care for Medicare patients, CHA offers the following comments on the CY 2024 OPPS proposed rule:

- *Provide an Adequate Market Basket Update*: CHA respectfully asks that CMS use data that better reflect the input price inflation that hospitals have experienced and are projected to experience in 2024 and provide a forecast error adjustment for underestimating the update in CY 2022. Further, as in prior years, CHA respectfully asks CMS to eliminate the unjustified reduction to the market basket update as a result of the Affordable Care Act (ACA)-mandated productivity adjustment for any year covered under the COVID-19 public health emergency (PHE).
- *Preserve Access to Outpatient Services*: CHA believes that CMS' decision in the 2023 final rule to define rural sole community hospital (SCH)off-campus provider-based clinics as "excepted" from its site-neutral clinic visit policy was an important step in preserving access to care for a segment of the underserved population. While we greatly appreciate this bold action, we respectfully ask CMS to except all off-campus provider-based clinics from the site-neutral clinic visit policy. Doing so is aligned with CMS' stated goals of expanding access to underserved populations and reducing inequitable outcomes.
- *Price Transparency:* CHA strongly supports efforts to provide patients with data that will help them make value-based decisions about where to receive their care. We appreciate CMS' efforts to standardize the machine-readable files. However, we have concerns about the viability of including certain new variables in the machine-readable file and new, duplicative, enforcement requirements.

[6] https://subscriber.politicopro.com/article/2023/08/its-a-crisis-maternal-health-care-disappears-for-millions-00109106?source=email
[7] https://insidehealthpolicy.com/daily-news/maternal-care-deserts-increasing-policymakers-struggle-fixes?utm_medium=mh
[8] https://www.beckershospitalreview.com/finance/10-hospitals-closing-departments-or-ending-services.html
[9] https://www.beckershospitalreview.com/finance/hospitals-cuts-continue-but-cash-running-out-for-some.html
[10] https://www.beckershospitalreview.com/finance/3-hospitals-announce-closures-in-1-week.html
[11] https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf
[12] https://www.fresnobee.com/news/local/article272712840.html

- *Support 340B Safety-Net Hospitals*: CHA thanks CMS for proposing to pay for separately payable drugs acquired under the 340B program at average sales price (ASP) +6%. Given California's hospitals' fragile finances and the crucial role 340B plays in maintaining access to care for underserved and at-risk populations, CHA greatly appreciates CMS' proposal in CMS-1793-P to repay hospitals in a lump sum. However, we do not share CMS' belief that this repayment must be done in a budget-neutral manner. Finally, we are deeply concerned that for many of California's financially challenged 340B hospitals, repayment will come too late.
- *Partial Hospitalization and Intensive Outpatient Programs*: CHA appreciates CMS' efforts to increase access to these services for Medicare beneficiaries by using an expanded set of claims data to calculate the proposed 2024 PHP and IOP payment rates. CHA respectfully asks CMS to use all of the measures at its disposal, including Section 1135 waivers available under the ongoing opioid PHE to ensure that underserved beneficiaries have access to these services.
- *Packaging Policies and Non-Opioid Treatment Alternatives:* CHA appreciates CMS' request for information regarding separate payment for non-opioid treatment alternatives. While Sections 4135(a) and (b) of the Consolidated Appropriations Act (CAA) are not effective until Jan. 1, 2025, we ask CMS to begin separate payment for non-opioid pain treatment alternatives for services provided on or after Jan. 1, 2024, by issuing a waiver under the opioid PHE.
- *Essential Medicines*: CMS requests feedback on the concept of providing a separate payment for the costs that hospitals incur to build and maintain a stockpile of certain essential medicines. While CHA cautiously supports the separate payment, we are concerned that the need for such payment is symptomatic of the larger issue of inadequate payment updates (discussed in detail below). While we appreciate the proposal, we believe that CMS should first concentrate on providing all hospitals adequate market basket updates that keep pace with input price inflation and allow hospitals to invest in resilient supply chains for pharmaceuticals, PPE, and other supplies.

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, by 2.8%[13] in 2024. CHA notes that CMS finalized a net market basket update of 3.1%[14] 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, we anticipate that the final rule OPPS market basket update will be the same as IPPS. A 3.1% 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[15] on the federal fiscal year (FFY) 2024 IPPS proposed rule and reiterated here, we believe this inadequate update is the result of methodological issues associated with the data CMS uses to calculate the market basket update. **Further, given that Section 1833(t)(3)©(iv) of the Act ties the OPPS market basket update to the IPPS update, we respond to CMS' comments in**

[13] This includes a market basket of 3.0% reduced 0.2 percentage points for total factor productivity.

[14] This includes a market basket of 3.3% reduced by 0.2 percentage points for total factor productivity.

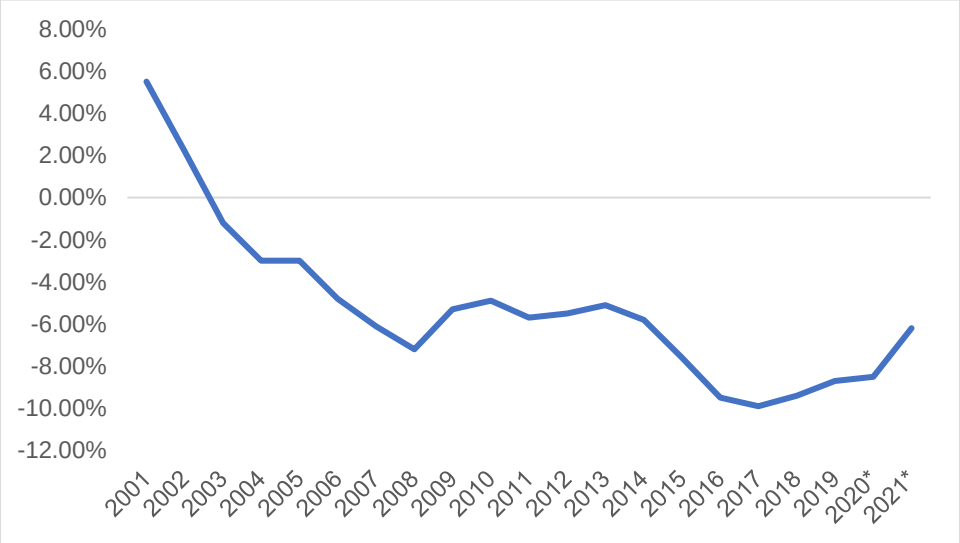
[15] https://calhospital.org/wp-content/uploads/2023/06/CHA-FFY-2024-IPPS-Proposed-Rule-Comment-Letter-060923-Final.pdf

the IPPS final rule and again respectfully ask the agency to re-calculate both the IPPS final rule market basket update using data from the Medicare cost report or other more appropriate data source and incorporate a forecast error adjustment. We believe a more timely and accurate proxy for the cost increases hospitals are facing and correcting CMS' previous market basket inaccuracies is necessary. If CMS fails to provide an adequate payment update, CHA is deeply concerned that inadequate payments will create access issues that negatively impact those who are already at risk for inequitable outcomes.

Given that the 2024 OPPS market basket update is tied to the IPPS final rule market basket update, we believe 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, Section 1833(t)(3)(C)(iv) specifically references "the market basket percentage increase applicable under section 1886(b)(3)(B)(iii)." Below, please find CHA's specific comments and responses to CMS' discussion of the IPPS market basket update in the FFY 2024 final rule.

Despite sustained cost reduction and efficiency efforts by hospitals, Medicare margins have declined over the last 20 years, as illustrated below. CHA believes this is due to persistently inadequate Medicare market basket updates relative to input price inflation, as discussed above. Hospitals' financial situations are so precarious that MedPAC recommended to Congress that it increase IPPS and OPPS payments over current law to preserve access.[16] This is the first time in memory that MedPAC has made such a recommendation. Further, MedPAC recommended that Congress increase payments to hospitals that are necessary to provide access to care for individuals most at risk of inequitable outcomes by $2 billion. This additional financing is necessary given the fragile finances of these institutions.

IPPS Hospital Medicare Margin: 2001 to 2021[17,18,19]



[16] https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC.pdf
[17] https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch3_SEC.pdf
[18] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch3_sec.pdf
[19] www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC.pdf

This longstanding underpayment trend has been exacerbated by the labor dislocations and supply chain breakdowns directly resulting from the COVID-19 pandemic. These exacerbations are expected to persist beyond 2024,[20] driving further inflation in input costs. Expenses have accelerated dramatically, offsetting the limited increases in revenue hospitals have experienced, which has resulted in reduced margins that threaten hospitals' financial viability. As discussed above, California hospital expenses increased 25% since 2019 (pre-pandemic). However, during this same period, Medicare payments only increased 7.16%[21] to account for input price inflation.

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. We understand 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 after-effect. As employed nurses have 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, but the per unit rate for these individuals has increased with demand for agency staff as evidenced by data from CHA members and analysis of Medicare cost reports (discussed in subsequent paragraph). California's hospitals, for example, spent $3.8 billion more on contract labor in 2022 than they did in 2019 even though there were decreases in patient discharges (18%), ED visits (2%), and observation days (9%) comparatively.[22] Not surprisingly, during this same time frame median contract labor expense as a percentage of labor expense increased 250% for California's hospitals. Further, while contract labor expense is declining relative to the peak of the COVID-19 pandemic, we anticipate that contract labor utilization will remain persistently elevated over 2019 levels for the foreseeable future. This is 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.[23]

While acknowledging the considerable flaw in the ECI, CMS attempts to downplay concerns about it. In the IPPS final rule the agency states:

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

CHA appreciates CMS' perspective. However, we believe its analysis of this issue using only hours worked and only focusing on the most recent data is inadequate. We note that in 2019 — prior to the pandemic — clinical contract labor was 2% of total allowable hours worked.[24] This implies that clinical contract labor as a percentage of total hours doubled during the pandemic. Further, CMS does not

[20] 2023 Median Ratios: Not-for-Profit Hospitals and Healthcare Systems, Fitch Ratings, July 25, 2023
[21] CHA analysis of Medicare market basket update data.
[22] www.kaufmanhall.com/sites/default/files/2023-04/CHA-Financial-Impact-Report.pdf
[23] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10074070/
[24] CHA analysis of Medicare cost report data submitted in 2019 and 2021.

analyze the dollars associated with these hours. We note that the average hourly wage for clinical contract labor in 2019 was $61.96 and $98.83 in 2021, an increase of 52%. In contrast, the fully loaded average hourly wage for employed staff in 2019 was $38.92 and $42.39 in 2021, an increase of just 9%. We note that the spread between the average hourly rate for contract staff vs. employed staff in 2021 was $56.44. This is 2.45 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 52% prior to the pandemic. This has significantly increased expenditures on clinical contract labor when comparing 2019 (pre-pandemic) to 2021 (during the pandemic). In 2019, hospitals spent $12 billion on clinical contract labor, while in 2021 that amount grew to almost $32 billion. **As a percentage of total allowable salaries, contract labor increased from less than 4% in 2019 to over 9% in 2021. While contract labor only reflects 4% of allowable hours worked in 2021, it represents almost 10% of allowable salaries, which is material to the calculation of the market basket update. Therefore, we again ask CMS to identify more accurate data inputs and use its existing authority to calculate the final rule "base" (before additional adjustments) market basket update with data that better reflect the rapidly increasing input prices facing hospitals.**

Given the unprecedented, continued cost growth (described earlier) triggered by a unique event — the COVID-19 pandemic — and the inadequate market basket resulting from the use of the ECI, CHA asks CMS to consider using the average growth rate in allowable **Medicare costs per risk-adjusted discharge** for IPPS hospitals between FFY 2019 and FFY 2021 to calculate the FFY 2024 final rule market basket update. We note that this growth rate will capture the increased cost of contract labor, unlike the ECI. Further, as discussed in our 2024 IPPS comment letter, we believe using the growth rate in Medicare costs per risk-adjusted discharge meets the statutory definition of "market basket percentage increase" as defined at section 1395ww(b)(3)(B)(iii) of the Act.

