



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

June 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, D.C. 20201

SUBJECT: CMS-1716-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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule, Federal Register (Vol. 84, No. 86) May 3, 2019

Dear Administrator Verma:

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 outlining rate updates and policy changes to the Medicare inpatient prospective payment system (IPPS) for federal fiscal year (FFY) 2020.

In summary, CHA:

- Strongly opposes CMS' proposal to increase the wage index of hospitals in low-wage states by decreasing the area wage index of those in high-wage states. Such a policy is inappropriately redistributive and only serves to help one group of hospitals while endangering another.
- Urges CMS to include the seven hospitals excluded from the area wage index file, as their data are accurate and reflect California's complex labor markets
- Encourages CMS to strongly consider FFY 2017 Worksheet S-10 data as a viable option to meet its current policy objectives in distributing the Medicare disproportionate share hospital (DSH) uncompensated care dollars in FFY 2020. Further, we urge CMS to honor its commitment to mitigating the volatility of these payments to providers by considering blending FFY 2019 uncompensated care payments with FFY 2017 payments.
- Does not support CMS' proposal to change the severity level designation for nearly 1500 codes. We urge the agency to not finalize this policy, make additional data available for meaningful comment, and gather additional stakeholder input before phasing in any changes in the future.

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

Area Wage Index

Hospitals and health systems across California are committed to providing high-quality patient care to all who walk through our doors, a mission of care supported by the more than 480,000 full-time equivalent professionals employed across the state. As we strive to retain a workforce robust enough to meet patients' needs, the gap between supply and demand is only increasing.

Combine this with California's high cost of living — in 2017, the cost of goods and services in California was 14.8% above the national average¹ — and it is abundantly clear why hospitals must expend greater resources on staffing compared to other states. Upwards of 57% of hospital spending statewide is on labor-related costs². In short, providing health care in California simply costs more — but we remain committed to meeting our patients' needs.

That commitment is evidenced through the high quality of care provided by a highly trained clinical workforce. California hospitals have made — and continue to make — great progress in improving outcomes for our patients. Notably, California hospitals:

- Perform better than the national rate on five of six mortality measures
- Have the lowest maternal mortality rate in the nation
- Are among the 10 best states (tied for eighth place) for providing appropriate care for severe sepsis and septic shock
- Have made consistent progress toward reducing health care-associated infections over the previous two years, including a 16% reduction in central line-associated bloodstream infections, a 9% reduction in catheter-associated urinary tract infections, and a 17% reduction in Methicillin-resistant *Staphylococcus aureus* infections

California's hospitals operate in the most highly regulated health care market and do so under significant financial distress. More than 38% of hospitals in California operate in the red³. In addition, California has unique, significant regulatory requirements — such as nurse staffing ratios and limited scopes of practice for a number of clinical specialties — that contribute to labor costs. Further, the ban on the corporate practice of medicine makes integration with our physicians vastly more expensive than in other states that are able to employ their physicians directly. **Our performance on quality, cost and efficiency — despite our intense regulatory environment — is due to our highly trained workforce. Many health care workers obtain education and training in California and, because of the high cost of living, benefit from providers' extraordinary efforts to retain them. Our labor costs are a true reflection of the challenging labor market in which we operate.**

Our commitment to our patients in delivering high-quality care is fundamentally undermined by the CMS FFY 2020 IPPS proposal, which would disregard the labor costs reported and audited annually. Not only is this proposal financially destabilizing to California's hospitals, which stand to lose more

¹ Bureau of Economic Analysis, US Department of Commerce. <https://www.bea.gov/news/2019/real-personal-income-states-and-metropolitan-areas-2017>, last accessed June 17, 2019

² 2017 Office of Statewide Health Planning and Development Hospital Annual Financial Data

³ 2017 Office of Statewide Health Planning and Development Hospital Annual Financial Data

than \$100 million in FFY 2020 under wage compression policy alone, but we believe it is unlawful. We urge CMS to withdraw this proposal.

Further, the exclusion of seven hospitals' data in the area wage index files — data CMS notes are accurate — will decrease payments to hospitals in those core-based statistical areas (CBSAs) by \$5.7 million. In the proposed rule, CMS suggests excluding all hospitals in the same health system as the seven that are presently excluded; doing so would result in a further decrease of \$173 million. The ripple effects of such an arbitrary and capricious policy are devastating and jeopardize access to care for Medicare beneficiaries across California. We urge the agency to withdraw this exclusion and reinstate all health system hospital data for the purposes of the FFY 2020 area wage index.

Finally, CHA supports CMS' efforts to address the many challenges faced by our nation's rural hospitals. Rural hospitals in California face similar challenges to rural hospitals in other states but would be disproportionately harmed by this policy, which CMS states is designed to help them. This short-sighted payment policy harms not only our rural hospitals, but also every single IPPS hospital in California. If CMS believes it would be good payment policy to provide additional funding to low-wage hospitals, it should work with Congress to seek authority to do so, rather than proposing unilateral changes inconsistent with previous congressional action.

We agree that the area wage index policy needs reform — but this policy offers more problems than solutions. We stand ready to work with the agency in developing workable solutions to address the many inequities in the area wage index system. Our detailed comments are noted below.

I. [The Proposed Wage Compression Rule Violates The Medicare Act \(Section III.N.3 - Proposals To Address Wage Index Disparities Between High And Low Wage Index Hospitals\)](#)

CMS' proposal to increase the wage index of the hospitals with a wage index in the lowest quartile and to pay for it by decreasing the wage indexes of the hospitals in the highest quartile (the "wage compression" proposal), violates the provision of the Medicare Act requiring the agency to adjust payments to reflect area difference in wages, and is not supported by the exceptions provision on which CMS purports to rely. Rather, the wage compression proposal would result simply in a shift of Medicare funds from high wage states to low wage states, completely untethered from labor costs incurred by hospitals

A. **The Wage Compression Proposal Is Beyond CMS' Legal Authority**

1. **Authority under 42 U.S.C. § 1395ww(d)(3)(E)**

CMS asserts it has the legal authority to artificially alter the correct wage data values for hospitals in the bottom and top quartiles (affecting 50% of hospitals in the nation) under Section 1395ww(d)(3)(E). CMS states, but does not explain why, the statute setting forth the wage index provision gives it broad authority to institute a wage compression policy that, in essence, makes inaccurate the wage data values for half of the nation's hospitals. Section 1395ww(d)(3)(E) provides a process for the adjustment of 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[,]" and requires those

adjustments to be budget neutral. The wage compression proposal violates the plain language of the statute because it will not result in an adjustment to the payment rates that reflect the actual wage data difference between the relative hospital wage levels in a geographic area compared to the national average, subject only to those adjustments that have been specifically set forth by Congress.⁴ Indeed, the proposal is designed to ensure that this does not happen and clearly contradicts Congress' mandate. Moreover, Section 1395ww(d)(3)(E) illustrates that Congress writes rules and exceptions, but here, Congress has not written an exception for what CMS is proposing. As such, CMS' action is *ultra vires*.

(i) **CMS' proposal contradicts the congressional mandate**

While certain of the 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."). CMS' wage compression proposal does not "remove the effects of local wage differences" but instead disregards accurately reported wage data for 50% of the nation's hospitals. This is beyond the authority delegated to the agency and ignores the text of the statute whereby CMS is 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."

Congress instituted this statute 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 those adjustments that Congress has specifically authorized (see footnote 3).⁵ Apart from an adjustment for frontier hospitals, Congress never sought to penalize or benefit certain areas over others by deviating from the actual wage data.

⁴ As discussed below, Congress has authorized several adjustments in Section 1395ww(d)(3)(E) to the hospital wage index adjustment, such as a budget neutrality adjustment, an adjustment to fix the wage-related portion at 62%, and a floor for frontier hospitals. CMS has acted consistently with Congress' directives in the past, and has calculated the wage index based on actual wage data, subject only to those modifications specifically permitted by Congress. Congress has not authorized the wage compression adjustment.

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.

Moreover, CMS has instituted a process — the Wage Index Development Timetable — with detailed instructions for the sole purpose of ensuring that CMS has accurate wage index data from all IPPS hospitals. 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 the data reported on Worksheet S-3 of the Medicare cost report are 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 now proposing a policy that would use the wage data in a manner to rank the various hospitals so that the data of 25% of hospitals will be inaccurately and artificially pushed downwards to allow the data of a different 25% of hospitals to be inaccurately and artificially pushed upwards. Nothing in the statute suggests that Congress authorized CMS to institute a policy whereby half of the hospitals would receive wage index values that did not accurately match their actual values.⁶ Thus, CMS' proposal is beyond the authority granted by Congress, and CMS cannot lawfully institute this wage compression policy under 1395ww(d)(3)(E).

(ii) **CMS' proposed action is *ultra vires***

Section 1395ww(d)(3)(E) has three clauses. The first has been discussed above and concerns the agency's authority to adjust the proportion of hospitals' costs that are attributable to wages and wage-related costs by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage index. The second clause establishes an alternative proportion to the one set forth in the first clause. The third clause sets forth, in significant detail, a floor on area wage index for hospitals in frontier states. These are the only two exceptions to the first clause of Section 1395ww(d)(3)(E).

Congress writes rules as well as exceptions. In Section 1395ww(d)(3)(E), Congress did both, establishing the basic rule in clause (i), and exceptions in clauses (ii) and (iii). These are the only exceptions that Congress has made. Congress never made any type of special exception

⁶ CHA wonders if there will be unintended consequences of a policy that punishes providers for accurate data, such that providers are incentivized to under- or over-report their data to limit the cut to their AWI or to increase the benefit to themselves under the policy. If implemented, this flawed policy could fundamentally undo the process that CMS has developed and implemented over a number of years to limit MAC variation in desk reviews and improve the accuracy of provider reporting.

to the first clause that would allow CMS to institute the wage compression policy. Moreover, Congress did not give CMS the authority to do so. As such, the CMS-proposed action is *ultra vires*. The agency could not institute this proposal in conformance with Section 1395ww(d)(3)(E). Moreover, if Congress wanted to change the wage index in the manner proposed by CMS, it could have. Thus, CMS does not have authority under Section 1395ww(d)(3)(E) to establish the proposed wage compression policy.

2. **Authority under 42 U.S.C. § 1395ww(d)(5)(I)**

CMS states that it can make this change under the exceptions and adjustments authority in 42 U.S.C. § 1395ww(d)(5)(I) (“Section 1395ww(d)(5)(I)”), which 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.” However, (1) this catchall cannot be used in a manner that vitiates the language and purpose of the rest of the statute, including 1395ww(d)(5)(A)-(H), as there must be limits to the authority granted to CMS under this catchall; (2) CMS is not acting by regulation, and, therefore, is not following 1395ww(d)(5)(I); and (3) if CMS does have the authority to make this change, this special authority is not required to be done in a budget neutral manner, as is clear from the statute where (d)(5)(I)(ii) references budget neutrality, but (d)(5)(I)(i) does not, and as is clear from relevant case law.

(i) **The catchall exceptions and adjustments authority cannot be read to vitiate the rest of the IPPS statute**

The IPPS payment system is an extraordinarily detailed framework with very specific subsections and paragraphs identifying how the complicated reimbursement methodology is to work. Section 1395ww(d)(3)(E) sets forth the development of a wage index to accurately reflect and account for labor differences across the nation. Section 1395ww(d)(5) sets forth various exceptions to the reimbursement rates prescribed under the IPPS. These 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). Then Section 1395ww(d)(5)(I) sets forth a catchall provision whereby CMS has general authority to “provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.”

This catchall provision must be read in context and cannot be given such broad authority to wipe away all of 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 does not match the reimbursement methodology designed by Congress. CHA does not believe the exception can mean that CMS can do anything that CMS deems appropriate to implement whatever policy CMS wishes to advance, and this is especially the case where the wage index statute is specific as to how the wage index is supposed to work.⁷

Moreover, read in context, the provision follows a list of exceptions and adjustments and then precedes a clause which would be rendered completely superfluous if the catchall provision was given the breadth of authority that CMS requires to effectuate the wage compression policy. 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 exception 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.

Further, Section 1395ww(d)(5)(I) has two clauses. The first sets out the adjustment and exception 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 into 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

⁷ Otherwise, if the only limit of Section 1395ww(d)(5)(I) was whatever CMS deems to be appropriate, it could change the IPPS reimbursement system to a per diem system, for example, or could even change the IPPS reimbursement system such that all states that start with the letter “C” could get a 10% payment reduction. This cannot be the breadth of authority delegated to CMS by Congress, given the text of the provisions of Section 1395ww(d).

otherwise been made in such fiscal year.” If CMS were to interpret the adjustments and exceptions catchall provision as broadly as it is trying to do in the FFY 2020 IPPS proposed rule, then the second clause would be irrelevant, and 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 authorized CMS the sort of broad authority sought here to institute this wage compression policy.

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 a rule designed to further a policy of its own making, to supposedly provide additional funding to low wage hospitals to incentivize them to increase wages.

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 so as to provide funding to hospitals in certain areas in the hope that they increase employee wages. Further, where Congress has wanted to increase the wage 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 exception 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 at the expense of hospitals in high wage areas, CMS should work with Congress to seek its authority, and not make unilateral changes inconsistent with previous Congressional action as it proposes to do here.**

CMS cannot claim to have unfettered authority, only limited 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 Congress’ statute. Therefore, the catchall provision cannot be read to grant CMS authority to implement its wage compression policy.

(ii) **The Secretary is not acting by regulation**

Even if the catchall provision could be read to provide for such broad authority to institute the wage compression policy, CMS has not followed the statute. The statute states that the Secretary “shall provide by regulation” for exceptions or adjustments, but CMS has not proposed or adopted a regulation to implement the wage compression proposal and, therefore, does not have the authority to implement the wage compression policy (42 U.S.C. 1395ww(d)(5)(I)(i)).

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 wage compression policy in the preamble to the proposed rule is not a regulation, as the proposed rule does not contain a provision embodying the wage compression policy that it proposes to add 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 point between regulations and general statements of policy is publication in the Code of Federal Regulations”).

(iii) **Special exception authority allows for a non-budget-neutral change**

Last, even if CMS had the authority to use the catchall provision in the manner it claims, and even if CMS acted by regulation, Section 1395ww(d)(5)(I)(i) does not require budget neutrality. See *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2018 U.S. Dist. LEXIS 217391 (Dec. 28, 2018) (“In certain areas, the Medicare Act does require budget neutrality. See, e.g., (42 U.S.C. §§ 1395ww(d)(8)(D) (geographic reclassifications); 1395ww(d)(4)(C)(iii); 1395l(t)(2)(E). [Section 1395ww(d)(5)(I)(i)], however, is not one of them.”). Accordingly, there is no legal requirement that the exception and adjustment authority be applied in a manner so as to reduce the wage indexes of the hospitals in the top quartile.

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 those in the highest quartile. The disparities in average hourly wages paid across the country, reported as part of the audited cost report 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 MedPAC, the Institute of Medicine and CMS, hospitals in the highest quartile are required to pay higher wages in order to obtain qualified employees, as this reflects 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	\$106,950	\$71,805	\$549,000
NY	\$85,610	\$64,894	\$429,000
NJ	\$82,750	\$80,088	\$339,000
AL	\$59,470	\$48,123	\$219,900
MS	\$58,490	\$43,529	\$186,000
TN	\$61,320	\$51,340	\$255,000

1. Source: Bureau of Labor Statistics, Occupational Employment Statistics, May 2018 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates 2. Source: US Census Bureau Household Income: 2017 American Community Survey Briefs 3. Source: Zillow.com Home Prices & Values. Data as of April 30, 2019

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

Further, even if it is a worthwhile policy goal to increase the wage index for hospitals in the lowest quartile to provide an incentive to increase wages, and even if those wages in fact are increased, such an increase would have absolutely no effect on the labor costs that must be incurred by the hospitals in the highest quartile. Again, those wages are the result of the local labor market.

CMS claims budget neutrality is best here for two reasons, but neither withstand scrutiny. First, CMS says that negatively impacting the highest quartile increases the impact on the wage index disparities. While true, this misses the point. The disparities are not the problem; wage-related costs are real and due to market conditions. As such, this is not a legitimate basis for budget neutrality. While we appreciate that CMS wishes to address the financial challenges of our nation's rural hospitals, CMS has proposed a broad policy to help not only rural, but all hospitals in the lowest quartile. **CHA agrees that helping rural hospitals is a laudable goal. Doing so in a permissible manner is an effort we would**

support. But nearly 60% of the funding will flow from California’s hospitals, including rural California hospitals, and wage compression would disproportionately harm all hospitals in the top quartile.

Because the wage index is calculated on a budget neutral basis nationally, the IPPS payments for low wage hospitals are depressed in a manner that does not fully recognize their labor costs, and provides insufficient funding for such hospitals to elect to increase their wages and meet other operational needs. This is a significant contributor to the financial difficulties faced by many rural hospitals. **However, this policy does nothing to minimize disparities. Instead, it creates greater disparities and fundamentally fails to recognize the legitimate differences in geographic labor markets.**

Second, CMS says that hospitals in the middle will not have their values affected by this proposed policy, but this is incorrect. Because CMS has proposed to apply a budget neutrality adjustment to the standardized amount to pay for the proposed stop-loss transition for hospitals that could be negatively impacted by the wage compression policy, hospitals in the middle two quartiles will be negatively impacted by this proposal.

In summary, there are no bases for implementing this policy in a budget-neutral manner, and the provision on which CMS relies, Section 1395ww(d)(5)(I), does not require budget neutrality. To do so would irrationally penalize hospitals simply because they are in areas with higher wage rates, and would result in the Medicare program failing to pay its fair share of costs necessarily incurred to provide covered services to Medicare patients.

II. [CMS’ Exclusion Of Hospitals Within A Specific Hospital System From The Wage Area Data Is Legally Impermissible \(Section III.C - Verification Of Worksheet S-3 Wage Data Comment\)](#)

As part of the FFY 2020 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.” (84 Fed. Reg. at 19375.) CMS excluded 81 providers with “aberrant” data and, most notably, excluded eight (now seven) hospitals that are all part of the same health system. CMS claims this is due to the current private business practice whereby, according to CMS, the health system in recent years negotiated its labor contracts with unions on a regional basis in California and that, as a result, the salaries within each region “are the same regardless of prevailing labor market conditions in the area in which the hospital is located.”

CMS states that it proposes to exclude the seven hospitals because it does not believe the average hourly wages of the hospitals accurately reflect the economic conditions in their respective labor market areas (e.g., the core-based statistical areas (CBSAs)). Additionally, CMS asserts that inclusion of these data would distort the comparison of the average hourly wage of each of these hospitals’ labor market areas to the national average hourly wage.

CMS argues that, under section 1886(d)(3)(E) of the Social Security Act (42 U.S.C. § 1395ww(d)(3)(E) (“Section 1395ww(d)(3)(E)”)— the statute that requires the Secretary to establish a wage index reflecting the relative hospital wage level in the geographic area of a hospital compared to the national

average hospital wage level —it has the discretion to remove from the wage index hospital data that do not reflect the relative hospital wage level in the hospital’s geographic area. Although CMS does not say it overtly, it alludes that the seven hospitals’ wage data are high compared to their labor market areas. Most concerning, CMS says it is considering removing all 38 hospitals that are part of the health system from the wage index calculations in FFY 2021, “not because they are failing edits due to inaccuracy, but because of the uniqueness of this chain of hospitals, in particular, the fact that the salaries of their employees are not based on local labor market rates.” 84 Fed. Reg. at 19376.

As discussed below, the exclusion of the seven hospitals would be unlawful for at least five critical reasons:

- 1. 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, or because the hospitals are part of a system that negotiates regional or statewide labor contracts. 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.**
- 2. Even if CMS had authority to exclude certain hospitals even though their data were accurate and verifiable (as is the case with the seven hospitals), the exclusion of the seven 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 — yet, where it does not like the result, it has decided to deviate from this process by excluding hospitals with accurate data.**
- 3. CMS’ exclusion of the seven hospitals is procedurally improper, as CMS has failed to promulgate a rule in accordance with the APA that would authorize the exclusion of hospitals with aberrant data or to set forth the standards to be applied in determining whether data are aberrant.**
- 4. 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.**
- 5. CMS’ basis for excluding the health system hospitals is inconsistent with federal labor law because it interferes with collective bargaining.**

Moreover, CMS’ threat to exclude all seven hospitals in FFY 2021 is completely untethered from the relevant statute and is unsupportable. Further, the proposed exclusions for FFY 2020 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. These consequences 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 as 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 ground that the hospital has high labor costs, is part of an organization that contracts with unions on a regional basis, or is part of a “unique” health care delivery system**

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 on the grounds offered by CMS for excluding the seven hospitals, 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, wages paid by hospitals that are part of a health care system that the Secretary alleges has labor contracts in place with unions requiring uniform wages on a regional basis, or wages paid by hospitals because they are part of what CMS calls a “unique” health care delivery system. 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 seven hospitals proposed for exclusion are in the geographic area of the CBSAs in which they are located. Excluding these facilities, therefore, will necessarily not reflect the relative wage level of hospitals in those CBSAs.

CMS does not have the discretion to ignore the wages paid by the seven hospitals.⁸ CMS’ proposal to do so would violate Section 1395ww(d)(3)(E) and be unlawful. CHA does not take issue with CMS’ exclusion of hospitals 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 that 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. CMS does not dispute whether the seven hospitals’ wage data are accurate and supported.⁹

2. The exclusion of the seven 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 seven 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 — or the opposite, too low — to be included in the wage index determination. Further, the agency has provided no standard or definition that would support excluding a hospital because CMS understood it was part of a system that had collective bargaining agreements establishing wages on a regional basis or that the hospital was part of

⁸ CMS appears to have understood and interpreted Section 1395ww(d)(3)(E), as long ago as 1994, to require that the data from all hospitals in operation be 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.”).

⁹ Moreover, CMS’ basis for ignoring the actual wages paid by the seven hospitals appears to stem, at least in part, from CMS’ antipathy for the terms of the privately negotiated collective bargaining agreements between the health system and various labor unions. This is highly troublesome if it portends that CMS will ignore other privately negotiated business and contracting arrangements and interfere in multiple aspects of our health care delivery system, so that it would appear this administration is seeking to use its perceived authority to more uniformly bring our health care system under greater government control.

what CMS labels a “unique” health care delivery system. CMS defines neither 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, what types of collective bargaining agreements will be acceptable, and what health care systems will be deemed to be “unique” so as to exclude their 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.

Moreover, CMS’ actions here demonstrate that it is acting without standards. CMS stated in the proposed rule that eight hospitals in the health system would be excluded and that all 38 hospitals in the health system might be excluded next year. However, without explanation, CMS included the wage data for one of the eight hospitals, as of the April 30, 2019, public use file. This unexplained change in approach is exactly the problem, and demonstrates that CMS is engaging impermissibly in arbitrary and capricious decision making in abuse of its discretion.

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 seven 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*, No. 17-1484 (U.S. Supreme Court June 3, 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 rather stating 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, or because the hospital is part of a system that negotiates collective bargaining agreements on a regional basis, or because a health system is “unique,” 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.¹⁰ (See 42 U.S.C.

¹⁰ 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

§1395hh.¹¹) 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. The agency seems to simply not like the result and, therefore, is seeking to exclude the hospital system's data in a manner that ignores proper process under the APA and Medicare Act.

4. The exclusion of the health system facilities 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 not proposed any ascertainable standards, the public has no meaningful opportunity to comment on the factors that should be considered.

The factors CMS has indicated it has considered — higher wages than other hospitals in the CBSA, regional contracting with labor unions, and some undefined unique nature of the health care delivery system of which the hospital is a part — in proposing to exclude the health system facilities are not factors identified in the applicable statute, Section 1395ww(d)(3)(E). Because CMS has considered and relied on factors not provided for in the statute, its action to exclude the seven hospitals is arbitrary and capricious.

5. CMS' basis for excluding the health system hospitals is inconsistent with federal labor law because it interferes with collective bargaining

Congress enacted the National Labor Relations Act (NLRA) in 1935 to protect the rights of employees and employers, to encourage collective bargaining, and to curtail certain private sector labor and management practices that can harm the general welfare of workers, businesses, and the U.S. economy. Section 1 of the NLRA highlights the policies of the NLRA and how "[e]xperience has proved that protection by law of the right of employees to organize and bargain collectively safeguards commerce from injury, impairment, or interruption, and promotes the flow of commerce by removing certain recognized sources of industrial strife and unrest, by encouraging practices fundamental to the friendly adjustment of industrial disputes arising out of differences as to wages, hours, or other working conditions, and by restoring equality of bargaining power between employers and employees."

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.

¹¹ The criteria used by CMS to exclude the seven 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, or providing any standards for excluding hospitals. 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 seven hospitals (if there are any) as an interpretative rule, notice-and-comment rulemaking would be required before applying the criteria.

Now, CMS has proposed the exclusion of seven hospitals in FFY 2020 (and threatened the possible exclusion of all 38 hospitals in FFY 2021), because it asserts that since the health system collectively bargains with unions, its negotiated salaries do not reflect local labor market salaries. CMS appears to be interfering with collective bargaining and ignoring more than eight decades of established labor law principles. By singling out a health system due to its collective bargaining practices, CMS is threatening hospitals that collectively bargain as allowed for under the NLRA.

In addition, the proposed rule indicates that CMS is considering removing all 38 of the health system’s hospitals from the wage index data beginning in FFY 2021. CHA understands that the agency would have to include this proposal in the notice of proposed rulemaking for FFY 2021 to afford the health system, and other interested members of the public a meaningful opportunity to comment. In the event CMS brings forth this ill-conceived proposal, CHA intends to provide comprehensive comments at that time. Without waiving our ability to submit further comments in response to a future notice of proposed rulemaking, we do note that we are strongly opposed to such an exclusion for the reasons discussed above in connection with the proposal to exclude a select number of the health system’s hospitals for FFY 2020. We have seen neither any proffered standards, data,-nor rationale for excluding all of the hospitals to date, and the exclusion of all the hospitals in the absence of properly adopted and lawful standards that are correctly applied would be invalid.

6. The impact of excluding the health system is far greater than hospital inpatient payments; Medicare beneficiary access is threatened

CMS’ actions have far-reaching consequences not contemplated in the FFY 2020 IPPS proposed rule. If implemented, this proposal will most certainly have devastating financial implications not only for the seven 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, LTCHs, and inpatient psychiatric facilities (IPFs) and units.

CHA estimates the exclusion of the seven hospitals in FFY 2020 will have an estimated range of impact on the unadjusted area wage index from negative 3% to negative 10%, as follows:

CBSA #	CBSA Name	Unadjusted AWI WITHOUT Health System (Proposed)	Unadjusted AWI WITH Health System	Impact %
11244	Anaheim-Santa Ana-Irvine, CA	1.1953	1.2338	-3.22%
23420	Fresno, CA	1.0662	1.1477	-7.64%
40140	Riverside-San Bernardino-Ontario, CA	1.1313	1.1903	-5.22%
41740	San Diego-Carlsbad, CA	1.1982	1.2256	-2.29%
44700	Stockton-Lodi, CA	1.3639	1.5012	-10.07%

CMS proposed to utilize the FFY 2020 unadjusted wage index in the FFY 2020 IRF and IPF proposed rules to be further aligned with the SNF PPS. This is a change from previous years, when the unadjusted AWI lagged by a year. 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 devastating to

many — most notably, to hospital-based post-acute care providers that care for the most medically complex patients.

In the following table, CHA estimates the FFY 2020 financial impacts attributable to the changes in the area wage index for our member hospital-based and free-standing LTCHs, IPFs, IRFs, and SNFs, as well as their units.

Provider Type	Number of CHA Member Facilities and Units	Estimated FFY 2020 Wage Index Financial Impact Attributable to the CBSAs Where Health System Hospitals are Excluded*
Skilled-Nursing Facilities (e.g. distinct part)	15	-\$595,551
Inpatient Rehabilitation Facilities (and units)	18	-\$2,679,300
Inpatient Psychiatric Facilities (and units)	29	-\$3,082,363
Long-Term Acute Care Hospitals	6	-\$4,721,500

Source: CHA DataSuite, June 2018.

MedPAC has acknowledged the continued decreasing Medicare margins of hospital-based post-acute care providers and has made several recommendations to address the inequities and to ensure that the payment incentives are aligned and access remains available to even the most clinically complex patients. CMS has recently made significant changes to the SNF PPS to address this concern explicitly. Those changes take effect on October 1, 2019, with the implementation of the new PDPM model. Further, CMS has made significant changes to the IRF PPS, which will shift dollars across the case-mix system. Finally, CMS this year proposed to rebase the IPF PPS.

The changes proposed and scheduled for implementation in the post-acute care PPS systems are significant. Additional changes resulting from the health system hospital exclusions from the area wage index calculation are untenable and must be rectified by reversing the exclusion of seven hospitals in both the IPPS adjusted and unadjusted area wage index.

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.

CMS has also failed to consider the downstream impact on Medicare Advantage rates paid to health plans and providers that may currently contract based on the Medicare fee schedules. CMS adjusts Medicare Advantage payments based on a five-year rolling average. For 2020 rates, CMS will re-price the historical inpatient, hospital outpatient, SNF, and home health claims from 2013–17 to reflect the

most current (i.e., FFY 2019) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2019) Geographic Practice Cost Indices. As of May 2019, 2.74 million beneficiaries in California (41.2% take-up rate) relied on Medicare Advantage as their form of coverage. CHA remains concerned that these exclusions will have significant implications for rates moving forward.

The mere mention of exclusion of all 38 health system hospitals (31 in California) will have untold consequences the agency appears not to have contemplated. The ripple effects of such an arbitrary and capricious policy are devastating and jeopardize access to care for Medicare beneficiaries across California. We urge the agency to withdraw this exclusion and reinstate all health system hospital data for the purposes of the FFY 2020 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 seven hospitals may not lawfully be implemented.

Medicare DSH

Beginning with federal fiscal year (FFY) 2014, CMS was required by statute to split Medicare DSH payments into two separate payments: 1) empirically justified payments equal to 25% of the traditional DSH formula; and 2) an aggregate dollar pool of uncompensated care based on 75% of DSH and reduced for decreases in the uninsured population since FFY 2013. The uncompensated care pool is allocated based on each hospital's share of national uncompensated care costs.

Worksheet S-10 of the Medicare cost report is used to record charges and costs for uncompensated care. However, concerns arose over both how data were reported on Worksheet S-10 as a result of its limited prior use and a lack of clarity in the reporting instructions. Therefore, CMS previously adopted the use of low-income patient days from before FFY 2014 as a proxy for uncompensated care from FFY 2014 through FFY 2017. CMS has been unwilling to continue using low-income patient days as a proxy from data years after FFY 2014 because of Medicaid expansion that has occurred in some — but not all — states. CMS began transitioning from use of proxy data to Worksheet S-10 beginning with FFY 2018.

For FFY 2018, CMS used two years of low-income patient days (Medicaid days from FFY 2012 and FFY 2013) and one year of Worksheet S-10 data (FFY 2014) to distribute uncompensated care payments. For FFY 2019, CMS is using one year of low-income patient days (Medicaid days from FFY 2013 and two years of Worksheet S-10 data, FFYs 2014 and 2015). Other than some adjustments for extreme values (high cost-to-charge ratios and high charity care costs as a percent of total costs), CMS had not reviewed or audited the data before using them in the distribution. In a departure from previous years of using multiple sources of data over time, for FFY 2020, CMS proposes to use only one year of FFY 2015 Worksheet S-10 data in the uncompensated care distribution, but requests comments on whether it should use FFY 2017 data in the final rule.

In August 2018, CMS instructed the Medicare administrative contractors (MACs) to review 600 hospitals, or approximately 25% of the hospitals eligible to receive uncompensated care payments. CMS notes that these reviews represent approximately half of the uncompensated care pool dollars. It is our understanding that the vast majority of reviews were completed by January 31, 2019.

It is important to note that the pool of uncompensated care payments is a fixed amount distributed to each hospital based on its own share of national uncompensated care costs. Reducing a hospital's

uncompensated care costs does not result in any savings to Medicare — it only reduces that hospital's share of national payments, thereby increasing the share for all other eligible hospitals. **We applaud the agency for taking this first step in the review process, as stakeholders requested. As anticipated — in even this short window — CMS, its subcontractors, MACs, and providers have uncovered a number of remaining challenges that must be addressed.**

We strongly believe that data that have never been reviewed will only improve with greater scrutiny. However, in this early stage of review, including the reported challenges of the initial desk reviews discussed under separate cover, we believe it would be inequitable to distribute a limited and fixed pool of uncompensated care payments based on one year of cost report data. **Rather, we ask the agency to consider blending FFY 2019 uncompensated care payments with payments calculated using one year of the FFY 2017 for FFY 2020, and reevaluate the reliability and validity of the data on a yearly basis to determine next steps.**

[CMS Should Strongly Consider FFY 2017 \(instead of FFY 2015\) Cost Reports for Distribution of FFY 2020 Uncompensated Care Payments; Mitigate Volatility Going Forward Using a Blend](#)

Subject to our recommendation for averaging the data across multiple years described in the next section, CHA recommends that CMS move to using FFY 2017 Worksheet S-10 in the uncompensated care distribution for FFY 2020. For FFY 2020, CMS proposes to use only FFY 2015 data in the uncompensated care distribution but requests comments on whether it should use FFY 2017 data in the final rule. The proposed rule indicates that:

hospitals contend that there are issues regarding the instructions in effect for FY 2015, especially compared to the reporting instructions that were effective for cost reporting periods beginning on or after October 1, 2016, and some of these adjustments would not have been made if CMS had chosen as an alternative to audit the FY 2017 reports. (84 FR 19419)

This language is referencing Transmittal 11 dated September 29, 2017, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added edits to ensure the integrity of the data reported on Worksheet S-10. Transmittal 11 further clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy may be included on Line 20, Column 1 of Worksheet S-10.

Transmittal 11 also modified the application of the cost-to-charge ratio (CCR). The CCR is no longer being applied to deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. It will still be applied to the charges for uninsured patients approved for charity care or uninsured discounts, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs.

As noted in our January 31, 2019, letter to CMS, the above changes were effective for cost reporting periods beginning on or after October 1, 2013. However, the instruction is dated September 29, 2017, after submission of many FFY 2015 cost reports. As these changes to cost report instructions were effective retroactively to October 1, 2013, it is reasonable to believe that reporting consistent with the revised instructions is likely to be better prospectively than it was for cost reporting periods either in

progress or already closed and submitted (e.g., many cost reporting periods beginning on or after October 1, 2016).

Further, CHA analysis completed by Toyon & Associates shows marked improvements in the FFY 2017 data. A review of HCRIS data from March 2019 shows there are fewer hospitals (449 DSH hospitals) reporting coinsurance and deductible amounts greater than 25% of total charity charges, as compared to FFY 2015 (520 hospitals). Some of the 449 hospitals received letters from CMS with instructions to verify or correct “aberrant data” by March 24, 2019, meaning that the actual number of hospitals reporting amounts greater than 25% could be even lower. Over-reporting uncompensated care is expected to be less frequent when using amended FFY 2017 data as compared to FFY 2015 S-10 data, especially when the combined findings are considered. Further, many hospitals took action in early 2019 to amend their FFY 2017 cost reports to address this and other issues. We are grateful for the MACs' cooperation in accepting those changes in a timely manner; we believe these changes will be reflected in the updated HCRIS files used for the final rule.

Lastly, hospitals have clearly stated that the instructions for reporting uncompensated care cost under FFY 2017 instructions are easier to follow than the instructions in place during FFY 2015. Not only are hospital personnel more readily able to access reports by write-off amounts and write-off date, but the 2017 instructions have significantly less complex steps. For instance, using FFY 2015 instructions, hospital personnel must take additional and administratively burdensome steps to ensure they do not duplicate charity care and bad debt amounts, because charity care is reported under total hospital charges. This issue is less prevalent under FFY 2017 instructions, as these amounts are reported by separate and individual write-off amounts, which reduces the chance of inadvertent duplication.

While there is significant room for improvement, we believe this is a reasonable argument for using one year of the FFY 2017 cost report calculated payments blended with FFY 2019 payments, rather than FFY 2015 cost reports alone. We detail this proposal below.

CMS made another significant change related to how charges were reported on line 20 of Worksheet S-10, effective only for cost reporting periods beginning on or after October 1, 2016 (e.g., for FFY 2017 and later cost reporting periods). For cost reporting periods beginning prior to FFY 2017, the instructions required hospitals to report **full charges** for patients eligible for a hospital's charity care policy or financial assistance policy. For cost reporting periods beginning in FFY 2017 and later, hospitals are only to report **charges written off** to charity care on line 20.

This distinction led to the issue described briefly above, where hospitals could potentially receive no credit for charity care or financial assistance despite having discounted charges by tens of millions of dollars. The issue arises because hospital charges on line 20 for pre-FFY 2017 cost reporting periods are discounted by the hospital's CCR on line 21 before subtracting undiscounted charges that remain due from the patient. CMS instructed the MACs to subtract the actual amounts due, referring to these as the “expected” payment from the patient even though hospitals are ordinarily unable to collect these amounts. Subtracting undiscounted charges due from discounted full charges could lead to zero or negative charity care.¹²

¹² CMS' concern is the potential for the charges that remain due to be reported as bad debt and also be credited to charity care. While CMS' concern is valid, the solution should be to ensure the unpaid charges are not counted as bad debt as well as included in charity care charges. Removing them from charity care as originally instructed results in comingling of charges due with discounted charges and leads to the problem of negative charity care.

This issue affects the FFY 2015 hospital cost reports that CMS proposes to use for the FFY 2020 uncompensated care distribution, but not the FFY 2017 and subsequent cost reporting periods because only written off charges are included on line 20. Line 21 is used only to report actual payments for charges written off to charity care or the hospital's financial assistance policy (amounts expected to be zero, as patients are unlikely to pay charges that they no longer owe the hospital). We refer to this as the "expected/actual" issue, as the concern is whether to report charges that remain due after discounts (what CMS referred to as "expected" payments on line 20 in its initial instructions to deduct amounts due from full charges) or the "actual" payments received from the patient toward a bill where the patient is eligible for charity care. **We are pleased that CMS reversed some of the most challenging adjustments related to this issue after the HCRIS files were submitted. We remain concerned that the FFY 2015 data do not reflect those adjustments. This presented a challenge in providing fully informed comments on CMS' proposal.**

While the challenges with the FFY 2015 data are significant, we believe using the FFY 2017 data is a viable option for two reasons in particular: 1) FFY 2017 cost reports will better reflect changes to the cost report instructions that CMS released on September 29, 2017; and 2) FFY 2017 and future year cost reports will not have the "expected/actual" issue. **With that said, it remains difficult to make informed policy decisions due to the unpredictability of reporting in any given year, as variation in audit protocols and implementation of those protocols by the MACs and their subcontractors continues. In addition, providers report that, even after the audits, they remain confused as to the rationale for adjustments other than those noted above.**

Therefore, rather than focusing on less-than-perfect data that we believe will improve over time, we suggest CMS undertake a more strategic long-term approach to achieve its payment policy goal of providing stability in Medicare DSH payments to hospitals. More specifically, CHA believes that because the agency is currently beginning its reviews of the FFY 2017 data, the most desirable option for this year is using unaudited Worksheet S-10 from FFY 2017 for one year only, with a commitment to continued use of multiple years of Worksheet S-10 data to moderate the year-to-year impacts. To achieve this goal, for FFY 2020, CHA recommends blending the current FFY 2019 distribution of uncompensated care payments, with a weight of two-thirds, with an uncompensated care distribution based on FFY 2017 Worksheets S-10, with a weight of one-third. Using blended data as we recommend will improve stability in the allocation of uncompensated care payments while allowing CMS to continue moving toward the full use of audited Worksheet S-10 data in the uncompensated care payment distribution.

While we believe the FFY 2015 HCRIS data have some significant limitations, in California, using a single year of FFY 2015 Worksheet S-10 to distribute uncompensated care payments results in an aggregate payment loss in excess of \$184 million in FFY 2020. Six states would see aggregate losses of uncompensated care payments exceeding 25%. While California hospitals in the aggregate would fare better using FFY 2017 data to distribute uncompensated care payments — the \$184 million loss would be reduced to \$162 million — eight states would still see aggregate losses of uncompensated care payments exceeding 25%. It is difficult to determine whether these numbers are correct.

Regardless, these types of payment losses year over year are untenable and should be avoided. The volatility is devastating to hospitals and, for some, it pushes them further into the red. Using CHA's recommended blending approach for FFY 2020 would substantially mitigate payment swings relative

to using one year of data. According to our analysis using CMS' published data, for California hospitals, the aggregate loss would decline from 22.9% to 4.7% (26% to 6% based on FFY 2015 data). Under the blending methodology, only one state would see more than a 10% loss in the next fiscal year when using FFY 2017 Worksheet S-10 data as the 1/3 component, and no states would see a decline in uncompensated care payments of more than 10% based on the FFY 2015 data. Payment gains in FFY 2020 would also be less: only two states would see a gain in excess of 25% under our proposed method.

Our recommended approach would allow CMS to eventually use fully audited Worksheet S-10 data going forward before introducing a new year of data into the uncompensated care distribution. For FFY 2021, CMS could choose to blend one-third of 2019 uncompensated care payments with two-thirds of the uncompensated care payment a hospital would receive based on the average of its FFY 2017 audited cost report. CMS may, however, also consider factoring in FFY 2018 data for FFY 2021, but this would require CMS to implement its audits on a more expedited timeline. We believe this is doable if process improvements are undertaken as soon as possible.

Once the uncompensated care distribution reflects a three-year average, it would roll forward each year, dropping the oldest year and including the newest year until year-to-year changes in uncompensated care payment stabilize. At that time, CMS could consider whether the allocation is sufficiently stable to revert to using one year of data.

CHA and other public commenters have suggested CMS develop a process similar to its desk reviews of Worksheet S-3, which is used for the hospital wage index for Worksheet S-10 and the distribution of uncompensated care payments. Under that process, there is a four-year lag between the year in which the data is reported (e.g., FFY 2016) and the year in which the data are used for payment (e.g., FFY 2020). This lag period allows sufficient time for all hospital cost reporting periods for the fiscal year to be submitted to CMS, updated and corrected after being released by CMS as public use files, desk reviewed by the MACs, and for unresolved issues between the MAC and the hospital to be appealed to CMS.

If CMS were to follow a similar process for Worksheet S-10 and the distribution of uncompensated care payments, CMS would first use **audited** FFY 2017 data for distributing FFY 2021 uncompensated care payments. (It would use **unaudited** FFY 2017 data for distributing FFY 2020 uncompensated care payments in combination with FFY 2019 uncompensated care payments.) Incorporating CHA's recommendation to use a three-year average, CMS could then introduce audited FFY 2017 and FFY 2018 Worksheet S-10 data into the FFY 2021 uncompensated care distribution, while phasing out use of the prior year's uncompensated care payments. By FFY 2023, CMS could be fully using FFY 2017, FFY 2018, and FFY 2019 audited data. For each subsequent year, CMS would drop the oldest year and include the newest year in the distribution.

CMS may question whether it is possible to adopt our recommended policy in the final rule without having first proposed it. CHA believes the recommended policy would meet the requirements for being a "logical outgrowth" of CMS' proposed policy and, therefore, permissible to include as its final rule policy in the FFY 2020 IPPS final rule. Section 1871 and the Administrative Procedures Act both recognize that changes may be made to a proposed rule based on public comments and, as long as those changes could have been reasonably anticipated by the public (i.e., the changes are a logical outgrowth to policies in the proposed rule), the agency may finalize them in accordance with those statutes. As noted above, CMS proposed use of FFY 2015 Worksheet S-10 data for the FFY 2020

uncompensated care distribution but requested public comments on a single alternative to its proposal — use of FFY 2017 data. While CMS proposed one policy and requested public comments on an alternative, it is not uncommon that the public comment process would yield suggestions for related policies that CMS did not describe in the proposed rule.

The FFY 2006 IPPS final rule published on August 12, 2005, (70 FR 47289) provides an example where CMS adopted final rule policy in response to a public comment that was not proposed but appears to be a logical outgrowth of information provided in the proposed rule. In response to one public comment, CMS deleted DRGs 107, 109, 111, 116, 478, 516, 517, 526 and 527 and created new DRGs 547 through 558 in their place. CMS did not explicitly propose or solicit comments on this policy option. The only evidence that this final rule policy is related to anything included in the proposed rule can be found in the May 4, 2005, IPPS proposed rule where CMS reviewed Medicare Payment Advisory Commission recommendations on physician-owned specialty hospitals. CMS stated it was considering “a selective review of the specific DRGs, such as cardiac, orthopedic, and surgical DRGs, that are alleged to be overpaid and that create incentives for physicians to form specialty hospitals.” (70 FR 23454) The changes to the DRGs in 2005 resulted in changes in payment, including decreases in a number of DRGs providing hospitals with a material interest in the outcome.

In this case, CMS made significant revisions to a large group of high-volume MS-DRGs in response to a public comment based on a statement it was “considering a selective review of specific DRGs.” The public was not notified as to which specific DRGs would be changed and how they would be changed, or informed of the impact of those changes — yet CMS apparently considered its final rule policy a logical outgrowth of its proposed rule. For the FFY 2020 uncompensated care payment distribution, CMS requested comments on two alternatives (using either FFY 2015 or FFY 2017 Worksheet S-10 data) to distribute FFY 2020 uncompensated care payments, but that does not preclude either the public from making comments or CMS from adopting other options related to the two alternatives proposed. If the revisions to the DRGs described above constitute a logical outgrowth of the proposed rule, CHA’s suggested final rule policy certainly would be as well, given that the policy we recommend CMS adopt is closely linked to policies CMS either solicited public comments on or proposed.

Further, it seems reasonable that public suggestions for additional alternatives would be considered a logical outgrowth of CMS’ proposal, as CMS proposes to move from averaging three years of data to one year of data, making the distribution of uncompensated care payments inherently more unstable. Stability of uncompensated care payments was among the reasons CMS decided to use three years of data in the distribution to begin with. As CMS states:

We recognize that, in FY 2019, we used 3 years of data in the calculation of Factor 3 in order to smooth over anomalies between cost reporting periods and to mitigate undue fluctuations in the amount of uncompensated care payments from year to year. (84 FR 19419)

CMS is making a major policy change by moving from three years of data to one year of data and abandoning stability in year-to-year payments — a prior principle upon which CMS established policy. Given that using one year of data in place of three years would be a policy change, it is certainly reasonable for the public to comment that CMS should continue to further stability in the year-to-year change in payments by using an average of multiple years of data to allocate uncompensated care payments. CHA also notes that the decision between FFY 2015 and FFY 2017 will have a directional impact on payments — our suggestion to blend these data would only moderate those impacts.

For all of these reasons, we believe CMS has the authority to adopt in the final rule the policy we are suggesting as a logical outgrowth of public comments on the proposed rule.

While we recognize that CMS needs time to ramp up its audit protocols, as previously stated, CHA believes that **all** hospitals should be audited using the same audit protocols and that auditor education is paramount. As a fixed amount is available for uncompensated care, CHA does not believe it is equitable to subject only some hospitals to desk reviews.

Comprehensive CC/MCC Analysis

In the FFY 2018 IPPS final rule, CMS provided public notice of its plans to conduct a comprehensive review of the Complications or Comorbidities (CC) and Major Complications or Comorbidities (MCC) lists for FFY 2019. This is similar to the FFY 2008 IPPS comprehensive review of the CC list performed to better recognize severity of illness that ultimately resulted in the implementation of MS-DRGs. CMS states in the proposed rule that it has used the same methodology as in FFY 2008 to conduct this analysis.

CMS analysis resulted in its clinical advisors recommending changes in severity level designations for 1,492 ICD-10-CM diagnosis codes. As a result of these proposed changes, of the 71,932 diagnosis codes included in the analysis, the net result would be a decrease of 145 (negative 4.5%) codes designated as an MCC, a decrease of 837 (negative 5.87%) codes designated as a CC, and an increase of 982 (1.8%) codes designated as a non-CC. According to CMS, these proposals are based on review of the data as well as consideration of the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses.

In review of proposed changes, CHA does not believe CMS has provided adequate analysis to justify its changes. We urge CMS to reconsider its proposals and to delay implementing such a significant revision to the MS-DRGs until it can make available additional data and information for stakeholder review. For example, CMS provided inaccurate information in certain instances and when applying its methodology treated similar codes inconsistently.

Moreover, we urge CMS to carefully consider the comments, in particular the clinical examples put forth in the comments of our colleagues at the American Hospital Association that more clearly articulate our concerns. The most obvious error that gives us pause is ICD-10 was first implemented in 2015, and we do not believe the data in the early years of reporting accurately reflect resource use; rather, the data reflect a period of time in which providers were learning the new code set. We urge the agency to work with the field to refine the MS-DRGs in a transparent and clinically appropriate manner.

Finally, CHA appreciates CMS' additional review and consideration of peripheral extracorporeal membrane oxygenation (ECMO) procedures, including the indications, treatment difficulty, and the resources utilized that support the assignment of the new ICD-10-PCS procedure codes for peripheral ECMO procedures to the same MS-DRG as the predecessor code for open (central) ECMO procedures for FFY 2020.

Specifically, CHA supports CMS' proposal to reassign the following procedure codes describing peripheral ECMO procedures from their current MS-DRG assignments to Pre-MDC MS-DRG 003 (ECMO

or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure). We agree that the conforming changes to MS-DRGs 207, 291, 296, and 870 are appropriate.

In light of this revision and the significant financial impact it has had on providers, CHA urges CMS to consider reprocessing these claims. We believe these codes were inappropriately classified last year and urge CMS to allow hospitals to recoup the payments they are due.

CAH Payment for Ambulance Services

Currently, a critical access hospital (CAH) can be paid 101% of reasonable costs for ambulance services if it is the only provider or supplier of ambulance services within a 35-mile drive of the CAH. The CAH can be paid 101% of reasonable costs for ambulance services even if its ambulance company is more than a 35-mile drive from the CAH, as long as it is the closest provider or supplier of ambulance services to the CAH. Otherwise, the CAH is paid for its ambulance services using the ambulance fee schedule (AFS).

To address situations where a non-CAH owned ambulance service is within a 35-mile drive of the CAH but is not legally authorized to transport individuals to or from the CAH because it is in another state, CMS proposes to exclude consideration of ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals either to or from the CAH in applying the 35-mile distance criterion. **CHA supports this proposal and believes that it will improve access to care to individuals living in remote and rural areas, particularly in emergency situations and when individuals have no other mode of transportation due to hazardous traveling conditions.**

Graduate Medical Education

For the purposes of both indirect medical education (IME) and direct graduate medical education (DGME), hospitals can count residents who train in non-provider sites if they incur the costs of the resident's salary and fringe benefits and the resident is providing patient care. Under current statutory language, a CAH cannot be considered a non-provider site. Currently, CAHs that train residents in approved graduate medical education (GME) programs are paid at 101% of reasonable cost. In light of concerns that CAHs may be too small to support residency training programs or may not be in a financial position to incur the associated cost, CMS proposes to modify the statutory language associated with its policy that a CAH cannot be considered a non-provider site. Specifically, CMS proposes that — for cost reporting periods beginning October 1, 2019 — a hospital could include residents training in a CAH in its FTE count as long as it meets the requirements for counting residents in non-provider sites. CAHs would continue to be paid at 101% of costs for the training of these residents, but would not be able to claim them for purposes of GME when treated as a non-provider site. **CHA supports this proposal and appreciates that CMS will allow hospitals additional flexibility in training physicians in our rural communities.**

Chimeric Antigen Receptor (CAR) T-Cell Therapy

CAR T-cell therapy is a cell-based gene therapy in which a patient's T-cells are genetically engineered to add a chimeric antigen receptor that will bind to a certain protein on the patient's cancerous cells. The CAR T-cells are then administered to the patient by infusion. Two CAR T-cell therapy drugs, KYMRIAH™ and YESCARTA™, received FDA approval in 2017. Both manufacturers were approved for new technology add-on payments for FFY 2019. These new and innovative treatments far exceed the cost of other therapies.

In FFY 2019, CMS finalized the assignment of CAR T-cell therapy ICD-10-PCS procedure codes XW033CS (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3), and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3) to MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy).

The September 2018 update of the FFY 2018 MedPAR data file does contain some claims that include the new procedure codes identifying CAR T-cell therapies. However, the number of cases is limited, and the submitted costs vary widely due to differences in provider billing and charging practices for this therapy. While these claims could be used to create relative weights for a new MS-DRG, CMS does not have the comprehensive clinical and cost data that generally are needed to create relative weights for a new MS-DRG.

Given the relative newness of CAR T-cell therapy and CMS' proposal to continue new technology add-on payments for FFY 2020 for the two CAR T-cell therapies that currently have FDA approval, CMS proposes not to modify the current MS-DRG assignment for cases reporting CAR T-cell therapies for FFY 2020 and requests comments on payment alternatives. **CHA supports the proposal to continue assigning CAR T-cell therapy to MS-DRG 016.** Because a new MS-DRG must be established in a budget-neutral manner, CHA is concerned that, over time, payments will be redistributed from core hospital services to specialized hospitals, which might affect payment for core services. Notably, YESCARTA™ and KYMRIAH™ have list prices of \$373,000. In addition to the cost of the therapy, there also are extremely high patient care costs — both before and after infusion of the therapy — including multiple-week stays in the intensive care unit. **CHA appreciates CMS' willingness to consider multiple options for adequately paying for these services and ensuring access to these lifesaving treatments, while also ensuring payment adequacy and limiting potential redistribution of dollars.**

While CHA supports CMS' proposal to continue assigning CAR T-cell therapy to MS-DRG 016 for FFY 2020, we think it is important to continue exploring the most appropriate way to eventually create a new MS-DRG specifically for CAR-T. In doing so, we urge CMS to exclude cases in clinical trial. The absence of drug costs on claims for cases involving clinical trials would significantly impact the relative weight of the new MS-DRG. The MedPAR Medicare claims file included 124 cases of CAR T-cell therapy performed at PPS hospitals from October 1, 2017, to September 30, 2018. Of these 124 cases, more than two-thirds were for clinical trial cases. For comparison, the clinical trial cases incurred an average of \$100,000 in pharmacy charges, while the non-clinical trial cases averaged almost \$625,000 in pharmacy charges. Analysis shows that including the clinical trial cases in the MS-DRG weight would result in a decrease of the weight from 28.8 to 16.5 — meaning the base MS-DRG payment would drop from \$180,000 to \$100,000. This payment reduction is not sustainable to ensure continued access to CAR T-cell therapy once the NTAP expires. Therefore, these clinical trials must be excluded when developing the weight of the new CAR-T MS-DRG.

CMS invites public comment on alternative payment approaches for CAR T-cell therapy. **We urge CMS to finalize an alternative method of determining the cost of the CAR T-cell therapy that ensures the agency captures that cost accurately, such as using the therapy's average sales price (ASP) as a proxy for its cost.** Doing so is critical because the standard method of calculating CAR T-cell costs would vastly underestimate the cost of this therapy.

CMS also requests comment about establishing a specific cost-to-charge ratio (CCR) for reporting procedures involving the use of CAR T-cell therapy. For example, stakeholders have suggested a CCR of 1 for determining outlier payments and for the purposes of a new technology add-on payment. This change would result in a higher outlier payment, higher new technology add-on payment and the determination of higher costs for IPPS-excluded cancer hospital cases. CHA is concerned that the assumption hospitals are charging their actual acquisition cost may be incorrect, since hospitals are required to have a set of uniform charges and payments made to providers under contract to private plans also dictate how the charge is set. For example, should a hospital have a private contract that pays a percent of charges, covering the cost of the service under that specific contract may require the charge structure to be higher than the acquisition cost. We agree with the agency that this issue is complex and look forward to additional dialogue on this topic.

The IPPS provides additional payments, known as New Technology Add-on Payments (NTAPs), for cases with relatively high costs involving eligible new medical services or technologies. NTAPs are allotted at a rate of 50 percent of the marginal cost of a case, up to 50 percent of the cost of the technology, and are not budget neutral. CMS proposes changing the NTAP from 50 percent to 65 percent of the marginal cost of the case, capped at 65 percent of the cost of the technology. This change would apply to all technologies approved for NTAPs, including CAR T-cell therapy.

According to CMS, the cost of administering either of the current CAR-T products approved for NTAPs, KYMRIA[™] or YESCARTA[™], is \$373,000; thus, the proposal would increase the maximum NTAP for CAR-T from \$186,500 to \$242,450 per case. While CHA is pleased that CMS is taking steps to address the extraordinarily high cost of CAR-T, it still does not go far enough to cover the costs hospitals will pay to provide this lifesaving treatment. **We are concerned this rate would not ensure beneficiary access to care and urge CMS to make NTAPs for CAR-T at a rate of 100% of its marginal cost.**

To ensure the integrity of the IPPS and beneficiary access in the long-term, additional solutions will be necessary. This is especially true given that both new and existing therapies are expected to be approved for additional indications. The current payment systems — of any payer, not just Medicare — were not built to sustain access to therapies with costs of these magnitudes. As technology continues to advance, such therapies will become more and more prevalent, and it is critical that CMS set a precedent that ensures beneficiary access to care. This requires not only appropriate payment, but also provider certainty of coverage determinations, as one post-care-provision denial would be devastating to both providers and beneficiaries. **We urge CMS to continue to engage all stakeholders to ensure we have long-term sustainable solutions that can be adapted over time and account for innovations that transform how we treat disease.**

Hospital Inpatient Quality Reporting Program

Proposed New Opioid-Related eQMs

CMS proposes to add two new opioid-related eQMs beginning with the FFY 2021 reporting year: Safe Use of Opioids - Concurrent Prescribing (NQF #3316e) and Hospital Harm - Opioid-Related Adverse Events.

The proposed Safe Use of Opioids - Concurrent Prescribing measure would calculate the proportion of patients age 18 and older who are prescribed two or more opioids or an opioid and benzodiazepine

concurrently at discharge from a hospital-based encounter (inpatient, observation stays, or emergency department). The measure excludes patients with an active diagnosis of cancer or order for palliative care during the encounter. While measure developers did take steps to improve the measure following recommendations from the Measure Applications Partnership in 2017, hospitals continue to have concerns that the exclusions may not properly address patients with chronic pain. We urge the agency to continue to work with stakeholders in refining the measure exclusions in the future.

CMS also proposes, beginning with the 2022 reporting period/FFY 2024 payment determination, to require all hospitals participating in the IQR program to report the Concurrent Prescribing eCQM and three additional eQMs of their choosing. **CHA does not oppose the addition of the Concurrent Prescribing eCQM to the available measure set. However, we do not support its required reporting beginning with the 2022 reporting period. In addition to our concerns with the current measure exclusions, we continue to believe hospitals should have the flexibility to choose to report the eQMs that are most appropriate to their specific quality improvement priorities.**

CMS also proposes to add the Hospital Harm - Opioid-Related Adverse Events measure to the eCQM measure set beginning with the FFY 2021 reporting year. This measure would assess the proportion of an acute care hospital's patients with an opioid-related adverse event during an admission, as indicated by administration of naloxone. The measure includes patients who received naloxone outside the operating room more than 24 hours after hospital arrival or during the first 24 hours following hospital arrival with evidence of hospital opioid administration prior to naloxone administration. This is intended to exclude patients who receive naloxone within 24 hours of arrival due to an opioid overdose that occurred in the community prior to hospital arrival.

CHA agrees that measuring adverse events is important, and the growing abuse of opioids and the treatment of patients with dependencies is a national priority. However, we remain concerned that the measure has not yet been adequately tested for reliability and validity and is not yet endorsed by the National Quality Forum. In addition, we encourage the agency to be watchful of any unintended consequences the measure may result in, such as encouraging more invasive efforts to combat respiratory events (like intubation) over the necessary use of naloxone. Despite these concerns, we understand the importance of the availability of measures that address the national opioid crisis, and do not oppose the measure as an option in the eCQM measure set.

eCQM Reporting Requirements

For the FFY 2022 and 2023 payment determinations, CMS proposes to continue to require that hospitals report one self-selected calendar quarter of data for four self-selected eQMs. This proposal would apply to both the hospital IQR and Medicare and Medicaid Promoting Interoperability programs. CHA strongly supports this proposal, which reduces regulatory burden and gives hospitals the flexibility to focus their efforts on measures most important to their quality improvement priorities. However, as previously mentioned, CHA opposes CMS' proposal to require all hospitals to report one self-selected calendar quarter of data for the proposed Safe Use of Opioids Concurrent Prescribing eCQM plus three additional self-selected eQMs beginning with the FFY 2024 payment determination.

Proposed Mandatory Reporting of Hybrid Hospital-Wide Readmission Measure (NQF #2879)

In the FFY 2018 IPPS final rule, CMS adopted the Hybrid Hospital-Wide Readmission (HWR) measure – which combines claims data with patient data extracted from hospital EHRs – as a voluntary measure. In this rule, CMS proposes a stepped approach to mandating reporting of the Hybrid HWR measure and

replacing the existing claims-based HWR measure. CMS proposes to establish two new expanded voluntary data collection periods: July 1, 2021, through June 30, 2022, and July 1, 2022, through June 30, 2023. Beginning with the FFY 2026 payment determination, CMS proposes mandatory reporting from July 1, 2023, through June 30, 2024.

CHA supports continued voluntary reporting of the Hybrid HWR measure. However, we urge the agency not to finalize a certain date for mandatory reporting. In the proposed rule, CMS states that only 80 hospitals submitted EHR data during the first six-month voluntary reporting period. While CHA agrees that hybrid measures have potential to improve risk adjustment, hospitals report that the measures can be challenging — if not impossible — to implement. Currently, there is wide variation in EHR vendor support for the required data elements, with some large vendors like Epic not supporting the measure at this time. We urge the agency not to underestimate the time required for vendors to develop, implement, and test new measures, particularly as they prepare to implement recently proposed changes to certification criteria. Only after hospitals have had the opportunity to voluntarily report the measure with wide vendor support should CMS consider required reporting of the measure. In addition, we are concerned that CMS does not have a robust infrastructure to collect these data. Hospitals continue to report challenges in submitting eCQM data to CMS portals such as QualityNet, and the files associated with the Hybrid HWR data elements are particularly large. Before proceeding further, we ask CMS to make the infrastructure investments needed to ensure timely upload and receipt of data.

Finally, CMS proposes to begin public reporting of the Hybrid HWR beginning with the data collected from first proposed required reporting period of July 1, 2023, through June 30, 2024. **CHA urges CMS to delay public reporting until at least the second required reporting period, allowing all hospitals to gain experience under mandatory reporting with a dry run of the measure.**

Confidential Reporting of Stratified Data for Hospital Quality Measures

As a first step to addressing disparities due to social risk factors, CMS in its FFY 2019 IPPS final rule adopted plans to include stratified data on the Pneumonia Readmission measure (NQF #0506) data for dually eligible patients in hospitals' confidential feedback reports beginning in August 2018, using two methods: a within-hospital disparity method that compares readmission rates for dually eligible and other beneficiaries within a hospital, and an outcome measure that compares care performance for dually eligible patients across hospitals. In this proposed rule, CMS proposes to expand these reports to include five additional measures in the spring of 2020: acute myocardial infarction (AMI) readmission measure, coronary artery bypass grafting (CABG) readmission measure, chronic obstructive pulmonary disease (COPD) readmission measure, heart failure readmission measure, and total hip arthroplasty/total knee arthroplasty (THA/TKA) readmission measure.

CHA appreciates that CMS is working to understand and address disparities in quality measurement, including those that can be attributed to dual-eligible status, and we support the expansion of confidential reporting of stratified data to additional measures. However, we continue to be concerned that dual-eligible status has important limitations as a risk adjustor. Most notably, the generosity of state Medicaid program benefits varies and, in the long run, the adjustor may be sensitive to differences in state-level decisions to expand Medicaid. Dual-eligible status also may not fully reflect the poverty in communities. For example, it would not reflect the proportion of undocumented immigrants in communities, as such individuals who are not eligible for either Medicare or Medicaid.

Unfortunately, failing to adjust measures for sociodemographic factors when necessary and appropriate can adversely affect patients and worsen health care disparities because the associated penalties divert resources from hospitals and other providers that treat large proportions of vulnerable patients. It also can mislead and confuse patients, payers, and policymakers by shielding them from understanding important community factors that contribute to poor outcomes. **We urge the agency to work with stakeholders and do more to address the impact of sociodemographic and social risk factors on quality and resource use measures through future rulemaking.**

Hospital Value-Based Purchasing Program

To account for the previously finalized removal of the National Health Safety Network (NHSN) health care-associated infection (HAI) measures from the IQR program — effective with January 1, 2020, data collection — CMS proposes to use the same data to calculate the NHSN HAI measures for the VBP program that it uses to calculate these measures for the HAC reduction program. The review and correction and data validation processes adopted for these data for the HAC reduction program would also apply. **CHA supports this proposal but asks CMS to clarify whether failing HAI measure validation in the HAC Reduction Program would affect a hospital’s ability to participate in the VBP program.** Under the IQR validation policies, a hospital that fails validation on these measures receives a full payment reduction and would be ineligible for the VBP program. Under the HAC validation policies, a hospital is assigned the maximum Winsorized z-score only for the set of measures that CMS validated rather than an “all or nothing” assignment of maximum scores for the entire domain. The proposed rule is unclear as to how application of the HAC program data validation processes would impact a hospital’s VBP score or ability to participate in the program.

Hospital-Acquired Conditions Reduction Program

CMS proposes a set of eight factors it would use to determine whether a measure should be removed from the HAC. These factors are currently in use for the IQR and VBP programs, and CMS also proposes to adopt them in the HRRP. CHA supports the adoption of these factors in both programs — particularly the adoption of Factor 8, which allows the removal of a measure for which CMS has determined the associated costs outweigh the benefit of its continued use. **Further, CHA urges CMS to remove the PSI-90 composite safety measure from the HAC program under Factor 8. Despite attempts by the developer and CMS to improve the measure, CHA continues to have significant concerns with the underlying lack of reliability and accuracy with individual component PSI measures and the measure’s ability to generate actionable data. The burden of reporting this measure significantly outweighs any benefit to continued use in the HAC program.**

Hospital Readmissions Reduction Program

CMS proposes to create a subregulatory process for nonsubstantive modifications to other components of the HRRP adjustment — such as updated naming or locations of data files or other minor discrepancies that do not change the policy’s intent — so that minor changes can be rapidly adopted. CMS states that substantive changes — those that impact the payment adjustment factor component so significantly that it could no longer be considered to be the same as the previously finalized component — would continue to go through notice-and-comment rulemaking. CMS also proposes to modify the definition of “dual eligible” to avoid undercounting the status of beneficiaries who die within a month of hospital discharge, and uses this as an example of a policy that would not have a “substantive” impact and be modified under a subregulatory process in the future.

CHA does not oppose the creation of a subregulatory process for nonsubstantive modifications, such as updated naming or locations of data files. However, we disagree that the proposed modification to the definition of dual eligible would fall into this category. Though the change may affect a small number of beneficiaries, it could shift a hospital from one peer grouping to another. The notice-and-comment rulemaking process provides hospitals with an important opportunity to review, analyze, and provide input on changes that could affect their performance in the program. CHA urges CMS to be transparent in its rationale for implementing changes through a subregulatory process, and to engage in notice-and-comment rulemaking for any change that could potentially impact a hospital's performance, no matter how small.

Medicare and Medicaid Promoting Interoperability Program

Reporting Periods

CMS previously adopted reporting period of a minimum of any continuous 90 days for the Medicare Promoting Interoperability Program in 2019 and 2020. CMS proposes to extend this continuous 90-day reporting period for 2021. **CHA strongly supports the proposed 90-day reporting period, which would provide hospitals with flexibility and reduce regulatory burden. We urge CMS to continue to implement a 90-day reporting period going forward as hospitals focus efforts on improving interoperability and patient access to health information.**

Proposed Changes to Previously Adopted Measures

CMS proposes changes to the two opioid-related measures under the ePrescribing objective previously adopted in the FFY 2019 IPPS final rule. Specifically, CMS proposes to modify the Query of PDMP measure and remove the Verify Opioid Treatment measure.

CMS proposes to modify the Query of PDMP measure in three ways: (1) the measure would remain optional for 2020 reporting and eligible for five points; (2) beginning with 2019 reporting, it would be changed to a yes/no measure instead of a numerator/denominator measure; and (3) because the measure would be optional, its exclusion would be removed. **CHA applauds CMS for responding to our comments on the FFY 2019 IPPS proposed rule, which urged the agency to retain this measure as optional for 2020. We agree that consultation of a PDMP is important for tracking prescribed controlled substances; however, the technology to integrate this process into the EHR is still under development. Further, CMS' proposal to change the measure to yes/no reporting will reduce burden on hospitals in implementing and reporting the measure.**

Similarly, CHA strongly supports CMS' proposal to remove the Verify Opioid Treatment measure — which would remain optional for 2019 — beginning with 2020 reporting. CHA did not support this measure for inclusion in the program when it was adopted in the FFY 2019 IPPS final rule, expressing concerns related to the lack of defined data elements, structure, standards, and criteria for the electronic exchange of opioid agreements; calculation of the 30-day lookback period; and the burden caused by lack of a definition for an "opioid treatment agreement." We appreciate that CMS has responded to these concerns by removing the measure beginning in 2020, while still allowing the flexibility of optional reporting for any hospital that has already initiated plans to optionally report the measure in 2019.

CHA appreciates the opportunity to share our comments on the proposed rule. If you have any questions, please do not hesitate to contact me at (202) 488-4688 or akeefe@calhospital.org, or my colleague Megan Howard, senior policy analyst, at (202) 488-3742 or mhoward@calhospital.org.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs