September 13, 2022

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

SUBJECT: **CMS-1772-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, *(Vol 87, No 142), July 26, 2022***

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) 2023.

CHA's members remain appreciative of the federal government's efforts to support hospitals during the COVID-19 public health emergency (PHE). This includes CMS-provided waivers offering flexibility that remain in place and financial support through the Provider Relief Fund that offsets costs and lost revenue related to COVID-19 and incurred through March 31, 2021. These continued flexibilities and financial support are crucial if hospitals are to continue operations and invest in the staffing, supplies, and infrastructure necessary to maintain access for all who need care.

Three years into the PHE, California's hospitals — like other hospitals across the nation — continue to face unprecedented challenges posed by COVID-19. Despite these challenges, California's hospitals are providing care to those afflicted by COVID-19, addressing the backlog of services that has resulted in sicker patients[1], and taking steps to address the conditions that give rise to inequitable health outcomes. And our member hospitals are doing this in the face of considerable financial headwinds. At the same time, federal support for COVID-19 relief has evaporated — leaving hospitals to shoulder the expenses of protecting patients and communities from the PHE alone — while labor and supply costs are increasing in an unsustainable manner.

[1] https://www.aha.org/system/files/media/file/2022/08/pandemic-driven-deferred-care-has-led-to-increased-patient-acuity-in-americas-hospitals.pdf

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A recent analysis by Kaufman Hall,[2] a nationally renowned consulting firm, estimates that even after federal support, California's hospitals lost more than $12 billion in 2020 and 2021. Median expenses per discharge for California hospitals rose 15% in 2021, outpacing the 11% national average. These cost increases were largely driven by higher labor costs (+16%) and supply chain shortages impacting pharmaceuticals (+41%) and medical supplies (+19%).[3] As a result of COVID-19-related losses and increasing costs per adjusted discharge that outstrip Medicare payment updates, 51% of California's hospitals had negative margins in 2021. These margins are unsustainable and jeopardize the stability of the delivery systems that are essential to ongoing efforts to respond to the pandemic, ensure access for all who need care, and address the social determinants of health in communities that give rise to inequitable outcomes. If negative margins persist, hospitals and health systems that are experiencing them will be forced to discontinue services needed by the community but that are financially unsustainable and rationalize those of questionable financial viability.

Given these losses, CHA's members are deeply concerned by the inadequate market basket update proposed in the CY 2023 rule. Despite these concerns, CHA appreciates that in the CY 2023 proposed rule CMS has indicated that it will, in the final rule, make payments for separately payable Part B drugs acquired under the 340B program at average sales price (ASP) +6% and provide an add-on payment in the inpatient prospective payment system (IPPS) and OPPS for domestically manufactured N95 respirators.

In summary, CHA:

- Is deeply concerned that the proposed market basket update is wholly inadequate given the input cost inflation providers have experienced, and will continue to experience, in the face of ongoing labor shortages and supply chain disruptions. CHA again respectfully asks CMS to use alternative sources of data that better reflect input price inflation to calculate the 2023 market basket update in both the IPPS and OPPS. Additionally, we again respectfully ask CMS to use its existing authority to eliminate the productivity adjustment from the market basket update calculation for any year impacted by the COVID-19 PHE.
- Appreciates CMS' intention to adhere to the recent Supreme Court ruling and pay for separately payable Part B drugs at ASP + 6%. Further, CHA respectfully asks the agency to recalculate payments for 340B-eligible hospitals for the years 2018-22 at ASP + 6% (as required by the Supreme Court decision for 2018 and 2019 and implied for the years 2020 through 2022) in a non-budget-neutral manner.
- Believes that CMS has overestimated the fixed-loss outlier threshold. We ask the agency to calculate the outlier threshold using data that better reflect the lower anticipated COVID-19 caseload hospitals will experience in CY 2023.
- Supports CMS' proposal to exempt some hospitals from the site-neutral clinic visit payment policy. We believe this is a necessary step to expanding access to primary care in areas where patients are at risk of inequitable outcomes.
- Supports CMS' decision to provide an add-on payment for domestically manufactured N95 respirators. CHA encourages CMS to expand the types of personal protective equipment (PPE) eligible for this payment and work with Congress to make the payment in the OPPS in a non-budget-neutral manner and on an all-payer basis.
- Is deeply concerned about the reduction in payment for partial hospitalization programs. CHA asks that, in light of the ongoing opioid PHE, CMS ensure access to PHP services by increasing

[2] https://www.kaufmanhall.com/sites/default/files/2022-04/KH_CHA-2021-Financial-Analysis-Ebook.pdf
[3] Expense increases based on per adjusted discharge

the payment rate. Otherwise, CHA is deeply concerned that inadequate rates will further exacerbate challenges faced by Medicare beneficiaries when they attempt to access mental health services.

- Supports CMS' proposal to establish payment under the OPPS for remote mental health services furnished in the patient's home but urges the agency to ensure payment rates reflect the full cost of providing remote care while maintaining the capacity for in-person services
- Supports CMS' proposal to return to voluntary reporting status of Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) in the Outpatient Quality Reporting (OQR) Program and urges CMS not to consider the development of a volume indicator measure for the program in the future
- Urges CMS to reconsider the addition of new services to the list of those subject to prior authorization and asks the agency to provide information on provider exemption determinations for the prior authorization program

Our detailed comments on CMS' proposals follow.

Outpatient Market Basket Update

CMS proposes to increase the outpatient market basket update to the conversion factor, net of the total factor productivity (TFP), by 2.7%[4] in 2023. **CHA is deeply disappointed in the proposed 2.7% market basket update. 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 approximately .83%[5] after implementation of the 340B budget neutrality adjustment and a similar increase in the final rule OPPS market basket update, as was provided in the IPPS final rule. This 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[6] on the federal fiscal year (FFY) 2023 proposed IPPS rule and reiterated here, we believe this is the result of methodological issues associated with the data CMS use to calculate the market basket update. **Further, given that Section 1833(t)(3)(C)(iv) of the Act ties the OPPS market basket update to the IPPS update, we respond to CMS' comments in the IPPS final rule and again respectfully ask the agency to calculate both the IPPS final rule market basket update and the OPPS proposed rule market basket update using data from the Medicare cost report. We believe this is a more timely and accurate proxy for the cost increases hospitals are facing.** 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.

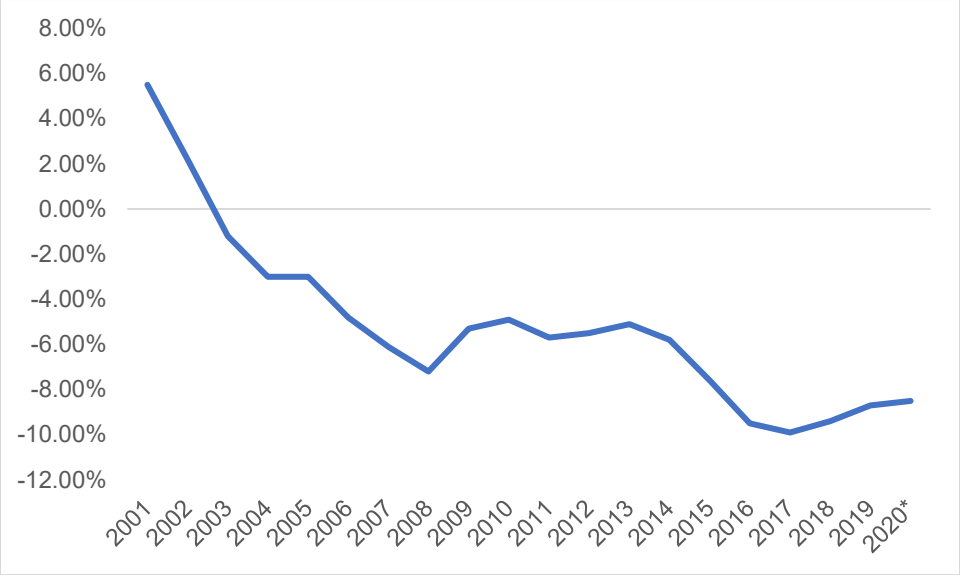
While CMS may claim in the CY 2023 OPPS final rule that comments related to revisions to the IPPS final rule market basket update are out of scope, they — respectfully — are clearly not. In defining the outpatient department (OPD) fee schedule, Section 1833(t)(3)(C)(iv) specifically references "the market basket percentage increase applicable under section 1886(b)(3)(B)(iii)." Below, please find CHA's specific

[4] This includes a market basket of 3.1% reduced 0.4 percentage points for TFP.
[5] This includes an IPPS final rule market basket update of 4.1% reduced by 0.3 percentage points TFP, includes a budget neutrality adjustment for 340B, and assumes other proposed rule budget neutrality adjustments are held constant.
[6] https://calhospital.org/wp-content/uploads/2022/06/CHA-Comments-FFY-2023-IPPS-Proposed-Rule-Comment-Letter-061722-Final.pdf

comments and responses to CMS' discussion of the IPPS market basket update in the FFY 2023 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.