CMS, as it did for FFY 2023, declined to adopt this this approach in the FFY 2024 IPPS final rule stating:

> *We disagree that costs as reported on the Medicare cost report are a suitable data source for determining the trend in compensation prices for the market basket update. The Medicare cost report data also reflects factors that are beyond those that impact wage or price growth. For instance, overall Medicare costs per discharge as reported by hospitals on the Medicare cost report would also reflect observed IPPS case-mix (and associated higher payments to hospitals), which from 2019 to 2022 has increased faster than in prior years and would be associated with the use of more skilled care and medical/drug supplies needed to provide these services.*

CHA would again like to respectfully raise several points that we believe CMS overlooked in its response to the 2024 IPPS final rule. First, using the Medicare case mix index to risk adjust the costs per discharge will eliminate any case-mix changes and provide an accurate comparison of the resources used to treat cases. Second, by using only the difference between FFYs 2019 and 2021 expenses per CMI-adjusted discharge, there should be minimal changes in the mix of inputs used to deliver care as a result of changes in technology. Therefore, this methodology sufficiently addresses CMS' objections in the IPPS final rule. Third, we note that even if the data were not risk-adjusted the increase in case mix CMS observes is a direct result of hospitals caring for sicker, more resource-intensive patients. This is due to the continued shifting of procedures and medical services that previously required an inpatient admission (e.g., lower joint replacement surgery) that can now be performed in the outpatient setting and are covered by Medicare.

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 the Medicare cost report. Based on CHA analysis, this would yield an unadjusted market basket update of 4.39%. A net market basket update of 4.19%[25] for FFY 2024 better reflects the actual input price inflation that California's hospitals anticipate facing in the coming year, rather than the 2.8% net market basket update proposed by CMS (and 3.1% net market basket update CMS will finalize). We note that this net market basket update is in line with MedPAC's recommendation to Congress of market basket update plus one percentage point (3.1+1.0 = 4.1%).

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

> *For purposes of this subparagraph, subject to paragraph (17)[26] and subparagraph (F)[27] 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)[28] 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 good and services …" as described in section 1886(b)(3)(B)(iii) necessary to provide hospital care to Medicare beneficiaries. We again believe these data are a more accurate projection of the cost inflation anticipated by hospitals during CY 2024 than the forecast IGI data used in the IPPS final rule and the OPPS proposed rule. Therefore, we respectfully ask 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 2024 IPPS final rule and therefore by reference, the 2024 OPPS final rule.

Market Basket Update – Productivity Adjustment

The productivity adjustment required under the Affordable Care Act is estimated to be -0.2 percentage points. The adjustment is based on IGI's fourth-quarter 2022 forecast.

[25] 4.19% = (4.39% MBU - .2% ACA-mandated productivity factor)
[26] Section of the Act that adjusts the market-based update based on quality reporting requirements
[27] Section of the Act that implements the productivity adjustment
[28] 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."

CMS itself has acknowledged that hospitals are unable to achieve the productivity gains assumed by the general economy over the long run.[29] CHA appreciates this acknowledgment and agrees the assumptions underpinning the productivity adjustment are fundamentally flawed. We strongly disagree with the continuation of this policy — particularly during years subject to the COVID-19 PHE. The productivity adjustment to the market basket update assumes that hospitals can increase overall productivity — producing more goods with the same or fewer units of labor — at the same rate as productivity increases in the broader economy. However, providing hospital-based care to Medicare beneficiaries is highly labor intensive, as CMS' projection of the labor-related portion of the federal rate in both the IPPS (67.6%) and OPPS (60%) — implies in the FFY 2024 IPPS final rule and CY 2024 OPPS proposed rule.

Hospital care must be provided on-site and has a high "hands-on" component. Therefore, hospitals — particularly in states that have nurse staffing ratios — cannot improve productivity using strategies like offshoring or automation that are commonly deployed in other sectors of the economy that produce goods (robotic automation of manufacturing plants) or services (dine-in restaurants that use automated ordering systems to reduce overall staffing count). CMS' own research, conducted prior to the COVID-19 PHE, indicates that hospitals can only achieve a productivity gain that is one-third of the gains seen in the private nonfarm business sector.[30]

CHA notes that during the COVID-19 PHE, productivity fell[31] as a result of increased staff turnover. Over 100,000 nurses are estimated to have left the field during 2021 and 2022[32] alone. During that time, hours worked by temporary staffing increased by 50% from prior to the pandemic to address the labor shortage. While substituting contract labor for employed staff allowed hospitals to continue delivering care to the communities they serve, it also had a negative impact on productivity.

Temporary staff are not accustomed to a specific facility's workflows, which increases the number of hours required to provide patient care. This decrease in productivity can be seen in hospital discharge and labor expense data. While discharges were down in 2020, 2021, and 2022 compared to 2019, labor expenses increased significantly, implying that hospitals needed more labor to produce fewer units of care. Further, an October 2021 survey conducted by Kaufman Hall confirms this phenomenon. It found that many hospitals and health system leaders feel the COVID-19 pandemic made it significantly more difficult for them to improve their performance.[33]

Given that CMS is required by statute to implement a productivity adjustment to the market basket update, CHA asks the agency to work with Congress to permanently eliminate this unjustified reduction to hospital payments. Further, due to the extreme and uncontrollable circumstances associated with the COVID-19 PHE that reduced labor productivity, we ask CMS to use its "exceptions and adjustments" authority to remove the productivity adjustment for any fiscal year that was covered under the PHE determination (e.g., 2020 -.4%, 2021 -.0%, 2022 -.7%, and 2023 -.3%) from the calculation of market basket for in the FFY 2024 IPPS and CY 2024 OPPS final rules.

[29] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf
[30] ibid.
[31] https://www0.gsb.columbia.edu/faculty/abartel/papers/human_capital.pdf
[32] https://www.aha.org/news/headline/2023-04-13-study-projects-nursing-shortage-crisis-will-continue-without-concerted-action
[33] https://www.kaufmanhall.com/insights/research-report/2021-state-healthcare-performance-improvement-report-covid-creates

Market Basket Update – Forecast Error Adjustment

In prior comment letters CHA, along with other stakeholders, expressed concern that the market basket update proposed (and subsequently finalized) in a given year was inadequate relative to input price inflation.[34,35,36] Unfortunately, as discussed above, those concerns continue to be realized as a result of the impact that a unique event — the COVID-19 PHE — had on hospital labor, supply, and pharmaceutical expenses. In the 2024 IPPS final rule, CMS acknowledges this issue.

> *While the projected IPPS hospital market basket updates for FY 2021 and FY 2022 were under forecast (actual increases less forecasted increases were positive), this was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE.*

As discussed 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 market basket update. It is clear, based on rapidly rising labor costs, that CMS' current inputs for updating the IPPS (and therefore OPPS) market basket update are ill-suited to a highly inflationary environment. Based on files recently released by CMS, the actual market basket update for 2022 should have been 5.7%. Instead, CMS finalized an unadjusted market basket update of 2.7%, resulting in hospitals being underpaid relative to inflation by 3.0 percentage points. While CMS states forecast errors can go in either direction and will average close to zero over time, the most recent understatements of inflation have been considerably larger than those in favor of the agency and come at a time when hospitals are facing insurmountable financial pressure, which is negatively impacting access to care.[37,38,39,40]

CHA respectfully asks that CMS apply a *one-time* 3.0 percentage point "forecast error adjustment" to the proposed FFY 2024 IPPS and OPPS market basket update. We believe this update is necessary to account for the unprecedented hospital input price inflation — particularly for contract labor costs — stemming from the COVID-19 pandemic. This inflation — as discussed above — was not captured in the market basket update for FFY 2022 as the input proxy used to account for labor costs does not include contract labor which saw significant growth relative to prior to the pandemic. This unique convergence of factors resulted in hospitals being significantly underpaid for services provided in FFY 2022 to Medicare beneficiaries.

Hospital Outpatient Visits and Critical Care Services

For off-campus provider-based departments (PBDs) being paid a physician fee schedule (PFS) equivalent rate, CMS proposes to continue paying 40% of the full OPPS rates. Beginning in 2023, CMS is exempting off-campus PBDs of rural sole community hospitals from being paid the PFS equivalent rate for a clinic visit. **CHA again would like to thank CMS for exempting off-campus PBDs of rural SCHs from being paid the PFS equivalent rate. We believe this is an important step to maintaining access to clinic visits in communities served by SCHs.** Not only will this improve patient outcomes by allowing easily

[34] https://calhospital.org/cha-issues-draft-comments-on-opps-proposed-rule/
[35] https://calhospital.org/wp-content/uploads/2023/06/FFY-2022-2023-IPPS-Comment-Letters-Combined.pdf
[36] https://calhospital.org/cha-issues-draft-comments-on-ipps-proposed-rule/
[37] https://www.beckershospitalreview.com/finance/10-hospitals-closing-departments-or-ending-services.html?
[38] https://www.beckershospitalreview.com/care-coordination/18-hospitals-scaling-back-care.html?
[39] https://www.beckershospitalreview.com/finance/19-hospital-closures-bankruptcies-in-2022.html?
[40] https://www.beckershospitalreview.com/finance/9-hospitals-have-closed-this-year-here-s-why.html

treatable conditions to be addressed in a timely manner but will reduce total Medicare spending as these conditions will be treated in the most appropriate setting.

