CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

June 28, 2021

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

SUBJECT: CMS–1752–P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program (Vol 86, No 88), May 10, 2021

Dear Administrator Brooks-LaSure:

On behalf of our more than 400 member hospitals and health systems, as well as their related post-acute care providers, the California Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule updating the Medicare inpatient prospective payment system (IPPS) for federal fiscal year (FFY) 2022.

California's hospitals — like other hospitals across the nation — are still navigating the unprecedented challenges posed by the public health emergency (PHE) and providing care to those suffering from COVID-19. We are greatly appreciative of the federal government's continued partnership and efforts to support hospitals during the PHE. This includes CMS-provided waivers offering flexibility and financial support through the Provider Relief Fund and Treasury programs to ensure that hospitals can continue operations, invest in the supplies and infrastructure necessary to effectively respond to the pandemic, and provide succor to those who need care.

Despite the flexibility and financial support provided, California's hospitals are struggling. Costs associated with maintaining health care delivery system capacity during the pandemic have increased significantly. At the same time, revenue declined with patient volumes due to the public's general hesitance to seek necessary care and intermittent moratoriums[1] on non-emergent procedures. A recent analysis by Kaufman Hall, a nationally renowned consulting firm, estimates that even after federal support California's hospitals lost more than $8 billion in 2020. And additional losses during 2021 due to COVID-19 could exceed $2 billion, further jeopardizing the stability of the delivery systems that are essential in continuing efforts to respond to the ongoing pandemic.

In light of the pandemic, CHA appreciates that CMS in the FFY 2022 proposed rule has taken necessary steps to further minimize the negative impact of the COVID-19 PHE on hospitals. We strongly support

[1] Nationally in the spring of 2020 and in local hot spots during the fall of 2020.

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CMS' proposals to use alternative data for rate-setting when the data sets CMS would traditionally use demonstrate aberrant utilization patterns that are unlikely continue into FFY 2022. We also support CMS' efforts to suppress quality measures from the calculation of value-based payment programs when they were impacted by the pandemic. However, we are deeply concerned by unjustified proposals related to wage index policy and organ acquisition costs that will further stress already fragile hospitals, as well as the care delivery systems and communities they support.

In summary, CHA:

- Strongly supports CMS' efforts to mitigate the impact of COVID-19 on IPPS rate setting by using FFY 2019 Medicare Provider Analysis and Review (MedPAR) data and FFY 2018 Hospital Cost Report Information System (HCRIS) data to establish the relative weights and calculate the fixed loss outlier threshold.
- Strongly opposes CMS' proposal to continue its low-wage index policy, increasing the wage index for hospitals with wage index values in the bottom quartile of the nation at the expense of all IPPS hospitals. CHA continues to believe this policy is inappropriately redistributive and penalizes all IPPS hospitals in an effort that is mis-targeted and ineffective to achieve the agency's stated goal.
- Is concerned the methodology CMS uses to rebase and revise the labor-related share of Medicare inpatient payments for hospitals with a wage index of 1 or greater is premised on the flawed assumption that some categories of labor costs are not subject to geographic variation. The significant reduction in the labor-related share is driven by this assumption. CHA asks that CMS revise its methodology for rebasing the labor-related share to account for the geography wage variation inherent in all home office and non-clinical professional services costs.
- Asks CMS to mitigate the impact of the COVID-19 PHE on the calculation of Factor 1 of the uncompensated care disproportionate share hospital (DSH) formula by using the CMS Office of the Actuary's (OACT's) estimate of FFY 2021 Medicare discharges from the FFY 2021 IPPS final rule, which we believe reflects the more normalized inpatient utilization hospitals will experience during the remainder of FFY 2021. We also ask the agency to provide additional transparency into the changes in the "Other" component of Factor 1 between the FFY 2021 final rule and the FFY 2022 proposed rule.
- Strongly supports CMS' proposal to withdraw the market-based relative weight policies finalized in the FFY 2021 IPPS proposed rule. We agree with the agency's concerns about the utility of the data and the accuracy of MS-DRG weights this process would yield.
- Urges CMS to withdraw its proposed change to the definition of a "Medicare organ" for purposes of calculating Medicare allowable organ acquisition costs. We are concerned the proposed policy will reduce the number of available organs for transplantation. This unintended consequence is not contemplated in the preamble. Further, we do not believe that it is currently possible for an excising transplant hospital to obtain the organ recipient's insurance information, as required by the proposal, in instances where an excised organ is sent to an organ procurement organization.
- Supports CMS' proposed measure suppression policies in the value-based quality programs to address the impact of the COVID-19 PHE on hospital performance. However, we urge CMS to continue to evaluate the data for its FFY 2023 programs to avoid unfairly penalizing hospitals that were severely impacted by the COVID-19 PHE beyond 2020.
- Urges CMS to reconsider several proposals under the Promoting Interoperability Program, including an increased reporting period for 2024.

- Applauds the administration for its commitment to addressing racial disparities and improving health equity. CHA urges CMS to focus its efforts on improving, standardizing, and incentivizing the collection of demographic data.

Our detailed comments on CMS' payment and quality proposals follow.

Recalibration of the Relative Weights and Fixed Loss Outlier Threshold

CMS normally uses the MedPAR file from the second year preceding the rate-setting year (e.g., FFY 2020 for FFY 2022). However, CMS believes that FFY 2020 inpatient utilization has been significantly affected by the COVID-19 PHE. In the proposed rule, CMS offers compelling evidence that the claims data from the FFY 2020 MedPAR file are atypical, showing declines in non-emergent surgeries and a shift in case mix. Neither of these trends is expected to continue into FFY 2022. Additionally, in the proposed rule CMS presents an analysis that concludes there would be a material effect on IPPS rate setting from using atypical FFY 2020 inpatient utilization rather than continuing to use the more typical utilization patterns from FFY 2019.

CMS proposes to use FFY 2019 MedPAR data and FFY 2018 HCRIS data to set the relative weights and calculate the fixed loss outlier threshold for FFY 2022, rather than using the FFY 2020 MedPAR and FFY 2019 HCRIS data. Based on utilization trends observed from our members, CHA agrees with CMS' analysis that the FFY 2020 MedPAR data are aberrant and would have a negative impact on California's hospitals. **We strongly support CMS' proposal to use FFY 2019 MedPAR data and FFY 2018 HCRIS data to set the relative weights and calculate the fixed loss outlier threshold.**

Basis for Proposed FFY 2022 MS-DRG Updates

In the FFY 2021 IPPS final rule, CMS finalized a proposal to expand the existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG. Specifically, CMS finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split.

For the FFY 2022 IPPS proposed rule, CMS analyzed how applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would affect the MS-DRG structure beginning in FFY 2022. Applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would result in the deletion of 96 MS-DRGs (32 MS-DRGs x 3 severity levels = 96) and the creation of 58 new MS-DRGs.

Given the COVID-19 PHE, CMS proposes to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FFY 2023 and maintain the current structure of the 32 MS-DRGs that currently have a three-way severity level split (total of 96 MS-DRGs), which would otherwise be subject to these criteria for FFY 2022.

CHA strongly supports delaying implementation of the NonCC subgroup criteria in light of the COVID-19 PHE and the need for additional analysis of this proposal. Given that MS-DRG weights are relative, this policy will impact the weighting of all MS-DRGs – not just the 96 MS-DRGs that are deleted and 58 that are created. Therefore, CHA respectfully asks that CMS make available for public comment a version of Table 5 that is calculated under the current policy and a version of Table 5 that is calculated using the proposed NonCC subgroup criteria before this proposal is implemented. Providing

comparative Table 5s will allow individual hospitals to understand the impact the proposed methodology will have on their case mixes and payments for inpatient services.

This impact will extend beyond Medicare FFS given that MS-DRG weights are frequently used as the basis of payment for inpatient services in Medicare Advantage and commercial health plan contracts. Therefore, the impact of CMS' proposed structural change will be amplified across multiple payer classes. Given this amplification, CHA is specifically concerned that a change to the underlying MS-DRG structure may inadvertently exacerbate payment differentials between different types of hospitals (e.g., urban vs. rural) based on the types of services they provide, which may negatively impact Medicare beneficiary access to some services.

Given the impact of COVID-19 on Medicare utilization, CHA respectfully asks that CMS delay implementation of this policy until at least FFY 2024. This will allow the agency to use claims data from FFY 2022. We anticipate these data will reflect normalized utilization, allowing for comprehensive impact analysis, which can be made available and discussed in the FFY 2024 IPPS proposed rule.

Potential Change to Severity Level Designation for Unspecified Diagnosis Codes for FFY 2022

For FFY 2022, CMS is considering changing the severity level diagnosis of all "unspecified" diagnosis codes to a NonCC, where there are other codes available in that code subcategory that further specify the anatomic site. CMS states that the use of these "unspecified" diagnosis codes may contribute to less reliable data for researching clinical outcomes, and more robust claims data would inform its decision-making in determining the most appropriate CC subclass assignment. The proposed rule notes there are 3,490 "unspecified" diagnosis codes designated as either CC or MCC, where there are other codes available in those code subcategories that further specify the anatomic site with an equivalent severity level designation which would be impacted if CMS finalizes this change.

CHA notes that CMS outlines its nine guiding principles for establishing the severity level of an ICD-10 code, which it discussed in the FFY 2021 IPPS rule. These, as listed in the FFY 2022 proposed rule at 86 FR 25175, include:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility
- Denotes organ system instability or failure
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline
- Serves as a marker for advanced disease states across multiple different comorbid conditions
- Reflects systemic impact
- Post-operative/post-procedure condition/complication impacting recovery
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay)
- Impedes patient cooperation and/or management of care
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use

The presence (or absence) of laterality is not included in these principles for establishing the severity level of an ICD-10 code. Therefore, we ask CMS to withdraw its proposal, as the agency's own principles for establishing the severity level of an ICD-10 code do not support this change.

CHA notes this is a significant change from an operational perspective that, if implemented as proposed, will create significant administrative burden for hospitals at a time when administrative and clinical resources are still stretched thin by the COVID-19 PHE. If CMS persists in finalizing this proposal, we ask the agency to delay its implementation for two years to give hospitals and their physicians time to prepare. This change will require hospitals to provide additional education to physicians and coders related to documentation practices. Additionally, hospitals will need time to update computer-assisted coding systems to incorporate this change.

A delay may reduce the administrative burden on physicians related to documentation. Under current coding guidelines, a coder may only determine laterality based on a physician's clinical note. However, CHA is aware of an effort underway by the cooperating parties who are responsible for Coding Clinic to revise coding guidance and allow a coder to determine laterality based on the documentation of other clinicians. Once this guidance is clarified, it may ameliorate the additional physician administrative burden created by this change and reduce the policy's impact on physician burnout.

Proposed FFY 2022 Status of Technologies Approved for FFY 2021 New Technology Add-On Payments (NTAP)

Due to CMS' proposal (discussed above) to use the FFY 2019 MedPAR claims data for FFY 2022 rate-setting, CMS also proposes to use its authority to allow for a one-year extension of new technology add-on payments for 14 technologies that would have otherwise had discontinued NTAP beginning with FFY 2022. **CHA supports CMS' proposal to continue NTAP for these 14 technologies.** We believe this will allow CMS appropriate time to collect the necessary data to accurately set MS-DRG weights that incorporate these technologies once NTAP status expires.

Extending the New COVID-19 Treatments Add-on Payment (NCTAP) Through the End of the FFY in Which the PHE Ends for Certain Products and Discontinue NCTAP for Products Approved for New Technology Add-on Payments in FY 2022

CMS proposes to extend the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends. CMS also proposes to discontinue the NCTAP for discharges on or after October 1, 2021, for a product that is approved for new technology add-on payments beginning FFY 2022. **CHA supports CMS' proposal to continue the NCTAP through the end of the FFY in which the PHE ends.**

Hospital Area Wage Index

CHA appreciates CMS' thorough discussion of hospital area wage index policies proposed for FFY 2022. In general, we are supportive of the agency's efforts to accurately adjust Medicare payments to hospitals, based on audited wage index data, to reflect geographic variation in the cost to deliver care to Medicare beneficiaries. However, we do not support CMS' proposed continuation of its Low Wage Index Hospital policy, arbitrary removal of certain hospitals whose data CMS deems aberrant despite being audited during the annual wage index review process, and process for reclassifying a portion of labor-related professional fees to non-labor-related, thereby reducing the labor-related share during the rebasing process.

CHA believes that CMS continues to exceed its statutory authority by pursuing the Low Wage Index Hospital policy and arbitrarily removing certain hospitals whose data it deems aberrant. Further, we are concerned the assumptions CMS relies on to assert that a portion of the non-medical labor-related professional fees are not subject to geographic wage variation (and as a result reclassify that portion to non-labor-related) are erroneous. The financial impact of these policies on Medicare inpatient payments to California's hospitals is illustrated in the table below.

Proposed Area Wage Index Policies – Impact to California Hospitals

FFY 2022 Proposed Policy	Medicare Payment Impact $, Millions	
Labor Related Share Rebasing - Pro Fee Non-Labor Related Cost Assumption	$	(28.3)
Low Wage Index Hospital Policy	$	(24.0)
"Aberrant" Data Removal - Acute Care Hospitals	$	(16.6)
"Aberrant" Data Removal - Other Providers	$	(1.1)
Total	$	(70.0)

California's hospitals are still struggling to recover from the operational and financial impact of the COVID-19 PHE. A recent report by Kaufman Hall finds that the COVID-19 pandemic resulted in 254 California hospitals (58%) finishing 2020 with negative operating margins. It is projected that as many 206 California hospitals (47%) will have negative operating margins in 2021[2]. This is not sustainable. If these policies are finalized, they will have a significant negative impact on Medicare inpatient payments, further threatening the financial viability of already weakened California hospitals.

To mitigate the financial impact of CMS' adoption in the FFY 2021 IPPS final rule of the updates in OMB Bulletin 18-04, CMS placed a 5% cap on any decrease in a hospital's wage index from the hospital's final wage index in FFY 2020 so that a hospital's final wage index for FFY 2021 would not be less than 95% of its final wage index for FFY 2020. CMS implemented this transitional cap in a budget-neutral manner, reducing payments to all IPPS hospitals to offset the cost of the transitional cap for those that benefited from it.

In the proposed rule, CMS seeks feedback on extending the transitional cap for FFY 2022, which could potentially take the form of holding the FFY 2022 wage index for those hospitals harmless from any reduction relative to their FFY 2021 wage index. **Given the devastating financial impact the COVID-19 pandemic has had on California's hospitals, CHA believes it would be appropriate for CMS to extend the 5% transitional wage index cap in *a non-budget-neutral manner***. We are concerned that if this policy were implemented in a budget-neutral manner the further reductions to Medicare inpatient payments would exacerbate the considerable financial challenges California's hospitals are currently facing.

Below, please find our specific concerns about CMS' proposed area wage index policies.

Area Wage Index – Low Wage Index Hospital Policy

In the FFY 2020 IPPS final rule, CMS finalized a policy that increases the wage index values for certain hospitals with low wage index values. CMS implemented this Low Wage Index Hospital Policy through a

[2] https://www.kaufmanhall.com/sites/default/files/2021-04/kh-cha-financial-forecast-ebook_final.pdf

budget neutrality adjustment that reduced the standardized amount for all IPPS hospitals in FFY 2020. In finalizing the policy for FFY 2020, CMS stated that the "policy will be effective for at least 4 years."

In the FFY 2022 IPPS proposed rule, CMS proposes to continue to apply the Low Wage Index Hospital Policy and concomitant budget neutrality adjustment to the standardized amount for all IPPS hospitals. CHA opposed this policy in its comments on the FFY 2020 and FFY 2021 IPPS proposed rules[3] and continues to strongly oppose decreasing payments to all hospitals to offset an increase in the area wage index (AWI) for the hospitals in the lowest AWI quartile.

CMS continues to assert that the policy will "help mitigate wage index disparities." However, CMS has not provided any further rationale or justification for its continuation of the Low Wage Index Hospital Policy and the associated reduction to the standardized amount for all IPPS hospitals (the Low Wage Index Redistribution) or satisfactorily addressed concerns raised by CHA and other commenters in either the FFY 2020 or FFY 2021 IPPS final rules. In the intervening period between the FFY 2021 IPPS final rule and the FFY 2022 proposed rule, the HHS Office of the Inspector General (OIG) released a report questioning the efficacy of CMS' Low Wage Index Hospital Policy and providing data from a period prior to implementation of the policy that illustrates the deep conceptual flaws with this policy. Furthermore, CMS does not have the legal authority to make this reduction under IPPS. **CHA strongly opposes any reduction to payments under IPPS that would result from the continued implementation of the Low Wage Index Redistribution.**

HHS Office of the Inspector General (OIG) Report: The Centers for Medicare & Medicaid Services Could Improve Its Wage Index Adjustment for Hospitals in Areas With the Lowest Wages[4]
CHA believes that not only is CMS' Low Wage Index Hospital Policy beyond the agency's legal authority, as discussed below in detail, it is mistargeted and ineffective relative to achieving CMS' stated purpose.

Low-Wage Index Hospital Policy Is Mistargeted: CMS stated in the FFY 2020 IPPS proposed rule that the Low-Wage Index Hospital Policy is intended to help poor and/or rural hospitals. However, the OIG finds that only 53% of bottom quartile hospitals are considered rural, and of all bottom quartile hospitals (urban and rural), less than 39% (303) have negative profit margins. Therefore, if the agency's intent is to help rural hospitals, its current policy many hospitals it seeks to help. And, instead of helping unprofitable hospitals achieve sustainability, it is reducing the standardized amount for all hospitals – many of which are not profitable – to provide a payment increase to the 61% of bottom quartile hospitals (480) that are already profitable.

While CHA strongly supports providing assistance to rural hospitals and those struggling financially in a non-budget-neutral manner, it is clear from the OIG report that the Low-Wage Index Hospital Policy is not narrowly or well targeted, as CMS asserts. And contrary to CMS' stated goal, the policy reduces payments to numerous rural hospitals across the country and those that are not profitable to provide additional payments to bottom quartile hospitals in urban areas and those that are profitable.

Low Wage Index Hospital Policy Is Ineffective: CMS also asserts in the FFY 2020 final rule that it is implementing a "technical correction" to address the effect of the Medicare wage index on Medicare payments to hospitals in low-wage index areas, which impacts these hospitals' ability to increase the

[3] CHA also submitted comments in opposition of the CY 2020 outpatient prospective payment system proposed rule, which incorporated the Low Wage Index Redistribution from the FFY 2020 IPPS final rule.
[4] https://oig.hhs.gov/oas/reports/region1/12000502.asp

salaries they offer to staff. However, the OIG report provides evidence questioning the assertion that the Medicare wage index is the root cause of lower quartile hospitals' inability to offer higher wages. The report finds that:

> *"The average hourly wages of hospitals in the same area sometimes varied significantly. (That is, some hospitals already were paying significantly higher wages than other hospitals in the same area prior to the bottom quartile wage index adjustment.)"*

This finding suggests that Medicare's wage index policy, as it existed before the implementation of the low-wage index policy in FFY 2020, was not an insurmountable barrier in lower quartile core based statistical areas (CBSAs) that prevented those hospitals from paying higher wages. Instead of Medicare payment policy as the root cause, the OIG report identifies other issues that impact hospital net revenue and the cost of labor in a given market that could lead to lower hospital wages and wage index values. First, the OIG report finds almost half of states with hospitals in the bottom quartile have not expanded Medicaid and that 57% of hospitals in the bottom quartile are located in these non-expansion states. Hospitals in these CBSAs experience increased levels of uncompensated care relative to hospitals in markets that have expanded Medicaid. This places additional downward pressure on hospital margins in non-expansion states, limiting their ability to increase wages.

Second, the OIG report finds that 17 of the 22 states that had a minimum wage equal to the federal minimum wage were states with hospitals in the bottom quartile. These 17 states represent 71% of the bottom quartile wage index states. A minimum wage equal to the federal minimum wage depresses the market clearing rate for some types of labor, which results in lower wage index values in these states relative to states that have minimum wage levels in excess of the federal minimum.

The OIG report provides strong evidence that a more complicated set of issues in local labor markets – beyond the Medicare wage index – determines hospital wages. Therefore, any policy solution CMS crafts will need to address these root causes. Based on these findings, the OIG recommends that CMS study the reasons some hospitals in a particular area were able to pay higher wages than others in the same area prior to the implementation of the Low Wage Index Hospital Policy. **CHA agrees with this recommendation and asks that CMS repeal its Low Wage Index Hospital Policy for FFY 2022 and concomitant budget neutrality adjustment while it gathers more information that might enable the agency to focus its support for rural and unprofitable hospitals more precisely, in a manner that is permissible under the statute, and in a non-budget-neutral fashion.**

The Policy to Increase Area Wage Index Values for Low-Wage Index Hospitals at the Expense of All IPPS Hospitals Violates the Medicare Act

CHA cannot support CMS' continuation of the policy to increase the wage index values of low-wage index hospitals by decreasing the standardized amount for all hospitals. This is because the Low Wage Index Redistribution violates the provision of the Medicare Act, which requires the agency to adjust payments to reflect area difference in wages; additionally, the reasons given by CMS in the FFY 2020 IPPS final rule for this policy are inadequate. Also, the budget neutrality adjustment is not supported by the exceptions and adjustments provision on which CMS may be relying. Rather, the Low Wage Index Redistribution will result simply in a shift of Medicare funds from high and middle wage hospitals to low-wage hospitals, completely untethered from labor costs incurred by hospitals.