PPS Hospital Medicare Margins: 2001 to 2020[7,8]



*Includes Provider Relief Funds

This longstanding trend has continued in 2022 and has been exacerbated by the labor dislocations and supply chain breakdowns resulting from the pandemic and other geopolitical forces beyond the control of hospitals. These exacerbations are expected to persist beyond 2023, driving further inflation in input costs. Expenses per adjusted discharge have accelerated dramatically, offsetting the limited increases in revenue hospitals have experienced, which has resulted in reduced margins that threaten hospitals' financial viability. As an example, total California hospital expenses rose 15% in 2021 from pre-pandemic (2019) levels, compared with 11% nationally.[9]

While CHA appreciates that CMS will refresh the OPPS market basket update in the final rule with more recent data, as stated above, we are deeply concerned that the revised update will still be insufficient relative to input cost inflation — particularly for labor. For instance, 53% of the hospital market basket is attributed to wages, salaries, and total benefits for hospital-employed workers. In the IPPS final rule, CMS states that IHS Global Inc.'s FFY 2023 forecast figure for this element of the market basket is based on a historical figure of 4.8% for the four quarters ending March 31, 2022 — a figure that is considerably lower than what California's hospitals have recently experienced.

The employment cost index (ECI) that is the basis for the above number only includes hospital-employed staff. Driving the growth in labor expenses has been an increased reliance on contract staff, especially contract nurses, due to persistent clinical labor shortages. These are integral members of the clinical care

[7] https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch3_SEC.pdf
[8] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch3_sec.pdf
[9] https://www.kaufmanhall.com/sites/default/files/2022-04/KH_CHA-2021-Financial-Analysis-Ebook.pdf

team; without them, inadequate staffing would force hospitals to reduce services. In 2019, hospitals spent a median of 4.7% of their total nurse labor expenses on contract travel nurses. This skyrocketed to a median of 38.6% in January 2022. A quarter of hospitals — those that have had to rely disproportionately on contract travel nurses — saw their costs for contract travel nurses account for over 50% of their total nurse labor expenses.[10] CHA understands the ECI that is used for 53% of the hospital market basket will not account for these higher labor costs associated with contract nurses. This illustrates one of the flaws with the current data CMS are proposing to use for the CY 2023 market basket update.

In the IPPS final rule, CMS attempts to address technical comments about labor cost inflation as a result of the significantly increased utilization of contract labor by stating:

> *As such, the IPPS market basket increase would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage price growth or higher energy prices) but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract and staff nurses (which would be reflected in the Medicare cost report data). We note that cost changes (that is, the product of price and quantities) would only be captured in the market basket weights when the index is rebased and the base year is updated to a more recent time period.*[11]

Respectfully, CHA disagrees with CMS' statement that the changes in labor costs that hospitals are currently experiencing as a result of increased use of contract labor would be captured by rebasing the market basket update. Rebasing the market basket captures changes in labor and other costs as a percent of total costs. As a result of shortages of employed nursing and clinical staff during the PHE, hospitals have been forced to use more expensive contract labor. Effectively, this substitution of contract labor for employed labor has increased per-unit costs of labor that are not captured by the ECI or the market basket.

Even before the application of the productivity adjustment (discussed further below) the methodology — based on IGI data — has failed to keep up with cost growth year over year as illustrated above. Inflation has reached levels not seen in 40 years,[12] which predates the implementation of the IPPS in October 1983. It is clear, based in particular on rapidly rising labor costs, that CMS' current inputs for updating the OPPS market basket update are ill-suited to a highly inflationary environment. CMS has acknowledged that "payment updates during times of economic uncertainty can often result in larger forecast errors in either direction."[13] **Therefore, we ask CMS to use the "exceptions and adjustments" authority found in Section 1886(d)(5)(I)(i) of the Act to use more accurate inputs to calculate the IPPS final rule "base" (before additional adjustments) market basket update that better reflects the rapidly increasing input prices facing hospitals.** Given that Section 1833(t)(3)(C)(iv) ties the IPPS market basket update to the OPPS market basket update, using more accurate inputs and CMS' exceptions and adjustments authority to correct methodological issues with the IPPS market basket update is the only way to correct methodological issues with the OPPS market basket update.

[10] Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems, American Hospital Association, April 2022
[11] Emphasis added
[12] https://www.npr.org/2022/02/10/1079260860/january-inflation-consumer-prices-cpi-economy-federal-reserve
[13] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/info.pdf

CHA asks CMS to consider using the growth rate in allowable ***Medicare costs per CMI adjusted*** discharge for acute PPS hospitals between FFY 2019 and FFY 2020 to calculate the FFY 2023 final rule (and as a result CY 2023 OPPS) market basket update(s). Given the high labor component of both in and outpatient care, CHA believes that the rate of cost increase for inpatient acute discharges between FFY 2019 and FFY 2020 is an accurate proxy for the increase in the growth in costs to provide outpatient care to Medicare beneficiaries.

The data for the calculation described above 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 (e.g., prior to productivity, documentation and coding, budget-neutrality adjustments) market basket update of 7.99%. A market basket update of 7.99% for both FFY and CY 2023 better reflects the actual input price inflation California's hospitals anticipate facing in the coming year rather than the 2.7%[14] market basket update in the OPPS proposed rule (or the 3.8%[15] market basket update finalized in the IPPS and anticipated .83% OPPS final rule update).

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

> *For purposes of this subparagraph, subject to paragraph (17)[16] and subparagraph (F)[17] 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)[18] 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 personnel costs and excluding 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 2023 than the forecast IGI data used in the proposed rule.

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[14] Net of productivity adjustment, does not include other budget neutrality adjustments
[15] Net of productivity adjustment, does not include other budget neutrality adjustments, or documentation and coding adjustment
[16] Section of the Act that adjusts the market-based update based on quality reporting requirements
[17] Section of the Act that implements the productivity adjustment
[18] 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."

CHA recommended in its comments on the IPPS proposed rule (and continues to recommend in this letter) using the CMI-adjusted cost per discharge to address the issues raised by CMS in its response to comments in the FFY 2023 IPPS final rule. In the rule, CMS states:

> *"…the Medicare cost report data also reflects factors that are beyond those that impact wage or price growth. For instance, overall costs as reported by hospitals would also reflect changes in the mix of inputs used to provide services; since 2020, observed IPPS case-mix (and associated higher payments to hospitals) has increased faster than in prior years and would likely reflect the use of more skilled care needed to provide these services."*

First, using the CMI-adjusted 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 2020 expense 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.

Further, CMS typically uses proxy data wherever possible to avoid circularity issues. However, CHA does not believe this is a reasonable argument against using cost report data. In many instances, the "proxy data" used to construct the market basket update are based on Bureau of Labor and Statistics' (BLS) surveys of hospitals.[19] Therefore, we do not believe that using cost report data in this instance introduces any additional circularity to CMS' calculation of the market basket update than already exists.

Additionally, while any hospital data obtained from the BLS are only a representative sample, using as-filed cost report data will allow CMS to base the market basket update on all IPPS/OPPS hospitals. The cost reports that supply these data won't be audited and "finalized." However, CHA notes that BLS data are not audited either.

The data reported on Worksheets D-1, Part II, and S-3 Part I of the Medicare cost report are likely to be more accurate than the data reported to the BLS. Hospitals have decades of experience completing these worksheets (which have detailed instructions) and the data input into Worksheets A (hospital expenses) and C (hospital revenue) — from which Worksheet D-1, Part II is derived — must reconcile to the hospital's audited financial statements when the cost report is filed. Neither of these things can be said about the BLS data.

Market Basket Update – Productivity Adjustment

The productivity adjustment required under the Affordable Care Act (ACA) is estimated to be -0.4 percentage points in the CY 2023 proposed rule. CMS uses the total factor productivity adjustment as calculated by the BLS. The adjustment is calculated, as it has been in the past, as the 10-year moving average of changes in multifactor productivity for the period ending September 30, 2023, based on IGI's fourth quarter 2021 forecast.

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 outpatient care to patients is highly labor intensive, as CMS' projection of the labor-related portion of the federal rate — 60% — implies in the FFY 2023 proposed rule. **CMS itself has acknowledged that hospitals are unable**

[19] For example, the labor portion of the market basket update is based on the BLS' hospital Employment Cost Index.

to achieve the productivity gains assumed by the general economy over the long run.[20,21] CHA appreciates this acknowledgment and agrees that the assumptions underpinning the productivity adjustment are fundamentally flawed. We strongly disagree with the continuation of this punitive policy — particularly during the PHE.

Hospital-based outpatient care must be provided on-site and has a high "hands-on" component. Therefore, hospitals cannot improve productivity 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 non-farm business sector.[22] **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 in hospital payments.**

CHA also notes that during the COVID-19 PHE, productivity fell as a result of increased staff turnover and deployment of temporary staffing due to the labor shortage. The use of contract labor substituting for employed staff has also had a negative impact on productivity. As has been widely documented,[23] temporary staff are not accustomed to a specific facility's workflows, which increases the number of hours required to provide care to patients.