CHA respectfully asks the agency to reverse its site-neutral clinic visit policy and refrain from further expanding site-neutral payment policies. As shown below, the population receiving care in hospital-based outpatient departments is sicker and poorer — and therefore more at risk of inequitable outcomes — than the average Medicare beneficiary. Further, hospital outpatient department (HOPD) site-neutral payment policies are grounded in the false assumption that the PFS provides an appropriate payment level for services delivered in freestanding settings.

HOPD ambulatory payment classification (APC) weights are set annually based on Medicare claims and audited cost report data. While the hospital market basket update is badly flawed, as discussed above, the OPPS conversion factor is updated annually to reflect some level of input price inflation. By contrast, the process for updating the relative value units used to calculate PFS payments is based on an opaque process (compared to APC weight setting) that relies on physician survey[41] data. This has led to questions about its reliability.[42] Further, as a result of the Sustainable Growth Rate and subsequent adjustments provided by the Medicare Access and CHIP Reauthorization Act (MACRA), the PFS conversion factor has failed to keep pace with the physician practice expense growth.

As an example, the 2023 Medicare PFS conversion factor is $33.8872. If the current conversion factor were to have been adjusted solely for inflation as measured by the Medicare Economic Index (MEI), less an adjustment for multifactor productivity, it would be approximately $41.81 or nearly $8 higher per relative value unit.[43] To further illustrate the example, the national average non-facility Medicare PFS payment for a moderate complexity physician office visit[44] in CY 2023 is $128.43.[45] Had the PFS conversion factor been updated by the productivity-adjusted MEI since its 1992 implementation, that payment would be approximately $158.47.[46] CHA notes that the national average total Medicare payment — inclusive of the professional fee — for an HOPD clinic visit of similar complexity is $218.46.[47] While there is a difference of just under $60 between the total amount paid by Medicare for a level 4 office visit between the physician office and the outpatient department, CHA notes that approximately $7 of the difference is associated with drugs and devices that are packaged into the APC payment for a clinic visit in an HOPD, which are billed separately when they are provided in a freestanding setting.[48] The remaining higher payment in the outpatient department is necessary to account for the increased regulatory cost associated with hospital-based clinics, caring for a sicker patient population, providing the full range of medical services, and some departments being open 24/7 to be able to accommodate emergencies. These are costs that freestanding physician practices do not have.
A recent analysis of Medicare claims[49] indicates that beneficiaries receiving care in HOPDs are more likely to be non-white (1.5 and 1.4 times more likely to be Black and Hispanic, respectively), and enrolled

[41] www.ama-assn.org/system/files/ruc-update-booklet.pdf
[42] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4872854/
[43] This figure was determined by controlling for the effect of budget neutrality adjustments on the conversion factor. The 2023 conversion factor of $33.8872 was deflated by the actual updates applied between 1992 and 2023 and then inflated for the same time period by the MEI.
[44] CPT code 99214
[45] https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=0&H1=99213&M=1
[46] CHA analysis.
[47] This equals the sum of the OPPS payment for APC 5012 ($120.86) and the amount paid to the physician under the physician fee schedule for 99214 at the "facility price" ($97.60) or $218.46
[48] https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc
[49] https://www.aha.org/system/files/media/file/2023/03/Comparison-of-Medicare-Beneficiary-Characteristics-Between-Hospital-Outpatient-Departments-and-Other-Ambulatory-Care-Settings.pdf

in Medicaid (1.9 times more likely to be dually eligible) than in independent physician offices (IPO). They are also clinically more complex. Among other measures of complexity, HOPD beneficiaries were more likely to enter the Medicare program due to disability or end-stage renal disease (ESRD). Additionally, 31% of HOPD beneficiaries were originally enrolled in Medicare due to disability and/or ESRD as compared to 19% for IPO patients (1.6 times more likely for HOPD than IPO). As a result of these complicating factors, HOPD patients were 2.8 times more likely to have visited an emergency department in the past 90 days than ambulatory surgery center patients. **CHA strongly believes that eliminating the site-neutral clinic visit policy is aligned with CMS' emphasis — which CHA supports -- — on reducing inequitable health care outcomes and increasing access to care for underserved populations.**

Payment of Intensive Cardiac Rehabilitation (ICR) in a Non-Excepted Off-Campus PBD

By statute, Medicare's payment for ICR in a physician's office is equal to the payment rate for CR under the OPPS. However, CMS has been paying ICR at a PFS equivalent rate when furnished in a non-excepted off-campus PBD. A non-excepted off-campus PBD is an off-campus PBD of a hospital that first began providing services on or after Nov. 2, 2015, is not paid under the OPPS, and is instead paid at PFS equivalent rate for its outpatient hospital services at 40% of the full OPPS rate.

Paying for ICR at a PFS equivalent rate has produced an anomalous result of ICR being paid at $120.47 in on-campus hospital departments, excepted off-campus PBDs, and physician offices but $48.03 in a non-excepted off-campus PBD in 2023. To address this anomaly, CMS proposes to pay for ICR in an off-campus non-excepted PBD at the full OPPS rate effective Jan. 1, 2024. This policy would apply to the HCPCS codes G0422 and G0423 for ICR with and without exercise respectively. **CHA strongly supports CMS' proposal to pay ICR services at the correct payment amount. We respectfully ask that CMS clarify that ICR services provided in non-excepted PBDs that were provided before Jan, 1, 2024, and underpaid may be rebilled so that the hospital can receive the correct amount.** Similar to what was proposed in its 340B remedy, CHA asks the agency to include in the repayment amount for services provided prior to Jan. 1, 2024, the incremental beneficiary cost sharing or clarify that hospitals are not compelled to bill for that cost sharing, so that hospitals are not forced to rebill patients for amounts related to underpaid services. Finally, we ask that as part of this clarification, CMS instruct the Medicare Administrative Contractors to expeditiously reprocess these claims, including those that are beyond the timely filing and/or claims reopening time limits.

Price Transparency

The CY 2024 OPPS rule proposes several changes to the hospital price transparency requirements related to standardization, new data elements, file accessibility, an accuracy and completeness affirmation, and changes to CMS' monitoring and enforcement processes. CHA is supportive of efforts to provide patients and consumers (hereafter, patient, unless otherwise specified) with information to make a value-based decision on where to receive their health care. We believe this information should be provided to patients and consumers first and foremost in a manner that is easy for them to understand and act upon. In promulgating regulations to achieve this shared goal, CMS must fully appreciate the financial costs and staffing resources (discussed in detail below) associated with complying with these requirements and take steps where available to reduce the costs and staffing requirements. Unnecessary administrative costs are not ethereal and are borne by both governmental and commercial payers. While CHA is supportive of many of the proposed improvements to the hospital price transparency program,

we have concerns about certain aspects that do not improve patients' ability to make value-based care decisions and increase compliance costs.

Even though the proposed template (if adopted) will not be finalized until late October or early November, CMS proposes that many of these requirements are effective on Jan. 1, 2024. While CMS proposes a two-month enforcement "grace period" to allow hospitals to come fully into compliance, this does not leave sufficient time for hospitals to implement the anticipated changes. Updating the price transparency machine-readable files is a complex, resource-intensive process that typically requires the involvement of a hospital's revenue cycle, information technology, clinical, and compliance staff. Frequently, these teams are also supported by external consultants.

The internal staff hospitals will tap to do this work are involved in projects designed to improve patient safety and the experience of care that were delayed by the COVID-19 pandemic. Meeting the unrealistic time frame that CMS has proposed will require re-purposing these individuals. Not only will the current timeline result in a delay of quality and the patient experience of care improvement projects but will increase costs to execute these projects. If these projects are delayed or curtailed, work completed thus far could be wasted and valuable momentum lost.

Further, many hospitals depend heavily on a finite pool of consultants to create machine-readable files. The proposed unrealistically short implementation timeline, if finalized, will create a capacity bottleneck for the consulting support hospitals rely on to comply with the price transparency requirements. Not only will this drive up the cost of consulting engagements due to the mismatch between the supply of available consultants and the demand for their services but smaller hospitals and health systems that are not tier one clients of these consulting firms will not be able to get the support before the enforcement moratorium ends on March 1, 2024.

CHA is deeply concerned about CMS' proposed compliance time frame for multiple reasons. First, we note that many hospitals have either updated their machine-readable files for 2024 or are in the process of doing so, given that hospitals must update their files every 12 months. The proposed time frame will result in duplicative spending as the files that were recently updated or are in the process of being updated will need to be scrapped.

Second, and more importantly, the proposed time frame does not provide sufficient time for hospitals to implement the sweeping changes finalized with the OPPS rule on or about Nov. 1. **We respectfully ask that CMS allow hospitals up to 18 months to adopt the new standards following the release of final technical guidance (discussed below).** Given the complexity of these files, detailed guidance is required to ensure that the new standard format is implemented consistently across hospitals and to avoid excessive updates to the guidance in the future. This time frame also provides sufficient time for hospital staff to complete the current projects focused on improving quality and patient experience of care while making the changes necessary to comply with the price transparency requirements finalized in this rule. It also spans a CMS OPPS "rulemaking cycle" to allow the agency to incorporate any changes that Congress may make to the hospital price transparency requirements before the end of this year.[50] Given these concerns, any time less than 18 months from when the technical guidance is released could result

[50] CHA notes that legislation with the potential to significantly alter the hospital price transparency requirements is currently under consideration in Congress. We respectfully ask CMS to include the flexibility in the final rule to delay implementation of any requirements in the OPPS final rule to the effective day of any new requirements passed by Congress. If CMS fails to do so we are concerned that hospitals and data aggregators will incur significant, unnecessary costs chasing ever-evolving regulatory requirements.

in a hospital duplicating its effort for the year, resulting in significant added cost and staff time that would be better deployed to other patient care and patient experience endeavors.

Below, please see CHA's specific comments.

Standard Template Requirement for Machine-Readable Files

CMS proposes requiring hospitals to conform to a standardized format to comply with the hospital price transparency machine-readable format requirements. **CHA appreciates that CMS is now attempting to standardize the machine-readable files and provide technical guidance.** Had this been done from the outset, as requested by hospitals and other stakeholders by CMS, it would have streamlined implementation, reducing unnecessary expenditures by hospitals and confusion by all stakeholders. With this lesson in mind, we encourage CMS to carefully consider its and Congress' goals for price transparency before it finalizes additional requirements.