A. The Low Wage Index Hospital Policy and Standardized Amount Reduction Are Beyond CMS' Legal Authority under 42 U.S.C. § 1395ww(d)(3)(E)

1. CMS' Policy Is Contrary to the Plain Language of 42 U.S.C. § 1395ww(d)(3)(E)

In finalizing its Low Wage Index Redistribution in FFY 2020, CMS asserted that it has the legal authority under 42 U.S.C. § 1395ww(d)(3)(E) ("Section 1395ww(d)(3)(E)") to increase the wage index values for hospitals in the lowest quartile above the values that were calculated based on actual wage data. Section 1395ww(d)(3)(E) provides a process for adjusting hospital payments to account "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level," requires that factor to be updated annually "on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of [IPPS-participating] hospitals in the United States," and requires those adjustments to be budget neutral. CMS appears to understand Section 1395ww(d)(3)(E) as giving it such broad authority to institute a wage index proposal, which, in essence, makes inaccurate the wage data values for 25% of hospitals in the nation. However, nothing in Section 1395ww(d)(3)(E) or any other provision of the Medicare Act permits CMS to alter payment in order to influence and skew the wage market by altering the wage index for a subset of hospitals. The Low Wage Index Redistribution violates 42 U.S.C. § 1395ww(d)(3)(E) by altering wage index values for the lowest quartile so that they are not based on actual data.

The Low Wage Index Redistribution is contrary to the plain language of the statute because it adjusts IPPS payment rates in a way that does not reflect the actual difference between the relative hospital wage levels in a geographic area compared to the national average. Indeed, the Low Wage Index Redistribution is designed to do the opposite by artificially and inaccurately inflating wage index values for a quarter of IPPS hospitals. CMS acknowledged this in the FFY 2020 IPPS final rule and reiterated it in the FFY 2021 final rule, when it stated that the Redistribution "is based on the actual wages we expect low-wage hospitals to pay," rather than the actual wages paid by these hospitals.

Moreover, CMS has instituted a process — the Wage Index Development Timetable — with detailed instructions to ensure that CMS has accurate wage index data from all IPPS hospitals with which to create the annual wage index. This is a laborious process, and a hospital will not have an opportunity to later fix any wage data errors if it fails to follow this process. It is important to note that where the wage data are reported on Worksheet S-3 of the Medicare cost report is the only section of the cost report that is subject to a Medicare administrative contractor (MAC) review every single year. In addition to the MAC review, there is a subsequent additional secondary auditor with oversight of the MACs to ensure data are reported accurately. CMS has invested significant resources to ensure that the data reported and reflected in each year's cost reports are reliable and valid for the purposes of payment. Yet CMS is proposing to continue a policy that violates its own rules by adopting and continuing to implement the Low Wage Index Redistribution, which improperly increases the wage index for 25% of IPPS hospitals without any wage data to support the increase.

In the FFY 2020 IPPS final rule, CMS said the policy increases accuracy of the wage index by giving low-wage hospitals an opportunity to increase wages to levels that CMS believes they would pay if they could, but this rationale is hard to justify. Moreover, CMS stated, but did not explain why, "the lag in the process between when a hospital increases its employee compensation and when that increase is reflected in the calculation of the wage index[]" harms low-wage index hospitals (84 Fed. Reg. 42,044,

42,327/Aug. 16, 2019). CMS did not assert that hospitals with wage index values above the lowest quartile do not experience this “lag in the process” in the same manner as hospitals in the lowest quartile. Rather, the lag between any changes in employee compensation relative to the national average applies to all IPPS hospitals, whether they are low- or high-wage hospitals. There is no reason to believe that this phenomenon disproportionately impacts the lowest quartile of hospitals and, in fact, the lag might help low-wage hospitals in labor markets with falling hospital wages avoid being assigned even lower wage index values. Moreover, Congress only authorized the Secretary under Section 1395ww(d)(3)(E) to consider survey data in updating the wage index and, therefore, when adjusting payments to hospitals to account for geographic wage differences, the Medicare Act confines CMS to consideration of actual wage costs and not concerns for “data lag” or any other policy concerns. Accordingly, CMS considered factors that Congress did not intend it to consider in promulgating the Low Wage Index Redistribution, in that CMS based the policy on the data lag and its speculation that hospitals in low-wage areas would increase their wages if their wage indices were increased, rather than basing it on the survey data.

In the FFY 2020 IPPS final rule, and as acknowledged by the OIG in its report, CMS conflated low-wage cost hospitals with poor and/or rural hospitals. Undeniably there is some overlap, but low-wage costs cannot be synonymous with poor or unprofitable hospitals any more than high-wage costs can be synonymous with rich and profitable ones. California rural hospitals have high-wage costs compared to hospitals across the nation, but these are labor costs that rural California hospitals experience because of real geographic labor cost differences that CMS acknowledges exist across the nation. To suppose that these rural hospitals in high-wage cost areas are not in need of more reimbursement indicates that CMS is using the wage index as a policy vehicle, not as a “technical correction,” as the agency claimed numerous times in the FFY 2020 IPPS final rule.

CMS has not explained in the FFY 2020 IPPS final rule, the FFY 2021 IPPS final rule, or in this proposed rule why or how Section 1395ww(d)(3)(E) gives it the broad authority to institute a policy that creates wage index values for a quarter of the nation’s hospitals that are not based on evidence and are, in fact, contrary to the evidence. CMS’ policy is also contrary to the wage index statute, which requires the Secretary to adjust IPPS payments by a factor “reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level” and is permitted to update this factor based only on “a survey . . . of the wages and wage-related costs” of IPPS hospitals in the United States. 42 U.S.C. § 1395ww(d)(3)(E).

2. CMS’ Redistribution Contradicts Congressional Purpose

While certain details of the creation and implementation of the wage index may have been delegated by Congress to the agency, the statute nevertheless “requires the Secretary to develop a mechanism to remove the effects of local wage differences.” *See Methodist Hospital of Sacramento v. Shalala*, 38 F.3d. 1225, 1230 (D.C. Cir. 1994). Moreover, the payment adjustments to reflect area wage differences must be accurate. *See id.* at 1227 (citing H.R. Rep. No. 98-25, at 132 (1983), reprinted in 1983 U.S.C.C.A.N. 219, 351; S. Rep. No. 98-23, at 47 (1983), reprinted in 1983 U.S.C.C.A.N. 143, 187) (“[A]t any given time the wage index must reflect the Secretary's best approximation of relative regional wage variations.”). And the wage index must be uniform. *Atrium Med. Ctr. v. U.S. Dep’t of Health & Human Servs.*, 766 F.3d 560, 569 (6th Cir. 2014) (Subsection (d)(3)(E)’s “consistent use of the singular — ‘the proportion’ and ‘a factor’—indicates that the wage index must be uniformly determined and applied.”) (citing *Sarasota Mem’l Hosp. v. Shalala,* 60 F.3d 1507, 1512-13 (11th Cir. 1995)). CMS’ Low Wage Index Hospital Policy does not create a uniformly determined and applied wage index, nor does it “remove the effects of local

wage differences." Instead, the policy destroys uniformity by treating 25% of the nation's hospitals differently than the rest, and it disregards accurately reported wage data for those 25% of hospitals. This is beyond the authority delegated to the agency by Congress.

Congress instructed CMS in Section 1395ww(d)(3)(E) to identify actual differences in geographic labor costs relative to the national average and to account for them in the payments to hospitals, subject only to limited statutory exceptions adopted by Congress.[5] Over time, Congress amended Section 1395ww(d)(3)(E) to (a) add a budget neutrality adjustment as part of subsection (d)(3)(E)(i); (b) fix the wage-related portion of the standardized amount at 62% where the wage index value is less than or equal to 1.0 in subsection (d)(3)(E)(ii); (c) impose a wage index "floor" for frontier hospitals in subsection (d)(3)(E)(iii); and now as of this year, (d) impose an imputed floor for all-urban states. In adopting subsection (d)(3)(E)(ii) in particular, Congress has already sought to temper the impact of the wage index on low-wage index hospitals by reducing the labor-related portion of the standardized amount from 67.6%, as proposed in the FFY 2022 IPPS rule, to 62% for hospitals with a wage index value of less than the median (1.0). Congress, however, did not authorize CMS to take any further steps to mitigate the impact of the wage index on low-wage index hospitals. Rather, Congress instructed that all updates to the wage index must be based on actual wage data.

Moreover, when Congress established limited wage index exceptions in subsection (d)(3)(E)(ii), (d)(3)(E)(iii), and (d)(3)(E)(iv), it ensured that these policies would not be funded with budget neutrality payment reductions by providing that the Secretary "shall apply" the budget neutrality provision of subsection (d)(3)(E)(i) as if clauses (ii), (iii), and (iv) "had not been enacted." 42 U.S.C. § 1395ww(d)(3)(E)(i). In other words, Congress has reserved for itself the power to adopt exceptions to the data-driven wage index process and has only exercised this power in a non-budget-neutral manner that ensures hospitals do not pay for these exceptions through payment reductions.

Until FFY 2020, CMS had acted consistently with Congress' directives by calculating the wage index based on actual wage data, subject only to modifications specifically permitted by Congress. Congress has not authorized the Secretary to adjust the wage index based on anything other than the actual area differences in hospital wage data, and it certainly has not authorized the Secretary to adopt a budget neutrality payment adjustment to fund the counterfactual inflation of wage index values. Thus, CMS' Low Wage Index Redistribution contradicts the will of Congress.

3. CMS' Policy Is *Ultra Vires*

Section 1395ww(d)(3)(E) illustrates that Congress writes rules and exceptions. In Section 1395ww(d)(3)(E) Congress did both, establishing the basic requirements that the wage index must be based on actual wage data in clause (i) and adopting narrow exceptions in clauses (ii), (iii), and (iv). These are the only exceptions that Congress made to the data-driven wage index policy required under clause (i). Congress did not grant CMS the authority to institute the Low Wage Index Redistribution or craft any policy (whether disguised as a "technical adjustment" or not) to adjust the wage index. Because CMS is not authorized to adjust wage index values in the absence of supporting wage data, a budget neutrality payment reduction associated with any such adjustment is likewise not authorized under Section 1395ww(d)(3)(E). As such, the Low Wage Index Redistribution is *ultra vires*.

[5] "The purpose of a wage index is to recognize real differences in wages across labor market areas, including changes over time in a labor market area's relative wages." MedPAC, Potential Refinements to Medicare's Wage Indexes for Hospitals, June 2007.

B. The Standardized Amount Reduction Is Beyond CMS' Legal Authority Under 42 U.S.C. § 1395ww(d)(5)(I)

1. Because the Low Wage Index Hospital Policy is Beyond CMS' Authority, the Standardized Amount Reduction Is Also Unlawful

In the FFY 2020 IPPS final rule, CMS invoked the exceptions and adjustments authority in 42 U.S.C. § 1395ww(d)(5)(I) ("Section 1395ww(d)(5)(I)") as alternative authority to implement the 0.2016% payment reduction[6] component of the Low Wage Index Redistribution, if Section 1395ww(d)(3)(E) did not give it such authority.[7] Section 1395ww(d)(5)(I) states "(I)(i) The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate."

CMS implemented the 0.2016% payment reduction "in order to offset" the Low Wage Index Hospital Policy (84 Fed. Reg. at 42,622). Because the Low Wage Index Hospital Policy is beyond CMS' authority, the 0.2016% payment reduction cannot be implemented to offset the unlawful Low Wage Index Hospital Policy. The 0.2016% payment reduction is, therefore, also unlawful.

2. Section 1395ww(d)(5)(I) Does Not Create a Broad Exception Allowing for the Standardized Amount Reduction

Additionally, the use of Section 1395ww(d)(5)(I)(i) for a global rate reduction does not fit within the language, structure, or intent of the statute. The IPPS is an extraordinarily detailed framework with very specific subsections and paragraphs specifying how the complicated payment methodology is to work. Subparagraphs (A)-(H) that precede Section 1395ww(d)(5)(I) identify distinct exceptions and adjustments to the payment rates prescribed under the IPPS in very specific circumstances that include: outliers ((d)(5)(A)); indirect costs of medical education ((d)(5)(B)); special needs of rural referral centers ((d)(5)(C)); sole community hospitals ((d)(5)(D)); reimbursement for services described in 1395y(a)(14) ((d)(5)(E)); low-income patients ((d)(5)(F)); Medicare-dependent, small rural hospitals ((d)(5)(G)); and Alaska and Hawaii ((d)(5)(H)). In the context of the statute as a whole, Section 1395ww(d)(5)(I)(i) does not convey sweeping authority for CMS to apply across-the-board rate reductions but, rather, only exceptions and adjustments of the kind similar to what appears in the preceding clauses.

Section 1395ww(d)(5)(I) cannot be interpreted to give CMS such broad authority as to wipe away all the specific reimbursement methodology that is set forth in the relevant statute. Otherwise, the only limit would be whatever CMS deems to be appropriate. This sort of unfettered delegation of power by Congress to the agency would violate the separation of powers doctrine and is inconsistent with the reimbursement methodology designed by Congress. CHA does not believe the exception can mean that CMS can do anything that it deems appropriate to implement whatever policy CMS wishes to advance. This is especially the case where the wage index statute is specific as to how the wage index is supposed to work.[8]

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[6] CMS continues to propose a budget neutrality adjustment factor for FFY 2022 of -0.1890%.

[7] CMS may also be relying on this provision as an alternative basis for increasing the AWI of the lowest quartile hospitals, although at no point in the FFY 2020 final rule did CMS explicitly state this was the case, nor has CMS attempted to clarify itself in the FFY 2021 final rule or this proposed rule. However, this position is unsupported by the language of Section 1395ww(d)(5)(I), which authorizes exceptions and adjustments only to "payment amounts," not to any wage index value established under Section 1395ww(d)(3)(E).

[8] Otherwise, if the only limit of Section 1395ww(d)(5)(I) was whatever CMS deems to be appropriate, it could

Moreover, read in context, the provision follows a list of exceptions and adjustments and then precedes a clause that would be rendered completely superfluous if Section 1395ww(d)(5)(I) was given the breadth of authority that CMS requires to effectuate the reduction to the standardized amount associated with the Low Wage Index Reduction. First, under the canon of *ejusdem generis* — where general words follow specific words, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words — the exceptions and adjustments authority should be limited due to the context that precedes it.

The payment exceptions and adjustments from (d)(5)(A)-(H) concern particular categories of hospitals or unique cases where Congress has offered an exception to the way the reimbursement methodology will function so as to reward, and not punish, hospitals that might need additional reimbursement given their unique circumstances. They do not concern the overall wage index scheme, which is set forth in Section 1395ww(d)(3)(E) and incorporated into the overall reimbursement methodology, but rather concern smaller adjustments and exceptions that add on to the overall reimbursement methodology. Given the ways in which the exceptions and adjustments are limited in (d)(5)(A)-(H), the "catchall" provision in Section 1395ww(d)(5)(I) is similarly limited in scope and cannot be used to unravel the IPPS reimbursement methodology that is specifically set forth in the rest of the statute.

Second, Section 1395ww(d)(5)(I) has two clauses. The first sets out the exceptions and adjustments authority discussed above. The second states, "In making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year." If CMS can continue to interpret the exceptions and adjustments catchall provision as broadly as it is claiming in the FFY 2020 IPPS final rule, then the second clause would be irrelevant; the canon against surplusage shows that CMS' interpretation is too broad.

The second clause gives CMS the authority, when making adjustments for transfer cases, to adjust the standardized amounts to achieve budget neutrality. This would be entirely superfluous and unnecessary if the first clause already granted CMS the sort of broad authority needed to institute and continue the Low Wage Index Redistribution.

Even if the exceptions and adjustments provision can be read to afford broad authority to CMS, the exercise of that authority must be consistent with, and cannot frustrate, the intent of Congress. Congress has mandated an adjustment to reflect the geographic differences in area wages. Congress has mandated that the adjustment be based on relative hospital wages from different areas of the country. CMS may not unilaterally implement (and continue) a rule designed to further a policy of its own making to provide additional funding to low-wage hospitals to supposedly incentivize them to increase wages.

Certainly, Congress could adopt such a policy and direct CMS to implement it, but Congress has not done this. Rather, the policy adopted by Congress as set forth in the Medicare Act is to recognize actual wage differences, not to ignore those differences to provide funding to hospitals in certain areas in the hope that they increase employee wages. Furthermore, where Congress has wanted to increase the wage

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change the IPPS reimbursement system to a per diem system, for example. This cannot be the breadth of authority delegated to CMS by Congress, given the text of the provisions of Section 1395ww(d).

index for low-wage states, it has explicitly done so (e.g., frontier floors under Section 1395ww(d)(3)(E)(iii)). CMS has no authority under the exceptions and adjustments provision or otherwise to act in a manner that is inconsistent with Congress' intent. If CMS believes it would be good payment policy to provide additional funding to low-wage hospitals, CMS should work with Congress to seek its authority to do so, and not make unilateral changes inconsistent with previous Congressional action, as it has done.

CMS cannot claim to have unfettered authority limited only by what CMS deems appropriate. Such an interpretation would violate separation of powers principles, especially as the executive is attempting to claim that Congress delegated to it extraordinarily broad authority in a manner that would vitiate the rest of the Medicare Act. Therefore, the catchall provision cannot be read to grant CMS authority to implement and continue the standardized amount reduction associated with its Low Wage Index Redistribution.

3. The Secretary Did Not Act by Regulation as Required by Section 1395ww(d)(5)(I)

Even if the catchall provision could be read to provide for such broad authority to institute (and continue) the payment reduction associated with the Low Wage Index Redistribution, CMS has not followed the requirements of Section 1395ww(d)(5)(I). Section 1395ww(d)(5)(I)(i) requires adjustments made under this exception to be "provide[d] by regulation." Similarly, 42 U.S.C. § 1395hh(a) requires that "[n]o rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for service . . . shall take effect unless it is promulgated by the Secretary by regulation. . . ." CMS did not promulgate a regulation to effectuate the payment reduction, but merely applied it as a rate adjustment in the preamble to the FFY 2020 and FFY 2021 IPPS final rules (and proposed to apply it as a rate adjustment in the preamble of this proposed rule).

The term "regulation" in Section 1395ww(d)(5)(I) must mean something different than "rule" as defined in the Administrative Procedures Act (APA). Otherwise, Congress would have used the word "rule" rather than regulation. The mere discussion of the Low Wage Index Redistribution in the preamble to the FFY 2020 IPPS proposed or final rule is not a regulation. Neither the FFY 2020 and FFY 2021 IPPS proposed and final rules, nor the proposed rule for FFY 2022, contain a provision embodying the Low Wage Index Redistribution that was added to the Code of Federal Regulations. It is, of course, well established that preambles to regulations are not themselves regulations. *See Utah Power & Light Co. v. Sec 'y of Labor*, 897 F.2d 447, 450 (10th Cir. 1990) ("[P]reamble to the regulations . . . is not part of the regulations as published in the Code of Federal Regulations."); ("[I]t is well-settled that preambles, though undoubtedly 'contribut[ing] to a general understanding' of statutes and regulations, are not 'operative part[s]' of statutes and regulations." (quoting *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002))). Moreover, publication in the *Federal Register* simply does not suffice to create a "regulation"; instead, publication in the Code of Federal Regulations is required. *See Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538-39 (D.C. Cir. 1986). ("The real dividing line between regulations and general statements of policy is publication in the Code of Federal Regulations"), *quoted in AT&T Corp. v. Fed. Commc'ns Comm'n*, 970 F.3d 344, 350 (D.C. Cir. 2020). Even if CMS had the authority to implement and continue a payment reduction (which it does not), CMS implemented it (and proposes to continue to implement it) in a way that violates the statutory requirements of its allegedly authorizing statute (and others) and, therefore, is invalid.

4. CMS' Exceptions and Adjustments Authority Does Not Authorize Budget Neutrality Adjustments, Except with Respect to Transfer Cases

Even if CMS had the authority to institute the Low Wage Index Redistribution under Section 1395ww(d)(5)(I)(i) — which it does not — such exceptions and adjustments authority does not permit the implementation of the policy in a budget neutral manner. Rather, subsection (d)(5)(I)(ii) provides CMS with limited authority to adopt budget neutrality adjustments only in the context of adjustments for transfer cases and does not provide any similar budget neutrality authority for any other type of adjustment.

C. CMS Failed to Provide a Valid Rationale for the Low Wage Index Redistribution in the FFY 2020 and FFY 2021 IPPS Final Rules and the Proposed Rule for FFY 2022

In the FFY 2020 IPPS final rule, CMS provided a confusing rationale for the Low Wage Index Redistribution (which was summarized and reiterated in the FFY 2021 IPPS final rule), stating that the policy "would provide certain low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index." CMS continued that its "proposal to increase the wage index for low wage index hospitals will increase the accuracy of the wage index by appropriately reflecting the increased employee compensation that would occur (to attract and maintain a sufficient labor force) if not for the lag in the process between when a hospital increases its employee compensation and when that increase is reflected in the calculation of the wage index." CMS further stated that "the intent of [the Low Wage Index Redistribution] is to increase the accuracy of the wage index as a technical adjustment, and not to use the wage index as a policy tool to address non-wage issues related to rural hospitals, or the laudable goals of the overall financial health of hospitals in low-wage areas or broader wage index reform." It is irrational, however, for CMS to assert that it makes the wage index, which is required by statute to be data-driven, more accurate by changing the wage index values for 25% of IPPS hospitals so that they are not based on actual data.

CMS continued in the FFY 2020 IPPS final rule that under this Low Wage Index Redistribution "the wage index for low wage index hospitals will appropriately reflect the relative hospital wage level in those areas compared to the national average hospital wage level [, b]ecause our proposal is based on the actual wages that we expect low wage hospitals to pay[.]" Essentially, CMS asserted that by making wage index values inaccurate for 25% of the nation's hospitals, it was making them more accurate because the data would reflect what CMS conjectures it could possibly become if low-wage index hospitals adjust their wages under the policy. This circularity is illogical and does not provide a legitimate basis for the Low Wage Index Redistribution.

Furthermore, CMS denied it was using the wage index as a policy tool while implicitly acknowledging that it was using the Low Wage Index Redistribution to change hospital labor markets because it expected wage payments in low-wage markets to increase under the policy. CMS emphasized that the Redistribution provides "an opportunity for low-wage hospitals to increase their employee compensation." But CMS did not require low-wage hospitals to use the increased payments to pay for higher wages. CMS' assertion that the wage index for the lowest wage area hospitals will increase in the future is nothing more than wishful speculation, at best, and thus, the Redistribution lacks a factual predicate.

Moreover, CMS' rationale — that making wage data inaccurate will actually make it more accurate — is patently unreasonable. First, CMS is required by statute to determine the wage index by using actual wage data, not a projection of what it speculates the data might be if it were to artificially increase the wage index based on an unsupported guess as to how the lowest quartile hospitals may behave.[9] Second, in the FFY 2020 and FFY 2021 IPPS final rules and the FFY 2022 proposed rule, CMS has offered no data, analysis, survey, or other evidence to support the notion that bottom quartile hospitals will pay higher wages if their AWI is increased. Third, hospitals, like other employers, pay salaries based on the local labor market, which is largely unaffected by the payments received by a hospital. That labor market is affected by local factors such as the labor supply in the area, the availability of a labor force with appropriate skills and education, the demand for labor, and the cost of living. CMS has offered no information to the contrary. Fourth, the lag issue referenced by CMS in the FFY 2020 IPPS final rule as to why low-wage index hospitals cannot benefit from wage increases applies to all IPPS hospitals, not just those with low wages. Any hospital that increases wages to respond to the local labor market will not see the impact of the wage increase in the AWI for several years. In fact, some low-wage hospitals are benefited by the lag where their wages decrease from year 1 to year 2. The only way to truly address the lag would be to retroactively correct the wage index and adjust Medicare payments after the actual data for a period are known, which of course is not compatible with a prospective payment system.

While CHA can appreciate CMS' desire to limit costs to the Medicare system, there is no requirement that it help hospitals in the lowest quartile by harming all other IPPS hospitals. The disparities in average hourly wages paid across the country, reported as part of audited cost reports and used to calculate the area wage index, are real. While the wage index is imperfect, as noted by several nationally recognized studies, including those of Medicare Payment Advisory Commission (MedPAC), the Institute of Medicine, and CMS, the object is to capture accurate wage data that reflect the significant cost of living differences among states, more generally. The following data are illustrative:

State	Average Annual Nurse's Salary[1]	Median Household Income[2]	Median List Price of Houses for Sale[3]
CA	$120,560	$80,440	*$654,629*
NY	$89,760	$72,108	*$358,853*
NJ	$85,720	$85,751	*$394,553*
TN	$64,120	$56,071	*$218,121*
AL	$60,230	$51,734	*$165,334*
MS	$61,250	$45,792	*$138,216*

[9] Neither CMS, nor any other federal agency, can know how private actors will act in the future. Even CMS accepted this as true in the FFY 2020 IPPS final rule, responding to comments that the Low Wage Index Redistribution does not have any method to ensure that low-wage hospitals actually increase employee compensation by stating that the policy "is intended to provide an *opportunity* for low-wage hospitals to increase their employee compensation." (84 Fed. Reg. 42327) (emphasis in original). CMS continued that, because the policy is not a permanent one, "[a]t the expiration of the policy, hospitals that have not increased their employee compensation in response to the wage index increase may experience a reduction in their wage index compared to when the policy was in effect." CMS added that "[t]he future wage data from those hospitals will help us assess our reasonable expectation based on comments received in response to the request for information as well as proposal that low-wage hospitals would increase employee compensation as a result of our proposal." In other words, while CMS claims to be making the wage index more accurate, it effectively admits this is an experiment, and the results are uncertain. Rather than being a "technical adjustment," CMS is clearly attempting to implement policy changes through the wage index, despite its statements to the contrary in the FFY 2020 IPPS final rule.

Sources: 1) Bureau of Labor Statistics, Occupational Employment Statistics, May 2020 State Occupational Employment and Wage Estimates; 2) US Census Bureau 2019 Median Household Income in the United States; 3) Zillow.com Home Prices & Values. Data as of May 19, 2021

The labor costs incurred by hospitals are largely a function of the market in their respective geographic areas. CMS has offered no data or other evidence to the contrary.

While we appreciate that CMS wishes to address the financial challenges of our nation's rural hospitals, CMS has finalized (and seeks to continue) a broad policy to help only those hospitals in the lowest quartile, rural or not. **CHA agrees that helping rural hospitals is a laudable goal. Doing so in a permissible manner is an effort we would support. But as finalized in the FFY 2020 and FFY 2021 IPPS final rules and as continued in this proposed rule, the policy harms numerous rural hospitals, including all of California's rural hospitals, and it fundamentally fails to recognize the legitimate differences in geographic labor markets. And, as demonstrated by the OIG's findings, CMS' current low wage index policy is mis-targeted and ineffective relative to its stated purpose.**

In summary, there are no bases for implementing and continuing this policy at all, let alone in a budget-neutral manner, since Section 1395ww(d)(5)(I)(i) does not authorize budget neutrality. CMS' decision to continue to do so irrationally penalizes all IPPS hospitals in an effort to benefit those low-wage hospitals that CMS views as deserving. Far from a technical adjustment, this is CMS weaving policy into the area wage index to create inaccurate wage index values to benefit 25% of the nation's IPPS hospitals. Neither Section 1395ww(d)(5)(I) nor Section 1395ww(d)(3)(E) provides CMS with authority to do this. We, therefore, ask CMS not to continue the Low Wage Index Redistribution in FFY 2022.

Area Wage Index – Audited Hospital Data Arbitrarily Excluded from Proposed Rule AWI File

As part of the FFY 2022 IPPS proposed rule, CMS verified the Worksheet S-3 wage data by instructing its MACs to revise or verify data elements that result in "specific edits failures" (86 FR 25398). CMS excluded 86 providers with "aberrant" data the agency claims should not be included in the wage index.

Several of the 86 hospitals CMS identifies as having "aberrant" data are California hospitals whose wages are higher than their core-based statistical average (CBSA) average. In the FFY 2022 proposed rule CMS does not cite specific reasons why the agency believes the data from these hospitals are "aberrant[10]." Therefore, CHA, the excluded hospitals, and other stakeholders are left to infer that CMS is excluding these hospitals because their wages are higher than those of other hospitals in the CBSA.

That stakeholders must infer why CMS has deemed the excluded data are aberrant is a problem unto itself. In the absence of explanation from the agency, stakeholders are left to make educated guesses as to why CMS has deemed the wage data aberrant, limiting their ability to fully comment on the exclusion of individual hospitals. It also highlights CMS' use of arbitrary and undisclosed criteria to exclude these hospitals.

Further, CHA notes that the FFY 2022 wage data from worksheet S-3 of cost reports filed during FFY 2018 for the excluded hospitals with average hourly wages that are higher than the CBSA average — like

[10] CMS has not defined – either in regulatory or sub-regulatory guidance – the criteria it uses to determine when a hospital's audited Medicare wage index data from worksheet S-3 is aberrant.

all hospitals — have been reviewed by CMS and its MAC as part of the well-established Medicare wage index review process. In accordance with the wage index review process — as defined in CMS's Wage Index Development Timetable — at least one of the hospitals in question submitted corrected data in a timely manner that was reviewed and accepted by the MAC. Therefore, in accordance with Medicare's wage index review process, the excluded hospitals' FFY 2018 worksheet S-3 wage data were determined by the MAC to be accurate.

Given this, CHA believes that by excluding several California hospitals with average hourly wages higher than other hospitals in the same CBSA from the FFY 2022 Medicare wage index, CMS is exceeding its statutory authority for the following reasons:

- **Nothing in the applicable statute, Section 1395ww(d)(3)(E), permits CMS to exclude general acute care hospitals from the wage index data simply because those hospitals' wages are higher than the wages of other hospitals in their area. Rather, as indicated by CMS in past rulemakings, the wages of all short-term acute care hospitals must be included unless such data are incomplete or inaccurate.**
- **Even if CMS had authority to exclude certain hospitals despite the fact that their data were accurate and verifiable (which is the case with these hospitals), the exclusion of these hospitals would be arbitrary and capricious, as CMS has promulgated no standards to govern the exercise of its discretion. CMS has established an extensive process to ensure the accuracy and reliability of hospital wage data, which the excluded hospitals have been subjected to. Yet, where the agency does not like the result, it has decided to deviate from this process by excluding hospitals with accurate data.**
- **CMS' exclusion of these hospitals is procedurally improper, as CMS has failed to promulgate a rule in accordance with the Administrative Procedures Act (APA) that would authorize excluding hospitals with aberrant data or to set forth the standards to be applied in determining whether data are aberrant.**
- **CMS has failed to consider the relevant factors and has relied on factors that are not relevant under the applicable statute. As a result, its action is arbitrary and capricious.**
- **The proposed exclusions for FFY 2022 will cause significant harm to not only IPPS hospitals, but also inpatient psychiatric hospitals, skilled-nursing facilities (SNFs), inpatient rehabilitation hospitals (IRFs), and many others. The consequence of these exclusions negatively impacting more than the IPPS hospitals appear to be unintended by CMS, as it failed to even consider them in its regulatory fiscal impact analysis in the proposed rule, which it is legally required to do. Thus, the exclusions are legally impermissible.**

1. **CMS is not authorized to exclude a hospital from the determination of the wage index on the grounds that the hospital has high labor costs.**

Under Section 1395ww(d)(3)(E), "the Secretary shall adjust the proportion . . . of hospitals' costs which are attributable to wages and wage-related costs . . . for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." Nothing in Section 1395ww(d)(3)(E), or any other provision of law, authorizes CMS to ignore the wages paid by hospitals that have wages

that are higher than other hospitals in the same CBSA. And, CMS has pointed to no such provision in the proposed rule.

Specifically, Section 1395ww(d)(3)(E) does not exclude from the determination of wages paid by hospitals those wages paid by hospitals that pay higher than other hospitals in the area. Rather, Section 1395ww(d)(3)(E) requires that the Secretary adjust the labor component of payments to reflect the "relative hospital wage level in the geographic area" to the national average. The hospitals proposed for exclusion are in the geographic area of the CBSAs in which they are located. In addition — despite being allegedly "aberrant" by CMS — the wages paid by these hospitals are the market clearing rates for those employees. If the hospitals did not pay these rates, they would be unable to staff their facilities and provide high-quality clinical care to communities they serve. Excluding these facilities, therefore, will not reflect the relative wage level of hospitals in those CBSAs.

CMS does not have the discretion to ignore the wages paid by the excluded hospitals.[11] CMS' proposal to do so would violate Section 1395ww(d)(E)(3) and would be unlawful. CHA would not take issue if CMS' proposed exclusion of hospitals was for "unresponsiveness to requests for documentation or insufficiently documented data, terminated hospitals' failed edits for reasonableness, or low Medicare utilization." 81 Fed. Reg. 56,762, 56,915 (Aug. 22, 2016). Exclusion of those hospitals violates the mandate for CMS to determine the area wage levels, as those data would be facially inaccurate and, therefore, the inclusion of the data would lead to an inaccurate determination of the wages paid by area hospitals. However, CMS does not dispute the accuracy of the wage data or supporting documentation provided for the California hospitals with average hourly wages that are higher than other hospitals in the CBSA that the agency proposes to exclude.

2. **The exclusion of the hospitals would be arbitrary and capricious and an abuse of the agency's discretion in the absence of ascertainable standards consistently applied.**

CMS' exclusion of the hospitals from the wage index would be an abuse of discretion because it has provided no standard for when a facility's labor costs are too high to be included in the wage index determination. CMS has defined no standard and, as such, an exclusion could be applied across the board to a multitude of health care delivery systems — destabilizing the entire area wage index calculation. It is arbitrary and capricious for CMS to make unilateral *ad hoc* decisions about what constitutes excessive costs so as to exclude a hospital's data from the area wage index data without affording providers any kind of advanced notice or guidance.

Previously, CMS instituted the Wage Index Development Timetable to ensure that it receives accurate wage index data from all IPPS hospitals. Under the established process, hospital-reported data are reviewed by at least one, and maybe two MACs to ensure that the data reported are accurate. This process is undertaken each year, and CMS invests significant resources to ensure the data reported and used in the wage index are reliable and valid. However, CMS' proposal to exclude hospitals for having accurate wage data that are too high ignores this process in an arbitrary and capricious manner.

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[11] CMS appears to have understood and interpreted Section 1395ww(d)(3)(E), as long ago as 1994, to require that data from all hospitals in operation are included in the wage index. *See e.g.*, 59 Fed. Reg. 45,330, 45,353 (Sept. 1, 1994) (CMS explaining why terminated hospitals should not be eliminated from the wage index computation: "[w]e have always maintained that any hospital that is in operation during the data collection period should be included in the database, since the hospital's data reflects conditions occurring in that labor market area during the period surveyed.").

It is imperative that CMS reject this type of unilateral agency action. To allow its implementation opens the door to a complete unraveling of the area wage index calculation and makes an already imperfect index completely and woefully inaccurate — the very opposite of the statute's intent.

3. **The exclusion of the hospitals, as proposed, violates the notice and comment requirements of the APA.**

The APA and the Medicare Act itself require that CMS engage in notice-and-comment rulemaking before applying a rule of general application, whether such rule is an interpretative rule or a substantive rule. CMS must provide notice of the proposed rulemaking, afford interested parties an opportunity to comment on the proposed rulemaking, and consider the relevant matters presented in such comments. 5 U.S.C. §553; 42 U.S.C. § 1395hh. *Allina Health Services v. Price*, 863 F.3d 937, 944 (D.C. Cir. 2017) *affirmed by Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019) ("[T]he Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement. . . . [o]n the contrary, the text expressly *requires* notice-and-comment rulemaking.").

In this instance, CMS is not putting forward a rule through a formal notice-and-comment process but is implying that it has the discretion to remove hospital data without any standards. If the agency wishes to exclude the data of hospitals where the hospital's labor costs appear to be unusually high, it is incumbent on CMS to promulgate proposed rules setting forth proposed standards so that the public may review and comment. That has not occurred here. Rather, CMS is applying either no standards whatsoever or standards known only to the agency. In either case, CMS is acting improperly and in violation of the APA and 42 U.S.C. § 1395hh.[12] (*See* 42 U.S.C. §1395hh.[13]) There has never been (and this does not so constitute) a public notice-and-comment process related to the agency's purported policy calling for the exclusion of high-cost facilities from the wage index. In the absence of a proper rulemaking process, such policy cannot be validly enforced.

Further, because CMS does not dispute the data's accuracy, its decision to exclude them is even more egregious because CMS is simply removing accurate data without any appropriate rationale and without following proper process under the APA and the Medicare Act.

4. **The exclusion of the hospitals would be arbitrary and capricious because CMS has failed to consider the relevant factors.**

Agency action is arbitrary and capricious and, therefore, invalid when an agency fails to consider the relevant factors or considers factors that should not be considered under the governing statute. Because CMS has not conducted notice-and-comment rulemaking to establish standards for excluding hospitals from the wage index, it is unknowable what factors CMS considered. Further, since CMS has

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[12] In both the 2016 and 2017 IPPS final rules, CMS, in relation to the determination of the area wage index, acknowledged that "it has never been CMS' policy to disclose audit protocol." 80 Fed. Reg. at 49,491 and 81 Fed. Reg. at 56,915. Moreover, in the 2017 IPPS final rule, the Secretary further stated that "the protocol is for the Secretary and MAC internal use only." 81 Fed. Reg. at 56,915. CMS cannot hide behind the talisman of "audit protocol" to avoid promulgating the standards used to exclude hospitals from the wage index calculation, if any such standards exist.

[13] The implicit criteria used by CMS to exclude the hospitals are a substantive rule, as there is nothing in the Medicare statutes directing CMS to exclude hospitals with labor costs viewed as high for the area. However, as set forth in *Allina,* the Secretary must follow notice-and-comment rulemaking in connection with Medicare payment policy regardless of whether a rule is substantive or interpretative. Thus, even if CMS were to (incorrectly) view the criteria used to exclude the hospitals (if there are any) as an interpretative rule, notice-and-comment rulemaking would be required before applying the criteria.

not proposed any ascertainable standards, the public has no meaningful opportunity to comment on the factors that should be considered. Because CMS has considered and relied on factors not provided for in the statute, its action to exclude the hospitals is arbitrary and capricious.

5. **The impact of excluding these hospitals is far greater than hospital inpatient payments; Medicare beneficiary access is threatened in the impacted CBSAs.**

CMS' actions have far-reaching consequences not contemplated in the FFY 2022 IPPS proposed rule. If implemented, this proposal will most certainly have negative financial implications not only for the hospitals and the hospitals within their CBSAs, but also for other providers whose payments are based on the "unadjusted" area wage index in the CBSA, such as SNFs, IRFs, home health agencies, long-term care hospitals (LTCHs), and inpatient psychiatric facilities (IPFs).

CMS proposed to utilize the FFY 2022 unadjusted wage index in the FFY 2022 IRF, IPF, and SNF rules. In these payment systems, due to the significant labor share, more than 70% of a provider's payment is adjusted for the area wage index. The financial consequences are significant to facilities — most notably, to hospital-based post-acute care providers that care for the most medically complex patients.

However, CMS has not identified the fiscal impacts on acute psychiatric hospitals and units, IRFs, and SNFs in its respective regulatory impact statements for the IPF, IRF, SNF, and IPPS proposed rules. Such failure ignores the agency's required duties under Executive Order 12866, Executive Order 13563, section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995, Executive Order 13132, the Congressional Review Act, and Executive Order 13771. In the IPPS proposed rule — as well as the IRF, SNF, and IPF proposed rules — CMS has failed to consider the implication of these exclusions and, as such, has failed to consider the relevant factors, as required under the APA.

The exclusion of these hospitals will have significant negative consequences the agency appears not to have contemplated. The ripple effects of such an arbitrary and capricious policy will jeopardize access to care for Medicare beneficiaries in the impacted CBSAs. **We urge the agency to withdraw the exclusion of the California hospitals that CMS has excluded for having higher average hourly wages than their CBSA and reinstate their data for the purposes of the FFY 2022 area wage index. The absence of discussion of these exclusions, as well as their fiscal impacts, renders the notice of proposed rulemaking inadequate, and in itself is a reason that the proposed exclusion of the impacted hospitals may not lawfully be implemented.**

Area Wage Index – Labor-Related Share Rebasing

CMS is currently using a national labor-related share of 68.3% to adjust payments to hospitals with an AWI greater than 1. As a result of its proposal to rebase and revise the hospital market-basket from 2014 to 2018 data, CMS proposes to use a revised national labor-related share of 67.6% to adjust payments in FFY 2022 for hospitals with a wage index of 1 or greater. This decline of 0.7 percentage points (illustrated in the table below) is estimated to reduce operating payments to California's hospitals by $28 million in FFY 2022.

Comparison of 2014-Based Labor-Related Share and Proposed 2018-Based Labor-Related Share[14]

Labor Related Categories	2014-Based IPPS Market Basket Cost Weights	Proposed 2018-Based IPPS Market Basket Cost Weights	Difference[1] *(calculated)*
Wages and Salaries	43.4	41.2	(2.20)
Employee Benefits	12.4	11.7	(0.70)
Professional Fees: Labor-Related[2]	6.8	8.6	1.80
Administrative and Facilities Support Services	1	1.1	0.10
Installation, Maintenance, and Repair Services	2.4	2.4	-
All Other: Labor-Related Services	2.3	2.6	0.30
Total Labor-Related Share	68.3	67.6	(0.70)

Notes: 1) Difference column added by CHA.

The decrease of 0.7 percentage points from the current labor-related share (based on 2014 cost weights) to the proposed labor-related share (based on 2018 cost weights) is a result of weight shifting from the Wages and Salaries and Employee Benefits categories to the Professional Fees: Labor Related categories. The Professional Fees category includes both Home Office/Related Organization salary, wage, and benefit costs and Non-Medical Professional Fees (e.g., accounting & auditing, legal, engineering, and management consulting services) cost categories.