As discussed above, the section of the Act that implements the outpatient market basket update does so by referencing the inpatient market basket update. In CHA's comments[24] in response to the FFY 2023 IPPS proposed rule, we respectfully asked CMS to use its "exceptions and adjustments" authority under Section 1886(d)(5)(I)(i) of the Act to remove the productivity adjustment from the inpatient market basket for any fiscal year that was covered under the PHE determination (e.g., 2020, 2021, and 2022) from the calculation of market basket for FFY 2023 and any year thereafter. In the IPPS final rule, CMS states:

> *While we appreciate the commenters' concerns, section 1886(b)(3)(B)(xi)(I) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPPS market basket update when determining the applicable percentage increase. Section 1886(d)(5)(I)(i) of the Act authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.*

While the agency does not say it explicitly, the quote above implies that CMS believes its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act is limited to only provisions in section 1886(d) and, therefore, CMS lacks the authority to waive the productivity adjustments because they are not in that section.

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[20] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf
[21] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/info.pdf
[22] ibid
[23] https://www0.gsb.columbia.edu/faculty/abartel/papers/human_capital.pdf
[24] https://calhospital.org/cha-issues-draft-comments-on-ffy-2023-ipps-proposed-rule/

Section 1886(b)(3)(B)(xi)(I) states:

> *For 2012 and each subsequent fiscal year, after determining the applicable percentage increase* ***described in clause (i)***[25] *and after application of clauses (viii) and (ix), such percentage increase shall be reduced by the productivity adjustment described in subclause (II).*

CHA notes that 1886(b)(3)(B)(xi)(I) (above) references 1886(b)(3)(B)(i) (below):

> *For purposes of* ***subsection (d)***[26] *and subsection (j) for discharges occurring during a fiscal year, the "applicable percentage increase" shall be—…*

Section 1886(b)(3)(B)(i) references subsection (d) — 1886(d) — to which the exceptions and adjustments authority applies. This form of statutory construction is certainly not uncommon in the Medicare program. **Therefore, by reference, CHA respectfully believes Congress has extended to CMS the exceptions and adjustments authority found under section 1886(d)(5)(I)(i) to the productivity adjustment in section 1886(b)(3)(B)(xi)(I). Given the statutory linkage between the IPPS and OPPS productivity adjustment, CHA again respectfully asks CMS to use its "exceptions and adjustments" authority and remove the productivity adjustment from the inpatient market basket update (and thereby also the outpatient market basket update).**

If CMS fails to take the steps described above and provide an adequate market basket update, CHA is deeply concerned about access to robust hospital-based outpatient services for Medicare beneficiaries. Given that payment rates for governmental health care programs do not cover the cost to provide care, we believe access could be challenged — particularly in economically disadvantaged areas — for services that are not financially self-sustaining.

Conversion Factor Calculation

On pages 44527 – 44528, CMS discusses its calculation of the OPPS conversion factor for 2023. The detail regarding this adjustment can also be found on page 24 of the Medicare CY 2023 OPPS Proposed Rule Claims Accounting.[27] CHA has concerns about two specific adjustments that CMS proposes to make for budget neutrality. Both relate to Medicare's 340B payment policy.

The first issue relates to the budget-neutrality adjustment for the 340B policy proposed on page 44648. On June 15, 2022, the United States Supreme Court struck down CMS' policy of paying for drugs acquired under the 340B program at ASP -22.5%. Given that the Supreme Court's decision occurred shortly before the release of the 2023 proposed rule, CMS lacked the necessary time to reflect a payment policy other than the one it intended to propose — ASP -22.5% — in the payment rates, tables, and addenda for the proposed rule. However, CMS fully anticipates adopting ASP +6% in the final rule for drugs acquired under the 340B program and has provided alternate supporting data files on the impact of removing the 340B program payment policy for 2023.

In the 2018 OPPS final rule (82 FR 59482-59483), CMS described its methodology for determining the savings associated with its 340B policy of paying for separately payable drugs at ASP -22.5%. Based on

[25] Emphasis added.
[26] Emphasis added.
[27] 2023-nprm-opps-claims-accounting.pdf (cms.gov)

these modeling assumptions and data from that time, CMS estimated that OPPS drug payments would be reduced by $1.6 billion and a budget-neutrality adjustment of +3.19% would be applied to all non-drug OPPS items and services to meet the statutory budget-neutrality requirement of section 1833(t)(9)(B) of the Act. CMS has not changed or updated this budget neutrality despite public comments asking CMS to do so.[28]

CMS' failure to update the 340B adjustment is inconsistent with its application of other policy adjustments (outliers, pass-through, wage index), where CMS updates a budget-neutrality adjustment based on updated data even when the policy is unchanged. For outliers and pass-through, CMS annually removes the prior year's adjustment before applying the new payment year adjustment. CMS' failure to follow this same practice for 2020, 2021, and 2022 has resulted in underpayments to hospitals for these years.

CMS now proposes in the final rule to reverse its 340B policy and apply a budget-neutrality adjustment of -4.04% (0.9596), even though it only ever increased OPPS rates for the reduction in 340B drug payments by 3.19%. This proposed policy will result in a permanent reduction in OPPS payments equal to the 0.85 percentage point difference between the +3.19% adjustment made in 2018 and the -4.04% adjustment CMS proposes to apply for 2023 or $410 million based on data in the 2023 proposed rule. This adjustment is inequitable and inconsistent with the statutory requirement for budget neutrality under section 1833(t)(9)(B) of the Act. CMS is limited to removing the +3.19% adjustment it added to OPPS rates in 2018 for the 340B policy. **CHA requests that CMS only apply a budget-neutrality adjustment of -3.19% for reversing its 340B policy in 2023.**

The second issue relates to pass-through payments. On page 44528 of the proposed rule, CMS says the difference between pass-through payments is 1.24% in 2022 and 0.9% in 2023, or a net adjustment of +0.34 percentage points to the update for budget neutrality. However, on page 44661 of the proposed rule, CMS says after taking into account the 340B policy that will be adopted in the final rule, pass-through payments will be nearly $593 million lower[29], or 0.21% of OPPS payments. As pass-through payments will be 0.21% of OPPS payments, the net adjustment for pass-through will be the difference between 1.24% in 2022 and 0.21% in the final rule. The net adjustment should now increase to +1.03 percentage points. **CHA requests that CMS apply a net +1.03 percentage point adjustment for pass-through payments in the 2023 final rule.**

Outpatient Outlier Payments

CMS proposes to adopt an outlier threshold for CY 2023 of $ 8,350, an increase of 35.2% from the CY 2022 amount ($6,175). CMS projects that the proposed outlier threshold for CY 2023 will result in outlier payments equal to 1% of OPPS payments.

CMS proposes using hospital-specific overall ancillary cost-to-charge ratios (CCRs) from the April 2022 update to the outpatient provider-specific file (OPSF) to determine the 2023 proposed rule outlier threshold. The rule explains that since the April 2022 OPSF contains cost data primarily from 2021 and 2022 and is the basis for determining current 2022 OPPS outlier payments, CMS believes the April 2022

[28] 85 FR 86054 and 86 FR 63648

[29] Under CMS' 340B policy, drugs on pass-through are paid at ASP +6% instead of ASP -22.5%. As the proposed rule reflects the continuation of the 340B payment policy, CMS estimates $593 million in drug payments as pass-through by paying for them at ASP +6% instead of ASP -22.5%. As CMS final rule policy will be to pay all drugs at ASP +6%, these drugs will no longer require pass-through payments to be paid at ASP +6%. As a result, pass-through payments will decline by $593 million in the final rule compared to the proposed rule.

OPSF provides a more updated and accurate data source for determining the CCRs that will be applied to 2023 hospital outpatient claims. However, CMS proposes using June 2020 cost report data for determining the 2023 OPPS relative weights. CMS believes using pre-2020 cost reports are the better data source for determining the 2023 relative weights, given the impact of COVID-19 cases on the more recent vintage of cost report data.

CHA greatly appreciates CMS' efforts to adjust the outlier threshold calculation so that it better reflects anticipated COVID-19 impacts on costs for hospital outpatient services. However, given the significant increase in the outlier threshold, we are deeply concerned that CMS has not fully corrected the calculation to account for the anticipated decrease in COVID-19 cases and overestimated the outlier threshold. **Similar to the actions it took in the FFY 2023 IPPS rule, CHA asks CMS to calculate the CY 2023 OPPS outlier threshold using an average of the outlier fixed-loss amounts calculated with and without COVID-19 cases in the FFY 2021 data.** Taking this step will better adjust the outlier threshold calculation to reflect the expectation of a decreased COVID-19 caseload in FFY 2023.

340B Separately Payable Drugs

In the CY 2023 OPPS rule, CMS proposes to continue paying ASP –22.5% for separately payable Part B drugs and biosimilar biological products, if purchased under the 340B program. This includes those drugs (other than vaccines and drugs on pass-through payment status) provided at non-excepted off-campus provider-based departments.

However, in the proposed rule CMS also states it anticipates finalizing a payment rate of ASP +6% as a result of the Supreme Court decision in *American Hospital Association v. Becerra*. Given the timing of the Supreme Court ruling, CMS was unable to incorporate adjustments to the proposed payment rates and budget-neutrality calculations to account for the decision before issuing this proposed rule. **CHA strongly encourages CMS to adhere to the Supreme Court ruling and finalize a payment rate of ASP + 6% for non-pass-through separately payable drugs and biosimilar products acquired under the 340B program.**

Concerns Regarding CY 2023 Conversion Factor Adjustment

The average PPS hospital Medicare margin is -8.5% based on a recent MedPAC analysis of 2020 hospital cost report data. Moving ahead and implementing this change in a budget-neutral manner will result in an alternative 2023 conversion factor that is -.37%[30] *S* than the 2022 conversion factor, as illustrated in the table below.

2022 Conversion Factor Compared to Proposed and Alternative 2023 Conversion Factor

	Final CY 2022	Proposed CY 2023	Percent Change
OPPS Conversion Factor	$84.177	$86.785	+3.10%
OPPS Conversion Factor (340B alternative)		$83.865	-0.37%

[30] CHA anticipates the final rule conversion factor, unless modified, will be approximately .83%. This includes an IPPS final rule market basket update of 4.1% reduced by 0.3 percentage points TFP, includes a budget neutrality adjustment for 340B, and assumes other proposed rule budget neutrality adjustments are held constant.

As discussed above, California's hospitals lost more than $12 billion in 2020 and 2021. As a result of COVID-19-related losses and increasing costs per adjusted discharge that outstrip Medicare payment updates, 51% of California's hospitals had negative margins in 2021. These margins are unsustainable and threaten access to care for not only Medicare beneficiaries but all Californians.

In undoing the agency's unlawful policy, CMS is proposing a new budget-neutrality adjustment to the OPPS conversion factor to account for this increase in payment. As discussed above in detail, CHA has concerns that the agency's calculation of this adjustment is incorrect and will result in further underpayment to all hospitals. These payments are critical for California's hospitals to cover the costs associated with caring for Medicare patients. Given the losses California's hospitals have recently suffered, they simply cannot afford to endure further underpayments. **Therefore, we urge CMS to correct the proposed budget-neutrality adjustment to ensure that the appropriate amount is added back into the CY 2023 OPPS conversion factor and no hospital is underpaid.**

Potential Remedies for Prior Year Underpayments to 340B Hospitals

In the proposed rule, CMS seeks public comment on potential remedies for the CY 2018 and CY 2019 payments. Below, please find our recommendations for how CMS should resolve payment issues related to not only CYs 2018 and 2019, but also CYs 2020 through 2022.

CHA respectfully asks CMS to make refund payments to each affected 340B hospital. These payments should be calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018–2022 hospital OPPS rules. This remedy would not disrupt the Medicare program, does not require new rulemaking, and is consistent with remedies for past violations of law.

Specifically, the agency can recalculate the payments due to 340B hospitals based on the statutory rate of ASP +6%. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and the amount they are entitled to, including ASP +6% *plus interest*. Claims that have not yet been paid should be paid in the full amount, including ASP +6%. While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor — which will be uniform across hospitals — to determine how much should have been paid and, thus, how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced, *plus interest*.

CHA does not believe it is required (or appropriate) to apply this remedy in a budget-neutral manner. First, the budget-neutrality provision in the OPPS found in section 1833(t)(9)(B) of the Act only requires budget-neutrality adjustments based on *prospective estimates* of changes in payment resulting from CMS' policy updates. But there is nothing prospective about the current situation. The current situation is a retrospective recalculation of appropriate payments to 340B hospitals as a result of the agency's erroneous legal interpretation.

As noted earlier, 51% of California's hospitals experienced negative margins in 2021. And we do not expect that to improve in 2022, given that revenue per adjusted discharge[31] is flat compared to prior to the pandemic, while labor and supply costs continue to accelerate to unsustainable levels. Implementing

[31] https://www.kaufmanhall.com/sites/default/files/2022-07/KH-NHFR-July-2022.pdf

the Supreme Court ruling in a budget-neutral manner would add further pressure to hospitals, which would negatively impact Medicare beneficiary access to care. Margin pressure is causing many hospitals to close or consider closing service lines that generate a negative margin to ensure that the hospital can continue operations. An unnecessary reduction to OPPS payments would only result in the closure of more services, which would be contrary to the administration's goals of reducing inequitable health outcomes. Any additional service closures will have a disproportionately negative impact on access to care for the most disadvantaged.

In California, Medicare and Medi-Cal operating margins are -21% and -24%,[32] respectively. Historically, hospitals have been able to cross subsidize losses related to providing services that are aligned with the organizations' missions to help the disadvantaged in the communities they serve. However, given that Medicare and Medicaid payments do not cover the cost to provide care and the losses on these patients are rapidly growing as the number of individuals covered by governmental payers increases, we have reached an inflection point. If a hospital continues providing these services in the face of deeper Medicare payment cuts, it will jeopardize the organization's financial viability and access to care for the entire community.

Second, the Department of Health and Human Services (HHS) has previously demonstrated its authority to remedy the underpayments caused by its unlawful rule. This includes *Cape Cod Hospital v. Sebelius* (D.C. Cir. 2011) — HHS corrected errors for the future and past claims for which hospitals had been underpaid; *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar* (D.D.C. 2018) — HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required; and *Shands Jacksonville Medical Center v. Burwell* (D.D.C. 2015) — HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6%. Further, the agency does not consistently apply budget neutrality to fix its missteps and in other relevant instances. For example, HHS allows for retroactive correction of the wage index without any budget-neutrality adjustment if it makes the error and it was not something a hospital could have known or corrected. In addition, budget neutrality does not apply to changes in enrollment or utilization for drugs when the ASP increases.
If the agency remedies its illegal action in a budget-neutral manner — contrary to existing precedent — CHA is deeply concerned that it will further exacerbate access issues for not only Medicare beneficiaries, but all Californians — particularly those who rely on safety-net facilities.

Finally, CHA does not believe that new patient copayments are required. Today, Medicare reimburses hospitals at 80% for covered outpatients, and the remaining 20% is collected from the patients or their insurance. Because HHS deviated from the lawful payment rate for 2018 through 2022, in theory, hospitals could collect from patients or their insurance companies the difference between 20% of the lawful payment rate and the 20% copay that was actually collected.

Although the agency has previously raised requiring patient copayments to be adjusted retroactively as a possible remedy, **CHA does not believe that there is any law that would require hospitals to collect payments altered by the agency's illegal act. Neither the False Claims Act nor anti-kickback statutes would apply since patients would not have been induced to seek services.** But more importantly, California hospitals do not believe in pursuing patients for additional copayments when patients believe they had fully paid for their portion of hospital care provided months, or in some cases years, prior. For

[32] CHA analysis of California Department of Health Care Access and Information data on hospital financial performance

California hospitals and Medicare beneficiaries, this is not a satisfactory remedy to a problem that the agency has unlawfully created. We urge HHS to state this clearly when it puts forth a proposed remedy.

JG and TB Modifiers

CHA notes that despite CMS signaling in the final rule that it will resume paying hospitals for separately payable Part B drugs acquired under the 340B program at ASP +6% for CY 2023 as required by law, the proposed rule is silent on whether 340B hospitals will be required to continue reporting the JB[33] and TB[34] modifiers. Once CMS resumes paying hospitals for separately payable drugs acquired under the 340B program at ASP +6%, there is no need to identify those drugs so they can be paid at a lower rate. **Given that it is no longer necessary to identify separately payable drugs acquired under the 340B program, CHA asks CMS to confirm that hospitals no longer need to report them on claims. Eliminating reporting of these modifiers will reduce the costs associated with billing claims for separately payable Part B drugs acquired under the 340B program.**

Partial Hospitalization Program (PHP)

The PHP is an intensive outpatient psychiatric program to provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding community mental health center (CMHC). PHP providers are paid on a per diem basis with payment rates calculated using CMHC-specific or hospital-specific data.

Proposed 2023 PHP Payment Rates

Despite anticipating the continued effects of COVID-19 on Medicare PHP utilization, CMS believes that CY 2021 claims data will better represent the CY 2023 volume of PHP services and proposes to use 2021 claims data for rate setting. Similar to other services paid under the OPPS, CMS also proposes to use cost reports from the June 2020 HCRIS file set, which only includes data through 2019 in an effort to mitigate the additional impact of COVID-19 on rate-setting.

For CMHCs, the 2023 geometric mean per diem cost for all CMHCs for providing three or more services per day is $131.71 (an increase from $129.93 or 1.4% — calculated for 2022). However, CHA notes that the calculated 2023 geometric mean per diem cost for all CMHCs for providing three or more services is less than the 2021 geometric mean per diem cost — $136.14 — which was used as a floor for rate setting in the CY 2022 final rule. In the CY 2022 final rule, CMS did this to address concerns that fluctuations in cost over time would negatively impact beneficiary access.

For hospital-based PHP providers, the calculated geometric mean per diem cost for CY 2023 for all hospital-based PHP providers for providing three or more services per day is $265.97, which is a significant increase (5.12%) from the CY 2022 geometric mean per diem cost for these providers of $253.02. CHA notes that the CY 2022 calculated geometric mean cost per diem was less than the CY 2021 mean per diem costs ($253.76) for hospital-based PHP services. CMS used the CY 2021 geometric mean cost per diem as a floor out of concerns about negatively impacting access to PHP services.

Despite the increases in mean calculated cost for PHP services provided in hospital-based CMHCs, the proposed ambulatory payment classification (APC) payment rate decreases compared to that finalized in the CY 2022 rule. This implies that the average cost of a clinic visit (APC 5012) increased at a greater rate

[33] Drug or biological acquired with 340B drug pricing program discount
[34] Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

than the costs for both hospital-based and CMHC-based PHPs. The table below compares the final CY 2022 and proposed CY 2023 PHP payment rates.

	Final Payment Rate 2022	Proposed Payment Rate 2023	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$142.70	$130.54	-8.5%
APC 5863: Partial Hospitalization (3+ services) for hospital-based PHPs	$265.97	$261.73	-1.6%

As discussed above, CMS expressed concern in the CY 2022 final rule that fluctuating payment rates for PHP services provided in both hospital-based and CMHC settings would negatively impact beneficiary access to PHP services. In the face of an ongoing opioid PHE that has been in effect since 2017,[35] we share CMS' concern about ensuring access to PHPs, which play an important role in providing access to intensive outpatient treatment for substance use disorder and other mental health issues. At a time when Medicare payment updates are already failing to keep pace with the growth in costs to deliver care, reducing payments for desperately needed mental health services like PHPs will limit beneficiaries' access to treatment. Not only will this result in needless suffering for affected Medicare beneficiaries and their families, but it will increase costs to the Medicare program long-term as untreated mental health issues result in emergency room and inpatient admissions or contribute to acute exacerbations of other chronic diseases afflicting beneficiaries.[36] **CHA asks CMS to freeze the APC weights for both hospital-based and CMHC PHP services at their CY 2022 levels. Or, if CMS does not believe it has the statutory discretion to freeze the weights, it should explore other avenues for avoiding cutting payments for desperately needed mental health services during an opioid PHE. At a minimum, for CMHCs, CMS should consider — as it did in the CY 2022 final rule — using the CY 2021 final PHP APC geometric mean per diem cost of $136.14 as a floor for rate setting for CY 2023.**[37] While payments for CMHC PHP services under this approach would still be less than in CY 2022, the percentage reduction would be reduced.

Allowing Exempted Provider-Based PHPs to Expand Access in Response to the Ongoing Opioid PHE

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 that 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, hospital-based outpatient department (HOPD) — they would be financially viable. This financial viability would allow hospitals to expand access to desperately needed outpatient intensive mental health services — including substance use disorder treatment — for Medicare beneficiaries. Further expanding outpatient capacity would allow for some individuals who are currently receiving inpatient treatment to receive care in a more appropriate setting. This would also improve access to inpatient psychiatric services which — as CMS is aware — are also in short supply.

[35] https://aspr.hhs.gov/legal/PHE/Pages/Opioids-30Jun22.aspx
[36] https://www.milliman.com/-/media/milliman/pdfs/articles/milliman-high-cost-patient-study-2020.ashx
[37] CHA notes that the CY 2021 final rule final hospital-based PHP APC geometric mean per diem cost - $253.76 – is less than the CY 2023 mean per diem cost.

CHA notes that CMS has already 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.[38] Further, we note that CMS has also used its 1135 waiver authority to allow a hospital-based PHP to relocate part of its exempted provider-based department to a new off-campus location while maintaining the original provider-based location.[39] CMS took these steps to improve access to care during the ongoing COVID-19 PHE.

CHA respectfully asks CMS to use its Section 1135 waiver authority to provide similar flexibilities to off campus hospital-based PHP programs during the ongoing opioid PHE. Specifically, we ask that even after the COVID-19 PHE ends, CMS continue waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 and the provider-based department requirements at 42 CFR §413.65 to allow provider-based PHP programs to establish and operate, as part of the hospital, any location meeting the conditions of participation that continue to apply. Further, we ask that CMS continue to allow exempted, provider-based PHPs to relocate part of their exempted 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.

Exempting Rural SCHs from Off-Campus Hospital Based Clinic Payment Limitation

CMS proposes that rural sole community hospitals (SCHs) will be excepted from being paid the physician fee schedule (PFS)-equivalent rate for clinic visits provided at excepted off-campus provider-based departments (PBDs). CMS is further soliciting comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds, from this policy. CHA notes that it has been long established that access to primary care has been strongly associated with improved health outcomes and diminished health disparities.[40]

CHA greatly appreciates CMS exempting rural SCH off-campus PBDs from the agency's site-neutral payment policy. Since the inception of this policy, CHA has been deeply concerned about the impact this misguided policy will have on access to care. We strongly support CMS' suggestion that the exemption be expanded to all rural hospitals with under 100 beds. As discussed in detail below, access to primary care physicians — particularly in rural areas — is particularly challenging for socio-economically challenged patients. **CHA believes that exempting rural hospitals and safety-net hospitals from this policy could greatly expand access and reduce disparities in health outcomes.**

Data from research conducted related to primary care access for new Medi-Cal beneficiaries[41] in eight Northern California counties spanning rural, urban, and suburban areas found that appointment wait times were highly variable, but longer than those mandated by state regulations. Median wait times for a scheduled appointment with any available primary care physician by county ranged from seven to 32.5 days. Across the region, on average, only 34% of primary care clinics contacted had any appointment

[38] https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf
[39] 85 FR 27561 (https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf)

[40] https://pubmed.ncbi.nlm.nih.gov/16202000/
[41] CHA believes that access data for Medicaid beneficiaries is a reasonable proxy for both dual eligible Medicare beneficiaries and other individuals experiencing socio-economic challenges accessing care.

available, and only 19% had an appointment within the state-required 10 business days. Further, counties with reduced access to primary care also had higher emergency department usage by Medi-Cal enrollees.[42]

Beyond rural hospitals, CHA respectfully encourages CMS to expand the exemption to the off-campus provider-based clinic visit policy to all safety-net hospitals (defined as hospitals eligible for Medicare disproportionate share payments). Based on documented improvements in access after the ACA's temporary increase in Medicaid payment rates for primary care went into effect, CHA believes exempting safety-net providers from the site-neutral policy will reduce wait times for Medicare beneficiaries (particularly those who are dually eligible and most vulnerable). Research from 10 states (not including California) found that after the temporary increase in Medicaid primary care payments, there was a 7.7% increase in appointment availability and a decrease in median wait times for an appointment of six days.[43] The states with the largest increases in availability tended to be the ones with the largest increases in Medicaid payment for primary care services. **We believe that if CMS expanded the exemption to all safety-net hospitals, it would allow for a similar improvement in primary care availability for dually eligible Medicare beneficiaries as was observed in many states after the ACA's temporary Medicaid payment increase. This improvement would be a meaningful step toward realizing this administration's goal of increasing access to primary care for dually eligible Medicare beneficiaries and disadvantaged populations, thus reducing inequitable outcomes.**

Payment Adjustments: Domestic NIOSH-Approved Surgical N95 Respirators

In the FFY 2023 IPPS proposed rule, CMS requested comment on potential payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators for IPPS and OPPS to offset costs incurred by hospitals when acquiring such equipment.

In the CY 2023 OPPS rule, CMS proposes to make such an adjustment beginning January 1, 2023, in a budget-neutral manner. This adjustment would be a biweekly interim lump-sum payment to the hospital and would be reconciled at the cost report settlement. The payments would initially be based on the estimated difference in reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. In future years, the payment would be based on information from the prior year's surgical N95 supplemental cost reporting form (which would be a new cost reporting form collected from hospitals). Payment amounts would be determined by the Medicare administrative contractor (MAC). While these payments would be provided in a non-budget-neutral manner under the IPPS, CMS believes that under the OPPS, the agency is statutorily required to make the payments in a budget-neutral manner. Therefore, the agency proposes a -0.01% offset to the OPPS conversion factor for CY 2023.

CHA strongly supports CMS' efforts to provide a payment to hospitals to compensate them for the additional, incremental cost of domestically produced PPE. In general, CHA agrees with the bi-weekly pass-through/reconciliation approach that CMS has proposed to determine reimbursement for domestically manufactured PPE. We greatly appreciate that CMS intends to allow hospitals to rely on the manufacturer's certification that the PPE item meets the proposed rule's requirements for the add-on payment. However, if the agency truly does not believe it has the flexibility to make the

[42] https://www.annfammed.org/content/annalsfm/18/3/210.full.pdf
[43] https://pubmed.ncbi.nlm.nih.gov/25607243/

payment for qualifying items of domestically produced PPE under the OPPS, we ask CMS to work with Congress to pass such an exception into law. Otherwise, making this payment in a budget-neutral manner in OPPS will "rob Peter to pay Paul" and weaken the incentive for hospitals to source and use domestically manufactured PPE.

As discussed in our IPPS proposed rule comment letter, CHA believes there are many benefits to adopting a broad policy of providing an add-on payment for the increased cost of acquiring domestically manufactured PPE. First, if CMS adopts a broad payment policy it will improve supply chain resilience and, therefore, national security. Second, such a policy will also have the effect of reducing carbon emissions in the health care industry by shortening the supply chain and encouraging producers of PPE to move manufacturing capacity from countries that have less-stringent environmental protections to the United States. **For these reasons, CHA encourages CMS to both expand the number of items covered under the proposed policy and expand Medicare payment beyond those items used for providing care to Medicare beneficiaries.**

First, our members report that during the pandemic they experienced shortages with a broad range of PPE. Common items mentioned include but are not limited to surgical masks, isolation gowns, surgical gowns, nitrile gloves, bouffant caps, shoe covers, and face shields. Second, we are concerned that CMS, by focusing on only N95s, is presuming that the next pandemic will be driven by a pathogen whose primary transmission mechanism is respiratory. This may not be the case and if the agency only focuses on N95s, we are concerned that while we may have adequate supplies of N95s during the next pandemic, we will run short of the necessary supplies to protect patients, caregivers, and the general population from the further transmission of said pathogen. **Therefore, we ask CMS to apply its policy of reimbursing hospitals for the incremental cost of domestically produced PPE to a broader basket of items necessary to respond to any potential PHE.** This will, to the greatest extent possible, ensure a stable, domestic supply of necessary items to protect Medicare beneficiaries, caregivers, and the broader population from the transmission of disease. It will also have the beneficial effect of further reducing the carbon footprint of the health care supply chain, which will positively impact health equity.

CMS proposes the payment would only be made for "Medicare's share" of the domestically produced PPE consumed by hospitals. CHA notes that Medicare only accounts for 28%[44] of California hospitals' total net revenue. Using this as a proxy for volume, we are concerned that if CMS limits this payment to only the "Medicare share" of PPE consumed by hospitals, the demand for domestically produced PPE induced by this additional payment will not be sufficient to support a sustainable manufacturing base in the United States. While the incremental add-on payment will be based in some manner on the amount of PPE consumed by a hospital while providing care to Medicare beneficiaries in the current fiscal year, this is not what CMS is purchasing by making this payment. Instead, this payment is purchasing the option of having a secure, domestic supply of a broad basket of PPE available to protect Medicare beneficiaries when the next PHE occurs. **Therefore, CHA strongly encourages CMS to expand the proposed incremental payment to cover the cost of domestically produced PPE used to care for all patients — not just Medicare patients — over the course of a hospital's fiscal year. This will create the demand necessary to sustain a domestic manufacturing capability and ensure that PPE will be available for caregivers to protect Medicare beneficiaries during a future pandemic.** If CMS does not have the statutory authority to do this, we ask the agency to work with Congress to embed this flexibility into the Medicare statute.

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

Packaging Policies and Non-Opioid Treatment Alternatives

As in prior years, for CY 2023 CMS proposes continuing to unpackage, and pay separately — at ASP +6% — the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ambulatory surgical center (ASC) setting (and not pay separately for these drugs when furnished in the HOPD setting). The continuation of this policy is to address the decreased utilization of non-opioid pain management drugs and encourage their use, rather than that of prescription opioids.

CHA appreciates the agency's continued work on the negative impact of packaging policies 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 continue unpackaging Exparel, Omidria, and Xaracoll when they are provided in ASCs and encourage 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 setting. 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.

Organ Acquisition Request for Information (RFI)

In this RFI, CMS seeks information on an alternative methodology for counting organs that will not require transplant hospitals (THs) and organ procurement organizations (OPOs) to track exported organs but would require TH/OPOs to report only organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs. CMS would exclude organs that a TH furnishes to other THs or OPOs from its Medicare share fraction, in both the numerator (Medicare usable organs) and denominator (total usable organs), and require revenue offsets against total organ acquisition costs for these organs. Such a methodology would result in apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries within the recipient TH, but it would not require TH/OPOs to track organs they furnish to other THs and OPOs.

CHA appreciates CMS' efforts to cover the costs associated only with organs that are transplanted into Medicare beneficiaries. **However, we are concerned that if the methodology in the RFI is proposed and finalized, it will reduce access to organ transplantation, exacerbate inequitable outcomes, and increase Medicare spending. Given the complexity associated with determining organ counts and Medicare's appropriate share of organ acquisition costs, CHA strongly encourages CMS to convene a workgroup that includes THs, OPOs, and other stakeholders to develop a methodology that addresses CMS' concerns without the unintended consequences of the policy contemplated in the RFI.**

Hospitals incur significant costs in excising organs that are subsequently transplanted into patients at other THs. If CMS limits the definition of "Medicare organs" to only those directly transplanted into Medicare beneficiaries at that hospital, it will result in fewer organs available for transplant. This has the potential to negatively impact equitable access to transplantable organs. CHA's members are particularly concerned about access to donor kidneys for individuals afflicted with end-stage renal disease (ESRD). As CMS is aware, kidneys are the most transplanted organ. The average wait time for a kidney transplant

is between three and five years.[45] Given the 30-month coordination period, most individuals who receive a kidney transplant are Medicare beneficiaries.

Conservatively, if the policy causes a 10% reduction in deceased donor kidneys due to the closure of small transplant programs or nationwide reductions in operations for larger centers, there would be 2,348 fewer kidneys available for transplant each year.[46] The drop in available kidneys alone could serve to exacerbate existing disparities in organ access. A 2017 study in the *American Journal of Nephrology* found that significant disparities currently exist between African Americans and Caucasian Americans in kidney transplantation, citing "reduced access to kidney transplantation [as] the most serious disparity."[47]

CHA notes that the proposed rule in its discussion of the RFI did not include an estimated impact on Medicare spending of the contemplated change methodology for counting Medicare organs. **As stated above, CHA strongly discourages CMS from proposing such a policy. However, if the agency does, it must provide an impact analysis that not only looks at any potential reduction in Medicare spending but offsetting increases in spending. Specifically, the impact estimate must include the offsetting dialysis costs — discussed below — that will reduce the savings to the Medicare program from the contemplated change in Medicare organ counting policy.**

One potential increased cost is related to longer periods of dialysis prior to transplantation. As discussed above, the policy contemplated in the RFI will decrease the available number of kidney donor organs. This will extend the time individuals with ESRD will receive dialysis while they wait for a donor kidney. In 2021, Medicare's estimated cost for dialysis was approximately $91,000 per beneficiary, per year.[48] Even a modest decrease in the number of available donor kidneys will not only increase program spending on dialysis services but significantly prolong the suffering of ESRD patients.

CHA also has technical cost reporting concerns related to the contemplated policy change. Specifically, hospital-based OPOs do not file a separate cost report. Their costs are included in the affiliated hospital's cost report. Given that excised organs, under this policy, would no longer be included in the numerator or denominator of the Medicare fraction, this change in policy raises the question of how a hospital-based OPO should count organs if this policy is proposed and finalized. Given that many of these organs will be transplanted into Medicare beneficiaries, we are concerned that CMS' policy will result in Medicare paying less than its share of organ acquisition costs for hospital-based OPOs. CHA is concerned that this issue is one of many potential hidden unintended consequences from the contemplated change in policy for counting Medicare organs. This contemplated policy will also result in decreased availability of donor organs, longer wait times for transplantation services, and adverse outcomes for patients in need of an organ transplant. **Therefore, we respectfully reiterate our request that CMS convene a stakeholder workgroup to determine an appropriate methodology for counting organs that ensures that CMS only covers the cost of those transplanted into Medicare beneficiaries and avoids unintended consequences that will ultimately reduce access to organs for those who require a life-sustaining transplant.**

[45] https://www.kidney.org/atoz/content/transplant-waitlist#what-average-wait-time-kidney-transplant
[46] Organ Procurement Transplantation Network (OPTN) Data Report Public Website, Advanced Report Run May 27, 2021. Available at: https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/; United States Renal Data System (USRDS) 2020 Annual Report. Available at: https://adr.usrds.org/2020/; Scientific Registry of Transplant Recipients (SRTR) Center Specific Reports. January 5, 2021. Available at: https://www.srtr.org/reports/program-specific-reports/.
[47] Harding K, Mersha TB, Pham PT, et al. Health Disparities in Kidney Transplantation for African Americans. Am J Nephrol. 2017;46(2):165-175. doi:10.1159/000479480. Accessed on June 11, 2021 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5827936/.
[48] Medicare per patient per year costs based on the USRDS 2020 Annual Report, Tables K.6, K.9. Available at: https://adr.usrds.org/2020/.

Clarification of Allocation of Administrative and General Costs

The proposed rule alleges that some THs incorrectly report the "purchase cost" for acquiring an organ in an accumulated cost statistic that is used to allocate administrative and general (A&G) costs. The rule proposes to clarify that when a TH receives organs from an OPO or other TH, the receiving TH must exclude from its accumulated cost statistic the cost associated with these organs because these costs already include A&G costs. The proposed rules state that this change is in accordance with cost-finding principles in 42 CFR § 413.24(d)(6). **CHA respectfully asks CMS not to finalize this policy, as it is contrary to CMS' methodology for allocating A&G costs based on each cost center's accumulated costs. It would result in the Medicare program *under-reimbursing* hospitals for the A&G costs associated with acquiring organs for transplantation.**

CHA believes that CMS is misinterpreting and misapplying 42 CFR § 413.24(d)(6). The section, as illustrated by the example below taken from the regulation, pertains to purchased A&G services. These purchased A&G services are separately acquired by a hospital from professional services firms for some cost centers in certain instances. The purchased A&G services substitute for the costs captured in line 5 of worksheet A of the Medicare cost that is normally "stepped down" using the accumulated cost statistic in column 5 of worksheet B-1 of the Medicare cost report. However, in these instances, the purchased A&G services are directly assigned to the cost center that uses them, and the remaining A&G costs that are stepped down are adjusted to account for this.

> *Example: A provider-based complex is composed of a hospital and a hospital-based rural health clinic (RHC). The hospital furnishes the entirety of its own administrative and general costs internally. The RHC, however, is managed by an independent contractor through a management contract. The management contract provides a full array of administrative and general services, with the exception of patient billing. The hospital directly assigns the costs of the RHC's management contract to the RHC cost center (for example, Form CMS 2552-96, Worksheet A, Line 71). A full allocation of the hospital's administrative and general costs to the RHC cost center would duplicate most of the RHC's administrative and general costs. However, an allocation of the hospital's cost (included in hospital administrative and general costs) of its patient billing function to the RHC would be appropriate. Therefore, the hospital must include the costs of the patient billing function in a separate cost center to be allocated to the benefiting cost centers, including the RHC cost center. The remaining hospital administrative and general costs would be allocated to all cost centers, excluding the RHC cost center. If the hospital is unable to isolate the costs of the patient billing function, the costs of the RHC's management contract must be reclassified to the hospital administrative and general cost center to be allocated among all cost centers, as appropriate.*

An organ acquired from another TH or OPO is not a purchased service as described at 42 CFR § 413.24(d)(6). The purchased organ fundamentally functions as a supply in a transplantation procedure. It plays the same role as a medical device like a hip implant (costs recorded on line 14 – Central Services and Supply of Medicare cost report worksheet A) in a joint replacement procedure. When a hospital makes a payment to Smith and Nephew for a hip implant, that payment (reported as a cost on the Medicare cost report) does not include any administrative and general costs that are duplicated in line 5 (administrative and general costs) of the Medicare cost report. As a result, CMS steps down A&G costs (line 5) to the hip implant (and other medical supplies whose costs are included in line 14), before the supply costs are allocated to the individual cost centers below line 14. Similar to the hip implant provided as an example, when a hospital acquires an organ from another TH or OPO, the cost associated with the

acquisition does not include overhead costs that are already captured in the organization's administrative and general costs (line 5). **Therefore, CMS should continue allowing the costs associated with organs obtained from another TH or OPO to continue to be included in the accumulated cost statistic.**

As noted above, CMS "steps down" A&G costs from line 5 to line 14 (central services and supply) because the hospital incurs A&G costs (e.g., information technology, legal, regulatory and other costs) in procuring and handling the hip implant. Hospitals incur similar A&G costs — if not more given the complexity of organ procurement — when they obtain organs from THs and OPOs. **If CMS finalizes this policy, it will result in underpayment of the administrative and general costs associated with acquiring organs.**

Rural Emergency Hospital (REH): Payment Provisions

In the CY 2023 OPPS rule, CMS proposes to define "REH services," as all covered OPD services that would be paid under the OPPS. This definition does not include services such as laboratory and outpatient rehabilitation therapy that may be provided in OPDs and are not paid under the OPPS. In general, CHA supports these definitions. Further, in the rule, CMS proposes payment methodologies for the services provided by an RHC. These proposals include:

- *Payment for REH Services*: CMS proposes that payments for REH services will equal the applicable OPPS payment for the same service plus an additional 5%.

- *Payment for Non-REH Services*: CMS proposes that any outpatient service furnished by an REH that does not meet the proposed definition of REH services would be paid at the same rate if performed in a hospital OPD and paid under a payment system other than the OPPS.

- *Ambulance Services:* CMS proposes that an entity that is owned and operated by an REH that provides ambulance services will receive payment under the ambulance fee schedule.

- *Skilled-Nursing Facility Services:* REHs are permitted under the law to have a distinct part unit skilled-nursing facility (SNF). CMS proposes to pay for post-hospital extended care services provided by an REH in a SNF unit through the SNF prospective payment system.

- *Payment for an Off-Campus PBD of an REH*: CMS proposes that an off-campus PBD of an REH would not be subject to the PFS-equivalent rate that applies to an off-campus PBD of a hospital that first began furnishing services after November 2, 2015.

- *Monthly REH Facility Payment*: CMS proposes that the monthly facility payment for REHs for 2023 would be $268,294. This amount would be increased in subsequent years by the hospital market basket.

In general, CHA supports the payment provisions for REHs described in the proposed rule. However, we are deeply concerned that CMS has not addressed several crucial hospital-based rural provider payment provisions. CHA again respectfully asks CMS to confirm that critical access hospitals (CAHs) that convert to an REH will still be able to use "Method II" to bill and receive payment for physician services provided at the REH. Further, we ask CMS to confirm that provider-based rural health clinics that meet the requirements under Section 130 of the Consolidated Appropriations Act (CAA) will retain their grandfathered status after the hospital converts to an REH provider type. Without the retention of

these important provider payment methodologies, CHA is concerned that converting to an REH will limit access to health care services instead of creating a sustainable platform from which to expand access.

Additionally, CMS has not addressed an REH's eligibility for certain Medicaid safety-net payments. Individuals under age 65 who live in rural areas are more likely to be uninsured than residents of urban areas. Approximately 12.3% of people in completely rural counties lacked health insurance compared to 10.1% for mostly urban counties.[49] Further, those who are insured are less likely to have coverage through a commercial health plan. This is due in part to lower labor-force participation and greater employment in jobs that do not offer insurance.[50] High rates of uninsured and coverage by governmental payers as part of a hospital's payer mix are frequently cited as key drivers of rural hospital closure[51] (and the need for models like REHs to maintain access to health care in rural communities). In California, the Medi-Cal global payment, federal disproportionate share hospital (DSH), and private DSH replacement programs play a vital role in ensuring the financial sustainability of hospital-based health care services in rural areas. **CHA asks CMS to clarify that nothing in the REH regulations prevents these hospitals from receiving these crucial payments that support safety-net hospitals.** If these payments are not preserved, it is unlikely that rural hospitals in California will be able to take advantage of the REH model to ensure access to services.

Mental Health Services Furnished to Patients in Their Homes

For the duration of the COVID-19 PHE, CMS waived certain requirements that allowed patients to receive mental health services in their homes using communications technology. These policies have been integral in expanding access to mental health and substance use disorder services by reducing barriers for patients in communities that lack mental health care providers or have transportation challenges, as well as improving rates of follow-up visits. Congress recognized the importance of allowing mental health care to be provided virtually in a patient's home when it removed Medicare telehealth geographic and originating site restrictions for the purpose of diagnosis, evaluation, or treatment of a mental health disorder after the end of the PHE as part of the CAA of 2021. **CHA strongly supports expanding access to care in the patient's home, and we appreciate that CMS is proposing payment for certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by the clinical staff of a hospital to a beneficiary in their home under the OPPS.**

Specifically, CMS proposes to create OPPS-specific coding for these services: code CXX78 for 15 to 29 minutes of mental health services provided by outpatient hospital staff to a patient located remotely in the home via telecommunications technology; code CXX79 for 30 to 60 minutes of service; and code CXX80 for each additional 15 minutes of service beyond 60 minutes. However, in determining payment for these codes, CMS states that it "does not believe that the hospital is accruing all the costs associated with an in-person service," and proposes to assign APCs based on PFS facility payment rates. **CHA strongly disagrees with this assessment, and we urge CMS to reconsider the value of the assigned APCs, 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.**

[49] https://www.census.gov/library/stories/2019/04/health-insurance-rural-america.html
[50] https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf
[51] https://www.kff.org/report-section/a-look-at-rural-hospital-closures-and-implications-for-access-to-care-three-case-studies-issue-brief/

As noted in our comments on the telehealth provisions CY 2023 PFS proposed rule, expanded 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 telehealth 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 is limited to supply costs, which will be de minimis given that these visits are for mental health services, not procedures. These lower payment rates are particularly problematic at a time when all hospitals are experiencing increasing financial challenges and 51% of California's hospitals[52] have negative margins. We are concerned that if not valued appropriately, providers could be inadvertently incentivized to see patients in the office, when it would be just as clinically appropriate and preferable for the patient to receive care remotely in their home.

CMS also proposes to require that the beneficiary receive an in-person visit within six months prior to the first time a mental health service is provided remotely, and that there must be an in-person visit within 12 months of each mental health service furnished remotely by the hospital clinical staff. While this is in line with policies finalized for telehealth mental health services, CHA opposes this arbitrary requirement, and we urge CMS to reconsider this proposal.

The behavioral health workforce is especially challenged by shortages, and more than 11.5 million Californians live in Mental Health Care Health Professional Shortage Areas.[53] We are concerned that in-person visit requirements will only exacerbate mental health access issues for beneficiaries in these areas because they are too far away from or are unable to travel to a mental health provider. Because of these concerns, we strongly support CMS' proposal to permit exceptions to the 12-month subsequent visit requirement when the hospital clinical staff member and the beneficiary agree that the risks and burdens of an in-person service outweigh the benefits. **We believe the clinician should have the flexibility to use their judgment in determining if in-person or remote services are more appropriate for a specific patient, and we urge CMS to finalize a policy that would make this the rule rather than the exception.**

Finally, CMS proposes to require the hospital clinical staff to use telecommunications systems that include audio and video equipment permitting two-way, real-time interactive communications for these services but would allow for an exception for audio-only communications depending on an individual patient's technological limitations, abilities, or preferences. **CHA supports this proposal, which will expand remote mental health care access to patients without access to broadband services or who are unfamiliar or uncomfortable with video technology.**

[52] https://www.kaufmanhall.com/sites/default/files/2022-04/KH_CHA-2021-Financial-Analysis-Ebook.pdf
[53] https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/

Remote Direct Supervision of Cardiac and Pulmonary Rehabilitation Services

Under current OPPS policy, cardiac, intensive cardiac, and pulmonary rehabilitation services may be provided in the hospital with the physician direct supervision being provided to a patient via a virtual presence; however, this virtual supervision policy will end with the conclusion of the COVID-19 PHE. After that time, the physician must be immediately available in order for the direct supervision requirement to be met for the hospital to be paid for the service. **At minimum, CHA urges CMS to extend this policy until the end of CY 2023, consistent with virtual direct supervision policies under the PFS. Further, CHA urges CMS to consider permanent policies that would allow for virtual direct supervision when the supervising physician has determined it to be clinically appropriate in line with the relevant standard of care.**

Hospital OQR Program

Modification of Reporting Requirements for Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)

CHA strongly supports CMS' proposal to change the reporting status of the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536) measure from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination and for subsequent years. CHA appreciates that CMS has responded to stakeholder concerns about the challenges of operationalizing this measure in the proposed rule. We continue to be concerned that the results of surveys used to assess pre- and post-operative visual function are not consistently shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before or after surgery. Further, because the measure allows for the use of any validated survey, it does not result in comparable results that are useful to improving quality performance. We urge CMS to continue voluntary reporting of the measure as currently specified indefinitely.

Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Adoption of Another Volume Indicator

CMS seeks comments on the potential inclusion of a volume measure in the hospital OQR program, either by readopting the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or adopting another volume indicator. As noted by CMS, OP-26 was removed from the OQR program in the CY 2018 OPPS final rule due to a lack of evidence to support the measure's link to improved clinical quality. **CHA continues to question the utility of volume measures for quality improvement activities, and we urge CMS not to consider the reimplementation of OP-26 or development of another volume indicator.**

In the proposed rule, CMS seems to justify potential re-adoption of this measure by noting a shift of procedures from the inpatient to the outpatient setting. However, there is not a volume measure included for inpatient quality reporting, and we question why such a measure would be appropriate for the outpatient setting. Further, we believe that volume alone does not provide an indicator of quality, and in the CY 2018 OPPS final rule, CMS agreed and removed the measure citing the measure removal criterion: performance or improvement on a measure does not result in better patient outcomes. We are also concerned that re-adoption of OP-26 would require hospitals to shift limited staffing resources from direct patient care to the submission of data via a web-based tool, while CMS is able to track volumes

using claims data. We urge CMS to instead focus efforts on developing outcomes-based quality measures with demonstrated impacts on quality and patient experience.

Overall Hospital Quality Star Ratings

CMS notes that data for nearly all measures used for the 2021 and 2022 Care Compare refreshes of Overall Hospital Quality Star Ratings were collected prior to the COVID-19 PHE declaration. This is because CMS issued a blanket exception from quality data reporting for Q1 and Q2 2020, including all data sources. However, quality data collection resumed with Q3 2020, and CMS has stated an intention to complete a refresh of the ratings in 2023. **CHA appreciates that CMS has clarified that the agency may choose to exercise its measure suppression authority should an analysis of the underlying measure data show it to have been substantially affected by the COVID-19 PHE. We continue to support efforts to mitigate the impact of COVID-19 on quality measurement and would support measure suppression if CMS analysis finds it to be appropriate.**

Addition of Services Subject to Prior Authorization

In the CY 2020 OPPS final rule, CMS established a prior authorization process as a condition of payment for certain hospital-based services. CMS proposes to add the service category of facet joint interventions to the prior authorization list, effective for dates of service on or after March 1, 2023. The proposed facet joint interventions service category would consist of facet joint injections, medial branch nerve blocks, and facet joint nerve destruction. CMS cites increases in utilization for these services relative to overall outpatient services. In addition, the Department of Health and Human Services Office of Inspector General (OIG) has published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions in its rationale for adding this service category to those subject to prior authorization.

CHA urges CMS to revisit its analysis and consider that increases in the utilization of these services — which are used for managing chronic neck and back pain — could be attributed to expanding access to non-opioid pain management therapies. We also note that an OIG report found that improper Medicare payments were the result of inadequate education of physicians and their billing staff with billing requirements for spinal facet-joint injections.[54] The OIG did not recommend that these services be included in CMS' prior authorization program, and instead urged the MACs to provide annual training to physicians and their billing staff specific to Medicare requirements for billing of facetjoint injections. **We urge CMS to reconsider its proposal to require prior authorization for these services — which can result in patients waiting in pain while the process is completed — and instead focus on existing Medicare processes such as developing national coverage determinations, or instructing MACs to conduct targeted probe and educate audits to help ensure that only medically necessary services are paid under Medicare.**

Finally, CHA notes that in the CY 2020 final rule, CMS states that it reserves the right to exempt a provider from the prior authorization process and would conduct semiannual assessments of providers submitting prior authorization requests. While not specifying in the regulatory text a threshold, in the preamble, CMS said that providers who maintain a 90% or higher provisional affirmation rate would be exempt from the process. **CHA urges CMS to swiftly conduct this assessment and provide additional information on providers deemed to be exempt from the process.**

[54] https://oig.hhs.gov/oas/reports/region9/92003010RIB.pdf

RFI on Use of CMS Data to Drive Competition in Health Care

In the wake of the COVID-19 pandemic and other forces that are reshaping the delivery of health care, partnerships among hospitals and health systems have taken on new importance in protecting and improving the quality of care as well as access to care in communities throughout California. In fact, a key lesson to be learned from the COVID-19 pandemic is that health systems — networks of hospitals and clinical partners — were integral to saving lives. Writing in *Health Affairs* during the height of the pandemic, respected researchers Jeff Goldsmith and Ian Morrison offered the following:

> "… both of us have been convinced by the last twelve months that health systems' scale was a major societal benefit in coping with COVID. Over this period, health systems have demonstrated that they are a vital part of our public health infrastructure. While the public benefits of health systems are difficult to quantify, they have performed far better than just about any other element of our society in responding to COVID.
>
> It is time for the policy community to reconsider what has been, in the past two decades, an increasingly hostile posture toward these large complex enterprises and consider what steps can be taken to encourage them to take a broader public health role. We think collaboration with state and local public health entities should be formalized by contractual ties that facilitate infectious disease surveillance and immunization; data gathering and analysis from anonymized electronic health record data bases; and actions that address inequities and social determinants which lead to health problems."

Hospital partnerships can take many forms — including affiliations, mergers, or acquisitions, or other relationships. The benefits of these partnerships extend far beyond the COVID-19 response, bringing specialized care such as cancer treatment, cardiac care, or organ transplants closer to home for millions of patients.

Against this backdrop, we are concerned with assumptions made in the proposed rule about the impact of health system integration. Specifically, CMS includes an RFI on "how data that CMS collects could be used to promote competition across the health care system or protect the public from the harmful effects of consolidation within healthcare." In its RFI, CMS cites studies that assert hospital consolidation leads to higher prices. However, a 2021 report by the national consulting firm Kaufman Hall refutes this conclusion, stating "there is no apparent correlation between higher levels of integration and lower levels of affordability for consumers." In fact, according to the report, "consumers in more highly integrated states may have more affordable insurance premiums and lower per capita health care expenditures."

This finding is supported by data in California, where 72% of hospitals have already partnered with larger health care systems. According to the California Health Care Foundation, per-capita health care spending in California is $7,549, more than 6% below the national average of $8,045. California's integrated systems have demonstrated that partnerships can hold in check per-capita spending, while increasing access to care by supporting financially struggling hospitals. For example, a recent affiliation in California between a CAH and multi-state health system not only kept a small, rural hospital open but also allowed it to expand its patient care services through the addition of 32 newly recruited doctors in such specialties as orthopedics, gastrointestinal care, and cardiac services.

As CMS examines data on hospitals' and nursing facilities' mergers, acquisitions, consolidations, and changes in ownership, the agency should take care to ensure it understands how health care partnerships

preserve or expand patient access to care, build high-quality networks and service portfolios for patients and health plans, attract the clinical expertise needed to create innovations in patient care, increase scale to spread the benefits and costs of innovation across a broader base, and reduce total cost of care by eliminating redundancies and duplicative services.

CHA appreciates the opportunity to comment on the CY 2023 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