CMS proposes requiring several new data elements, including the contracting type for payer-specific negotiated rates and an expected allowed amount for negotiated rates represented by percentages or other algorithms. **In general, CHA supports CMS' proposal to require the use of a standard template. If the recommendations below are finalized, we believe the use of a standard template accompanied by clear implementation guidance developed with input from hospitals will reduce instances of alleged non-compliance due to unclear requirements. CHA hopes this will also decrease the frequency with which external parties with vested financial interests inaccurately assert that hospitals are not in compliance with these requirements.**

Despite CHA's support of standardization, we question whether these changes or any changes that CMS might propose in the future, will help achieve the agency's ultimate goal — improving the comparability of hospital price data. The inability to compare payment rates for the same item or service for a hospital between two payers stems from differences in health plans' contracting methodologies, definitions of items and services bundled for payment, and other important nuances.[51] Given this, CHA is concerned that even after these changes, stakeholders will still be drowning in data but patients will be parched for insights to help them make value-based decisions about their health care.

If finalized, the proposed rule would require the following data elements in the standardized machine-readable file:

- Hospital name (or names if multi-campus), license number, and location name(s) and address(es) under a single hospital license for which the listed charges apply
- File version and date of the most recent update
- The gross charges, payer-specific negotiated rates, deidentified minimum and maximum negotiated rates, and discounted cash prices associated with the items or services
- The contracting method used to establish the negotiated rate and how the negotiated rate should be read (e.g., dollar amount, percent of charge, algorithm)
- The expected allowed amount representing the dollar amount a hospital expects to receive for an item or service if the negotiated rate associated with an item or service is not in dollar amounts
- Descriptions of the items or services, including whether they are provided in connection with an inpatient admission or outpatient visit

[51] Examples include, but are not limited to stop loss methodology, multi-procedure discounting, items/services carved out for separate payment, and etc.

- Any accounting or billing codes

The proposed rule states CMS plans to provide technical instructions to ensure consistency across hospitals in the display of these different types of data. **CHA strongly supports CMS efforts to provide technical guidance related to the display of data in the machine-readable file. To that end, we respectfully ask CMS to convene a technical expert panel (TEP) that includes hospital staff with expertise in revenue cycle, managed care contracting, and information technology systems to ensure that the guidance provided is clear and achieves CMS' desired goals in the most cost-efficient manner possible for hospitals.** CHA notes that when CMS developed the health plan Transparency in Coverage machine-readable file layout and supporting material the agency convened technical experts from health plans.[52]It is not unreasonable for CMS to convene a similar workgroup to ensure that the technical guidance provided by the agency is clear and will result in data that helps patients and consumers understand their costs. CHA notes that this technical guidance was not part of the work accomplished by the TEP convened by MITRE[53] discussed in the proposed rule. Only after CMS develops technical guidance with the help of a hospital TEP, solicits comment from a broader community of stakeholders on that guidance, and implements improvements based on the feedback it receives should CMS release the technical guidance.

Requirement That Hospitals Include the Algorithm That Determines the Dollar Amount for Items and Services That Do Not Have a Standard Price

As noted above, when a hospital's payment from a health plan is calculated based on an algorithm, CMS proposes requiring that the hospital include the actual algorithm used to calculate the payment. The proposed rule states that, "Knowledge of the algorithm for a standard charge that can only be expressed as an algorithm is necessary for consumer-friendly tools to estimate in dollars an individual's payer-specific negotiated charge." CHA does not believe that having the actual algorithm will allow data aggregators to calculate the price a plan has negotiated with the hospital for a given item or service. Many of the variables required to complete the calculation will not be available to the data aggregator as they are patient-specific and will not be known until after the service is provided. CMS' simplistic examples in the proposed rule of Patient X and Patient Y also serve to illustrate the issue. Both examples require the billed charges — which are not knowable for each patient until after the service is rendered — to calculate the price for the item or service.

Additionally, as discussed below, the number of items and services that have an algorithm-calculated payment are likely to be significant. For example, many health plans contract with hospitals for inpatient services using AP-DRGs. While the base payment could be considered "standard," these contracts typically have an "outlier" payment included to provide stop loss protection from high-cost cases. Outlier payments are calculated based on a complex algorithm (see IPPS outlier[54] as an example). If CMS considers any DRG-based payment that includes an algorithm-based stop-loss payment, it will significantly expand the number of algorithm formulas that must be included in the file. CHA notes there are over 1,300 AP-DRGs[55] alone. And hospitals typically contract using other versions of a DRG system — APR-DRG and MS-DRGs, which significantly increase the potential for this labor-intensive field to need to be completed. CHA's members believe that this single requirement will significantly increase the

[52] https://github.com/CMSgov/price-transparency-guide
[53] https://mitre.app.box.com/v/MITRE-MRF-TEP/file/1244177570809
[54] https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/downloads/outlier_example_fy07.zip
[55] https://www.3m.com/3M/en_US/health-information-systems-us/drive-value-based-care/patient-classification-methodologies/apr-drgs/#:~:text=3M%20APR%20DRGs%20define%20%22the,(including%202%20error%20DRGs)

staffing requirements (and therefore cost) to comply with proposed changes to the price transparency requirements.

If, as discussed below, "consumer-friendly allowed amount" is also included in the machine-readable file as proposed, CHA questions why CMS is also proposing to require hospitals to include the payment algorithm? **Given that requiring hospitals to include the algorithm used to calculate the payment amount for any item or service that does not have a standard price will increase costs and will not produce data that are meaningful to help patients make informed decisions about where to receive their care, CHA respectfully asks CMS to eliminate the requirement to include the payment algorithm in the final rule. As noted above, the average output from that formula will also be included in the file. Therefore, this requirement is duplicative and unnecessary.**

Consumer-Friendly Expected Allowed Amount
CMS proposes requiring hospitals to include a "consumer-friendly expected allowed amount" (CFEAA) which is the average dollar that a hospital estimates it will be paid by a third-party payer for an algorithm priced item or service. **CHA supports the inclusion of this variable in the machine-readable file.** We note that hospitals have asked CMS since the inception of the program to allow for the inclusion of an average allowed amount in instances where there isn't a standard price.

CHA notes this variable will be a historical average price for the item and service in question, likely calculated over the last 12 months. It is not going to be specific to an individual consumer but will be based on the data from all patients who have received the same item or service and were covered under the same health plan. However, patients will be able to receive specific estimates of allowed amounts from tools hospitals and health plans are making available on their websites in compliance with statutory and regulatory requirements. We also note that similar information will be provided to patients once the Advanced Explanation of Benefit (AEOB) is implemented. Given that the CFEAA is not based on a patient's actual clinical circumstances, we are concerned that some patients who access this information through a third-party application developer's tool will be confused when this amount is not aligned with any of the other estimates that they receive from a hospital and/or health plan price transparency tool or the AEOB. **Therefore, CHA strongly encourages CMS to rename this variable to the Average Historical Allowed Amount to eliminate one possible source of patient confusion.**

Finally, CHA's members are concerned that certain unscrupulous health plans will use the "expected allowed amount" data element to underpay hospitals for contracted services. Given many plans' ongoing behavior,[56,57,58,59,60,61,62] it is not difficult to imagine that some health plans will unilaterally pay hospitals the lesser of the actual algorithm-calculated amount or the amount posted in a hospital's machine-readable file. In this instance, hospitals' only recourse would be to contest the underpayment amount, which would likely entail costly and time-consuming litigation. The time and expense incurred by hospitals to secure the full amount of payment that is contractually owed to them by a health plan does nothing to improve patient outcomes or their experience of care. CHA notes that if this comes to pass, it,

[56] https://www.reviewjournal.com/crime/courts/united-healthcare-owes-60m-to-er-doctors-jury-rules-2492856/amp/
[57] https://www.fiercehealthcare.com/payers/ama-2-state-medical-societies-join-class-action-suit-against-cigna
[58] https://www.fiercehealthcare.com/hospitals/new-york-er-docs-sue-unitedhealth-over-allegedly-slash-out-network-payments
[59] https://www.beckerspayer.com/payer/unitedhealth-sued-for-alleged-underpayment-of-telehealth-claims.html
[60] https://www.beckerspayer.com/payer/cigna-drastically-underpaid-new-jersey-hospitals-lawsuit-alleges.html
[61] https://news.bloomberglaw.com/health-law-and-business/cigna-united-underpaid-out-of-network-claims-lawsuit-alleges
[62] https://medcitynews.com/2022/12/panel-orders-unitedhealth-to-pay-10-8m-for-allegedly-underpaying-physicians/

unfortunately, would not be the first time a health plan attempted to take advantage of regulations designed to assist patients and consumers to increase its own profits. **CHA respectfully asks CMS to monitor payer behavior to ensure that this data element is not abused similar to the No Surprises Act Qualifying Payment Amount.**[63]

Data Elements Related to Hospital Items and Services
CMS proposes that for drugs, hospitals must indicate the drug unit and type of measurement as separate data elements. CHA asks CMS to articulate the reason this information is needed by data aggregators in separate fields. We note that this information is already captured in the item description. Providing it in separate fields will significantly increase the cost and resources required to comply, as drugs are maintained in a separate database from the hospital chargemaster. **Therefore, CHA respectfully asks CMS to exclude this information from the final standard template.**

Inclusion of Modifiers
CMS proposes that hospitals include all relevant billing codes and specify any relevant modifiers that would change the negotiated price. CHA notes there are over 50 HCPCS modifiers alone.[64] And many items and services can be billed with multiple modifiers that will impact the calculated payment. If CMS finalizes this requirement, it will create an almost endless number of permutations that will need to be included in the machine-readable file. **This will significantly increase the cost of complying with the new requirements without providing data to help individual patients make value-based decisions about where to receive care. That patient-specific information will come from either a hospital's or health plan's out-of-pocket price estimator.**

Additionally, CHA notes that the more information CMS requires a hospital to include in the machine-readable file, the more it — illegally — forces a hospital to reveal the terms of its contracts with health plans. As discussed below, we do not believe that CMS has the legal authority to compel private entities to disclose the terms of their contracts with business partners to CMS.

Changes to Improve and Enhance Enforcement

CMS notes in the proposed rule that only 3% of hospitals fully failed to meet its price transparency website assessment criteria. The agency also, on multiple occasions, has stressed that only it — not outside entities — can determine if a hospital is in compliance with the price transparency requirements. **CHA thanks CMS for appreciating that the vast majority of hospitals are either fully compliant with the price transparency requirements or are making a meaningful effort to comply with the regulations as the hospital understood them. Further, we appreciate that in the proposed rule, CMS has taken the opportunity to remind certain stakeholders with vested financial interests — which may not be fully aligned with the patients they purport to represent — that only the agency can determine whether a hospital is in compliance.**

While the proposed rule attributes the increase in compliance to CMS' increase in the penalties for non-compliance that were included in the CY 2022 OPPS final rule, CHA reminds the agency that correlation is not causation. First, many hospitals were still managing surges of COVID-19 cases in 2020 and 2021 when hospitals would have been creating machine-readable files and consumer friendly displays of shoppable services. Many of the staff who were necessary for these efforts were tasked with supporting

[63] https://www.healthcaredive.com/news/blue-cross-nc-surprise-billing-act-provider-rate-reductions/610501/
[64] https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00003604

hospitals' ability to manage the surge of COVID-19 patients that overwhelmed many hospitals. Once the flood of patients subsided, these teams were able to turn their attention away from the necessary work of saving COVID-19 patients' lives and to the important work of complying with the price transparency requirements.