CMS, as it has done during prior rebasings, proposes to separate costs associated with professional fees for the proposed 2018-based IPPS market basket into "Professional Fees: Labor-Related" and "Professional Fees: Non-Labor-Related" cost categories. CMS justifies this by stating it "includes a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market*."

Of the 6.4 percentage points CMS assigns to the Non-Medical Professional Fees cost category, it proposes to apportion 4.1 percentage points to the Labor-Related Cost category using the results of a 2008 survey of 108 hospitals. The remaining approximately 2.3 percentage points are apportioned to the Non-Labor-Related Cost category.

To determine the portion of home office costs that CMS believes "vary with the local labor market," the agency compared the location of the hospital with the location of the hospital's home office and calculated the percentage of home office labor costs that were in the same labor market as the hospital based on ZIP code. Using this methodology, CMS determines 60% of hospitals' home office compensation costs were for home offices located in their respective local labor markets and is proposing to allocate 60% of Home Office/Related Organization cost weight to the Labor-Related Cost category.

[14] TABLE IV-07, FFY 2022 IPPS proposed rule pg. 868, display copy

As a result, of the 5.9 percentage points related to the Home Office/Related Organization cost weight, CMS is apportioning approximately 3.5 percentage points to the Professional Fees: Labor-Related cost category and designating the remaining approximately 2.4 percentage points into the Professional Fees: Non-Labor-Related Cost category. As illustrated in the table below, the weighted average of the labor-related costs for the Non-Medical Professional Fees and Home Office/Related Organization Cost categories is 61.8%. In essence, what CMS is assuming with this reduction to the Professional Fees: Labor-Related category is that a non-trivial portion of Home Office/Related Organization wage-related costs and Non-Medical Professional Services Fees (38.2%) does not vary based on geography – or if they do, that variance nets out to the national average wage index of 1.

CMS Split Between Labor and Non-Labor Weights for Professional Fees

	Labor	Non Labor	Total
Professional Services (pg 866)	4.1	2.3	6.4
Home Office (pg 867)	3.5	2.4	5.9
Total Labor/Non-Labor Weighting for Professional Fees	7.6	4.7	12.3
Weighted Percentage "Split" Between Labor and Non-Labor	61.8%	38.2%	100.0%

CHA questions CMS' assumption that a portion of Home Office/Related Organization labor costs and Non-Medical Professional Services Fees do not vary based on geography and labor market. We also question the methodology that CMS uses to determine the non-labor portion for Home Office/Related Organization Salary and Wages and Benefits.

Professional Services Fee Cost Weight

First, CHA questions the validity of CMS' assumption that fees for services provided by firms located outside of a hospital's CBSA do not vary based on geography. The implied underpinning of this assumption is that national and regional professional services firms do not compete with local professional services firms based in a hospital's CBSA. However, this is patently false. When hospitals seek professional services, the services they are seeking are not so unique (e.g., accounting, engineering, management consulting) that they could only be provided by regional or national firms. CMS' own survey data support this conclusion, as approximately 64% of these services are sourced from firms in the local market. Therefore, hospitals solicit proposals for "professional services" from local, regional, and national firms.

When competing with local firms for a given contract or project, regional and national firms have every incentive to adjust their pricing in response to local labor market conditions. If the local labor market has lower wages than the national average — which will influence the pricing of a local firm's response to a request for proposal from a hospital — regional and national firms must reduce the offered price of their services to be competitive with local firms that offer the same services. Conversely, if the local labor market has higher wages than the national average, regional and national firms have every incentive to price accordingly to increase their profit margins on a given contract. Therefore, pricing for services offered by regional and national firms to hospitals in differing CBSAs will vary significantly based on local rates due to these firms competing with local firms that provide the same service.

CHA respectfully asks CMS to offer evidence that pricing for professional services provided by regional and national firms to hospitals is offered in a national market without geographic cost variation. Unless the agency can produce strong evidence that prices for professional services provided by firms outside of a hospital's local labor market are homogenous — that a hospital in Sault Ste Marie, Michigan, is charged the same hourly rates for audit services by a national accounting firm as a hospital in Sacramento, California — CHA respectfully asks CMS to restore the 2.3 percentage points it proposes to reclassify to Professional Services: Non-Labor-Related to the Professional Services: Labor-Related category. In the absence of data that prove standardized pricing by regional and national professional services firms, CHA believes the Professional Services: Labor-Related category should be 6.4.

Home Office/Related Organization Cost Weight

CMS asserts, without providing additional data to support the assertion, that because 40% of hospitals' home office compensation costs were for home offices located outside of their respective local labor markets, those costs are not subject to geographic variation. Based on this limited analysis, CMS proposes to apportion 3.5 percentage points of the 5.9 percentage points to the Professional Fees: Labor-Related cost category and designates the remaining approximately 2.4 percentage points to the Professional Fees: Non-Labor-Related cost category. **CHA strongly disagrees with the assertion Home Office/Related Organization compensation costs that occur outside of a hospital's labor market are not subject to geographic wage variation and does not believe the proposed reclassification to the Professional Fees: Non-Labor-Related cost category is justified.**

Using the instructions provided by CMS in the proposed rule at 86 FR 25418 to 86 FR 252421 and the latest FFY 2018 Medicare cost report data related to home office/related organization costs, CHA replicated CMS' Home Office/Related Organization analysis. We identified approximately 840 hospitals (40% of hospitals with home office data) that were not in the same labor market as their home office. Of these hospitals, 214 were in labor markets with a wage index greater than 1. While these hospitals account for only 25% of hospitals with home offices outside of their labor markets, their salary, wage, and benefit costs are approximately 36% of the salary, wage, and benefit costs for hospitals with home offices outside their labor market.

Further, the analysis indicates that the home office/related party average hourly salary, wage, and benefit costs for hospitals with home offices outside of their labor market is $52.24. However, for the 214 hospitals in a labor market with a wage index greater than 1, the average hourly home office wage is $56.98 (9% higher than average). By contrast, the average hourly home office wage for the 626 hospitals in a labor market with a wage index of 1 or less is $49.96 (4% lower than average).

Analysis of Home Office Costs for Hospitals with Home Offices Outside Their Labor Market

	Hospital Count	% of Total Hospital Count	Home Office/Related Party Salary, Wage, and Benefit Costs	% Total Wage Related Costs	Home Office/Related Party Hours	Home Office Average Hourly Wage	% Difference from Total Average Hourly Wage
Hospitals with Wage Index Values <=1	626	75%	$ 6,978,653,226	64%	$ 139,690,982	$ 49.96	-4.4%
Hospitals with Wage Index Values >1	214	25%	$ 3,843,291,012	36%	67,451,045	$ 56.98	9.1%
Total	840	100%	$ 10,821,944,238	100%	207,142,027	$ 52.24	0.0%

These data indicate that, contrary to CMS' unsupported assertion, home office salary, wage, and benefit costs for hospitals with home offices outside of their labor market are subject to geographic wage variation. Hospitals in labor markets with wage indexes greater than 1 on average have higher home

office wage-related costs than hospitals with wage indexes of 1 or less. **Given this evidence of geographic wage variation in home office costs for hospitals that are not located in the same labor market as their home office, CHA respectfully asks CMS to withdraw its proposal to reclassify 2.4 percentage points of the Home Office/Related Organization cost weight to the Professional Fees: Non-Labor-Related cost category. Instead, we ask the agency to allocate the full 5.9 percentage points of the Home Office/Related Organization cost weight to the Professional Fees: Labor-Related cost category.**

If CMS does not withdraw its proposal and fully allocate the 5.9 percentage points of the Home Office/Related Organization cost weight to the Labor-Related cost category, we ask the agency to provide detailed analysis that supports its assertion that Home Office/Related Organization salary, wage, and benefits costs for hospitals with home offices outside of their labor market are not subject to geographic wage variation. We believe this information should be provided in such a manner that allows time for stakeholders to comment on the analysis prior to publication of the FFY 2022 final rule.

Should CMS be unable to provide detailed analysis that supports its assertions and persists with its proposals to allocate a portion of the Non-Medical Professional Fees and Home Office/Related Organization cost weights to the non-labor category, CHA is concerned that the agency will be in violation of section 1886(d)(3)(E) of the SSA. This section requires that:

> *…the Secretary adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.*

By excluding a cumulative 4.7 percentage points of the Non-Medical Professional Fees (2.3 percentage points) and Home Office/Related Organization (2.4 percentage points) cost weights from the labor-related share without sufficient data to support its assertions, the agency is clearly not adjusting the full proportion of hospitals' wages and wage-related costs subject to geographic variation.

Finally, if the agency determines that a reduction in the labor-related share is supported by data and appropriate for either Professional Services Fees or Home Office/Related Organization cost weight categories, CHA asks that — similar to other wage index related changes — CMS phase in a reduction of the labor-related share. We ask that any phase-in be over a period of three years and implemented in a non-budget-neutral manner in recognition of the precarious nature of hospital finances in the wake of the COVID-19 PHE.

Medicare Uncompensated Care DSH

As required by the Affordable Care Act (ACA) — beginning with FFY 2014 — Medicare DSH payments are split into two separate payments. Hospitals receive 25% of the overall Medicare DSH funds under the traditional DSH formula, known as the "empirically justified" DSH payments. The remaining 75% (Factor 1) is reduced for decreases in the uninsured population since FFY 2013 (Factor 2) and flows into a separate uncompensated care (UCC) pool for DSH hospitals. This UCC pool is allocated based on each hospital's share of national UCC costs (Factor 3). **Similar to prior years, for the FFY 2022 IPPS proposed rule CHA has concerns about the proposed calculation of Factor 1 and the data source used for Factor 3.**

Proposed FFY 2022 Factor 1

In the FFY 2022 proposed rule, CMS uses the OACT's January 2021 Medicare DSH estimates $14.098 billion to calculate Factor 1. The estimate is based on data from the September 2020 update of the Medicare HCRIS and the FFY 2021 IPPS/LTCH PPS final rule IPPS impact file. Applying the 75% adjustment to arrive at the UCC DSH pool, the proposed Factor 1 amount for FFY 2022 is $10.573 billion. This amount is approximately $805 million less than the final Factor 1 for FFY 2021.

The CMS OACT's estimate of Medicare DSH spending uses a baseline year updated to account for projected and actual changes in four component parts that impact DSH expenditures — the IPPS update factor, number of discharges, case mix, and a residual "other" factor to arrive at an estimated DSH amount. Below are tables from the FFY 2021 final and proposed FFY 2022 IPPS rules detailing the specific components of Factor 1 in each rule.

Factors Applied for FFY 2018 through FFY 2021 to Estimate Medicare DSH Expenditures Using FFY 2017 Baseline

	Update	Discharge	Case Mix	Other	Total	Est DSH Pmt, $ Billions
2019	1.0185	0.97	1.009	1.0179	1.0147	14.136
2020	1.031	0.853	1.038	1.0023	0.915	12.933
2021	1.029	0.968	0.998	0.9754	0.9696	12.541
2022	1.028	1.075	1.005	1.0122	1.1242	14.098

Source: FFY 2021 IPPS Final Rule (85 FR 58810)

Factors Applied for FFY 2019 through FFY 2022 to Estimate Medicare DSH Expenditures Using FFY 2018 Baseline

	Update	Discharge	Case Mix	Other	Total	Est DSH Pmt, $ Billions
2019	1.0185	0.97	1.009	1.0179	1.0147	14.136
2020	1.031	0.853	1.038	1.0023	0.915	12.933
2021	1.029	0.968	0.998	0.9754	0.9696	12.541
2022	1.028	1.075	1.005	1.0122	1.1242	14.098

Source: FFY 2022 IPPS Proposed Rule (88 FR 25446)

The table below compares the changes in the component parts of Factor 1 from the FFY 2022 IPPS proposed rule to the final FFY 2021 IPPS rule for the years in which these components overlap.

Uncompensated Care DSH Factor 1 Component Comparison: Proposed FFY 2022 to Final FFY 2021

	Update	Discharge	Case Mix	Other	Total	Est DSH Pmt, $ Billions
2019	0.0000	0.0040	0.0000	(0.0025)	0.0018	(0.8010)
2020	0.0000	(0.0380)	(0.0010)	(0.0173)	(0.0581)	(1.6026)
2021	0.0000	(0.0680)	0.0150	(0.0206)	(0.0741)	(2.6300)

Sources: 1) Factors Applied for FFY 2019 through FFY 2022 to Estimate Medicare DSH Expenditures Using FFY 2018 Baseline, (86 FR 25446); 2) Factors Applied for FFY 2018 through FFY 2021 to Estimate Medicare DSH Expenditures Using FY 2017 Baseline (85 FR 58810); 3) CHA Analysis

The decrease in Factor 1 is driven in part by a decrease of 0.0680 from the FFY 2021 final rule to the FFY 2022 proposed rule in the "Discharge" component for 2021 and decreases in the "Other" component of 0.0173 and 0.0206 for 2020 and 2021, respectively.

Discharge Component

Discharges for FFY 2021 are based on claims data from the December update of the FFY 2020 MedPAR file. This provides less than one quarter of claims data given the lack of time for "claims run out." **Given the proposed rule uses the OACT's January DSH estimate, CHA is concerned about the accuracy of inpatient utilization assumptions based on less than three complete months of Medicare inpatient claims data for FFY 2021 at a time when utilization is likely aberrant due to high COVID-19 positivity rates in many regions in the country — California in particular.**

The proposed rule states that CMS expects to update the economic assumptions and actuarial analysis used to develop Factor 1 in the final rule as part of a mid-session review of the President's budget. CHA believes that CMS should consider a break from its traditional practices for determining the Factor 1 estimates because of unusual and atypical utilization patterns during the pandemic. As CMS acknowledges in section I.F of the FFY 2022 proposed rule, the COVID-19 PHE has significantly impacted utilization patterns for FFY 2020 claims. The proposed rule states:

> *The FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset both contain data significantly impacted by the COVID-19 PHE, primarily in that the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE, as we discuss in this section. Accordingly, we question whether these data sources are the best available data to use for the FY 2022 rate-setting.*

Given the spike at the end of the year in COVID-19 cases, CHA notes that inpatient utilization continued to be materially impacted by the PHE in the fourth calendar quarter of 2020 and early calendar months of 2021. Therefore, as CMS notes in the proposed rule, Medicare claims data from the first three months of FFY 2021 will continue to exhibit the same aberrant inpatient utilization patterns CMS observed when it analyzed FFY 2020 Medicare claims data from the period impacted by the PHE. However, the first three months of FFY 2021 are also likely not reflective of inpatient utilization trends for the remaining months of FFY 2021. CHA anticipates that Medicare inpatient utilization will increase during the remaining months of FFY 2021 as vaccination rates increase and Medicare beneficiaries become more willing to seek hospital care for both emergent and non-emergent health care needs (both current and delayed due to the pandemic).

In other contexts (specifically for determining the relative weights, MS-DRG reclassifications, outlier threshold, and evaluating new technology add-on payments, among others), CMS is departing from its traditional practice of using the latest utilization data available to set FFY 2022 IPPS rates. CHA requests that CMS — faced with similarly aberrant data as in the other contexts describe above — apply an analogous approach for determining Factor 1 to set the size of the uncompensated care pool given the instability in FFY 2021 utilization due to the pandemic. **CHA respectfully asks CMS to use the OACT's estimate of FFY 2021 Medicare discharges from the FFY 2021 IPPS final rule. We believe this estimate**

reflects the anticipated return to normal inpatient utilization patterns that hospitals will experience during the remainder of FFY 2021.

Other Component

The "Other" column represents the increase in a variety of factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, various adjustments to Medicare payment rates that have been included over the years but are not reflected in the "Update" and "Discharge" columns, and changes to Medicaid enrollment. Similar to prior IPPS rules, the FFY 2022 proposed rule does not provide a table allowing readers to trace and understand the changes in each of these variables from the FFY 2021 final rule to the FFY 2022 proposed rule for a given year (e.g., 2020, 2021). Further, CMS' commentary on changes in the "other" variables is limited to discussing changes in estimated Medicaid enrollment. While CHA greatly appreciates this commentary, it does not provide the reader with sufficient data and insight to understand what is driving the reductions in the "other factor" from the FFY 2021 final rule to the FFY 2022 proposed rule for the three overlapping years covered by both rules.

Comparing the commentary on Medicaid enrollment projections in the FFY 2021 final rule to that included in the FFY 2022 proposed rule, it appears that CMS' estimate of Medicaid enrollment for FFY 2020 decreased by 1.1 percentage points (FFY 2021 final rule, 4%, FFY 2022 proposed rule, 2.9%). The change in estimate for FFY 2020 Medicaid enrollment from the FFY 2021 final rule to the FFY 2022 proposed rule may explain some portion of the 0.0173 decrease in the "Other" factor between the two rules. However, it does not align with publicly available reporting of Medicaid enrollment trends. Survey data from the Kaiser Family Foundation "shows that Medicaid/CHIP enrollment is increased amid the COVID-19 pandemic as actual adjusted data from February 2020 to preliminary data in November 2020 show that enrollment increased by 7.7 million or 10.8%[15]." **Given this, CHA respectfully asks CMS to provide additional rationale for reducing the FFY 2020 estimated rate of increase in Medicaid enrollment between the FFY 2021 final and FFY 2022 proposed IPPS rules at a time when economic dislocation due to the pandemic was at its peak. As we now know, the pandemic would, ultimately, worsen during the first two quarters of FFY 2021**.

Comparing commentary related to Medicaid enrollment projections included in the FFY 2021 final rule to that included in the FFY 2022 proposed rule, it appears that CMS' estimate of Medicaid enrollment for FFY 2021 increased by 0.9 percentage points (FFY 2021 final rule, 0.3%, FFY 2022 proposed rule, 1.2%). The increase in estimated FFY 2021 Medicaid enrollment from the FFY 2021 final to the FFY 2022 proposed rule does not explain the change in the "Other" factor given that it decreased. Without additional data or commentary from CMS, one can only infer there was a significant decrease in one or more of the other variables that negated the increased estimate of Medicaid eligibility from the FFY 2021 IPPS final rule to the FFY 2022 IPPS proposed rule. This leaves hospitals unable to meaningfully comment on the assumptions that comprise the "Other" factor.

CHA respectfully asks that CMS provide hospitals and other stakeholders with a supplementary table and additional commentary on the year-to-year changes from the FFY 2021 final rule to the FFY 2022 proposed rule for the variables that comprise the "Other" factor. Further, we ask that CMS provide this information prior to finalizing the FFY 2022 rule and allow for a brief comment period. If CMS is

[15] https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/#:~:text=Data%20show%20that%20Medicaid%2FCHIP,by%207.7%20million%20or%2010.8%25.

unable to provide the additional information in such a manner, CHA asks that CMS use the "Other" factors from the FFY 2021 final rule for the FFY 2022 final rule.

Proposed Use of Audited FFY Worksheet S-10 Data to Calculate Factor 3
Factor 3 of the DSH formula is equal to the hospital's amount of UCC relative to the amount of UCC for all DSH hospitals expressed as a percentage. The UCC pool established by Factors 1 and 2 multiplied by Factor 3 determines the amount of the UCC payment that each eligible hospital will receive.

In FFY 2018, CMS began transitioning to use of Worksheet S-10 as the data source for estimating the UCC attributable to a hospital. Worksheet S-10 of the Medicare cost report is used to record charges and costs for UCC. For FFY 2018, CMS used a blend of two years of low-income patient days and one year of Worksheet S-10 data (FFY 2014). In FFY 2019, CMS continued that transition by using one year of low-income patient days and two years of Worksheet S-10 data (FFY 2014 and FFY 2015). In FFYs 2020 and 2021, CMS used a single year of data from the audited FFY 2015 and FFY 2017 Worksheet S-10 cost report data.

CMS proposes to continue using a single year of data — from FFY 2018 cost reports — to calculate Factor 3 in the FFY 2022 methodology for all eligible hospitals except for Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. CMS notes that UCC payments to hospitals whose FFY 2018 Worksheet S-10 data have been audited represent about 99.6% of the proposed total UCC payments for FFY 2021. In addition, FFY 2018 cost reports reflect the revisions to the Worksheet S-10 instructions that were effective on October 1, 2017.

CHA has long been supportive of efforts to improve the Worksheet S-10 instructions and audits of the Worksheet S-10 cost report data. We applaud CMS for its commitment to improving the Worksheet S-10 data to ensure an equitable distribution of a limited and fixed pool of UCC payments. We specifically commend CMS and the MACs for increasing the percentage of proposed total UCC payments that have been subjected to audit from approximately 65% of FFY 2017 S-10 data (FFY 2021 payment year) to over 99% of FFY 2018 data (proposed FFY 2022 payment year). CHA has historically shared the agency's concerns that blending audited and unaudited data would be inappropriate and potentially lead to a less accurate result. However, given 65% of FFY 2017 S-10 data (FFY 2021 payment year) and over 99% of FFY 2018 data (proposed FFY 2022 payment year) have been audited by a MAC, CHA believes that the dedicated effort by CMS and the MACs to ensure the accuracy of the S-10 data addresses those concerns. **Therefore, CHA does not support CMS' proposal to use a single year of data from the audited FFY 2018 Worksheet S-10 data to calculate Factor 3 for FFY 2022.**

In the proposed rule, CMS justifies the continued use of a single year of data by stating that it continues to believe that mixing audited and unaudited data would introduce "unnecessary variability" and "potentially lead to a less smooth result." However, given high audit rates for S-10 data as discussed above, we believe the use of a single year of cost report data is a greater risk than mixing data that is 65% audited with data that is 99% audited. Using a single year of data could result in significant year-to-year "unnecessary variability" in UCC payments for hospitals. This is not an abstract concern. CHA compared the amount of UCC claimed by each hospital on its audited S-10 for 2017 to the audited 2018 S-10. The analysis finds that 1,521 hospitals (approximately 47%) experience a year-over-year change in the amount of UCC of at least +/-10%. Further, approximately 28% of hospitals (914) experience a year-over-year change of at least +/-20%. Given that upwards of 47% California's hospitals are projected to

have negative operating margins in 2021, this degree of variability in UCC DSH could further destabilize financially fragile safety-net hospitals.

As further evidence of variability, CMS proposes to use only FFY 2018 and FFY 2019 data (omitting FFY 2020) to calculate the per discharge amount due to concerns about the significant decrease in volumes as a result of the COVID-19 PHE. CHA believes these are compelling examples of the volatility inherent in using one year of UCC data reported on worksheet S-10 and support expanding the number of years of audited S-10 data used to calculate Factor 3. **Therefore, we respectfully recommend that, for FFY 2022, CMS use two years of audited data S-10 data from FFY 2017 and 2018 to calculate Factor 3. Assuming Worksheet S-10 audit rates for UCC data remain high (65% or above), CHA strongly encourages CMS to use three years of data to calculate Factor 3 in FFY 2023 and thereafter.**

CHA continues to believe that all hospitals should be audited using the same audit protocols and that auditor education is paramount. As a fixed amount is available for UCC, CHA does not believe it is equitable to subject only some hospitals to desk reviews. In addition, we encourage CMS to work with the MACs to improve the Worksheet S-10 audit process to further promote clarity, consistency, and completeness in the audits. For example, CMS should establish a standardized process across auditors, including standard timelines for information submission and acceptable documentation to meet information requirements. We also urge CMS to develop a transparent timeframe for the audit, with adequate lead time and communication to providers about expectations, and to establish a process for timely appeals. CHA believes that the Medicare Wage Index audit process could be a model for Worksheet S-10 audits.

Payments for Indirect and Direct Graduate Medical Education Costs

In the FFY 2022 proposed rule, CMS proposes policies to implement Sections 126 (distribution of additional residency slots), 127 (adjusting the full time equivalent [FTE] cap for hospitals facilitating rural training tracks), and 131 (adjusting the per resident amount and FTE count for hospitals that host a small number of residents for a short duration) of the Consolidated Appropriations Act of 2021 (CAA). **In general, CHA strongly supports efforts to create more Medicare-funded residency training slots to address existing and prevent projected physician shortages.**

The rule also proposes to require the data reported in the Intern and Resident Information System (IRIS) when a cost report is filed to match the cost report it relates to. **CHA asks CMS to delay this proposal to allow hospitals and MACs sufficient time to gain familiarity with this new software and address other potential process issues that could result in cost reports being inappropriately rejected.**

Finally, the COVID-19 PHE has disrupted the health care workforce in unprecedented ways. Specifically, the pandemic has created significant and ongoing disruption to hospitals in the process of establishing new medical residency programs that are crucial to address the looming physician workforce shortages that Congress sought to address when it passed the indirect medical education (IME)/graduate medical education (GME) provisions in the CAA. CHA is deeply disappointed that CMS has not provided additional cap building time to teaching hospitals impacted by the PHE that have been unable to build their new residency programs to full size before the cap is established. **We would like to use this opportunity to reiterate our request that the agency extend the five-year cap-building window for impacted hospitals by the length of the PHE plus the additional time needed to reach July 1, to align with the start date of the academic year when residency programs begin.**

Please find our specific comments related to Medicare payments for indirect and direct graduate medical education costs below.

Section 126 of CAA - Distribution of Additional Residency Positions

Section 126 of the CAA authorizes the Secretary to distribute 1,000 new FTE slots over five years (limited to 200 per year) to applicant hospitals beginning in FFY 2023. In determining the qualifying hospitals for which an increase is provided, the law requires the Secretary to take into account the demonstrated likelihood of the hospital filling the positions made available within the first five training years from the date the increase would be effective.

The Secretary is required to distribute at least 10% of the aggregate number of total residency positions available to each of four categories of hospitals:

1) Hospitals located in rural areas or treated as rural for IPPS purposes
2) Hospitals that are training more residents than their FTE cap
3) Hospitals in states with new medical schools or additional locations and branches of existing medical schools
4) Hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs)

Hospitals are limited to receiving no more than 25 additional FTE residency positions and must agree to use all of the slots made available to them.

CHA appreciates CMS' efforts to equitably and effectively distribute the new residency positions created by the CAA. However, we are concerned that CMS' proposed definition of Category 4 is overly restrictive, the use of population-based HPSA scores to award new residency positions to qualifying hospitals exceeds Congress' intent to address issues of physician shortages in certain areas to the exclusion of other policy goals, and the limitation on the number of positions a residency program may receive per application cycle is insufficient.

Category 4 Definition – Hospitals that Serve as HPSAs: To qualify for Category 4, CMS is proposing to consider geographic HPSAs for primary care and mental health providers for purposes of identifying hospitals that serve areas designated as HPSAs. The agency is also proposing that hospitals that only have campuses or provider-based facilities in mental-health-only geographic HPSAs may only apply for positions for psychiatry residency programs. Additionally, as part of the qualification requirements under Category 4, in the residency program for which the hospital is applying, at least 50% of the residents' training time over the duration of the program must occur at locations in the HPSA.

Geographic HPSA Requirement: CHA appreciates CMS' consideration of the HPSA Physician Bonus Program — which in general CHA supports — under 1833(m) of the Social Security Act in determining how to define a hospital that serves an HPSA. While the intent of the HPSA Physician Bonus Program and Category 4 requirements under the Section 126 distribution requirements are similar, the situations surrounding these programs are not analogous.

The intent of the HPSA Physician Bonus Program is to encourage physicians to establish practices in HPSAs by increasing their Medicare payments. Similarly, the intent of specifically requiring that at least 10% of the Section 126 slots be allocated to residency programs at hospitals that serve HPSAs is to address a shortage of physicians in these areas. However, while it is relatively easy for a physician to

establish a new practice in response to the economic incentives provided by the Medicare program, the same cannot be said for a teaching hospital that wishes to create a new program in an HPSA. The limited number of slots available through this distribution will not offset the costs of establishing a new site of care in the HPSA and then creating a new program that meets the current narrowly defined requirements. Therefore, CHA is concerned that, given this narrow definition, few hospitals will qualify and apply for slots under Category 4. And an opportunity to increase access to care for individuals in underserved areas — as was Congress' intent — will be missed.

As CMS discusses in the proposed rule, hospitals that are outside of HPSAs also provide much needed care to individuals who live in areas where the supply of physicians is insufficient to meet the demand. CHA believes if CMS expanded its definition of a hospital that serves an HPSA to include proximate hospitals, the agency would better meet Congress' intent of increasing access to care in underserved areas. **Therefore, we respectfully ask the agency to expand the definition of hospitals that qualify for residency positions under Category 4 to include those within 10 miles of the border of the HPSA.**

Mental Health HPSA Limitation: CHA supports Congress' efforts to expand access to mental health services by specifically including mental health HPSAs in the geographic HPSA criteria. However, we are concerned the agency, by excluding the use of these new slots for other specialty types in mental-health-only HPSAs, is creating a situation where the supply of slots may outstrip demand in many areas. **Therefore, we respectfully ask that CMS give preference to psychiatry residency programs in the final rule but allow other residency types to qualify to receive slots if they are located in mental-health-only HPSAs.**

50% Training Time Requirement: Requiring a hospital that receives one or more slots under Category 4 to attest that at least 50% of the resident's training time over the duration of the program will occur in a HPSA location potentially limits the residency program types these slots can be used to train. For those types of residency programs that could comply with this requirement, it may limit the resident's development opportunities if the program is forced order to adhere to the rigid requirement that the resident spend 50% of their time in a rural area. Finally, the requirement to track and document that 50% of this resident's time was spent in a rural rotation site creates considerable administrative burden for the hospital facilitating the residency program. **Given these challenges, CHA respectfully asks CMS to withdraw this burdensome requirement related to Category 4 that will hinder a physician's ability to gain experience practicing in multiple settings during their residency.**

If CMS does not withdraw the requirement, we ask the agency to clarify if (and how) this requirement would apply if CMS implemented the alterative residency position allocation model discussed in the proposed rule. Under this model, FTE slots would be allocated based on the number of statutory categories a hospital qualifies for. Specifically, we ask that CMS clarify that if Category 4 was one of the categories a hospital qualified for and it received residents as a result, whether it would need to attest that at least 50% of the resident's training time over the duration of the program will occur in a HPSA location.

Prioritization of Applications from Hospitals for Residency Programs that Serve Underserved Populations: CMS proposes to prioritize applications from qualifying hospitals that serve underserved populations using population-based HPSAs. This means that additional residency positions will be distributed to hospitals that qualify under Categories 1 through 4 based on the population HPSA score of the area by the residency program for which each hospital is applying. Programs serving higher HPSA

scores will receive higher prioritization. Similar to the use of geographic HPSAs, CMS proposes hospitals that only have main campuses or provider-based facilities in mental-health-only population HPSAs may only apply for positions for a psychiatry residency program. Hospitals applying for residency positions for programs that do not serve HPSAs are not categorically excluded, but those applications would have the lowest priority.

As CMS discusses in the proposed rule, prioritizing applications based on HPSA scores duplicates criteria that the agency is already mandated by Congress to consider as part of the application process. CHA shares this concern and notes that Congress only mandated a minimum of 10% of the new residency positions be allocated to programs serving HPSAs, not 100% — which is what CMS' scoring criteria implies. Had Congress wanted to achieve this outcome through Section 126 of the CAA, it would have explicitly done so. Therefore, using population based-HPSA scores to prioritize distribution of new residency positions over-emphasizes underserved populations to the detriment of Congress' other priorities — expanding residency slots for hospitals that are training over their cap, residency programs in rural areas, and states with new medical schools, or additional branches of existing medical schools.

Further, as discussed above, many teaching hospitals are adjacent to population HPSAs but are not located in one. Therefore, many teaching hospitals that care for underserved populations will be lower priority to receive FTEs under CMS' proposed criteria. And as such, CMS will have missed an opportunity to expand access to care for underserved populations. Additionally, CMS' proposal to score applications using the population HPSA score does not guarantee that the physicians trained in or adjacent to a population HPSA are the correct ones based on long-term projections of supply and demand by specialty. Therefore, use of population-based HPSAs does nothing to address the long-term imbalance between specialties. **Considering these concerns, CHA respectfully asks that CMS withdraw its proposal to use population HPSA scores to prioritize applications for additional slots. Not only does the proposal far exceed what Congress intended — to the detriment of its other priorities — when it included HPSAs as one of the statutory eligibility categories for distributing these newly created slots, but it may be ineffective to address projections of long-term physician shortages.**

As an alternative, the proposed rule discusses prioritizing hospitals that qualify in more than one of the four statutory eligibility categories. Hospitals that qualify under all four categories would receive top priority; hospitals that qualify under any three of the four categories would receive the next highest priority; then any two of the four categories, and finally hospitals that qualify under only one category. **For the FFY 2023 distribution, CHA strongly encourages CMS to use the alternative distribution methodology that prioritizes applicants for the additional slots created by section 126 of the CAA based on the number of categories for which the hospital qualifies. For FFY 2024 and beyond, CHA encourages CMS to develop an alternative scoring factor to prioritize applications for receipt of additional residency slots. We ask CMS to consider collaborating with teaching hospitals and exploring a methodology that gives priority to applications seeking to create or expand programs in specialties that have the highest projected future physician shortfalls. This would be conceptually similar to some of the criteria used to distribute unused residency slots in section 5503 of the Affordable Care Act.**

Limitation on Individual Hospitals: CMS anticipates that the 200-resident-per-year distribution will be oversubscribed, leaving the agency without enough slots to distribute to teaching hospitals that may qualify. To make additional residency positions available to more hospitals each year, the agency proposes to limit the increase in the number of residency positions made available to each individual hospital to no more than one FTE each year.

CHA appreciates that CMS would like to make additional residency slots available to as many hospitals per year as possible. However, from the perspective of a teaching hospital trying to build or expand a residency program this is impractical. The current proposed limit of one FTE per hospital per year makes it difficult to plan and build a program, as there is no guarantee that the hospital will receive slots in subsequent years to support the new or expanded program. As an example, in the table below, a teaching hospital that expands its internal medicine residency program by one FTE will face considerable uncertainty about the ability to sustainably fund that FTE position in future years if CMS finalizes its current proposal.

Example Ramp-Up of Internal Medicine Residency Program that Expands by One FTE

	Program Year			
	1	2	3	New FTEs
2023	1			1
2024	1	1		2
2025	1	1	1	3
2026	1	1	1	3

An internal medicine residency program is typically three years. Therefore, a program that expands by one FTE in 2023 will need to increase its Medicare FTE cap by three FTEs by 2025 for that expansion to be fully funded. Therefore, if the program applies for and receives one FTE beginning in 2023, under CMS' proposal the hospital will need to apply for and receive an additional slot in each of years 2024 and 2025 to ensure the added FTE is fully funded. However, the residency program will face considerable uncertainty about the funding source as the slot awarded in 2023 may impact the hospital's eligibility for subsequent distributions of residency slots. The uncertainty of future funding for these programs will limit the number of hospitals that are willing to add new or expand additional programs.

CHA believes that CMS can address this certainty by modifying the limitation on the number of residency slots the agency distributes per year. **We respectfully recommend that, instead of limiting a qualifying teaching hospital to one FTE per year and requiring it to reapply each year for additional slots for the residency program, the agency tie the number of slots allocated in response to an application to the duration of the residency program the teaching hospital is creating or expanding.** For example, if in 2023 a teaching hospital is expanding an internal medicine program by one FTE and it receives — based on its application filed on January 31, 2022 — a residency slot, CMS should allocate the teaching hospital one FTE per year in 2023, 2024, and 2025. The three FTEs provided over three years would fully support the expanded internal medicine residency program. This provides certainty and stability for new or expanding programs while reducing the administrative burden for both applicants and the agency.

Section 127 of CAA – Cap Adjustment for Urban and Rural Hospitals Participating in Rural Training Track (RTT) Programs: Effective for cost reporting periods beginning on or after October 1, 2022, Section 127 of the CAA 2021 revised section 1886(h)(4)(H)(iv) of the SSA to state that, in the case of a hospital not located in a rural area that *established or establishes*[16] a medical residency training program (or rural tracks) in a rural area, the Secretary must adjust in an appropriate manner the limitation under

[16] Emphasis added.

subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training.

While CMS proposes allowing resident FTE cap adjustments when an urban hospital (a hub) adds a new spoke (rural hospital training site) to an existing RTT, CMS is not proposing to allow expansion of existing RTT programs when a new rural training site is not added. CMS justifies this limitation as being consistent with the statute's direction that allows it to prescribe rules for adjustments to FTE caps while considering that Congress established caps to limit the number of residents subsidized by Medicare in the aggregate nationally. Further, CMS notes that the statute authorizes the Secretary to "adjust in an appropriate manner" the FTE cap for hospitals participating in RTTs.

CHA greatly appreciates and generally supports CMS' efforts in the FFY 2022 proposed rule to implement Section 127 of the CAA. We respectfully ask that CMS in the final rule clarify that rural hospital "spokes" that were established prior to the passage of the CAA may also have their resident FTE cap increased beginning on and after October 1, 2022. Additionally, we ask that CMS create an exceptions process where urban hubs and rural spokes that expand an existing RTT residency training program be allowed to count the expanded FTEs under certain circumstances that support Congress' and the administration's broader policy goals.

Clarify Rural Hospitals May Count FTEs Added by RTTs Established Prior to October 1, 2022: To implement Section 127 of the CAA, CMS proposes that each time an urban hospital and rural hospital establish an RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare payment purposes, both the urban and rural hospitals may receive a rural track FTE limitation adjustment. However, the proposed rule is silent on whether a rural spoke of an RTT, which would otherwise qualify for a cap expansion under section 127 of the CAA, would receive a cap adjustment for the FTEs related to a "new spoke" that was established prior to October 1, 2022, for cost reporting periods beginning on or after October 1, 2022. The proposed rule provides the following example, which CHA greatly appreciates.

> *For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and, as a result, received a cap/rural track FTE limitation adjustment to reflect residents in the RTT training in its facility. In July 2023, Urban Hospital A partners once again with Rural Hospital 1 to create a RTT in internal medicine. We are proposing that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their cap/rural track FTE limitations to reflect the time that residents train in the internal medicine RTT ''spoke'' in their respective facilities. Thus, Urban Hospital A and Rural Hospital 1 would have cap/rural track FTE limitations reflecting FTE resident training programs in both a family medicine RRT and an internal Medicine RTT*[17].

The last sentence implies that, effective for cost reports on or after October 1, 2022, that Rural Hospital 1 would be able to receive a cap adjustment for the family medicine program RTT it established in 2015. CHA believes this is consistent with Congress' intent. The statute specifically uses "established" (past tense) in Section 127 of the CAA to instruct the Secretary to provide rural hospitals that established RTTs prior to passage of the CAA an adjustment in their resident FTE cap for cost reporting periods on and after October 1, 2022, to reflect their portions of FTE residents training in the RTT. **CHA respectfully asks**

[17] Emphasis added.

that CMS in the final rule confirm that rural hospitals that created a qualifying RTT program prior to October 1, 2022, will receive an adjustment to their resident FTE cap to reflect the portion of FTE residents training in the RTT program for cost reporting periods beginning on or after October 1, 2022.

Exceptions Process for Urban Hub and Rural Spoke Cap Adjustment Related to an Expansion of an Existing RTT Program: CMS proposes to limit the increase to the urban and rural hospitals' RTT FTE limitations to instances where additional residents are recruited to add a new rural RTT spoke to the existing urban hub. The proposed rule does not allow increases under this section to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT spoke. The agency justifies this limitation by observing that the statute directs the Secretary to adjust the resident FTE cap in an "*appropriate manner*[18]." The agency believes that "appropriate" means not rendering the RTT FTE limitations meaningless, which it interprets as allowing adjustments to the RTT FTE limitations at any time, for any type or any amount of expansion to already existing rural site "spokes."

CHA appreciates CMS' concern about not rendering the RTT FTE limitations meaningless. However, we note that Congress, in using the phrase "appropriate manner," gave the Secretary considerable discretion in determining how to apply the caps in pursuit of broader policy goals. Addressing physician shortages is a broad policy goal of both Congress and the administration, as demonstrated by the criteria selected by Congress to apportion the new residency slots in Section 126 of the CAA — specifically providing additional FTEs to rural and underserved areas (HPSAs) — and the agency's commentary related to implementing these criteria. CHA believes it would be appropriate if CMS used the broad discretion that Congress afforded the agency when it selected the phrase in an "appropriate manner" to describe how the Secretary was to adjust the resident cap as it relates to the RTT program to advance the broader policy goal of ensuring there are sufficient numbers of physicians — now and in the future — to provide the high-quality care to residents in rural and underserved areas.

In pursuit of ensuring there is a sufficient supply of physicians to provide care to residents in rural and underserved areas, CHA respectfully asks that CMS create an exceptions process that allows an existing urban hub and rural spoke to apply for an FTE cap limitation based on the unique circumstances of each RTT. CHA believes that exception criteria might include, but should not be limited to, situations where the rural spoke is:

- Situated in a geographic or population-based HPSA
- The only hospital capable of/willing to support the rural spoke of an RTT in the immediate geographic area
- Expanding a primary care residency training program

The criteria above are provided as examples and not intended as a comprehensive list. And we do not believe that an RTT should be required to satisfy all of the criteria the agency might identify as being relevant. CHA encourages CMS to work with stakeholders to fully develop a list of criteria (and a transparent scoring system) that would indicate when an exception is merited, allowing for a resident cap expansion under Section 127 of the CAA when an urban (hub) and rural (spoke) hospital expand an existing RTT program in support of the broader policy goals related to increasing access to physicians in

[18] Emphasis added.

rural and underserved areas. CHA believes this would be a more effective application of the discretion afforded the Secretary by Congress as opposed to simply all prohibiting increases, regardless of the circumstances, in the FTE resident cap when an existing RTT is expanded.

Section 131 of CAA – Hospitals that Hosted a Small Number of Residents for a Short Duration: Section 131 of the CAA provides CMS with the opportunity to reset low or zero DGME per resident amounts (PRA) and to reset low direct graduate medical education (DGME) and IME FTE resident caps of hospitals that hosted a small number of residents for a short duration. Specifically, the Secretary is allowed to recalculate the PRA and redetermine the FTE caps if the hospital trains resident(s) in a cost reporting period beginning on or after December 27, 2020, and before December 26, 2025. The statute classifies two categories of hospitals that CMS refers to as "category A" and "category B":

- Category A: A hospital that, as of December 27, 2020, has a PRA that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997
- Category B: A hospital that, as of December 27, 2020, has a PRA that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020

CHA appreciates and generally supports CMS' proposals to implement Section 131 of the CAA. We believe this is an important step to expand the number of training opportunities for residents and increase the overall supply of physicians. In the final rule, we ask CMS to clarify two items related to the implementation of Section 131.

Triggering the Recalculation of an Existing PRA or FTE Count: The proposed rule states the agency plans on issuing instructions to the MACs and to hospitals to provide for an orderly process to request and review for the purpose of receiving replacement PRAs and resident FTE caps. **CHA believes it is CMS' intention that a qualifying hospital would trigger the recalculation of its PRA or resident FTE cap by formally requesting the MAC to do so. CHA respectfully asks that the agency confirm this in the final rule.** We are concerned that if MACs are allowed to proactively recalculate PRA or resident FTE caps of qualifying hospitals there may be instances where the qualifying hospital ends up with a lower PRA or resident FTE cap, contrary to Congress' intent.

Documentation to Establish a New PRA and FTE Cap: CMS proposes to continue following its existing predicate fact regulations at 42 CFR 405.1885. Under this policy, the agency would not reopen cost reports beyond their 3-year reopening period but would refer to and use whatever contemporaneous documentation is necessary to establish new PRAs and FTE resident caps. **CHA appreciates that CMS is not proposing to reopen cost reports that are beyond their reopening period. However, we ask that CMS limit the documentation the agency uses to establish new or revise existing PRAs and resident FTE caps to that which falls within the Medicare cost report document retention requirements.** CMS only requires that providers retain documents related to a cost report for five years after a cost report is "closed[19,20]." This requirement, coupled with the staffing changes over time, make it unlikely that hospitals will have access to certain documents necessary to meaningfully inform the PRA and resident FTE cap resetting process, which potentially disadvantages hospitals.

[19] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf
[20] https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1022.pdf

Intern and Resident Information System (IRIS)

CMS is proposing, effective October 1, 2021, that the FTE count on IRIS must match the counts the hospital claims on its cost report worksheets. CMS is proposing that the IRIS data must contain the same total counts of DGME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of DGME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

CHA respectfully requests that CMS delay its implementation to allow stakeholders to gain experience with the software and address practices by the MACs that may result in discrepancies between the cost report and IRIS data. First, as CMS notes in the proposed rule, the IRIS software is new and has not been used by hospitals to report resident counts. Therefore, we believe it is necessary to allow hospitals and MACs to gain experience using the software (and identify and address any operational flaws in the software) before requiring the IRIS data to match the data submitted on a hospital's Medicare cost report.

Additionally, based on conversations with CHA's members who host residency programs, we believe if this proposal is finalized effective October 1, 2021, it may result in teaching hospital cost reports being rejected for lack of supporting documentation through no fault of the hospital submitting the cost report. CHA understands that when the MAC uploads the IRIS data, there are edits that automatically remove certain residents (foreign nationals, dental residents). The resident counts contained in the IRIS and as-filed cost report are ultimately reconciled during the cost report audit. Therefore, CHA respectfully requests that CMS withdraw (or at a minimum delay) this proposal. We ask that if CMS does finalize the proposal, it delay implementation for a minimum period of three years. During this time hospitals and MACs can gain experience with the software, identify any flaws in it, and allow time for those flaws to be addressed. Additionally, the agency can understand why MACs may remove certain residents and provide further instructions or clarifications related to this practice.

COVID-19 Flexibilities for Teaching Hospitals in the Cap Building Period

The COVID-19 PHE has limited the ability of new residency programs to train residents as planned prior to the pandemic in several ways. Early in the pandemic, the Accreditation Council for Graduate Medical Education (ACGME) — which is responsible for the accreditation of new residency programs — suspended in-person site visits due to COVID-19, later switching to remote site visits, both of which delayed the process that can already take 18 to 24 months from recruitment of program directors and core faculty to preliminary accreditation following site survey and committee reviews. Additionally, the pandemic and related travel and infection-control restrictions have greatly impeded the ability of nascent GME programs to interview and recruit the program directors and core faculty required before new programs can even begin the accreditation process. For programs that were able to move forward once accredited, the PHE has created difficulty in fully staffing residency programs with enough faculty to train residents in their specialties, as well as difficulty recruiting new residents to fill the programs.

Unfortunately, these challenges can be costly to new teaching hospitals, which are under a time constraint to establish permanent DGME and IME residency caps. Prior to the pandemic, a CHA member in a GME-naïve community established an ambitious goal to operate 11 residency programs covering various specialties and training over 200 new residents. These programs are being established in underserved San Joaquin County, one of California's areas most hard hit by the pandemic, with an average of 871 new daily COVID-19 cases at its peak. The programs will serve a community with an aging physician population that is already facing a 4,100-physician shortfall. The pandemic struck 20 months

after the hospital started its first residency program. Now, due to the global pandemic, the hospital has lost at least 18 to 24 months of time because of the strict requirements of ACGME and one-time-per-year residency program start dates. Should CMS not extend the five-year cap-building window, this program will have its residency caps permanently reduced and will be unable to benefit its community to its full potential.

CMS has previously used its broad authority under 1886(h)(4)(F) of the Social Security Act to establish and modify the rules at 42 CFR §413.79. While CMS initially allowed newly participating medical residency training programs only three years to reach full capacity, in the FFY 2013 IPPS final rule, CMS changed its policy to allow medical residency training programs five years to reach full capacity.

According to the final rule, CMS changed its rule because:

> *Providers explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the qualifying teaching hospital wishes to start more than one new program. For example, we understand that a qualifying teaching hospital may not begin all of its new programs at the same time because of accreditation prerequisites; rather, a qualifying teaching hospital must wait until the first program is in place for a specified amount of time before it can begin training residents in a second or third program. This potential delay means that a qualifying teaching hospital may not be able to sufficiently ''grow'' all of its new programs by the end of the ''3-year window.'' (77 FR 53417)*

Hospitals establishing new teaching programs during the COVID-19 pandemic face a similar dilemma — they are unable to meet program accreditation requirements, particularly where a hospital is establishing more than one program, under timelines that were planned prior to the pandemic. As such, these programs are operating with a significant amount of operational uncertainty. **CMS can take action to reduce this uncertainty by extending the cap-building window for new programs impacted by the PHE in its FFY 2022 IPPS proposed rule.**

CHA notes that CMS has proposed a similar change in a different policy context as part of the FFY 2022 IPPS proposed rule. Under the new technology add-on payment (NTAP) payment rules, CMS provides hospitals with an add-on payment for a period of between two or three years. The policy's purpose is to pay for new medical services and technologies for the first two to three years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. The data collected during that time frame are ultimately used for DRG weight-setting purposes. As previously discussed, FFY 2020 utilization of inpatient services during the PHE is markedly different from what would have been expected in the absence of the PHE, which would negatively impact rate setting for a device or technology whose eligibility for NTAP would terminate beginning in FFY 2022. To mitigate this issue and ensure that MS-DRG payments accurately reflect the cost of impacted technologies and devices, CMS proposes in the FFY 2022 IPPS rule to provide a one-year extension for 14 technologies for which the new technology add-on payments would otherwise be discontinued beginning with FY 2022.

This situation parallels the concerns of hospitals establishing their DGME and IME residency caps during the PHE. Should CMS not extend the cap-building window to account for the impacts of the COVID-19 PHE, these programs will face a permanent limit to their GME payments, diminishing their ability to train

the next generation of physicians to the full size of the planned residency programs — and impacting the availability of physicians in their communities for years to come. **Therefore, we respectfully ask the agency to extend the five-year cap-building window for impacted hospitals by the length of the PHE plus the additional time needed to reach July 1, to align with the start date of the academic year when residency programs begin.**

Market-Based MS-DRG Relative Weights

In the FFY 2021 IPPS/LTCH PPS final rule, CMS finalized a requirement for hospitals to report the median Medicare Advantage (MA) payer-specific negotiated charge by MS-DRG on their Medicare cost report effective for cost reporting periods ending on or after January 1, 2021. CMS also finalized a policy to use the median MA payer-specific negotiated charge in the MS-DRG relative weight methodology beginning with FFY 2024. In the FFY 2022 IPPS rule, CMS proposes to repeal the reporting requirement and its plan to use payer-specific MA negotiated rates in the MS-DRG relative weight methodology for FFY 2024 and subsequent fiscal years. In doing so, the agency cites concerns about the usefulness of the data for rate setting, the unnecessary administrative burden foisted on hospitals, and the diversity of contracting arrangements hospitals negotiate with MA plans.

CHA thanks the agency and strongly supports its repeal of the market-based MS-DRG relative weight policies. As noted in both our 2021 IPPS proposed rule comment letter and our response to the Medicare Cost Report Paperwork Reduction Act package, we agree with the concerns raised by CMS in the FFY 2022 IPPS proposed rule about the utility of the data and the accuracy of MS-DRG weights this process would yield, coupled with the administrative burden created by the requirement. Therefore, we do not believe that CMS should consider implementing this policy at a later date as contemplated in the proposed rule.

Claims for Medicare Cost-Sharing for Dually Eligible Beneficiaries and Misaligned Medicare and Medicaid Provider Enrollment

In order for a provider to claim amounts as allowable bad debt when a state Medicaid program is the secondary payer, the provider needs to receive documentation from the state that the claim processing has been completed and the state's cost-sharing liability (the "remittance advice" (RA)) has been identified. This requirement is in effect even in instances where the state plan does not provide coverage for a Medicare-covered item or service. In some states where the Medicaid program does not recognize a particular service or provider type, the providers have been unable to enroll in the Medicaid program or receive an RA from the state program and, therefore, are unable to include those costs as allowable bad debt.

To address this issue, in the FFY 2022 IPPS rule CMS proposes that a state Medicaid agency would be required to allow enrollment of all Medicare-enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing if the providers or suppliers meet all Medicaid enrollment requirements, even if the Medicare-enrolled provider or supplier is of a type not recognized by the state Medicaid agency. **CHA strongly supports this proposal. We agree with CMS' commentary in the proposed rule that if this change is finalized, it will eliminate an unnecessary barrier that prohibits providers from claiming reimbursement for allowable Medicare bad debt they are entitled to receive. As a result, we believe this will have the beneficial effect of reducing appeals to the Medicare Provider Reimbursement Review Board.**

Organ Acquisition Payment Policies

In the FFY 2022 IPPS proposed rule, CMS proposes to codify into the Medicare regulations existing Medicare organ acquisition payment policies, with clarifications where necessary. The agency also proposes to change the definition of a Medicare organ for determining Medicare's share of a transplant hospital's organ acquisition costs. And the rule proposes to change how community donor hospitals charge organ procurement organizations for the service of excising organs from cadaveric donors.

In recent years, CMS has undertaken steps to increase access to organ transplants — particularly for those who would benefit from kidney transplantation[21]. CHA is generally supportive of policies that increase access to life saving transplants for both Medicare and non-Medicare patients. We are concerned — as discussed below in detail — that the policy changes proposed in the IPPS 2022 rule are not only operationally infeasible but contrary to the agency's recent efforts to expand access to transplantation services by limiting the number of organs available for both Medicare beneficiaries and non-Medicare recipients. Below please find our specific concerns and recommendations for addressing these issues.

Codifying Existing Regulations Related to Organ Acquisition Reimbursement

CMS proposes to codify a number of payment policies related to organ acquisition cost reimbursement that currently exist in sub-regulatory guidance. CHA is concerned that the specific language the agency proposes to codify related to allowable organ acquisition cost and living donor complications does not match the language in the relevant sections of Chapter 31 of the Provider Reimbursement Manual (PRM) or may be subject to misinterpretation by a MAC auditor. We do not believe it is CMS' intent to engage in retroactive rulemaking, therefore, we ask that the agency address the issues discussed below.

Proposed Items and Services Considered Organ Acquisition Costs: CMS at 86 FR 25659 proposes to codify the items and services it considers Medicare Part A covered organ acquisition costs at § 413.402(a) for both renal and non-renal organs. The specific items and services the rule proposes to codify include:

1) Tissue typing, including tissue typing furnished by independent laboratories
2) Donor and beneficiary evaluation
3) Other costs associated with excising organs, such as general routine and special care services *provided to the donor*[22]
4) Operating room and other inpatient ancillary services *applicable to the donor*[23]
5) Preservation and perfusion costs
6) OPTN registration fees
7) Surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys)
8) Transportation of the excised organ to the transplant hospital
9) Costs of organs acquired from other hospitals or organ procurement organizations
10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to admission)

[21] https://www.cms.gov/newsroom/press-releases/cms-announces-transformative-new-model-care-medicare-beneficiaries-chronic-kidney-disease
[22] Emphasis added.
[23] Emphasis added.

11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs
12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and surgeons' fees for cadaveric excisions, applicable to organ excisions including the costs of physicians' services

PRM 3101A and PRM 3101B currently define the allowable Medicare Part A standard organ acquisition cost for living and cadaveric donors respectively. Specific to item three above (general routine and special care services) CHA notes that the emphasized language related to the "donor" is not currently included in either PRM 3101A or PRM 3101B. We also note that in item four above (operating room and other inpatient ancillary services) PRM 3101B does not include the emphasized language related to donor.

CHA is concerned that the change in language may be inappropriately interpreted by some to imply that the costs associated with the services described by items three and four are only allowable when provided to a living donor. Therefore, CHA respectfully asks that CMS, in the final rule, clarify that these costs will be covered for living and cadaveric donors. This can be achieved by amending the proposed language for items three and four above to read at § 413.402(a) as follows:

3) Other costs associated with excising organs, such as general routine and special care services *provided to the living or cadaveric donor*
4) Operating room and other inpatient ancillary services *applicable to the living or cadaveric donor*

We believe these additions will clarify CMS' intent and eliminate the possibility of confusion over whether costs associated with general routine, special care services, operating room, and other inpatient ancillary services are covered for cadaveric donors.

Medical Complications Related to Living Kidney Donors: The proposed rule at 86 FR 25663 notes that CMS has received questions as to whether medical complications of a living organ donor are considered "organ acquisition costs." In response to this, CMS proposes to codify the language below at 42 CFR 413.402(c) to new subpart L:

> *Medicare covers costs incurred for living kidney donor complications only if they are directly* ***attributable to the kidney donation***[24]*. Costs incurred for complications arising after the kidney donor's discharge date are billed under the Medicare transplant recipient's MBI, including facility costs and physician services. The contractor reviews costs for kidney donor complications billed under the transplant recipient's MBI.*

CHA notes that the current language at PRM 3105B related to living donors reads as follows:

> *Expenses incurred for complications that arise with respect to the donor are covered only if they are directly* ***attributable to the organ donation***[25]*. Complications that arise after the date of the donor's discharge are billed under the recipient's health insurance claim number. This is true of both facility costs and physician services.*

[24] Emphasis added.
[25] Emphasis added.

Living donations are possible for organs other than kidneys (e.g., living donation of partial livers). In limited instances — like living kidney donations — these donors may experience post-discharge complications. We note, as emphasized above in the language from PRM 3105B, that CMS' current policy related to living organ donor complications is not specific to kidneys provided to Medicare beneficiaries. CHA is concerned that the proposed rule only addresses complications related to living kidney donors, as emphasized above from 86 FR 25663. **The proposed rule is silent on how the agency will cover living donor complications for organs other than kidneys provided to Medicare beneficiaries. Therefore, we respectfully ask that CMS affirm that it will continue covering post-discharge complications related to living organ donation for all organs provided to Medicare beneficiaries. Otherwise, if the cost of post-discharge complications must be shouldered by the donor or other entities, CHA is concerned that this will limit the availability of other organs amenable to living donation to Medicare beneficiaries.**

Given that the proposed rule is silent on an effective date for these changes, CHA assumes that CMS is proposing to make them effective retroactively. **If the agency does not address the issues described above related to items included in the Medicare Part A allowable standard acquisition charge and complications related to living organ donor complications, CHA respectfully asks CMS to make the changes to its policies related to allowable pre-transplant charges and living donor complications effective October 1, 2021.** We strongly believe it is inappropriate for the agency to engage in retroactive rulemaking.

Proposed Calculation of Medicare's Share of Organ Acquisition Costs
The proposed rule states that Medicare organ acquisition payment policy includes the presumption that some organs are not transplanted into Medicare beneficiaries, despite the category name "Medicare usable organs" or "Medicare kidneys." As a result (and contrary to Medicare's general policy prohibiting cross-subsidization) Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

The rule further explains that Medicare's decades-old presumption that most kidney transplant recipients are Medicare beneficiaries was also applied to non-renal organs because of the lack of organ tracking capabilities. This has led Medicare to reimburse transplant hospitals and OPOs for organ acquisition costs for organs that were not actually transplanted into Medicare beneficiaries. CMS now believes that organ tracking capabilities allow transplant hospitals and OPOs to discern organ recipients' health insurance payer information so that organ acquisition costs can be more appropriately assigned to the Medicare program for organs transplanted into Medicare beneficiaries.

CMS notes that each OPO must be a member of, participate in, and abide by the rules and requirements of the OPTN. OPTN policy provides that OPOs use organ tracking capability, and some transplant hospitals also optionally use organ tracking capability.

Based on these assumed tracking capabilities, CMS proposes that transplant hospitals must accurately count and report Medicare usable organs and total usable organs on their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare. For cost reporting periods beginning on or after October 1, 2021, CMS is proposing at (§413.408b) to narrow the definition of Medicare usable organs to include:

1) Only organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries with dates of service after January 1, 2021)
2) Organs for which Medicare has a secondary payer liability for the organ transplant
3) Pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation for Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial

CHA strongly opposes CMS' proposal to remove excised organs from the excising transplant hospital's count of Medicare organs unless the excising transplant hospital can provide auditable documentation that the organ in question was transplanted into a Medicare beneficiary. Not only will this proposal reduce access to organ transplantation, decrease health equity, and potentially increase Medicare spending, but it is operationally unworkable.

CHA is concerned the removal of CMS' current definition of "Medicare organs" will result in fewer organs available for transplant, particularly as it relates to the impact on equity in organ access. Conservatively, if the policy causes a 10% reduction in deceased donor kidneys due to closure of small transplant programs or nationwide reductions in operations for others, there would be 2,348 fewer kidneys available for transplant each year.[26] The drop in available kidneys alone could serve to exacerbate existing disparities in organ access equity. 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."[27]

CHA notes that CMS estimates this policy will reduce Medicare spending by $4.150 billion over 10 years. However, the agency's savings estimate does not include a discussion of offsetting dialysis costs that will reduce the savings to the Medicare program from this policy. As discussed above, this policy will decrease the available number of cadaveric kidney donor organs, which will extend the time individuals with end stage renal disease (ESRD) will receive dialysis while they wait for a donor kidney. In 2021 Medicare's estimated cost for dialysis is approximately $91,000 per beneficiary, per year.[28] 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. Therefore, CMS should reevaluate its savings estimate to account for the additional dialysis costs that would result from its proposed policy and provide an estimate of impact of this proposal on wait times for organ transplantation — particularly kidney transplantation.

Additionally, conversations with CHA members and an OPO call into question the validity of key assumptions that CMS makes about transplant hospitals' ability to obtain an organ recipient's insurance

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[26] 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/.

[27] 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/.

[28] 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/.

information that underpin this proposal. The operational capabilities for an excising transplant hospital or OPO to access an organ recipient's insurance information that CMS presumes to exist do not. And it is unlikely that an OPO will share any information about the recipient of an organ with the transplant hospital that excised that organ. Further, the proposed rule is silent on the quality, amount, and type of documentation that an excising transplant hospital would need to obtain and maintain to meet the agency's (and a MAC auditor's) burden of proof that an excised organ was, in fact, transplanted into a Medicare beneficiary.

Given the considerable issues with the proposed change — as discussed below in detail — CHA respectfully asks CMS to ensure that Medicare beneficiaries and other individuals who require organ transplantation have access to these lifesaving services by withdrawing the agency's proposed change to the definition of Medicare organs. If CMS wishes to continue pursuing this policy, CHA asks the agency to allow sufficient time for the capabilities that CMS presumes to exist to be developed and address any actual or perceived legal barriers to sharing organ recipient insurance information.

Operational Capabilities/OPO Information Sharing: CMS' proposal is underpinned by three key assumptions related to the ability of an excising transplant hospital to access information about the recipient of an organ sent to an OPO. Below please find detailed concerns about the validity of each of these assumptions based on conversations with CHA's members and an OPO.

1) *Insurance Information Is Available in Unet*: CMS asserts that all transplant hospitals are required to input information — including insurance information — into Unet when an individual is registered for a transplant waitlist. Based on this, CMS assumes that information about an organ recipient's insurance coverage is readily available to either the excising transplant hospital or the OPO. Based on conversations with CHA's members, excising transplant hospitals can only access insurance information in Unet about individuals that it has placed on a transplant waitlist. An excising transplant hospital cannot access insurance information about individuals placed on a transplant waitlist by other transplant hospitals. **Therefore, an excising transplant hospital (hospital A) cannot obtain insurance information from Unet related to an individual who receives the organ at another transplant hospital (hospital B) when that organ was excised at hospital A and provided to hospital B via an OPO.**

   The OPO confirms that the information they can access in Unet is limited to what is clinically necessary to successfully match an individual on a waitlist to a donated organ. Given that an OPO is paid for its services by the transplanting hospital it provides an organ to, the OPO stated that it has no need (or right) to know the organ recipient's insurance information. Further, concern was expressed by the OPO that if it had access to detailed demographic information — like source of insurance coverage — it could create the mistaken impression that socioeconomic factors were influencing decisions about who ultimately receives an organ. **The OPO does not have access to an organ recipient's insurance information. Therefore, an excising hospital cannot obtain an organ recipient's insurance information from the OPO it sent the organ to.**

2) *Determining Recipient of an Excised Organ Electronically*: CMS asserts that an excising transplant hospital can electronically track the recipient of an organ provided to an OPO. CHA's members with transplant programs state that they do not have this capability. **Given that transplant hospitals' access to information on Unet — as described above — is limited to individuals the transplant hospital has placed on a waitlist, there is currently no way for an excising**

transplant hospital to know who the recipient of an organ donated to an OPO is, much less their source of insurance coverage.

3) *OPOs Will Provide Recipient Information to Excising Hospitals Allowing for Manual Tracking*: CMS asserts excising transplant hospitals lacking automated organ tracking capabilities can obtain information about an organ recipient from the OPO "manually." As discussed above in item 1, the OPO also does not have access to the recipient's insurance information. But even if it did, the OPO believes that sharing any information (including the transplanting hospital that received the organ) other than what is clinically necessary to place an organ for transplant about the organ recipient with the excising hospital would "violate general privacy laws." Further, the OPO stated there is no legal requirement for it to share any information about the ultimate recipient of an organ provided by an excising transplant hospital to an OPO. **If OPOs do not provide the necessary information about the recipient of an excised organ, an excising transplant hospital cannot "manually" track an organ to determine the recipient's insurance information.**

   It is certainly possible that state medical privacy and security laws apply and do not permit these disclosures. It is unclear whether OPTN or OPOs are "health information networks" subject to the information blocking rules; even if they are, this would not be helpful to the extent that state medical privacy laws prohibit disclosure of information about a patient to a hospital that is not caring for that patient. Further, OPOs are also subject to Medicare Requirements for Certification and Designation and Conditions for Coverage (CfCs), which require OPOs to develop and implement policies and procedures to ensure the confidentiality and security of patient information. If CMS elects to pursue this policy, we ask the agency to revise the OPO CfCs to provide a mechanism that, in absence of state a privacy law prohibiting disclosure, encourages an OPO to provide an excising transplant hospital necessary information about the recipient and transplanting hospital to determine if an organ provided to an may be included in the count "of Medicare organs."

Accuracy of Insurance Information: Beyond the insurmountable operational issues discussed above, CHA has concerns about the accuracy of insurance data collected and maintained in the Unet system. These concerns include the frequency with which a potential organ recipient's insurance information is updated in Unet, the availability of secondary payer information, and the documentation required to substantiate an organ recipient's insurance status.

1) *Frequency of Insurance Information Update*: Based on conversations with CHA members and an OPO, insurance information is collected by the transplant hospital when that individual is registered for the transplant waitlist. However, this information is not used by the transplanting hospital to bill the organ recipient's health plan when transplantation occurs. The billing information is maintained in the hospital's patient accounting system. Insurance status — particularly for individuals with a serve chronic illness that requires an organ transplant —is not static. It is not uncommon for recipients to wait three or more years for an organ to become available for transplant during which time the individual may have aged into Medicare eligibility or become eligible due to disability. However, the information in Unet is infrequently updated after an individual is initially placed on a transplant waitlist.

Given Unet insurance data are infrequently updated once an individual is placed on an organ transplant waiting list, CHA does not believe it is sufficiently accurate for use in determining which organs that are excised and sent to an OPO are ultimately transplanted into a Medicare beneficiary. Therefore, it should not be used for this purpose. Further, CHA believes this lack of updating may contribute significantly to the lower Medicare organ share based on the Scientific Registry of Transplant Recipient data CMS provides at 86 FR 25666 to allege that Medicare is inappropriately cross-subsidizing organ acquisition costs that should be borne by other payers.

2) *Secondary Payer Information*: As CMS discusses and proposes to codify on 86 FR 25668 and 86 FR 25669, organs where Medicare is the secondary payer in qualifying situations are included in both the allowable cost and count of acquired organs for a transplant hospital. **CHA strongly supports this continuation and codification of existing policy.** However, secondary insurance information is not captured when an individual is placed on a transplant waitlist. CHA notes that the form CMS references (O.M.B. NO. 0915-0157) only has space for a single HIC number, and conversations with members confirm that only primary payer information is collected when an individual is registered for an organ transplant waitlist. An example of the form is available at https://unos.org/wp-content/uploads/unos/Adult-TRR-Kidney.pdf.

Even if secondary payer information is eventually captured, it will not be sufficient by itself — based on Medicare regulations — to conclude that an excised organ sent to an OPO and transplanted by another transplant hospital into an individual who has Medicare as a secondary payer may be counted as a Medicare organ. CMS proposes to codify that when Medicare is the secondary payer the program will cover the organ acquisition costs only if 1) the transplanting hospital's contract with the recipient's primary insurance does not require acceptance of the primary payment as payment in full and 2) the payment from the primary payer, after being prorated and allocated based on the costs of the transplant procedure and the organ acquisition costs, is insufficient to cover the costs of acquiring the organ. In cases where Medicare is the secondary payer for the recipient of an excised organ, the excising transplant hospital will need documentation from the transplanting hospital to support that the organ meets both criteria. This will require the transplanting hospital to share contracting, payment, and cost structure details with the excising hospital which will impose a significant administrative burden on both the excising and transplanting transplant hospitals.

3) *Auditable Documentation of an Organ Recipient's Health Insurance Coverage*: The proposed rule does not discuss what, specifically, an excising transplant hospital will need to produce when a Medicare cost report is audited to support a transplant hospital's count of excised organs that were sent to an OPO and subsequently transplanted into a Medicare beneficiary at another transplant hospital. **In addition to resolving the operational issues discussed above, CMS must clearly articulate for both their MACs and transplant hospitals what documentation is required to support an excising transplant hospital's assertion that a given organ that was excised and sent to an OPO was, in fact, transplanted into a Medicare beneficiary.**

Given the operational issues discussed above, CHA is concerned that if this policy is finalized as currently proposed for FFY 2022, excised organs that are sent to an OPO will no longer be allowed in the Medicare organ count, regardless of whether they were ultimately transplanted into a Medicare beneficiary. As discussed above, the operational capabilities do not exist for an excising transplant hospital to obtain an organ recipient's insurance information or track an organ sent to an OPO to the ultimate recipient. Also, OPOs do not believe they can share organ recipient information with the excising hospital.

Instead of ensuring that Medicare only pays for the costs associated with transplanting organs into Medicare beneficiaries, the agency's proposal will no longer reimburse the excising transplant hospital for its allowable organ acquisition costs when an organ is sent to an OPO and subsequently transplanted into a Medicare beneficiary. This policy change is contrary to 42 CFR 412.113(d), which states "payment for organ acquisition costs incurred by hospitals with approved transplantation centers is made on a reasonable cost basis" and will inappropriately transfer the costs of organ acquisition for some Medicare beneficiaries from the program to the transplant hospitals that excise these organs. This additional unreimbursed cost is not sustainable for transplant hospitals and will ultimately reduce access to organ transplantation for both Medicare and non-Medicare patients who require this life-saving procedure.

As such, CHA respectfully asks that CMS withdraw this proposal as it is clearly unworkable given the inability of excising transplant hospitals to obtain recipient payer information when an organ is donated via an OPO to a separate transplant hospital. If CMS does not withdraw this proposal, we ask the agency to delay implementation for at least five years. This will give transplant hospitals, the OPTN, and the OPOs sufficient time to develop and implement the processes and safeguards necessary to track organs from the excising hospital to the transplant recipient and report the recipient's insurance information. It will also give CMS and its MACs time to define the necessary supporting documentation excising transplant hospitals will be required to obtain and maintain. Additionally, CHA strongly recommends that if CMS intends to implement this policy, the agency must also clarify how federal data privacy and security laws — including HIPAA and Information Blocking — apply to OPOs in this situation. Further, the agency must understand how individual state privacy laws may prohibit an OPO from providing this information to excising transplant hospitals before implementing this policy. Finally, CMS must modify the OPO CfCs to provide a mechanism to encourage OPOs to provide the necessary organ recipient and demographic information to the excising transplant hospital, assuming this is not prohibited by state law.

Proposals Requiring Donor Community Hospitals to Charge OPOs Reasonable Costs, Charges Reduced to Costs

Medicare-certified hospitals that are not transplant hospitals but collaborate with OPOs to procure organs from cadaveric donors for transplantation are referred to as "donor community hospitals." Currently, when a donor community hospital incurs costs for services provided to the cadaveric donor, as authorized by the OPO following the declaration of death and consent to donate, it bills the OPO its customary charges (not reduced to cost) or a negotiated rate.

CMS alleges in the proposed rule that some donor community hospitals are charging OPOs amounts in excess of reasonable costs for harvesting organs from cadavers, resulting in Medicare paying more than reasonable costs for the acquisition of cadaveric donor organs for transplant. In response, CMS proposes to add § 413.418(b) in new subpart L, to specify that for cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital-specific cost-to-charge ratio for the period in which the service was rendered.

Based on conversations with an OPO, CHA believes that California community donor hospitals have negotiated rates with the OPO and, therefore, are not billing gross charges for excised organs. Additionally, while CHA appreciates CMS' concern, we note there is opportunity cost incurred when a

community donor hospital elects to use its operating room to excise cadaveric organs. Hospitals infrequently have operating rooms that sit idle, so when one is used for cadaveric organ recovery, it requires that a scheduled procedure be canceled or delayed. This results in lost margin for the community donor hospital, which must be offset in the payment from the OPO for harvesting the organ. If CMS finalizes its proposal and caps community donor hospital payment from OPOs for excised organs to the procedure's cost, CHA is concerned that it will decrease the number of viable recovered organs and ultimately reduce access to organ transplantation for both Medicare and non-Medicare individuals who are in need of this life saving procedure.

Therefore, CHA currently does not support CMS' proposal to require community donor hospitals to bill OPOs the charges associated with excising an organ reduced to cost using the hospital-specific CCR. If CMS believes this issue is widespread enough that it must address it, we ask that the agency:

1) Continue to allow community donor hospitals to negotiate standard acquisition charges with the OPOs
2) Work with community donor hospitals to determine a reasonable margin that compensates them for the opportunity cost of using an operating room and related resources to excise cadaveric organs. Once this is determined, it will allow CMS to move to a reasonable cost reimbursement model that fully accounts for the opportunity cost of delayed or canceled procedures to allow for the operating room time necessary for cadaveric organ recovery. This model should only be used when an OPO and a community donor hospital have not negotiated a standard acquisition charge.

CHA believes taking these steps will mitigate the negative impact changes to community donor hospital organ acquisition will have on the availability of organs for transplantation.

Solicitation of Comments Regarding Surgeon Fees for Cadaveric Kidney Donor Excisions
The FFY 2022 proposed rule indicates that cost report data from 48 OPOs showed average surgeon fee costs per local kidney of $745. Medicare's payment is limited to $1,250 for excising a cadaveric donor kidney. While this limit is above the costs that OPOs are incurring, CMS has received comments suggesting the $1,250 limit needs to be raised. **Based on conversations with CHA's members, the current limit of $1,250 is inadequate relative to the surgical, travel, and wait times and ancillary transportation expenses incurred when recovering cadaveric kidneys. CHA strongly encourages CMS to formally survey transplant programs to collect the data necessary to rebase payments for this service.**

Medicare Shared Savings Program (MSSP)

In response to the COVID-19 PHE, CMS created an option for a BASIC track accountable care organization (ACO) to forgo its first automatic advancement along the glide path for performance year (PY) 2021 before returning to the glide path for the following PY. At that time, the ACO would return to the glide path as if automatic advancement had occurred each year (e.g., an ACO that opted for a freeze at Level B instead of advancing to Level C would return a year later to the glide path at Level D). Given the uncertain nature of the COVID-19 PHE, CMS proposes for PY 2022 that an ACO may elect to remain in the same level of the BASIC track's glide path in which it participated during PY 2021. Under this proposal, an ACO that elects to freeze its participation level for both PY 2021 and PY 2022 would be automatically advanced for PY 2023 to the level of the BASIC track's glide path in which it would have participated during PY 2023, absent both of its elections to freeze.

In light of the challenges posed to MSSP participants by the COVID-19 PHE, CHA strongly supports allowing MSSP ACOs to freeze their participation for PY 2022 at their current level. However, we respectfully ask that for MSSPs that elected to freeze their participation, CMS advance them to the next risk level in the track, not the risk track they would have been in absent the PHE. For example, if a MSSP ACO was in Level A in in PY 2020 they would advance to Level B in PY 2023, not Level D. CHA believes that moving forward two risk levels is too great an assumption of risk, particularly at a time when the COVID-19 PHE has disrupted patient access to care. Additionally, providers' ability to focus on using data to re-engineer care pathways has similarly been disrupted as all participants in ACOs have been focused on responding the COVID-19 PHE. CHA is concerned that if ACOs are forced to assume more risk than they are prepared to take — both operationally and financially — it will lead to additional ACOs exiting the MSSP program, further delaying the transition to value-based care and result in missed opportunities to improve outcomes for Medicare beneficiaries.

Proposed Quality Measure Suppression Policy in Response to the COVID-19 PHE

Throughout the duration of the COVID-19 PHE, CMS has adopted several policies intended to address the impact of the pandemic on the Medicare value-based and quality reporting programs, including the Hospital Readmissions Reduction Program, the Hospital Value-Based Purchasing (VBP) Program, the Hospital Acquired Conditions (HAC) Reduction Program, and the Hospital Inpatient Quality Reporting program. These policies — such as blanket nationwide extraordinary circumstances exceptions (ECE) for reporting quality data, and the subsequent interim final rule that clarified CMS would not include any optionally reported data from the first or second quarter of CY 2020 in calculations for value-based program performance – have been welcomed by hospitals as they devoted clinical resources to caring for their communities in the midst of an unprecedented pandemic.

CHA appreciates that CMS continues to recognize the significant impact of the COVID-19 PHE on quality measurement and performance in the proposed rule, and we are supportive of proposals to suppress certain quality measures in the value-based quality programs. Specifically, CHA supports CMS proposed policy that would be applied to the HRRP, Hospital VBP Program, and HAC Reduction Program and would permit the agency to suppress certain measures in the value-based programs if it determines the PHE has significantly impacted performance on the measure. CMS proposes several specific factors it would consider in deciding whether to suppress hospital measure data, including significant deviation in national performance on the measure during the PHE or clinical proximity of the measure's focus to COVID-19. CHA agrees that it is necessary to suppress certain measures due to the impact of COVID-19 and will provide more detailed comments on the specific program proposals in the following sections.

Hospital Readmissions Reduction Program (HRRP)

As a result of CMS' September 2020 interim final rule that excludes data from the first and second quarter of 2020, the FFY 2022 HRRP performance period will be July 1, 2017, through December 31, 2019. CMS proposes to align the MedPAR data it uses to determine aggregate payment amounts and payment adjustments with the modified performance periods and would not use MedPAR data from Q1 and Q2 of 2020 in calculating HRRP payment adjustments in FFY 2022 and subsequent years. **CHA supports this proposal.**

For FFY 2023, CMS proposes two key policies to address the impact of COVID-19. First, CMS proposes to apply its measure suppression policy to the HRRP's pneumonia readmission measure citing proposed Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE. Under the proposal, CMS would calculate the

measure's rate for the relevant program year but then suppress the use of that rate to make hospital payment changes by weighting the suppressed measure at 0% in the HRRP scoring methodology. CMS would also continue to provide hospitals with confidential reports of their rates as calculated without suppression. **CHA agrees that the significant portion of COVID-19 diagnosed patients in the pneumonia readmission measure cohort — many of whom were severely ill — justifies suppression of the measure from the HRRP for FFY 2023, and we support this proposal.**

Second, CMS proposes to update the measure specifications to remove patients having secondary diagnoses of COVID-19 from the denominators of these five readmission measures. While CHA supports this proposal, we urge CMS to continue to evaluate the claims data to ensure it is not unfairly penalizing hospitals where significant operational changes due to the COVID-19 PHE could impact readmissions performance for patients without a COVID-19 diagnosis. For example, hospitals limited visitor policies to mitigate the spread of COVID-19, and the impact of a patient not having a family member with them to understand discharge instructions may have had an impact on readmission rates. Similarly, patients who would have typically been discharged to a SNF may have been discharged to home-based settings in communities where SNFs were not accepting patients, potentially impacting readmission rates for patients without COVID-19 as a secondary diagnosis. **CHA urges CMS to continue to analyze the wide-ranging impact of the COVID-19 PHE on readmissions in future rulemaking.**

Hospital Value-Based Purchasing (VBP) Program

CMS proposes several policies to address concerns that VBP payment adjustments may become inequitable due to COVID-19 impacts, especially for hospitals treating large numbers of COVID-19 patients. For the FFY 2022 payment year, CMS proposes to suppress all of the measures in three of the four program domains — Person and Community Engagement, Safety, and Efficiency and Cost — calculating a domain score for only the measures in the Clinical Outcomes domain. **CHA supports this proposal.**

Because the Clinical Outcomes domain represents just 25% of a hospitals Total Performance Score (TPS), CMS also proposes to adopt a special scoring and payment rule for FFY 2022 under which the agency would not calculate TPS for hospitals. CMS would continue to make the statutory 2% reduction to each hospital's base operating DRG payment amount. However, absent the availability of TPS, each hospital would be assigned a budget-neutral, value-based incentive payment percentage, returning to the hospital the amount lost through the DRG payment rate reduction. **CHA understands the statutory constraints of the agency to apply adjustments under the VBP Program, and we support the proposal to apply a special scoring and payment rule for FFY 2022 to avoid unfairly penalizing hospitals that were severely impacted by the COVID-19 PHE.**

For FFY 2023, CMS proposes policies similar to the HRRP program. Specifically, CMS would suppress the VBP Program's pneumonia mortality measure and update the measure specifications for the remaining mortality and condition-specific complication measures to exclude patients with COVID-19 from performance calculations. **CHA strongly supports CMS' proposal to suppress the pneumonia mortality measure from the FFY 2023 VBP Program. COVID-19 significantly increased mortality rates for patients in the pneumonia measure cohort, and it would be inappropriate to penalize hospitals for their performance in treating a novel and severe disease like COVID-19.**

CHA also supports CMS' proposal to exclude patients with a COVID-19 diagnosis from the remaining clinical outcomes domain measure denominators beginning with FFY 2023. However, we urge CMS to

continue to analyze its claims data to determine if this policy sufficiently addresses the impacts of COVID-19 on hospital VBP Program performance as part of the FFY 2023 IPPS rulemaking cycle.

Proposed Removal of PSI-90 from the FFY 2023 VBP Program

CHA strongly supports CMS' proposal to remove the Patient Safety and Adverse Events Composite (PSI-90) (NQF #0531) from the hospital VBP Program measure set beginning with the FFY 2023 payment year. CHA has long opposed the inclusion of PSI-90 in CMS' value-based and quality reporting programs, due to significant concerns about the measure's construction and its ability to provide actionable information to providers. CHA agrees that the costs associated with the measure outweigh the benefit of its use in the program, and we applaud the agency for reducing burdens on hospitals.

Hospital-Acquired Condition (HAC) Reduction Program

In response to concerns that HAC Reduction Program payments may become inequitable due to COVID-19 impacts, especially for hospitals treating large numbers of COVID-19 patients, CMS proposes to suppress measure data from all HAC Reduction Program measures (the five CDC NHSN HAI measures and PSI-90) for Q3 and Q4 of 2020 for the FFY 2022 and 2023 payment years. After accounting for the previously finalized ECE policies that exclude Q1 and Q2 of 2020, the proposal will result in shortened performance periods for the FFY 2022 and 2023 HAC Reduction Program.

CHA appreciates that CMS has addressed the impact of COVID-19 on the HAC Reduction Program, and we support proposals to remove 2020 data from the program's performance periods. However, we are concerned that the shorted performance periods in the FFY 2023 program, which include only 2021 data for the HAI measures and the first two quarters of 2021 for the PSI-90 measure, will inappropriately penalize hospitals in California that experienced their highest levels of COVID-19 hospitalizations in early 2021. While California was one of the earliest states to treat COVID-19 patients in 2020 — such as those repatriated from cruise ships and early cases of community spread — the largest numbers of hospitalized patients were seen in the first quarter of 2021. For example, at the height of the summer surge, California hospitals saw an average of 6,482 confirmed COVID-19 patients during July 2020. After a decline in cases through the early Fall, by January 2021 that number had increased to an average of 19,490 patients hospitalized with COVID-19. We urge CMS to continue to analyze data from early 2021 and consider additional approaches to addressing the impact of COVID-19 on HAC Reduction Program measures in future rulemaking.

Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes several changes to the IQR Program, including the addition of five new measures, the removal of five existing measures, and revisions to the current electronic health record (EHR) certification requirements.

Proposed COVID-19 Vaccination Coverage Among Health Care Personnel Measure

CMS proposes to add a new process measure to the IQR Program beginning with FFY 2023 to track the percentage of health care personnel who receive a complete COVID-19 vaccination course. CMS proposes an initial data submission period of October 1 through December 31, 2021, for use in the FFY 2023 IQR Program, with data reported for at least one week of every month in the reporting period using the CDC NHSN web-based surveillance system. For FFY 2024 and subsequent years, CMS proposes a full calendar year reporting period. CMS proposes to publicly report the CDC's quarterly summary of the COVID-19 health care personnel vaccination measure.

California's hospitals strongly support the nation's COVID-19 vaccination efforts and have been leaders in vaccinating their communities. **Hospitals remain committed to achieving high levels of vaccination among their employees; however, we are concerned that the adoption of a measure to assess COVID-19 vaccination rates among hospital staff is premature for FFY 2023 with reporting beginning October 1. Should CMS finalize the adoption of the proposed measure, we urge the agency to allow voluntary reporting for FFY 2023 and delay required reporting by at least one year.**

The first COVID-19 vaccine was approved by the Food and Drug Administration (FDA) under emergency use authorization (EUA) on December 11, 2020. EUAs have subsequently been issued for two additional COVID-19 vaccines, and the early evidence has been promising both in terms of vaccine safety and efficacy. Despite increasing levels of COVID-19 vaccination, a degree of vaccine hesitancy remains among the general population, as well as hospital staff. Given the recent availability of vaccines, misinformation, and because the vaccines are currently authorized for emergency use — rather than FDA-approved — many facilities have encouraged vaccination among their staff but have not established vaccination as a condition of employment, and do not control the vaccination status of their employees. As accurate information about the vaccines dispels myths and the vaccines receive full FDA approval (as opposed to emergency use authorization), we are hopeful more health care personnel will become vaccinated.

The measure will also increase data collection and reporting burdens on hospitals that do not provide COVID-19 vaccinations directly to their employees and staff. While CMS says that it has modeled this measure after previously required measures to assess influenza vaccination rates among health care personnel, there are key differences between COVID-19 and flu vaccination administration and data collection among staff. Whereas it is common, and in fact states like California require, that health care facilities provide influenza vaccination for their employees on an annual basis, COVID-19 vaccination administration has been much more fragmented. All Californians receive their COVID-19 vaccinations through providers that have been selected by the state's third-party administrator as part of the state's vaccination network, or through pharmacies participating in the Federal Pharmacy Partnership. Although some general acute care hospitals have joined, participation in the state's network is not universal.

Though early COVID-19 vaccination efforts prioritized certain health care personnel — some of whom were vaccinated within their facilities or health systems — the measure includes a very broad definition of health care personnel, which would include many employees, independent contractors, and volunteers who would have been vaccinated in the community. **This measure will place additional burden on hospitals to seek and verify complete vaccination status from their employees whose vaccine may have been provided in settings outside of the facility, such as a local pharmacy or county mass vaccination clinic. Hospitals will need to devote significant resources to developing systems to track employee vaccination, including which vaccines and how many doses are required for complete vaccination.**

CHA is also concerned that the definition of the measure numerator could be significantly impacted by the potential need for booster shots. Currently, the numerator would assess the cumulative number of health care personnel eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2. Unlike the influenza vaccination — which requires an annual course of vaccination — much remains unknown about the long-term efficacy of the existing COVID-19 vaccines, and a requirement for a booster shot could modify

the definition of a "complete vaccination course." **CHA urges CMS to consider delaying adoption of such a measure until more is known about the long-term efficacy, final FDA approval, and vaccination schedule for COVID-19 vaccines.**

CHA is also concerned that the proposed measure duplicates reporting efforts already underway. Currently, hospitals voluntarily report COVID-19 vaccination rates for health care personnel to the Department of Health and Human Services (HHS) through weekly COVID-19 Hospital Data Reporting via the TeleTracking portal. The proposed NHSN fields to capture health care personnel vaccination data will require additional information that is more detailed than what is submitted via the TeleTracking portal and will require more time and effort to collect. We urge CMS to consider the significant burden imposed on hospitals in reporting increasingly detailed health care personnel vaccination data, in addition to reporting duplicate data to different portals for various purposes. **We believe a voluntary approach is more appropriate given the challenges. In addition, CHA urges CMS not to publicly report any voluntarily reported data.**

Finally, the measure proposed by CMS has not been fully specified, tested, or endorsed by the National Quality Forum (NQF). While CHA understands the immediate challenges posed by the COVID-19 pandemic and the benefits of understanding health care personnel vaccination rates, we do not support the inclusion of measures that have not been thoroughly tested and are not endorsed by the NQF in the Medicare quality reporting programs. **CHA urges CMS not to adopt a COVID-19 health care personnel vaccination measure beginning with FFY 2023, and to fully develop and test the measure for reliability and validity — and seek NQF endorsement — prior to adopting it as a required measure in the IQR Program.**

Proposed Maternal Morbidity Structural Measure

CHA strongly supports CMS' proposal to adopt a structural measure to determine the number of hospitals currently participating in a structured state or national Perinatal Quality Improvement (QI) Collaborative, and whether participating hospitals are implementing the safety practices or bundles embedded in these QI initiatives, beginning with the FFY 2023 payment year. The California Maternal Quality Care Collaborative (CMQCC) has been a national leader in reducing maternal mortality and morbidity rates in California since its inception in 2006, despite simultaneous increases in the national rates. Currently, more than 200 hospitals in California — the vast majority of hospitals that provide inpatient labor and delivery services — participate in CMQCC. CHA appreciates that CMS recognizes the important role of Perinatal Quality Improvement Collaboratives in improving maternal health, and we welcome efforts to encourage broader participation in these efforts nationwide.

Proposed Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) (Hybrid HWM Measure)

CMS proposes to adopt one new hybrid measure (based on both claims and electronically submitted clinical data) intended to more comprehensively measure the mortality rates of hospitals and to improve its ability to measure mortality rates in smaller-volume hospitals beginning with the IQR Program FFY 2026 payment year. Prior to required reporting, CMS would adopt an initial voluntary reporting period for the Hybrid HWM measure to run from July 1, 2022, through June 30, 2023.

CHA opposes the adoption of the Hybrid HWM measure at this time. As the agency notes, this measure is similar to the previously finalized Hybrid Hospital-Wide Readmissions Measure (HWR, NQF #2789), which will be a mandatory IQR measure beginning with FFY 2026. While CHA supports the development

of additional hybrid measures, we continue to have significant concerns with hospital and vendor readiness to successfully report these measures. There remains variation in EHR vendor support for the required data elements, and we urge the agency not to underestimate the time required for vendors to develop, implement, and test new measures, particularly as they work to implement the 2015 Edition Cures Updates to certification criteria. In addition, we remain concerned that CMS does not have a robust infrastructure to collect these data. The files associated with the Hybrid HWR data elements are particularly large, and hospitals have previously faced challenges in submitting eCQM files to the QualityNet portal. We are concerned that the addition of a second mandatory hybrid measure in FFY 2026 will result in significant technical challenges for both hospitals and CMS. **We urge CMS to delay adoption of additional hybrid measures until hospitals, vendors, and the agency have gained sufficient experience with mandatory reporting for the previously finalized HWR measure.**

Proposals to Remove Measures From the Hospital IQR Measure Set

CMS proposes to remove five measures from the hospital IQR Program for the FFYs 2023 through 2026 payment determinations — in accordance with its previously established measure removal factors — including the Deaths Among Surgical Inpatients with Serious Treatable Complications measure beginning with FFY 2023, and four electronic clinical quality measures (eCQMs) beginning with FFY 2026. **CHA supports the proposed measures' removal and appreciates that CMS is reducing reporting burden on hospitals.**

Reporting and Submission Requirements for eCQMs

CMS proposes to require hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the IQR Program, beginning with the CY 2023 reporting period/FFY 2025 payment determination. In accordance with previously finalized policies, hospitals will be required to report a full calendar year of data for eCQMs in 2023. However, we note that the deadline for EHR vendors to make available technology certified to the updated criteria is December 31, 2022. Hospitals need significant lead time between upgrading their EHR technology and reporting on eCQMs. **CHA urges CMS to reconsider its requirement for reporting a full-calendar year of eCQM data for the 2023 reporting year to ensure hospitals have sufficient time between upgrading their EHRs to the 2015 Edition Cures Update and full calendar year eCQM reporting.**

Request for Information on Closing the Health Equity Gap in CMS Quality Programs

California hospitals are committed to improving health equity and eliminating disparities in health care outcomes. Unequal access to health care and health resources due to race, socioeconomic status, and other social determinants of health has long been of concern to our members, and the COVID-19 pandemic has further demonstrated racial and ethnic health disparities that can no longer be ignored. The reasons for health equity disparity are multi-faceted, and answers to the problem are just as complex. Overcoming these obstacles will require a long-term, systemic approach with collaboration across all levels of government and institutions.

CHA applauds the administration for its strong commitment to addressing health equity, as evidenced by several of President Biden's executive orders. We appreciate that as an early step, CMS is seeking comments on how it can leverage Medicare quality reporting programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for facilities, providers, and patients. Hospitals are uniquely positioned to help advance health equity and reduce disparities, and many of our members have already invested in efforts to improve data collection on race, ethnicity, language preference, and other sociodemographic data. As the agency considers its

future steps, we offer the following high-level principles on improving demographic data collection, stratification of quality measure results, and future measures to assess health equity.

Improving Demographic Data Collection

The collection of standardized, comprehensive, and accurate data is essential to assessing disparities in our health care system. Hospitals have invested significant resources in collecting these data from their patients; however, the data are not always captured in a consistent manner and format. For example, it is common for race and ethnicity information to be collected at registration, but other social demographic factors, such as access to transportation or food insecurity, may be captured as part of discharge planning or case management services. The data may also be maintained across separate systems and departments. **CMS should engage stakeholders to understand the current practices for demographic data collection and provide education to promote best practices that ensure consistency in these efforts.**

CHA also urges CMS to assess current efforts to collect demographic data beyond race and ethnicity, such as the standardized patient assessment data elements (SPADEs) required for post-acute care (PAC) settings and International Classification of Diseases, Tenth Revision (ICD-10) z-codes. CHA notes that while CMS expanded the SPADEs to include a new category for social determinants of health, data collection has been delayed due to the COVID-19 PHE. **CMS should implement and learn from the experience of PAC providers collecting the existing SPADEs before expanding to other settings or adding additional data elements. We also urge CMS to engage stakeholders in understanding how z-codes are currently used and consider how to better standardize and incentivize this coding.**

Finally, we urge CMS to ensure that its efforts to standardize demographic data collection reflect the entire federal government's approach to addressing equity and racial disparities. It is imperative that, as we consider how to best capture the data elements to better understand disparities across health care, housing, the workforce and beyond, we are not working in silos. As CMS considers adopting a standardized minimum data set for collection, it should ensure that there is coordination across federal agencies.

Stratification of Quality Measure Results

CMS says that it is considering providing facilities with reports that would stratify quality measure results by race and ethnicity, similar to its current approach to provide hospitals with confidential hospital-specific reports (HSRs) for several condition- and procedure-specific readmissions measure strategies for dual-eligibility status in the Hospital Readmissions Reduction Program. **CHA supports providing hospitals with confidential HSRs stratified by race and ethnicity in order to expose significant disparities. We also believe that understanding the additional causes of disparities — such as housing instability, access to healthy foods, and community violence — is key to addressing health inequity and requires an even more granular level of data collection.** While dual eligibility status and race or ethnicity have been shown to be accurate proxies for social risk, those characteristics intersect with other systemic factors that result in inequities in our health care system. We encourage CMS to continue to explore how it could provide hospitals with actionable data that allow them to work with community partners in advancing health equity in their communities.

Notably, CMS discusses providing these stratified measure results initially using a statistical modeling technique called "indirect estimation." CHA echoes the concerns of the agency that algorithms used to indirectly estimate race and ethnicity could unintentionally introduce measurement bias. We urge CMS

to support health system efforts to collect self-reported data, which CMS acknowledges in the RFI as the gold standard for collecting race and ethnicity data. As CMS works towards these goals, we ask that indirectly-estimated stratified HSRs not be publicly reported.

Future Measures to Assess Health Equity

CMS discusses the possible creation of a Hospital Equity Score that would synthesize results across multiple social risk factors and disparity measures. CHA is concerned that a measure requiring a complex aggregation methodology is unlikely to produce results that are actionable to the hospital for quality improvement purposes, and we do not support the development of an aggregate Hospital Equity Score. **We urge CMS to rethink the development of this measure and instead focus its resources on improving and standardizing data collection and reporting of social demographic data in such a way that provides providers with accurate and specific data on disparities within and across their facilities.**

Request for Information on Advancing to Digital Quality Measurement

In the proposed rule, CMS includes a wide-ranging request for information on the future of digital quality measurement and the goal of the agency to transform to a fully digital quality enterprise by 2025. While CHA supports the goals of utilizing technology to improve and align quality measurement across the public and private sectors, we urge CMS to take a measured approach to this transformational goal that recognizes the significant costs, time, and other resources necessary to enable successful, digital quality measurement.

We note that CMS provides a definition of digital quality measure (dQM) that is quite broad and lists data sources including administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. Under this definition, it could be argued that hospitals already report dQMs, therefore no transformation is necessary. However, it also could be interpreted that the agency intends to require providers to interact with all of these data sources and undertake more than a decade's worth of unfunded work in just a few years. While CMS establishes this definition, it is unclear what the purpose of defining dQM at this stage is, or what CMS expects of providers in defining a dQM. CHA urges CMS to provide additional clarity as to what it expects for the future of digital quality measurement, and how those expectations differ from the status quo.

CMS also seeks comments on the potential to use Fast Healthcare Interoperability Resource-based (FHIR) APIs to access quality data it already collects, as well as transitioning to FHIR-based quality reporting through APIs for eCQMs already adopted into several of the agency's quality reporting and value-based programs. CHA agrees there is promise in utilizing FHIR-based APIs to improve quality measurement and reporting, and we encourage CMS to broadly engage with stakeholders in advancing the use of this technology prior to adopting updated eCQM measure specifications that utilize these standards.

Promoting Interoperability Program Proposals

CMS proposes several significant changes to the Promoting Interoperability Program, which requires that hospitals meet certain requirements to be considered a meaningful user of EHR technology. Hospitals that are not identified as meaningful EHR users are subject to a reduction equal to three quarters of the market basket.

Proposed Reporting Periods for 2023 and 2024
CMS previously adopted a continuous 90-day reporting period for the Medicare Promoting Interoperability Program through 2022. CMS proposes to extend this continuous 90-day reporting period for 2023. **CHA strongly supports a consistent 90-day reporting period for the Promoting Interoperability Program.**

However, CHA opposes the proposal to increase the reporting period to a minimum of any continuous 180-day period for new and returning participants. While some larger health systems report that increasing the reporting period may be manageable, some small, independent, and rural hospitals that utilize less common EHR vendors continue to experience challenges that would make a 180-day reporting period challenging. For example, if a hospital upgrades its EHR technology in the middle of a year, the upgrade is likely to occur at a time that would disrupt the 180-day reporting period. Hospitals would be required to manage their reporting across two versions of their EHR, which would impact their ability to report information on certain measures. **CHA urges CMS to maintain the 90-day reporting period for 2024 and beyond.**

Voluntary Reporting of Query of Prescription Drug Monitoring Program (PDMP) Measure
CHA supports CMS' proposal to maintain and extend voluntary reporting of the Query of PDMP measure for the 2022 reporting period, and to increase eligible bonus for voluntary reporting from 5 to 10 points. California's PDMP is moving toward an electronic interface with hospital and provider EHRs; however, progress has been slow and the technologies employed have been varied. While there are pilots underway to connect certain HIEs with California's PDMP, these are generally in the early stages. After these pilots go live and have been thoroughly evaluated, we will be able to provide CMS with more specific timelines for when we believe this measure will be broadly achievable across the state.

Other elements about the PDMP program in California present financial and workflow challenges. Identity management is remains challenging, often requiring providers to sort through a list to identify the patient of interest. In addition, our state does not participate in cross-state data sharing even as many of our patients spend time in other western regions for some of the year. Until such time that we improve some of these and other barriers we face in connecting to California's PDMP, we urge CMS to continue to include the Query of PDMP measure as optional and eligible for bonus points under the Promoting Interoperability Program.

Provide Patients Electronic Access to Their Health Information Measure Under the Provider-to-Patient Exchange Objective
Beginning with the 2022 EHR reporting period, CMS proposes to modify the "Provide Patients Electronic Access to Their Health Information" measure to require eligible hospitals and critical access hospitals (CAHs) to ensure that patient health information remains available to the patient (or patient-authorized representative) **to access indefinitely** and **using any application of their choice** that is configured to meet the technical specifications of the API in the eligible hospital or CAH's certified electronic health record technology. This would include all patient health information from encounters on or after January 1, 2016. **CHA has several concerns with the proposed modification and urges CMS not to finalize its proposal.**

First, we are concerned that the policy to ensure that patient health information remains available indefinitely conflicts with medical record retention laws and could create additional burden and

confusion. For example, California state law requires that general acute care hospitals must retain patient records for seven years following discharge of the patient or, in the case of a minor, at least one year after the minor reaches 18 years older, whichever is longer. In addition, the proposed modification is not clear on the scope of the data that would be required, such as if it is limited to the data elements of United States Core Data for Interoperability (USCDI) or electronic health information (EHI) in alignment with the ONC's information blocking requirements, or if CMS defines a broader definition of health information.

In addition, CHA is concerned that the proposal does not account for certain security or technological upgrades that could impact the ability to maintain these records indefinitely. CMS must ensure that hospitals are able to take data offline to conduct security improvements, and at minimum should allow for an annual certification of data. In addition, the proposal fails to account for hospitals that switch to a new vendor from an obsolete EHR, where it may not be possible to map data and records across the disparate systems. Finally, should CMS finalize these changes, we urge the agency not to finalize a lookback period to January 1, 2016. Instead, CHA asks the agency to make the changes effective for patient encounters occurring after the effective date of the final rule.

Health Information Exchange Objective: Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

CMS proposes to add a new, optional attestation-based measure for the 2022 reporting period, "Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)." Hospitals and CAHs could attest to this measure in place of reporting the two existing measures, "Support Electronic Referral Loops by Sending Health Information" and "Support Electronic Referral Loops by Receiving and Incorporating Health Information." The measure would be worth 40 points under the Health Information Exchange objective. **While there is variation in the availability of HIEs for hospitals in California, we are supportive of efforts to encourage the bi-directional exchange through HIEs and support the proposed optional measure.**

Proposed Modifications to the Public Health and Clinical Data Exchange Objective

Beginning with the 2022 EHR reporting period, CMS proposes to require reporting on the following four measures under the Public Health and Clinical Data Exchange Objective: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. Currently, hospitals are required to report on two of the six measures finalized under the objective. **While CHA understands the goals of the agency in improving public health reporting to better support public health agencies' response to future threats — and to assist in the ongoing COVID-19 pandemic recovery — we are concerned that the proposal places requirements on hospitals that are unable to meet to the lack of public health reporting infrastructure in their communities**.

In California, the public health system is decentralized and managed at the county level. Many counties lack the infrastructure that would allow them to accept data submitted for each measure as specified, and in many cases are unable to provide documentation to verify that providers have or have not met the public health reporting objectives. Notably, the California Department of Public Health is prohibited by law from collecting (and, therefore, receiving) syndromic surveillance data, and very few counties accept this data. While CMS notes in the proposed rule high levels of national participation in the National Syndromic Surveillance Program (NSSP), it is clear by viewing the county level participation map that many of California's 58 counties have not provided recent data.

We are also concerned that the all-or-nothing nature of the scoring for this objective threatens a hospital's full payment update, as it would receive an overall score of zero of the Promoting Interoperability Program if unable to report on or claim an exclusion for any of the four measures proposed as mandatory. Hospitals should not be penalized for the lack of critical public health reporting infrastructure, and those who make a good faith effort to report despite these challenges should be eligible to achieve meaningful use of EHR technology. **Should CMS finalize its proposal to require all four measures, it should consider a scoring methodology that would offer points on a scale up to 10 as long as the hospital has reported on at least two measures — as currently required — under the objective.**

CHA is encouraged that Congress has allocated additional funds to improve public health reporting infrastructure in response to the COVID-19 PHE, and we are committed to ensuring these investments strengthen our public heath reporting systems. **We support CMS' efforts to encourage improvements in reporting data to public health agencies. However, until improvements are made to public health agency reporting systems, we urge the agency to consider additional flexibility for hospitals in reporting requirements or scoring methodologies under the Promoting Interoperability Program.**

CHA appreciates the opportunity to comment on the FFY 2022 IPPS 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