Second, many hospitals attempted to comply with the hospital price transparency requirements, however, they faced challenge given the lack of clarity around many of the provisions and dearth of implementation resources. We also note that many hospitals that were allegedly non-compliant, were in compliance once CMS staff reviewed the machine-readable file. **CHA appreciates CMS' efforts working with hospitals to address these issues and strongly encourages the agency to continue its "probe and educate first" approach.**

CMS proposes several changes to improve its ability to assess compliance with the hospital price transparency requirements.

Notification of Alleged Noncompliance
CMS proposes to notify health system leadership of any compliance activity within their system to accommodate health systems with a central office responsible for compliance. CMS would also contact the specific hospital's leadership. **CHA supports this approach.** While contacting the system office will, in many instances, help coordinate compliance activities, we believe it is important — as CMS has proposed — to provide a copy of all notices to the individual listed as the hospital contact on CMS 855A.

Publication of Compliance Actions and Outcomes
CMS proposes publicizing information related to CMS' assessment of hospital compliance. This would include any compliance actions taken against a specific hospital, the status of the compliance action(s), and the outcome of the action(s). The proposed rule notes that the public list would be accurate as of the published date and would not indicate the current state of compliance or noncompliance. In the proposed rule CMS refers to both warning letters as compliance actions.

CHA strongly disagrees with the characterization of "warning letters" as "compliance actions." Many of the warning letters CMS sent hospitals did not result in a determination of noncompliance or the request for a corrective action plan. Hospitals in these instances were able to respond to CMS' request, provide information that allowed the agency to determine that the hospital was in fact in compliance with the requirements, and resolve any misunderstandings.
CHA respectfully asks CMS to continue allowing the flexibility for the agency and hospitals to resolve any misunderstandings (either of the hospital's understanding of the requirements or CMS' understanding of the hospital machine-readable file). CHA strongly believes it is inappropriate for CMS to publicly "name and shame" a hospital that receives a warning letter and is ultimately found to be compliant. Finally, we ask that if a hospital receives a corrective action plan (CAP) and is posted on the CMS Hospital Price Transparency compliance website, that the agency removes the hospital as soon as they have satisfied the conditions of the CAP.

Attestation of Completeness
As part of the mandatory template, CMS proposes requiring hospitals to affirm the accuracy and completeness of their machine-readable files. Specifically, if finalized, CMS would require each hospital to include a statement in the standard machine-readable file affirming that the hospital has, to the best

of its knowledge, included all applicable standard charge information in accordance with the requirements and that the information is true, accurate, and complete. **CHA generally supports this proposal.** While CHA hopes this will alleviate public confusion that has thus far surrounded the completeness and accuracy of some hospitals' files, we are concerned that many stakeholders with vested business interests will continue their inaccurate characterizations of hospital compliance to generate sensational headlines[65,66] that only further their interests.

CMS also proposes requiring an authorized hospital official to certify the accuracy and completeness of the hospital's machine-readable file during the monitoring and enforcement process. This certification duplicates the affirmation in the machine-readable file discussed above. CHA questions why CMS needs to replicate the statement that is already in the machine-readable file. The explanation provided in the proposed rule is not compelling. We believe that a separate attestation is not as useful as the affirmation in the file as the data aggregators that are scraping these files from hospital websites will have to separately download this executive attestation. **Therefore, we respectfully ask CMS to not finalize this provision.**

Required Additional Documentation at CMS' Request

The agency also proposes requiring hospitals to provide additional documentation at CMS' request, including contracting documentation needed to validate the hospital's negotiated rates and verification of the hospital's licensing status and number. **CHA respectfully opposes the proposed addition of § 180.70(a)(2)(v) that would require hospitals and health systems to submit certain documentation to CMS.** Specifically, the proposed rule suggests that CMS may require hospitals to submit "contracting documentation to validate the standard charges the hospital displays." Courts have long held that certain contracting information — especially negotiated rate data — is commercially sensitive information that is shielded from disclosure by numerous legal protections. *E.g.*, *West Penn Allegheny Health Sys., Inc. v. UPMC*, 2013 WL 12141532 (W.D. Pa. Sept. 16, 2013) (trade secrets protection); *Medical Ctr. at Elizabeth Place, LLC v. Premier Health Partners*, 294 F.R.D. 87 (S.D. Ohio 2013) (discovery protections); 73 Fed. Reg. 30,664-01, 30,675–75 (May 28, 2008) (FOIA Exemption 4). There is no indication in section 2718(e) of the Public Health Services Act (*i.e.*, the statutory text on which the agency relies for this documentation requirement) that Congress authorized CMS to override these well-established legal protections by regulatory fiat. **To be clear, the CHA does not oppose CMS requiring the submission of other information (*e.g.*, verification of the hospital's licensure status or license number). But, requiring hospitals to submit private contractual information crosses a critical legal line, and that aspect of the proposed rule should not be finalized.**

Implementation Estimate

CMS estimates that these changes would result in a one-time cost of about $2,787 per hospital, or roughly $20 million for all hospitals combined. In addition, CMS estimates an additional $10.7 million annually across all hospitals, beyond what was previously estimated. CHA believes that CMS has grossly underestimated the cost of complying with the new requirements, particularly if the agency persists in requiring hospitals to include the algorithmic formula used to calculate payments as a required field. This would not be the first time that CMS has grossly underestimated the cost of compliance with the hospital price transparency requirements. In the CY 2020 final rule, CMS estimated that compliance

[65] https://www.aha.org/press-releases/2023-07-25-aha-statement-patient-rights-advocate-price-transparency-report
[66] https://www.aha.org/news/headline/2023-02-17-aha-blog-highlights-cms-report-showing-hospitals-are-implementing-price-transparency-policies-and

costs per hospital would be $11,898.60. However, actual compliance costs for hospitals were found to be as high as $2 million annually.[67]

CHA members have reported receiving estimates related to the implementation of the new template of $25,000 per hospital for the initial update. Annual maintenance and updating of the new template are estimated to cost approximately $20,000 per hospital. CHA notes the firm providing these estimates was widely used by hospitals to comply with the initial requirements. Based on CMS' analysis in the proposed rule that 7,098 hospitals would need to comply with the requirements, we believe that the actual initial implementation and ongoing annual maintenance costs are $178 million and $142 million, respectively. **We note that the implementation and annual maintenance costs are between 9 and 14 times greater than the amount CMS has projected in the proposed rule, which illustrates how significantly the agency has underestimated the cost of these new requirements. Given that over half of California's hospitals have negative margins and one in five are at risk of closing, we again ask that CMS pares back the requirements so that implementation and maintenance costs do not exceed its projections.**

Alignment with Transparency in Coverage and No Surprises Act

The proposed rule describes the consumer protections and transparency requirements in the No Surprises Act (NSA)and details the health plan transparency requirements incorporated into the Transparency in Coverage Act. CMS includes a request for information (RFI) in the proposed rule to gather feedback on how the hospital price transparency requirements can best support and complement the consumer-friendly requirements found in these other transparency initiatives. **CHA greatly appreciates CMS' thoughtful RFI. Below, please find CHA's detailed comments.**

California's hospitals strongly support providing patients and consumers with meaningful data that will help them make value-based decisions about where to receive health care services. To that end, CHA's members have a long track record of transparency. In accordance with state law,[68] California's hospitals provided uninsured patients with good faith estimates (GFEs) of their expected out-of-pocket costs for any planned health care service upon request prior to the passage of the NSA. Few states had such a requirement. And CHA's members have implemented out-of-pocket price estimation tools or posted a list of prices for 300 shoppable services to comply with CMS' price transparency requirements. **Of these requirements, CHA believes that the out-of-pocket price estimator has the most value as it provides patients with a specific estimate of what a health care procedure or service will cost a patient so that they can make an informed decision about where to receive their care. If CMS were to relax the hospital price transparency requirements, CHA anticipates that its members would continue making these valuable tools available on their websites to patients.**

CHA asks CMS to consider both the opportunity to reduce redundancy and the potential for unintended consequences created by myriad competing price transparency initiatives. The hospital price transparency requirements duplicate the data that are now available through the transparency in coverage requirements. And the insured GFE and AEOB duplicate existing CMS price transparency requirements for both hospitals and health plans related to providing information on shoppable services. These layers of duplication increase health plans' and hospitals' costs, translating into increased health insurance premiums without significantly improving the information available to patients to help them

[67] https://www.aha.org/system/files/media/file/2020/03/aha-reply-brief-case-to-prevent-disclosure-negotiated-contracts-2-28-2020.pdf
[68] California Health and Safety Code Section 1339.585

make value-based decisions about where to receive their health care. Given that the GFE and AEOB[69] provide patients with specific information about their out-of-pocket costs, CHA believes they present a significant opportunity to improve the information available to patients about their out-of-pocket costs and reduce administrative expenses.

The proposed rule notes that health plans are now posting machine-readable files containing all their negotiated rates with all providers for all items and services. This provides a "one-stop" data source for hospital prices that third parties can use to create transparency applications for employers, consumers, and other health plans. We have heard from some members who have reviewed the health plan machine-readable files to validate the prices posted for their hospital that they were unable to do so. The negotiated rate posted by the plan did not match the hospital's contract. As CMS notes, there are many ways to depict a negotiated rate (i.e., an algorithm, fixed dollar amount/fee schedule, expected allowed amount, etc.) as these processes are complex and don't translate easily to static spreadsheet fields. This complexity has led to inconsistency of the insurer and hospital files, which introduces confusion rather than clarity to the conversation around commercial rates.

Therefore, CHA recommends requiring just one entity to publish negotiated rates, with the understanding that those rates become the source of truth for commercial rate information. We recommend that the insurers carry this responsibility as they are the most complete source of this data for all of the health care providers they contract with to provide services to their members. This creates a more efficient one-stop shop for data aggregators that are using these files to create tools for employers and others who seek to use this data. To ensure the accuracy of the transparency in coverage data, CHA is aware that hospitals are working with their insurer partners to ensure the prices listed in the health plan machine-readable files accurately reflect the rates negotiated in the contract.

The statutory flexibility exists for CMS to harmonize these overlapping transparency requirements. Section 2718(e) of the Public Health Service (PHS) Act only requires hospitals to "make public … a list of the hospital's *standard charges*[70] for items and services provided by the hospital …" Based on widely accepted definitions of charges, we continue to believe that Congress did not intend for hospitals to post the prices they negotiate with health plans when it passed the Affordable Care Act (which included Section 2718(e) of the PHS Act). CMS has long defined "charges" in Section 2202.4 of the Provider Reimbursement Manual as follows:

> *Charges — Charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients' charges used in the development of apportionment ratios should be recorded at the gross value; i.e., charges before the application of allowances and discounts deductions.*

This definition is consistent with how other stakeholders have historically defined "charge" and was well understood by those drafting the Affordable Care Act. For example, the Healthcare Financial Management Association's (HFMA) Price Transparency Taskforce — which included consumer, hospital, health plan, and physician representatives — defined charge[71] and price as follows:

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[69] In an effort to support implementation of the AEOB CHA provided detailed comments in response to a request for information from the Departments of Health and Human Services, Treasury and Labor. This response is available here: https://calhospital.org/wp-content/uploads/2022/11/CHA-AEOB-RFI-Comment-Letter-Final-11.15.2022.pdf

[70] Emphasis added.

[71] https://www.hfma.org/content/dam/hfma/Documents/PDFs/Price%20Transparency%20Report.pdf

- *Charge:* The dollar amount a provider sets for services rendered before negotiating any discounts. The charge can be different from the amount paid.
- *Price:* The total amount a provider expects to be paid by payers and patients for health care services.

And the Provider Reimbursement Manual and commonly held definition of charges are consistent with how CMS initially interpreted Section 2718(e) of the PHS Act. In the FFY 2015 IPPS final rule (79 FR 50146), CMS required hospitals to post their chargemasters (a file that includes charges for all items and services provided by a hospital).

However, in the CY 2020 OPPS) proposed rule, CMS added a new meaning, not intended by Congress, to the well-defined phase "standard charge" in this proposed rule and the final regulations implementing the hospital price transparency requirements. At 84 FR 65524, CMS invented the term of art "payer-specific negotiated charges" in an attempt to fabricate a legal justification for requiring hospitals to post their negotiated rates. In it, CMS defines payer-specific negotiated charges as the "charge that a hospital has negotiated with a third-party payer for an item or service."

CHA notes that in attempting to define standard charges as payer-specific negotiated charges, CMS has materially edited Section 2718(e) of the PHS Act by deleting the word "standard" and adding the words "payer-specific negotiated." In CMS' rewriting of the statute, the concept described in the definition at 84 FR 65524 is actually the price based on the generally understood definition of that word. This is not what Congress intended when it used the words "standard charge" in Section 2718(e) of the PHS Act, based on the well-understood meaning of the word "charges" as evidenced by Section 2202.4 of the CMS PRM and HFMA Price Transparency Guidelines.

While we recognize that CMS prevailed in court on this issue, we fully believe the agency has the flexibility to revert to the requirements outlined in the FFY 2015 IPPS final rule. **Therefore, CHA respectfully asks CMS to eliminate the requirements for hospitals to post a machine-readable file containing the negotiated rates for all services.** We believe this requirement vastly exceeds what Congress intended in Section 2718(e) of the PHS Act. In its place, we ask that the agency reverts to its initial, correct interpretation of Section 2718(e) of the PHS Act in the FFY 2025 IPPS final rule (79 FR 50146) and require hospitals to post only their chargemasters. Taking this step will reduce unnecessary costs that do not improve patient outcomes or their experience of care and reduce the confusion that is inevitable if CMS persists in requiring both hospitals and health plans to post negotiated rate files. Further, we note that hospital negotiated rate will still be available for data aggregators through the health plan transparency in coverage machine-readable files. And, most importantly, patients will have access to specific estimates of their costs through the out-of-pocket price estimates hosted by health plans and hospitals on their website.

Partial Hospitalization and Intensive Outpatient Programs

Proposed CY 2024 Payment Rate Methodology for PHP and IOP

For CY 2024, CMS proposes to calculate hospital-based PHP payment rates for three services per day and four services per day based on cost per day using the broader OPPS data set, a change from the current methodology of using only PHP data. CMS believes using the broader OPPS data set allows the agency to capture data from claims not identified as PHP, but that includes the service codes and intensity required for a PHP day. This larger data set expands the sample size, allowing more precise rate

calculations. **CHA supports CMS' expansion of the set of claims used to calculate the PHP and IOP payment. We greatly appreciate CMS' efforts to increase access for Medicare beneficiaries to mental health services.** As discussed below, we strongly encourage the agency to use all the levers at its disposal to ensure that underserved populations can access these valuable mental health services.

Proposed Establishment of Medicare Benefit for IOP Services

CMS proposes policies to implement provisions of the CAA of 2023 that establish a new Medicare benefit category for IOP services. In general, CMS proposes policies that mirror requirements for PHP services, with the key difference being the level of intensity for services provided. Specifically, the IOP benefit is defined for patients who require at least nine hours per week of therapeutic services (compared to 20 hours per week for PHP services), are likely to benefit from a coordinated program of services, require more than isolated sessions of outpatient treatment, do not require 24-hour care, have an adequate support system while not actively engaged in the program, have a mental health diagnosis, are not judged to be dangerous to self or others, have the cognitive and emotional ability to participate in the active treatment process, and can tolerate the intensity of the IOP. Unlike PHP services, there is no requirement for the patient to need inpatient psychiatric care if the IOP services were not provided. **CHA strongly supports the establishment of the IOP benefit and we appreciate that CMS proposes to align most requirements with PHP services, including CMS' proposal to pay for IOP services using the same methodology as PHP for three and four service days.**

Payment Rates in Non-Excepted Off-Campus PBDs

CMS proposes to use the community mental health centers (CMHC) rates for PHP and IOP as the payment rates for PHP and IOP services furnished by non-excepted off-campus HOPDs. It would use the three services rate or the four-or-more-services rate based on how many services the non-excepted off-campus PBD furnished on that day.

Given the ongoing opioid PHE, the need for increased access to mental health services and substance use disorder treatment programs has never been greater. CHA members who have considered starting new, off-campus PHPs to meet the growing need for intensive outpatient mental health services report that doing so under the CMHC rate is not financially viable. However, if these off-campus, PHPs were paid as what they are — an off-campus, 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. This would also improve access to inpatient psychiatric services, which — as CMS is aware — are also in short supply.

CHA notes that 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.[72] Further, we note that CMS has also used its 1135 waiver authority to allow a hospital-based PHP to relocate part of its excepted provider-based department to a new off-campus location while maintaining the original provider-based location.[73] 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, we believe there is a compelling argument to be

[72] https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf
[73] 85 FR 27561 (https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf

made for using CMS' waiver authority under the opioid PHE to expand access to these desperately needed services.

Therefore, CHA respectfully asks CMS to use its Section 1135 waiver authority to provide similar flexibilities to off-campus hospital-based PHP and IOP during the ongoing opioid PHE. Specifically, we ask that CMS continues waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 and the PBD 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, we ask that CMS continues to allow excepted, provider-based PHPs to relocate part of their excepted provider-based PHP to a new off-campus location while maintaining the original location. We believe 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 CHA member 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.

Mental Health Services Furnished to Patients in their Homes

In the CY 2023 OPPS final rule, CMS established three HCPCS C-codes for mental health or substance use disorder services furnished by hospital staff to beneficiaries in their homes through communications technology. In the proposed rule, CMS proposes to remove the word "initial" from the descriptors of these codes, clarifying that the codes can be billed again if additional minutes of care are subsequently furnished. CHA supports this proposal.

In response to stakeholder input, CMS proposes to create a new, untimed, HCPCS C-code describing group therapy that can be reported when a beneficiary receives multiple hours of group therapy per day. Consistent with the three previously established codes, CMS proposes to assign the code based on the facility PFS payment for a similar service (CPT code 90853 for group psychotherapy) to reflect CMS' belief that the hospital has lower costs when providing a mental health service to a patient in the home rather than at the hospital. **CHA strongly disagrees with this assessment, and we urge CMS to reconsider the value of the assigned APCs for each of the remote mental health service codes, taking into account the significant investments in infrastructure and technology, as well as clinical and administrative staff necessary to provide remote services while maintaining access to in-person care.**

As noted in our comments on the CY 2023 OPPS proposed rule, increased access to virtual and remote services does not negate the need for providers — and especially hospitals — to maintain capacity for in-person care, which is the modality for the vast majority of patients. While hospital staff may be using communications technology to furnish a service remotely rather than in person, the hospital will still utilize administrative and nursing staff to "virtually room" the patients, while the clinician provides the same level of care as they would in person. A nurse's salary does not decrease just because they provide care to some patients virtually, and lower payment rates fail to fully value the level of care provided. Similarly, the costs associated with running a HOPD are not lowered simply because some patients are remote. The HOPD will still have the costs (both staffing and technology) related to scheduling, billing, and the electronic health record. And practices now incurring additional expenses related to additional hardware and software to support remote services on top of the cost required to maintain the physical clinic space from which the provider will see patients in person and virtually (in most instances). Any

potential cost savings are limited to supply costs, which will be de minimis given that these visits are for mental health services, not procedures. We are concerned that if not valued appropriately, providers could be inadvertently incentivized to see patients in the office, limiting access to mental health and substance use services that are more accessible for patients who live far from mental health providers and have health-related social risks such as transportation challenges.

In addition, we urge CMS to work with Congress to address statutory barriers to providing PHP and IOP services virtually. During the COVID-19 PHE, HOPDs expanded access to PHP services by providing services remotely to patients in their homes under the Hospital Without Walls waivers. We support policies that would allow for flexibility for PHP and IOP services to be provided in the home when the clinician determines it is clinically appropriate and the hospital clinical staff member and the beneficiary agree that the risks and burdens of an in-person service outweigh the benefits.

Finally, CMS proposes to implement provisions of the CAA of 2023 to delay in-person service requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until Jan. 1, 2025. CHA strongly supports this proposal and we encourage CMS to work with Congress to remove the statutory requirement for an in-person requirement permanently.

340B Separately Payable Drugs

CMS proposes to pay for separately payable drugs acquired under the 340B program at average sales price (ASP) +6%. **CHA strongly supports CMS' proposal.**

CMS has reconsidered the necessity of needing both the "JG" and "TB" modifiers. The proposed rule states that use of a single modifier will allow for greater simplicity and less burden on providers as they would only have to report only one modifier for all scenarios where a 340B drug is acquired. Effective Jan. 1, 2025, CMS proposes that all 340B-covered entities report only the "TB" modifier when a drug is acquired under the 340B program. The "JG" modifier will remain effective through Dec. 31, 2024, and providers will have the option to report either the "JG" or "TB" modifier during 2024. **While CHA appreciates CMS is proposing this change, we instead urge the agency to abandon the use of the 340B modifier entirely.**

The use and implementation of modifiers adds significant administrative cost — it requires considerable investment in systems and staff time to ensure that the modifiers are appropriately appended to the claims. In this case, even though the agency is attempting to consolidate modifiers, hospitals currently billing the "JG" modifier will need to modify their systems and programs to accommodate this change. These costs do nothing to improve patient care or outcomes.

Forcing hospitals to undertake this cost and staff burden directly contravenes CMS' longstanding policy to reduce provider burden, especially when less burdensome alternatives exist. Specifically, CMS states that it needs to have a 340B modifier in place to conform to the Inflation Reduction Act (IRA). However, we respectfully disagree. Specifically, the IRA excludes units of drugs that were purchased under the 340B program from being subject to the inflation rebate. To collect the necessary information, the agency could, for example, exclude all units of separately payable outpatient drugs (identified using the claim status indicator "K") that are billed by hospitals that participate in 340B. CMS also has the ability to identify which hospitals are currently participating in 340B, since that list is public and available through the Health Services and Resources Administration website. Under this alternative, the agency could use a far less burdensome approach, while still adhering to the IRA provision.

CMS in a separate rule[74] has proposed policies for repaying 340B hospitals for the years 2018-2022 when the agency inappropriately reduced reimbursement for separately payment drugs acquired under the 340B program to ASP – 22.5%. **CHA greatly appreciates and supports CMS' proposal to make a lump sum payment, including beneficiary cost sharing, for amounts owed to these hospitals for 340B drugs provided to Medicare beneficiaries. However, as discussed in our detailed comments, we strongly disagree that the agency is required to implement this payment in a budget-neutral manner. Therefore, we ask that CMS make these payments without the uncalled for and harmful reduction to the OPPS market basket update of -.5% beginning in CY 2025.**

Packaging Policies and Non-Opioid Treatment Alternatives

CMS proposes that the drugs described by HCPCS codes C9290 (i.e., Exparel), J1097 (i.e., Omidria), C9089 (i.e., Xaracoll), and J1096 (i.e., Dextenza) continue to meet the required criteria and should receive separate payment in the ASC setting. It proposes that the drug described by HCPCS code C9144 (i.e., Posimir) would not receive separate payment in the ASC setting under this policy as this drug will be separately payable during 2024 under OPPS transitional pass-through status.

Further, Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i), respectively, to provide for temporary additional payments for non-opioid treatments for pain relief**.** Because the additional payments are required to begin on Jan. 1, 2025, CMS plans to include its proposals to implement section 4135 amendments in the 2025 OPPS/ASC proposed rule. CMS seeks comments on the implementation of this provision.

CHA appreciates the agency's continued work on the negative impact packaging policies have on the use of non-opioid treatment alternatives in hospital outpatient settings. As in prior years, our members believe that the current packaging of non-opioid alternatives continues to present a barrier to their broader usage and, therefore, these treatments should be paid for separately.
We support CMS' proposal to unpackage Exparel, Omidria, Xaracoll, and Dextenxa when they are provided in ASCs. CHA encourages CMS to adopt a similar policy when they are provided in an HOPD. CHA also encourages CMS to consider unpackaging other non-opioid treatments, including drugs, devices, and therapy services that are not currently separately payable in both the ASC and HOPD settings. Based on feedback from our members, examples of other non-opioid treatments include the "On-Q" pain relief system, IV ibuprofen and acetaminophen, devices that use ice water for post-operative pain relief for knee procedures, therapeutic massage, and dry needling procedures. **While we appreciate that Section 4135(a) and (b) of the CAA is not effective until Jan. 1, 2025, we ask CMS to begin separate payment for non-opioid pain treatment alternatives for services provided on or after Jan. 1, 2024.** We believe this can be accomplished by issuing a waiver under the opioid PHE, which was declared on Oct. 26, 2017[75] and most recently renewed on July 7, 2023.

Payment for Dental Services

CMS proposes to assign 229 additional dental codes to clinical APCs to enable them to be paid for under the OPPS when payment and coverage requirements are met. OPPS payment will only be made for a dental code if it is among the types of dental services that are Medicare-covered when linked to covered

[74] CMS-1793-P, Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022; (Vol 88, No. 131); July 11, 2023
[75] https://aspr.hhs.gov/legal/PHE/Pages/Opioid-4Apr22.aspx

medical services. The dental services for which CMS proposes APC assignments are those dental services for which Medicare Part B payment can be made when they are inextricably linked to other covered medical services. **CHA strongly supports this proposal.**

RFI on Establishing and Maintaining Access to Essential Medicines

CMS is considering separate payment under the IPPS for 2024, and the OPPS for future years, for the costs of establishing and maintaining access to a buffer stock of essential medicines. This approach would be similar to the policy adopted for FFY 2023 under the IPPS and CY 2023 under the OPPS to maintain a supply of domestically sourced N-95 respirator masks. CMS would use its non-budget-neutral "exceptions and adjustments" authority under section 1886(d)(5)(i) for the IPPS payments and its budget-neutral section 1833(t)(2)(E) authority for OPPS payments.

CMS believes it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines. These potential separate payments would be in addition to payment for the essential medicines themselves, whether that payment is bundled with other items or services, or the essential medicines are separately paid.

The proposed rule indicates that it is challenging to quantify these additional resource costs precisely based on currently available information. Thus, CMS could initially base the IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock.

Costs could include those necessary to hold essential medicines directly at the hospital or contractually with a distributor or wholesaler. A hospital would report these costs in the aggregate on its cost report to CMS. These costs would not include the costs of the essential medicine itself. This information could be used to calculate a Medicare payment to establish and maintain access to a buffer stock of these essential medicines. Payments would be in accordance with reasonable cost principles through a biweekly payment with reconciliation during settlement of the cost report.
CHA thanks CMS for the RFI in the CY 2024 OPPS rule related to preserving access to essential medicines. We agree with CMS' assessment in the background discussion in this section that drug shortages are a persistent problem that, unfortunately, occurs with ever greater frequency. These shortages place patients at risk and unnecessarily increase health care spending as CMS details in the proposed rule. Like sourcing domestically produced N-95s, the cost — detailed below — necessary to establish and maintain a buffer stock of essential medicines is greater than the cost associated with more cost-efficient pharmaceutical supply chain models that require hospitals to hold minimal reserve stock and depend on frequent resupply from wholesalers to meet patient demand.

Hospitals have been pushed to rely on these more efficient supply chain models as the gap between the cost to provide care and payment for that care from Medicare and Medicaid has grown larger. This is an unintended byproduct of chronic underpayment from governmental payers. It has compressed hospital operating margins (as described in detail in the opening paragraphs of these comments) and forced hospitals to be extremely price-sensitive, even for essential generic medicines that on average may cost only a few dollars per vial and which are at high risk of drug shortage. Like the cost of procuring domestically produced N-95s and other personal protective equipment, the cost of carrying a buffer inventory adds to costs and threatens access to care by underserved populations by undermining a

hospital's financial sustainability. CHA thanks CMS for recognizing that a reserve inventory model will, on average, cost more than a cost-efficient model that uses a just-in-time approach.

CHA believes the availability of supplemental payments could encourage hospitals to maintain buffer stocks. However, we note that as a result of over 20 years of inadequate payment updates in the IPPS and OPPS, the agency is now slowly unbundling the MS-DRG and APC by providing supplemental payments to cover basic hospital operating costs. **CHA respectfully believes that a better approach — as requested above and in prior comment letters related to hospital payments — is to provide an adequate market basket update that addresses the inflationary pressures hospitals continue to face. If the agency persists in providing inadequate market basket updates, then CHA is supportive of these types of add-on payments.** However, we are concerned that smaller hospitals and health systems may not be able to meet the requirements to receive them and will face additional margin pressure. This will negatively impact access to care for all patients — particularly those who have historically faced access issues.

Costs Associated with Maintaining a Buffer Stock of Essential Medicines

Typically, very few hospitals hold their own buffer stocks due to the complexity of inventory management and associated expenses. These stocks are held upstream of an individual facility either in a health system's corporate warehouse or by a pharmaceutical wholesaler/distributor. The costs associated with maintaining buffer stocks of essential medicines in a health system-owned warehouse include the warehousing costs,[76] costs associated with supply rotation and inventory management, wastage for medicines that expire before they are used, and updating stockpiles. However, more commonly, hospitals and health systems contract with pharmaceutical wholesalers to provide access to buffer stocks of essential medicines. **CHA appreciates that the RFI discussed both models and supports, including the costs of both models as allowable for reimbursement if it provides an additional payment for maintaining a buffer stock of essential medicines.**

In the RFI, CMS suggests that hospitals would be required to maintain at least a three-month buffer stock of essential medicines to qualify for the additional payment for maintaining the supply. However, CHA asks that CMS exempt any medicine that is in short supply when hospitals and health systems build their initial stocks. Additionally, if CMS finalizes a payment for hospitals that maintain buffer stocks, the three-month buffer inventory is a target. **However, when one or more of the medicines deemed essential is in short supply, CHA asks CMS to clarify that hospitals and health systems may reduce inventory below the stated par level without becoming ineligible for the additional essential medicines buffer stock payment. CHA strongly believes that in this very likely circumstance, payment should not be reduced.**

In the RFI, CMS defines essential medicines as the 86 drugs included in the Administration for Strategic Preparedness and Response's report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*. CHA asks CMS to clarify that a hospital would not have to maintain a buffer stock of all 86 essential medicines to qualify for the additional payment. CHA strongly believes it is important that hospitals have the flexibility to maintain a buffer stock of only the essential medicines that are necessary for each specific facility. Setting a rigid standard that does not reflect the services and operations of each hospital will only serve to increase costs and create artificial shortages.

[76] This includes the capital costs associated with owning or leasing such a facility and the ongoing operating costs. Operating costs would also include the cost of cold storage.

Costs Associated with Acquiring Domestically Manufactured Essential Medicines

CMS states in the RFI that the potential payment would account for any increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines compared to non-domestically manufactured ones. CHA notes the incremental cost associated with domestic sourcing would be more challenging for any entity to calculate. In many instances, manufacturers do not list the location where their product is manufactured, so it may not be known to hospitals. Therefore, CHA respectfully asks the agency to clarify how it defines domestic manufacturing. Specifically, would all of the active pharmaceutical ingredients in an essential medicine have to be sourced in the United States or one of its territories for CMS to deem that it was domestically manufactured? Or would the agency consider a drug that was manufactured in the United States or its territories using active pharmaceutical ingredients that were sourced from outside of the United States domestically manufactured? In response to these questions, CHA urges CMS to work with the Food & Drug Administration (FDA) to develop a more expansive and appropriate definition of domestically manufactured drug products. We also urge the agency to consider adding drug products manufactured in Organization for Economic Co-operation and Development countries to this proposed policy such that it fulfills the intent of building a more resilient and reliable drug supply chain more meaningfully. Finally, we encourage CMS to work with the FDA and pharmaceutical manufacturers to ensure providers can efficiently and easily identify the origin of the drugs.

Cost Reporting Worksheets

CMS states that if it moves forward with this model it will need to develop a separate cost reporting worksheet to calculate the allowable costs associated with holding buffer stocks of essential medicines. CHA notes that buffer stocks for most hospitals that are part of health systems are held at the corporate level. In addition to developing a specific worksheet for the hospital cost report (CMS 2552-2010), CMS will also need to develop a form for the home office cost report (CMS 287-05) to accurately apportion the costs from the home office to the component hospitals.

CHA would like to stress that the information provided above is a high-level summary of the models used to hold buffer stocks of essential medicines and the costs associated with maintaining them. **As such, CHA strongly encourages CMS to convene a technical workgroup of hospital and health system pharmacists, supply chain, and finance experts to provide subject matter expertise on this highly complex area as the agency develops this additional payment.**

Allowable Cost for Maintaining Buffer Stocks of Essential Medicines

In the RFI, CMS states that it would "initially base the IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock." CHA interprets this statement as implying that payment would only be made for "Medicare's share" of the costs associated with maintaining a buffer stock of essential medicines. **CHA asks CMS to clarify that it will also include the costs associated with maintaining a buffer supply of essential medicines for Medicare Advantage patients in the lump sum payment if it is finalized**. We believe it would be appropriate to make separate payments for this, similar to how CMS pays hospitals for the Medicare Advantage patients' share of the direct and indirect costs of graduate medical education for teaching hospitals.

Further, we ask CMS to expand the costs it will cover beyond just the Medicare fee-for-service (FFS) and Medicare Advantage populations. Medicare FFS only accounts for 16.6%[77] of California hospitals' total

[77] CHA analysis of 2021 California Department of Health Care Access and Information data

patient net revenue. CHA is concerned that if CMS limits this payment to only the "Medicare share" of a buffer stock of essential medicines, the additional payment will not be sufficient to support a buffer stock of sufficient duration for all patients. And we are not aware of any other payer that is currently providing a specific payment related to maintaining a supply of essential medicines. Therefore, hospitals will not be able to afford to maintain a buffer stock for all patients if the payment only covers the cost of maintaining a supply of essential medicines for only Medicare patients. **CHA strongly encourages CMS to expand the proposed essential medicines payment to cover the cost of maintaining a stockpile for all patients — not just Medicare FFS and Medicare Advantage patients — over the course of a hospital's fiscal year.** If CMS does not have the statutory authority to do this, we ask the agency to work with Congress to embed this flexibility into the Medicare statute.

Essential Medicines Payment Should be Non-Budget Neutral

CHA believes it is necessary that any payment for maintaining a stockpile of essential medicines be made in a non-budget-neutral manner. If payment is expanded to patients whose services are paid for under the OPPS, CMS must work with Congress to exempt the additional spending on buffer stocks from the requirements at 1833(t)(2)(E). Otherwise, making an additional payment in a budget-neutral manner is robbing Peter to pay Paul and will harm smaller facilities and health systems that are unable to build and maintain stocks of essential medicines.

Hospital Outpatient Quality Reporting Program

Proposed Removal of the Left Without Being Seen (LWBS) Measure

CHA supports CMS' proposal to remove the LWBS measure — a process measure that assesses the percent of patients who leave the emergency department without being evaluated by a physician, advanced practice nurse, or physician assistant — beginning with CY 2024. CHA agrees with CMS' assessment that the LWBS measure does not provide enough granularity for actionable data toward quality improvement and lacks sufficient evidence that the measure promotes quality of care and improved patient outcomes.

Proposed Adoption of New Measures for the Hospital Outpatient Quality Reporting (OQR) Program Measure Set

Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (HOPD Procedure Volume) Measure

CMS proposes to adopt a modified version of the HOPD Procedure Volume measure — which was previously removed in the CY 2018 final rule due to a lack of evidence to support a link to overall facility performance or quality improvement — beginning with voluntary reporting for the CY 2027 payment determination, and mandatory reporting beginning with the CY 2028 payment determination.

The proposed measure collects data on the aggregate volume of selected surgical procedures, which are included in one of the following eight categories:

- Cardiovascular
- Eye
- Gastrointestinal
- Genitourinary
- Musculoskeletal
- Nervous system
- Respiratory

- Skin

CMS proposes to readopt the measure with the modification that instead of collecting and publicly displaying data on the eight categories broadly, it would collect and display more granular data for each category in the top 5 most frequently performed procedures in HOPDs. The top 5 procedures for each category would be updated annually. Hospitals would submit annual, aggregate-level data through the CMS web-based tool during the time of Jan. 1 through May 15 in the year prior to the affected payment determination year.

CHA does not support the re-adoption of the HOPD Procedure Volume measure in the OQR program. We disagree that volume is an appropriate proxy to indicate the quality of care provided by a facility. There are many reasons why volume may differ among facilities that are not tied to the quality of care delivered. For example, a hospital may serve a more complex patient population that necessitates more procedures provided in the inpatient setting but still provides excellent care to those in the outpatient setting. Further, CMS has not provided evidence for a threshold to determine at what volume patient outcomes improve for specific procedures, making comparisons among facilities highly arbitrary and potentially misleading to patients. We urge CMS to reconsider its proposal and instead focus on measures that directly measure the outcomes of outpatient procedures.

Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO–PM)
The THA/TKA PRO-PM was adopted in the FFY 2023 IPPS final rule into the Hospital Inpatient Quality Reporting (IQR) program. CMS proposes to adopt the measure into the OQR program, using the same measure specifications as used in the IQR program, but with modifications to include HOPD procedures. CMS proposes to adopt the measure with two initial voluntary reporting periods in 2025 and 2026, with mandatory reporting beginning with the 2027 Reporting Period/2030 payment determination. The measure uses standardized, validated survey instruments completed within three months pre- and at about one year post-operatively to assess patient-perceived pain and function.

As noted in our comments on the FFY 2023 IPPS proposed rule, CHA supports the concept of patient-reported outcome measures, but we remain concerned that measure results will not be useful for evaluating quality due to the significant challenges of collecting post-operative data from patients. Many patients travel to a specific facility for their elective surgeries — often from significant distances — and complete follow-up care back in their home communities under the care of other providers. Despite hospitals' best efforts to collect this data, patients do not always respond to surveys a year after their procedure. We urge CMS to carefully evaluate data submitted during the voluntary reporting periods — both in the IQR and OQR programs — to learn how it could reduce the reporting burden for facilities while improving patient engagement prior to finalizing a date certain for mandatory reporting.

Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults Measure (Excessive Radiation eCQM)
CMS proposes to adopt the Excessive Radiation eCQM — which provides a standardized method for monitoring the performance of diagnostic CT — beginning with voluntary reporting in the 2025 reporting period and mandatory reporting beginning with the 2026 reporting period/2028 payment determination. The measure is not risk-adjusted and is expressed as a percentage of eligible CT scans that are out-of-

range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.

CHA urges CMS not to finalize the Excessive Radiation eCQM as a mandatory measure beginning with the CY 2026 reporting period and to consider allowing additional years of voluntary reporting. The measure relies on specific software that would be used to calculate the data elements from multiple hospital sources. Though it would be offered for free, the integration of this software into facility electronic health record systems and the subsequent changes to processes needed to aggregate multiple data components into the hospital's workflow will be significant. In addition, the volume of CT scans is significant, particularly in outpatient settings like the emergency department, and hospitals will need to dedicate significant resources to the data submission process.

In addition, we are concerned that the measure specifications do not fully account for the myriad patient care considerations that go into determining and performing a CT scanning protocol. Considerations include the type and reason for the scan, the size of the patient, the patient's hemodynamic function and ability to cooperate, and the type of scanner. Simplifying these into a single threshold value may not appropriately measure the value of the scan to the patient and/or their treatment. We encourage CMS to review data voluntarily reported — both for the IQR program where the measure is available for hospital self-selection beginning with the CY 2025 reporting year, and voluntary OQR reporting — to determine if the measure results in data that are actionable for quality improvement prior to finalizing the measure as mandatory for the OQR program.

Proposed Modifications to Previously Adopted Measures

COVID-19 Vaccination Coverage Among HCP

CMS proposes to modify the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure to replace the term "complete vaccination course" in the measure specifications with a definition of "up to date" per the Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccines. The agency proposes this modification to incorporate evolving CDC guidance related to booster doses and their associated time frames. While the denominator of the current measure would not change — and is reflective of all HCP eligible to work in the hospital for at least one day during the reporting period — the numerator of the measure would be changed to be the cumulative number of HCP in the denominator population who are considered up to date with the recommended COVID-19 vaccines as defined by the CDC on the first day of the quarter.

CMS does not propose any changes to the data submission or reporting processes for the measure, and hospitals would continue to be required to collect data for at least one self-selected week during each month of the reporting quarter and submit that data to the CDC National Healthcare Safety Network prior to the quarterly deadline.

CHA notes that CMS has now finalized this change across its IQR programs in earlier rulemaking. While we continue to strongly support efforts to maintain high levels of up-to-date vaccination for COVID-19 among both HCP and the communities they serve, we remain concerned that the data reporting requirements associated with the measure will divert already stretched resources from patient care to administrative processes. The CDC's definition of "up to date," can change every quarter, and it is challenging for hospitals to collect and continuously assess the vaccination status of every single employee who works in the facility for a given reporting period. Further, the requirement that hospitals

collect and report on this data for at least one week each month has strained the already stressed workforce.

In developing the measure, CMS relied heavily on the specifications and experience with the Influenza Vaccination Among HCP measure. The flu vaccine measure assesses vaccinations during "flu season" — defined as October through March — and is reported annually. While there are still questions about the seasonality of COVID-19, future vaccination schedules, and how often new versions of a COVID-19 vaccine will be available, an annual data collection and reporting process is significantly less burdensome than reporting data for one week out of each month of the year. **We urge CMS to consider limiting the reporting requirements to at least one week for each quarter and work with the CDC to develop a version of the measure that could be reported annually.**

Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (Cataracts Visual Function) Measure
CHA supports CMS' proposal to modify reporting requirements for the voluntary Cataracts Visual Function measure by limiting the allowable survey instruments that may be used for the measure to three survey instruments. We appreciate that CMS has responded to stakeholder concerns with the burden of reporting this measure, and we agree that reducing the number of survey instruments will improve data collection standardization.

CHA appreciates the opportunity to comment on the CY 2024 OPPS proposed rule. If you have any questions, please contact me at cmulvany@calhospital.org or (202) 270-2143, or Megan Howard, vice president of federal policy, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy