



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314-G
Washington, D.C. 20201

SUBJECT: CMS-1717-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals-Within-Hospitals; Proposed Rule, Federal Register (Vol. 84, No.154), August 9, 2019

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the calendar year (CY) 2020 outpatient prospective payment system (OPPS) proposed rule.

CHA is very concerned that the agency’s payment and policy proposals are not only unlawful, but also threaten the OPPS’ financial stability — and, in turn, access to care for Medicare beneficiaries. In this rule, the Centers for Medicare & Medicaid Services (CMS) proposes several policies that would make administering the OPPS infinitely more complicated and add significant regulatory costs and burden to providers — the very opposite of this administration’s goals. We are deeply disappointed and urge the agency to change course.

Based on input from member hospitals and health systems across California, CHA urges CMS to:

- Withdraw its unlawful price transparency proposals, as CHA strongly believes they will only confuse beneficiaries.
- Immediately abandon its policy to fully implement and expand site-neutral payment policies for clinic visits in excepted and non-excepted off campus provider-based hospital outpatient departments, as required by the recent court decision and refund payments withheld in CY 2019.
- Halt the use of inpatient prospective payment system (IPPS) hospital area wage index policies finalized in August for FFY 2020 IPPS payments in the CY 2020 OPPS system. CHA continues to believe CMS’ policy of “robbing Peter to pay Paul” is not only unlawful but a dangerous precedent.
- Move forward with full retroactive adjustments that are not budget neutral for 340B hospitals.

On a more positive note, we continue to support efforts to assist all small and rural hospitals in addressing their unique challenges – including the more than 60 rural hospitals in California. **CHA strongly supports CMS’ proposal to change the minimum level of supervision required for hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and critical access hospitals (CAHs) beginning January 1, 2020, and we applaud the agency for taking this long overdue action.**

Our detailed comments on additional payment and policy proposals outlined in the proposed rule are discussed in detail below.

Price Transparency of Standard Charges and Negotiated Rates

In the CY 2020 OPSS proposed rule, CMS proposes to require that hospitals publicly post on the internet a machine-readable file containing both gross charges and “payer-specific negotiated charges” for all items and services. It also proposes to require hospitals to display, in an easy-to-understand format, negotiated charges and certain other information for 300 “shoppable” items and services.

CHA agrees that providing prospective patients with information on expected out-of-pocket costs for elective procedures in advance will help them understand their potential financial liability. California hospitals and health systems have developed numerous ways to provide patients information on estimated out-of-pocket costs from hospital charges associated with a procedure. They provide these estimates seven days a week, 365 days a year, and many are available 24 hours a day through innovative online tools. Out-of-pocket costs are what patients ask for, and CHA believes this is the **most** useful information to consumers as they decide, in consultation with their physician, where to seek and obtain care.

CHA strongly supports transparency. However, we stridently disagree with the assertion that CMS’ approach will be useful for improving transparency, as it will require hospitals to disclose the amount the *patient’s insurer* pays for health care services, not the amount the *patient* will be required to pay for treatment in a hospital. CHA is further concerned that CMS’ proposal will be highly burdensome to hospitals and take significantly more than the woefully inaccurate 12 hours that CMS estimates will be required for hospitals to comply with the provision by January 1. CMS’ proposal will result in hospitals diverting resources currently devoted to informing patients of their out-of-pocket costs for health care services to providing information that will be totally unhelpful and confusing to consumers. Moreover, we believe it will actually do more harm than good.

Below we outline in more detail our legal and policy concerns with CMS’ proposal.

Policy and Implementation Concerns

1. Information Required Is Not What the Patient Needs or Wants

As previously noted, CHA agrees that providing patients with information on expected out-of-pocket costs for elective and other common procedures in advance will help them understand their potential

financial liability. CMS requiring the hospital to disclose information on the amount the patient's insurer will pay, not the amount the patient will be required to pay, does not serve the patient's interest at all because it still doesn't give them critical information they are seeking.

California hospitals have developed ways to provide potential patients information on estimated out-of-pocket costs from hospital charges associated with a procedure. CHA believes that information on expected out-of-pocket costs is the type of information that is useful to consumers as they decide with their doctors' advice among various care settings and providers. However, for a full disclosure of the entire estimated out-of-pocket costs that a patient may expect for an elective procedure, insurers and group health plans are the most appropriate and efficient source of information for plan enrollees. Many insurers have developed price transparency tools to help consumers. For example, hospitals do not have information on whether prospective patients have met their deductible. Similarly, in most cases, a hospital cannot tell the patient what the out-of-pocket costs will be for the services of the physicians who perform the procedure. Again, this information is readily available from the plan or insurer.

2. Information Required Will Be "Indecipherable" to Patients

In the FFY 2019 IPPS rule, CMS required hospitals to make their charges for all items and services publicly available on their websites in a machine-readable format. Hospitals have charges for literally thousands of items and services and a patient will be unable to discern from this information the amount they would be expected to pay for services between hospitals. Shortly after the requirement to furnish this information became effective, there were several media stories reporting that the information was unhelpful and confusing to patients. An article in *Health Affairs* recently described this information as "indecipherable."¹ CMS' proposed requirement builds on the current requirement and will add the private payer rate for all services even though payment is not negotiated at the item level adding yet more confusion.

Further, CMS proposes to require hospitals to make available gross charges and private payer rates for 300 "shoppable" services or non-urgent services where CMS believes patients may select a hospital based on the hospital's gross charge or the negotiated payment between a hospital and a private insurer. However, absent any guidance from CMS as to what constitutes the service package, there will be no standardization among the information that hospitals post. This point was also acknowledged in the *Health Affairs* article: "...unfortunately, hospitals can vary the ancillary services that are grouped together under different primary services. This makes it difficult if not impossible for consumers to ascertain fully comparable pricing."

It is unrealistic to expect that this information should be available from hospitals or to expect that this information will be discernable to patients from the public disclosure of hospital charges and negotiated

¹ James C. Capretta, "The New Hospital Price Disclosure Rule Is Important, But Only A First Step," *Health Affairs*, August 26, 2019.

rates. As there are already tools available that provide consumers with meaningful information on issues that matter most (e.g., their potential out-of-pocket liability), there is no need for this proposal.

3. There Will Be Significant Burden to Hospitals to Disclose Information

CMS' proposal does not account for the many different payment methodologies that are negotiated between hospitals and payers, such as capitated rates, value-based purchasing payments, shared savings arrangements, etc. For example, a single hospital contracts with many different insurers and individual and group health plans that offer many different benefit packages. The proposed rule does not accurately account for the amount and scope of hospital resources required to gather the relevant data, to prepare for its electronic availability, to prepare for its display in what the agency describes as a user-friendly platform, and to regularly update that information. The 12-hour estimate in the proposed rule substantially understates the burden on hospitals. CMS believes that providing data on negotiated rates is a simple electronic exercise of extracting the information from hospital records. On the contrary, negotiated rates are not necessarily kept in hospital billing software in a form that can be accessed and reproduced electronically.

Hospitals will require significantly more than 12 hours to produce this information. Further, staff currently devoted to explaining the potential costs of a hospital stay to a patient or developing the price transparency tools earlier described will be diverted to complying with the requirements of CMS' proposed rule. Complying with the proposed rule will result in patients being less informed, rather than more informed, of the costs they can expect from receiving services at a hospital.

4. Healthcare Costs Will Increase, Not Decline

As noted above, CMS' proposal raises antitrust concerns as well as concerns about collusion and price fixing. CMS itself notes in the proposed rule that "the impact resulting from the release of negotiated rates is largely unknown."² Further, the proposed rule states:

Some stakeholders have expressed concern with the public display of de-identified negotiated rates which may have the unintended consequence of increasing health care costs of hospital services in highly concentrated markets or as a result of anticompetitive behaviors without additional legislative or regulatory efforts.³

Public disclosure of negotiated rates may result in a hospital raising rates so there is uniformity among payers for how much the hospital is paid for the same services. Similarly, payers could raise rates to eliminate differentiation in the amounts paid to different hospitals for the same services.

² 84 FR 39579.

³ 84 FR 39580 citing Jaime S. King et. al. "Clarifying Costs Can Increased Price Transparency Reduce Healthcare Spending?" University of California, Hasting College of Law, UC Hastings Scholarship Repository.

Legal Concerns

In the FFY 2019 IPPS final rule, CMS implemented section 2718(e) by requiring hospitals to make available a list of their standard charges online in a machine-readable format. In that final rule, CMS neither referenced nor imposed any enforcement mechanism for failure to comply with the requirement.

CMS proposes to revise its previous interpretation of section 2718(e) by expanding the definition of standard charge to require each hospital to make publicly available the rates it negotiates with private payers for items and services furnished to patients. This proposed requirement would extend to each private payer with which the hospital has entered into agreements and would further apply to each plan offered by each private payer. Further, if a hospital fails to comply with the proposed requirement, CMS would apply civil money penalties for each failure citing the enforcement authority established under a different provision of section 2718 of the Public Health Service (PHS) Act that relates to enforcement of requirements imposed on issuers of group or individual health insurance coverage. Section 2718(e) does not provide the Secretary the authority to either expand the definition of standard charges to include negotiated rates or to apply civil money penalties for a hospital's failure to publicly disclose proprietary information.

1. CMS Lacks Authority to Expand Standard Charges to Include Negotiated Rates

The descriptive heading and the text of section 2718(e) of the PHS Act provide as follows:

(e) Standard hospital charges.—Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act.

The heading to a statutory provision is one manner in which Congress describes the intent or scope of a particular provision. While a heading is helpful, it is not dispositive in interpreting the law. However, both the heading and the text of section 2718(e) clearly state that the scope of the requirement is limited to a hospital's standard charges for the items and services it furnishes to patients. In other words, the only express grant of authority to the agency on the issue of charges is to require the public availability of standard charges; nothing in section 2718(e) expressly grants the Secretary the authority to require public access to information on negotiated rates.

The adjective 'standard' is defined as meaning "regularly and widely used, available or supplied" and "substantially uniform."⁴ Standard when used in the context of hospital charges is a reference to a hospital chargemaster. The chargemaster is a list of all the billable items and services furnished to a patient during a hospital stay, including costs of each procedure, item and service, supply, drug, or diagnostic test, and the fees associated with services, such as equipment fees or room charges. The chargemaster is developed by the hospital as the list of standard charges to be presented in a bill to a

⁴ <https://www.merriam-webster.com/dictionary/standard>.

patient or the patient's group health plan or health insurance coverage, if any. What the patient or group health plan or insurance coverage may pay in response to such a charge will vary widely. There is nothing standard about the rates a hospital may negotiate with individual payers, and, in fact, those rates vary based on outcomes of the negotiations — as well as specific terms and conditions that apply to those rates, such as rate differentials based on care quality and patient outcomes. These rates also differ from year to year.

The agency's Provider Reimbursement Manual defines charges as follows:

2202.4 Charges. — Charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.⁵

Negotiated rates cannot in any reasonable interpretation be considered standard charges for hospital services. The agency's longstanding definition of charges runs directly counter to the notion that standard charges include rates individually negotiated with different payers each year. The agency's proposed expansion of the definition of standard charges is contradicted by both general usage of the adjective 'standard' generally, and as applied to charges, by the agency's longstanding policy.

Further, negotiated rates are proprietary information among private parties, as well as business trade secrets. Trade secrets generally refer to a company's business information that is not available or known to the public, which the company actively protects from disclosure, and that may provide the company an economic advantage over its competitors in the marketplace. Different rates that plans negotiate with a hospital are an essential tool of competition in the marketplace and, as such, they are both proprietary information and trade secrets. **If Congress had intended to give the Secretary authority to require the public disclosure of trade secrets or proprietary information, it would have had to specifically include that language in the text of the statute.**

Congress has enacted many laws providing for protections against disclosure of trade secrets. Trade secrets are generally exempt from disclosure under both federal and state freedom of information laws. Section 552(b)(4) of the Administrative Procedures Act⁶ exempts trade secrets and commercial financial information from disclosures by federal agencies. Congress has also enacted laws intended to prevent and provide recourse for companies that are subject to economic espionage.⁷

Another example of prohibition on disclosure of proprietary information can be found in Medicare law. Section 1834A(a) of the Act requires "applicable" laboratories to report private payer rates for laboratory services to the Secretary for purposes of determining Medicare rates under the clinical laboratory fee schedule. Section 1834A(a)(10) of the Act explicitly prohibits the Secretary from disclosing this information "in a form that discloses the identity of a specific payor or laboratory, or prices charged or payment made to any such laboratory..." In the physician fee schedule final rule for 2019, CMS

⁵ Provider Reimbursement Manual, No 15-1, ch. 22, § 2202.4.

⁶ 5 U.S.C. 552(b)(4).

⁷ See e.g., the Economic Espionage Act of 1996, which addresses theft of trade secrets.

adopted a regulatory provision that includes hospital laboratories in the definition of “applicable laboratory.”⁸ CMS’ proposed transparency requirement would require hospitals to disclose information that CMS itself is prohibited from making public. CMS cannot compel hospitals to disclose information that the agency itself is prohibited by law from disclosing.

These are three examples among many that show a consistent pattern of federal laws enacted by Congress designed to protect the proprietary information and trade secrets of business and other private sector entities. **The agency cannot read into section 2718(e) an implicit intent by Congress to accomplish the opposite policy goal by requiring the public disclosure of trade secrets without more evidence of congressional intent to permit that reading.**

The only explicit discretion provided to the Secretary by the language of section 2718(e) is how hospital standard charges are made available to the public; there is no other express grant of authority to the Secretary in this provision. **The authority to include negotiated rates within the meaning of hospital standard charges is not implied by the language of the provision or by other congressional enactments related to trade secrets and proprietary information. CMS is acting outside the scope of authority granted to the Secretary by the language of section 2718(e). The fact that the statute is silent on negotiated rates cannot be construed by the agency to constitute congressional authorization to require public dissemination of privately negotiated rates.**

Even if Congress had included a requirement in section 2718(e) to disclose negotiated rates, it would have had to explain that the requirement was notwithstanding other federal laws intended to prevent such disclosures; this could have been done by additional legislative language in the provision itself or through the Affordable Care Act’s (ACA) legislative history. There is neither any legislative history to support the proposed policy’s expansion of the term standard hospital charges nor anything in the text of section 2718(e) that supports the agency’s expanded interpretation of the term standard charges. Thus, the agency has exceeded its authority under section 2718(e) in proposing to require the disclosure of privately negotiated rates among hospitals, plans, and insurers.

2. Proposed Enforcement Is Not Supported by the Statute

CMS proposes to apply the enforcement authority under section 2718(b)(3) of the PHS Act to hospitals that fail to make publicly available information on their standard charges and negotiated rates. Section 2718(b) of the PHS Act applies **only** to the medical loss ratio and rebate requirements imposed by the ACA on health insurance issuers offering group or individual health insurance coverage. Section 2718(b)(3) was enacted by Congress to give the Secretary primary authority to enforce those medical loss ratio and rebate requirements on issuers. It reads as follows:

(3) Enforcement.—The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.

⁸ 83 FR 59667.

Structurally, the enforcement authority of section 2718(b)(3) is a subdivision of section 2718(b) of the PHS Act, and its placement within section 2718(b) indicates that the authority afforded to the Secretary in this provision applies with respect to matters included in section 2718(b) (i.e., the medical loss ratio and rebate requirements). Indeed, the Secretary has previously adopted a final rule to implement this requirement. The reference to “section” in section 2718(b)(3) is a reference to section 2718(b) — not to section 2718(e) or any other provision contained in section 2718 of the PHS Act outside of section 2718(b).

Further, section 2718(b)(3) does not specifically address enforcement of the requirement to publicly disclose hospital standard charges under a different section of the law, namely section 2718(e) of the PHS Act.

Had Congress intended to require the Secretary to enforce the requirement for public availability of hospital standard charge information, it would have done so in one of two ways: Congress would have added a provision similar to section 2718(e) clearly stating that it required or authorized the Secretary to develop an enforcement mechanism for disclosure of hospital standard charges through rulemaking, or it would have added a section 2718(f) requiring the Secretary to enforce requirements of sections 2718(b) and 2718(e).

Absent an express mandate for the Secretary in section 2718(b)(3) to enforce the requirements for hospitals to disclose their standard charges under a different provision of law (viz., section 2718(e)), the Secretary may neither imply an intent to do so nor reverse its previous rulemaking policy that limited the use of that enforcement authority to issuers that do not comply with medical loss ratio and rebate requirements imposed under section 2718(b). The proposal to do so now exceeds the mandate under the statute.

3. Unconstitutional Violation of First Amendment Free Speech Rights

The price transparency proposal violates free speech rights guaranteed under the First Amendment to the United States Constitution. A governmental regulation that forces private parties to disclose proprietary information or trade secrets is an unlawful requirement to compel speech that is otherwise protected by the First Amendment.

If Congress or an agency of the federal government seeks to compel private protected speech, it has a substantial legal burden to justify such a law or regulation. It is axiomatic that compelling speech among private parties must be a last resort to carry out a governmental interest. The proposed requirement must directly and materially advance a substantial government interest. Congress, or the agency involved, must also demonstrate that its desired outcome cannot be accomplished in a manner that does not regulate speech at all or to the same extent. Finally, to survive constitutional scrutiny, the requirement may not be unduly burdensome.

CMS' stated policy goals for its price transparency proposal include promoting health care competition and lowering health care costs for consumers. Unfortunately, the transparency proposal runs a

substantial risk of not only failing to accomplish those goals but, in fact, of accomplishing the exact opposite outcome. The Federal Trade Commission (FTC) has expressed concerns about statutory or regulatory requirements for the public disclosure of competitively sensitive information; this would clearly include rates negotiated between hospitals or other health care providers and insurers, and group health plans. The FTC has stated that public availability of this type of information could negatively impact competition; this is attributable in large part to the increased likelihood of collusion among the parties in the health care marketplace.⁹ The FTC also believes that public disclosures of commercially sensitive information reduces the beneficial impact of selective contracting that insurers and plans use to lower health care costs and ensure high quality in the care furnished to enrollees.¹⁰

The Department of Justice (DOJ), in conjunction with the FTC, has issued Statements of Antitrust Enforcement Policy in Health Care, including Statement 5 relating to when providers collectively provide fee-related information to buyers of health care services.¹¹ DOJ warns that there are potential antitrust concerns when price information is made available by competing health care providers, including use of the information to discuss or coordinate provider prices or costs. Statement 5 provides an antitrust safety zone for providers engaged in the collective provision of fee-related information that, if followed, will not be challenged by the DOJ or FTC under the antitrust laws, absent extraordinary circumstances. The requirements include the following:

- The collection is managed by a third party.
- Current fee-related information shared among or available to the competing providers furnishing the data must be more than three months old.
- For any information available to the providers furnishing data—
 - There are at least five providers reporting data upon which each disseminated statistic is based.
 - No individual provider's data may represent more than 25 percent on a weighted basis of that statistic.
 - Any information disseminated must be sufficiently aggregated such that it **would not allow recipients to identify the prices charged by any individual provider.**

The agency does not describe how its proposal would interact with these requirements, which protect against collusion, price fixing or other anti-competitive behavior. The proposal runs directly counter to the requirements of the safety zone, which reduce the potential for anticompetitive behavior among the parties involved.

The price transparency proposal does not, in fact, advance a substantial government interest; instead, it is likely to result in the unintended consequence of achieving the exact opposite of those goals. Rather than increasing competition and lowering prices, it will totally derail CMS and provider shared goals of

⁹ https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf.

¹⁰ Ibid.

¹¹ <https://www.justice.gov/atr/page/file/1197731/download>; page 43.

moving further from a fee-for-service payment model to a more value-based system, and allow health plans an unfair advantage in negotiations that will have untenable consequences in the market. None of these outcomes will be helpful to patients and, we believe, may do more harm than good.

Thus, because the proposal neither directly nor materially advances a substantial governmental interest, it is an unlawful violation of provider and plan First Amendment free speech rights. Further, as we outlined previously, the policy goals that the government intends to further with this proposal are already being undertaken by hospitals and health plans without the government's intervention. Because the government's interest is already being met by the private sector in a less burdensome manner and in a way that does not compromise the parties' free speech rights, the agency's proposal does not satisfy either of the requirements to pass constitutional muster.

In summary, CHA urges the agency to withdraw this proposal. The agency lacks the legal authority under the language and intent of section 2718(e) to either require the disclosure of privately negotiated rates (which constitute trade secrets and proprietary information) or to use the enforcement authority of another section of the PHS Act (viz., section 2718(b)(3) relating to enforcement of medical loss ratio and rebate requirements on insurers) to impose civil monetary penalties on hospitals that fail to post their standard charge data. Additionally, the requirement to force hospitals to publicly disclose commercially sensitive information is an unconstitutional mandate compelling speech, and it fails to meet the conditions imposed on the government when it seeks to impose a content-based regulation on the speech of private parties. **Further, the information required is neither what patients need nor what they want. The information CMS would require hospitals to post will increase patient confusion and detract from efforts to inform them of the amount they can be expected to pay for health care services furnished by the hospital.**

Site-Neutral Payment Policy for Off-Campus Provider-Based Departments

As required by Section 603 of the Bipartisan Budget Act of 2015 (BBA), CMS restricts OPPS payments for services provided by certain off-campus provider-based departments (PBDs) that opened after November 2, 2015, with limited exceptions. In CY 2019, CMS expanded the Medicare physician fee schedule (PFS) payment methodology to excepted off-campus PBDs, for HCPCS code G0463, with a two-year phase-in (70% of the OPPS rate for CY 2019 and fully reduced for CYs 2020 and beyond). For CY 2020, CMS proposes to fully implement the Medicare PFS payment methodology for excepted off-campus PBDs (40% of the OPPS rate) for the clinic visit service, implemented in a non-budget-neutral manner.

But on September 17, 2019, Judge Rosemary Collyer of the United States District Court for the District of Columbia **vacated this CMS rule** expanding the Medicare PFS payment methodology to excepted off-campus PBDs for HCPCS code G0462, finding that CMS had acted *ultra vires* (exceeded its authority) in implementing it. (See *American Hospital Association v. Azar*, 18-2841 (RMC) (D.D.C), Memorandum Opinion dated 9/17/2019.) Judge Collyer rejected each and every one of CMS' arguments in support of the rule and the agency's power to enact it. She wrote in her decision, "CMS believes it is paying millions of taxpayer dollars for patient services in hospital outpatient departments that could be provided at less

expense in physician offices. CMS may be correct. But CMS was not authorized to ignore the statutory process for setting payment rates in the Outpatient Prospective Payment System and to lower payments only for certain services performed by certain providers.” Further, Judge Collyer added that the final rule does not qualify as a method for controlling unnecessary increases in hospital use, as CMS had argued. Rather, according to Judge Collyer, CMS’ argument “does not make it clear what a ‘method’ is, but it does make clear what a ‘method’ is not: it is not a price-setting tool, and the government’s effort to wield it in such a manner is manifestly inconsistent with the statutory scheme.”

In accordance with settled principles of administrative law, Judge Collyer is remanding the matter back to the agency for further proceedings consistent with her order and the correct legal standard. These further proceedings will necessarily include implementing a remedy that will make whole those hospitals that had payments improperly withheld.

CMS has no choice but to rescind its proposal to fully implement the continuation of this rule that is estimated to reduce hospital outpatient payments by more than \$23 million to excepted off-campus provider-based departments across California. Further, as previously stated, CMS must make whole — with interest — those hospitals that had OPPS payments unlawfully withdrawn. Any delay in fully restoring these cuts will jeopardize beneficiaries’ access to care.

Many hospitals in California are on the verge of closing or relocating clinics vital to their community. In speaking with hospitals and health systems across California about the growing impact of these cuts on beneficiaries, we obtained several patient stories, many of them similar to the following:

As an adult child of two older parents (79 and 84), I am concerned about the potential closure of the clinic operated by my local hospital that provides primary care to my parents. Both of them have multiple medical conditions that require frequent monitoring and intervention. They live in a 55+ retirement community (a community of more than 5,000 homes). And fortunately for them and their neighbors, there is a hospital clinic across the street from their community and that is part of the community. Many of the residents receive primary care and internal medicine as well as specialty care services at the clinic. I am grateful to the clinicians who are readily available to help ensure that my parents are following the doctors’ orders. Such close interventions have kept my parents out of the hospital and in their own home – very different from the experience of some of my friends with aging parents. I have peace of mind knowing that these services are so close to their home.

I am concerned, however, that the clinic will soon close, as I understand the hospital may be forced to move or close permanently at the end of the year. If it closes, transportation becomes a huge challenge, and the nearest primary care clinic will now be a 20-minute drive for my parents, who don’t drive. Today they can walk up the street because of the clinic’s location. Such disruption will change their routine and mine, and I worry about their ability to continue to successfully manage their chronic illnesses, resulting in far greater consequences.

CHA urges CMS to rescind its CY 2020 proposal in accordance with this court ruling.

Area Wage Index

In the CY 2020 OPPS/ASC proposed rule, Section II.C – Proposed Wage Index Changes, CMS proposes to use the FFY 2020 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS. As a result, any adjustments for the FFY 2020 IPPS post-reclassified wage index are to be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020.

CHA submitted comments to CMS in response to the FFY 2020 IPPS rule, which has been finalized since the release of this OPPS Proposed Rule. CHA continues to strongly oppose decreasing payments to some or all hospitals to offset an increase in the area wage index (AWI) for the hospitals in the lowest AWI quartile.

The rationale provided by CMS in the final FFY 2020 IPPS rule in support of the reduction to the standardized amount under IPPS to pay for an increase in the wage index for the lowest quartile hospitals does not adequately address concerns raised by CHA and other commenters. Further, CMS does not have the legal authority to make this reduction under IPPS or to make any similar reduction under OPPS. CHA strongly opposes any reduction to payments under OPPS that would result from implementation of the IPPS policy to increase the AWI of the hospitals in the lowest AWI quartile.

Because CMS proposes simply to incorporate the AWI as set forth in the IPPS final rule into OPPS, CHA relies to a large extent on the comments it made to the IPPS 2020 proposed rule, which are restated below. CHA also briefly addresses CMS' responses to those comments in the final IPPS rule with respect to the adjustments to the AWIs of the hospitals in the lowest quartile. As discussed below, CMS' responses do not provide adequate legal or factual support for the policy and, in particular, for any corresponding adjustment to hospital payments to pay for the AWI increase for the lowest quartile.

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

CMS proposed in the 2020 Proposed IPPS Rule 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. CHA strongly opposed this “wage compression” proposal. In the FFY 2020 IPPS final rule, issued after the 2020 OPPS proposed rule, CMS revised this proposal (now the “low wage hospital assistance policy”) to still increase the wage index values of the hospitals with a wage index in the lowest quartile (FFY 2020 IPPS final rule, Section III.N.1.a – Providing an Opportunity for Low Wage Index Hospitals To Increase Employee Compensation), but to pay for this increase by instituting a reduction to the standardized amount to all IPPS hospitals (FFY 2020 IPPS final rule, Section III.B.1.b – Budget Neutrality for Providing an Opportunity for Low Wage Index Hospitals To Increase Employee Compensation).

While CHA appreciates that CMS did not decide to pay for the increase to hospitals in the lowest quartile by singling out hospitals in the highest quartile, CHA still cannot support CMS' finalized area wage index change to increase the wage index values of low wage index hospitals by decreasing the standardized amount for all hospitals. This is because the policy change violates the provision of the Medicare Act

requiring the agency to adjust payments to reflect area difference in wages; additionally, the reasons given by CMS in the IPPS final rule for this policy change are inadequate. Also, the policy is not supported by the exceptions provision on which CMS may be relying. Rather, the finalized low wage hospital assistance policy will result simply in a shift of Medicare funds from high and middle wage hospitals to low wage hospitals, completely untethered from labor costs incurred by hospitals.

A. The Low Wage Hospital Assistance Policy is Beyond CMS' Legal Authority

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

In finalizing its low wage hospital assistance policy, CMS asserts that it has the legal authority to artificially increase the correct wage data values for hospitals in the bottom quartile. In the FFY 2020 IPPS final rule, CMS did not clearly state what statutes or regulations provide it with such legal authority, but in the FFY 2020 IPPS proposed rule, CMS stated that it had this rulemaking authority under 42 U.S.C. § 1395ww(d)(3)(E) ("Section 1395ww(d)(3)(E)").

Section 1395ww(d)(3)(E) provides a process for adjusting hospital payments to account "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level[,]" and requires those adjustments to be budget neutral. In its IPPS comments, CHA contended that CMS appears to understand Section 1395ww(d)(3)(E) as giving it such broad authority to institute a wage index proposal which, in essence, makes inaccurate the wage data values for (now) the 25% of hospitals in the bottom quartile.

The low wage hospital assistance policy 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).¹² Indeed, the low wage hospital assistance policy is designed to ensure that this does not happen, clearly contradicting Congress' mandate. Moreover, Section 1395ww(d)(3)(E) illustrates that Congress knows how to provide exceptions when it chooses to do so; here, Congress has not written an exception that would allow CMS to adjust the wage index in the manner CMS has done. As such, CMS' action is *ultra vires*.

(i) CMS' policy 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.*

¹² 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 adjustment CMS has adopted for the lowest quartile hospitals, particularly if such adjustment is made at the expense of other hospitals by effectively underpaying them to subsidize low-wage hospitals to have the opportunity to increase employee wages.

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’ low wage hospital assistance policy does not “remove the effects of local wage differences” but instead disregards accurately reported wage data for 25% 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.¹³ 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.

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 is the **only** section of the cost report that is subject to a Medicare Administrative Contractor (MAC) review every single year. In addition to the MAC review, there is a subsequent additional secondary auditor with oversight of the MACs to ensure data are reported accurately. CMS has invested significant resources to ensure that the data reported and reflected in each year’s cost reports are reliable and valid for the purposes of payment.

Yet CMS is now going to institute 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 upwards. CMS might say the policy increases accuracy of the wage index by giving low wage hospitals an opportunity to increase wages to levels that CMS believes they would pay if they could, but this rationale is hard to justify. Moreover, CMS points to the existence of a lag between the year the wage data is being pulled from and the federal fiscal year in which the data is being applied in, to explain why low wage hospitals cannot immediately benefit from wage increases, but this lag applies to all hospitals equally, not just the low wage hospitals.

CMS is conflating low wage cost hospitals with poor and/or rural hospitals. Undeniably there is some overlap, but low wage costs cannot be synonymous with poor or unprofitable hospitals any more than high wage costs can be synonymous with rich and profitable ones. California rural hospitals have high wage costs compared to hospitals across the nation, but these are labor costs that rural California hospitals experience because of real geographic labor cost differences that CMS acknowledges exist

¹³ “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.

across the nation. To suppose that these rural hospitals in high wage cost areas are not in need of more reimbursement indicates that CMS is proposing to use the wage index as a policy vehicle, not as a “technical correction” as CMS claims numerous times in the IPPS final rule.

Ultimately, nothing in the statute suggests that Congress authorized CMS to institute a policy whereby 25% of the hospitals would receive wage index values that did not accurately match their actual values. Thus, CMS’ low wage hospital assistance policy is beyond the authority granted by Congress and cannot lawfully be instituted under Section 1395ww(d)(3)(E).

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

Section 1395ww(d)(3)(E) has three clauses. The first 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; this clause has been discussed above. The second clause establishes an alternative proportion than the one set forth in the first clause. The third clause details a floor on area wage index for hospitals in frontier states. These latter two are the only 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 to the first clause that would allow CMS to institute the low wage hospital assistance policy and did not grant CMS the authority to do so. Had Congress wanted to do either of these things, or had it wanted to itself change the wage index in the manner that CMS intends to implement, Congress could easily have done so. But it has not. Consequently, the CMS policy is *ultra vires*.

(iii) **The rationale offered by CMS in the IPPS Final Rule is inadequate**

In the IPPS final rule, CMS provided a confusing rationale for the low wage assistance policy, stating that the policy “would provide certain low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index.” 84 Fed. Reg. at 42326. CMS continued that its “proposal to increase the wage index for low wage index hospitals will increase the accuracy of the wage index by appropriately reflecting the increased employee compensation that would occur (to attract and maintain a sufficient labor force) if not for the lag in the process between when a hospital increases its employee compensation and when that increase is reflected in the calculation of the wage index.” 84 Fed. Reg. at 42327. CMS asserted that “the intent of [the low wage hospital assistance policy] is to increase the accuracy of the wage index as a technical adjustment, and not to use the wage index as a policy tool to address non-wage issues related to rural hospitals, or the laudable goals of the overall financial health of hospitals in low wage areas or broader wage index reform.” 84 Fed. Reg. 42331. CMS continued that it believes that under its low wage hospital assistance policy “the wage index for low wage index hospitals will appropriately reflect the relative hospital wage level in those areas compared to the national average hospital wage level[,

b]because our proposal is based on the actual wages that we expect low wage hospitals to pay[.]” *Id.* Essentially, CMS asserts that its new policy of taking accurate wage data and altering it to no longer be accurate in order to benefit hospitals in the lowest quartile, increases the accuracy of the wage index, because now the data will reflect what CMS conjectures it could possibly become.

This rationale — that making wage data inaccurate will actually make it more accurate — is patently unreasonable. First, CMS is required by statute to determine the wage index by using actual wage data, not a projection of what it speculates the data might be if it were to artificially increase the wage index based on an unsupported guess as to how the lower quartile hospitals may behave.¹⁴ Second, CMS has offered no data, analysis, survey, or other evidence to support the notion that lower quartile hospitals will pay higher wages if their AWI is increased. Third, hospitals, like other employers, pay salaries based on the local labor market, which is largely unaffected by the payments received by a hospital. That labor market is affected by local factors such as the labor supply in the area, the availability of a labor force with appropriate skills and education, the demand for labor, and the cost of living. CMS offers no information to the contrary. Fourth, the lag issue referenced by CMS as why low wage index hospitals cannot benefit from wage increases applies to all IPPS hospitals, not just those with low wages: any hospital that increases wages to respond to the local labor market will not see the impact of the wage increase in the AWI for several years. In fact, some low wage hospitals are benefited by the lag where their wages decrease from year 1 to year 2. The only way to truly address the lag would be to retroactively correct the wage index and adjust Medicare payments after the actual data for a period are known, which of course is not compatible with a prospective payment system.

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

In the IPPS Final Rule, CMS invokes the exceptions and adjustments authority in 42 U.S.C. § 1395ww(d)(5)(I) (“Section 1395ww(d)(5)(I)”) as alternative authority for reducing the standardized amount to pay for the low wage hospital assistance policy if Section 1395ww(d)(3)(E) does not give it such authority. CMS may also be relying on this provision as an alternative basis for increasing the AWI of the lowest quartile hospitals, although it has been far from clear regarding this point.

¹⁴ Neither CMS, nor any other federal agency, can know how private actors will act in the future. Even CMS accepts this as true, responding to comments that the low wage hospital assistance policy does not have any method to ensure that low wage hospitals actually increase employee compensation by stating that the policy “is intended to provide an *opportunity* for low wage hospitals to increase their employee compensation.” (84 Fed. Reg. 42327) (emphasis in original). CMS continued that because the policy is not a permanent one, that “[a]t the expiration of the policy, hospitals that have not increased their employee compensation in response to the wage index increase may experience a reduction in their wage index compared to when the policy was in effect.” CMS added that “[t]he future wage data from those hospitals will help us assess our reasonable expectation based on comments received in response to the request for information as well as proposal that low wage hospitals would increase employee compensation as a result of our proposal.” In other words, while CMS claims to be making the wage index more accurate, it effectively admits this is an experiment and the results are uncertain. Rather than being a “technical adjustment,” CMS is clearly attempting to implement policy changes through the wage index, despite its statements to the contrary.

Section 1395ww(d)(5)(l) states “(l)(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); (2) CMS is not acting by regulation, and therefore, is not following 1395ww(d)(5)(l); and (3) if CMS does have the authority to make this change, this special authority is not required to be exercised in a budget neutral manner, as (d)(5)(l)(ii) references budget neutrality, but (d)(5)(l)(i) does not.

CHA’s comments in response to the FFY 2020 IPPS Proposed Rule explained in detail why the exceptions and adjustments authority in Section 1395ww(d)(5)(l) cannot authorize either the low wage hospital assistance policy or instituting such policy in a budget neutral manner. CMS did not address any of these points in the FFY 2020 IPPS Final Rule, despite acknowledging the receipt of them. As such, CHA restates its comments herein and asks that CMS reconsider its position.

(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 specifying 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 hospital ((d)(5)(G)); and Alaska and Hawaii ((d)(5)(H)). Then Section 1395ww(d)(5)(l) 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; it 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 is inconsistent with the reimbursement methodology designed by Congress. CHA does not believe the exception can mean that CMS can do anything that it deems appropriate to implement whatever policy CMS wishes to advance. This is especially the case where the wage index statute is specific as to how the wage index is supposed to work.¹⁵

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

¹⁵ Otherwise, if the only limit of Section 1395ww(d)(5)(l) was whatever CMS deems to be appropriate, it could change the IPPS reimbursement system to a per diem system, for example. This cannot be the breadth of authority delegated to CMS by Congress, given the text of the provisions of Section 1395ww(d).

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 in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.” If CMS can interpret the adjustments and exceptions catchall provision as broadly as it is claiming in the FFY 2020 IPPS final rule, then the second clause would be irrelevant; the canon against surplusage shows that CMS’ interpretation is too broad.

The second clause gives CMS the authority, when making adjustments for transfer cases, to adjust the standardized amounts to achieve budget neutrality. This would be entirely superfluous and unnecessary if the first clause already granted CMS the sort of broad authority for which it argues here to institute the low wage hospital assistance policy by adjusting the standardized amounts for all IPPS hospitals to achieve budget neutrality.

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 CMS should work with Congress to seek its authority to do so, and not make unilateral changes inconsistent with previous Congressional action as it has done.**

CMS cannot claim to have unfettered authority limited only by what CMS deems appropriate. Such an interpretation would violate separation of powers principles, especially as the executive is attempting to claim that Congress delegated to it extraordinarily broad authority in a manner that would vitiate the rest of Congress' statute. Therefore, the catchall provision cannot be read to grant CMS authority to implement its low wage hospital assistance policy, whether in a budget neutral manner or not.

(ii) **The Secretary did not act by regulation**

Even if the catchall provision could be read to provide for such broad authority to institute the low wage hospital assistance policy, whether in a budget neutral manner or not, CMS has not followed the requirements of Section 1395ww(d)(5)(I). The statute states that the Secretary "shall provide by regulation" for exceptions or adjustments, but CMS did not propose or adopt a regulation to implement the low wage hospital assistance policy and therefore does not have the authority to implement such low wage hospital assistance 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 low wage hospital policy in the preamble to the proposed or final rule is not a regulation, as the proposed or final rule does not contain a provision embodying the low wage hospital assistance policy that it will 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. Unlike Section 1395ww(d)(5)(I)(ii), which specifically requires budget neutrality, Section 1395ww(d)(5)(I)(i) is silent on

budget neutrality. If the Secretary was authorized to apply budget neutrality under Section 1395ww(d)(5)(I)(i), Section 1395ww(d)(5)(I)(ii) would be unnecessary. Accordingly, the Secretary has no legal authority under the exception and adjustment authority cited to apply a reduction to the standardized amount to all of the IPPS hospitals in the country to make its low wage hospital assistance policy budget neutral.

While CHA can appreciate CMS' desire to limit costs to the Medicare system, there is no requirement that it help hospitals in the lowest quartile by harming all other IPPS or OPSS hospitals. The disparities in average hourly wages paid across the country, reported as part of 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, the object is to capture accurate wage data which 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. 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 their respective geographic areas. CMS has offered no data or other evidence to the contrary.

While we appreciate that CMS wishes to address the financial challenges of our nation's rural hospitals, CMS has finalized a broad policy to help only those hospitals in the lowest quartile, rural or not.

CHA agrees that helping rural hospitals is a laudable goal. Doing so in a permissible manner is an effort we would support. But as finalized, the policy harms numerous rural hospitals, including all of California's rural hospitals, and it fundamentally fails to recognize the legitimate differences in geographic labor markets.

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

therefore, ask CMS not to use the FFY 2020 post-reclassified IPPS wage index for the CY 2020 OPPS wage index.

B. CMS' Authority Under the Medicare Act OPSS Provisions Does not Authorize a Reduction to OPSS Payments Generally to Fund Increased Payments to the Lowest Quartile Hospitals

We have focused our comments on the action taken by CMS in the 2020 IPPS final rule, the authority CMS asserts for that action, and the rationale CMS has offered for it, as CMS states in the OPSS proposed rule that it is simply incorporating the final changes to the wage index policy under IPPS, rather than developing a wage index policy specific to OPSS. Accordingly, since the reduction to IPPS payments to fund increases to the AWI of the lowest quartile hospitals is not valid under IPPS for the reasons stated above, a reduction to OPSS payments to fund increases to the AWI of the lowest quartile hospitals is also not valid.

We note, however, that the OPSS proposed rule cites to section 1833(t)(9)(B) of the Medicare Act to support a budget neutrality adjustment that takes into account wage index changes. If as CHA strongly contends, the increase to the AWI of the lowest quartile hospitals is not supported under IPPS, particularly at the expense of other hospitals, then there is no basis under section 1833(t)(9)(B) for adjusting the OPSS conversion factor to reflect such an increase. CMS has not offered a rationale under OPSS that is independent of the rationale under IPPS to increase the AWI of the lowest quartile hospitals.

Additionally, budget neutrality is required under section 1833(t)(9)(B) only for adjustments under section 1833(t)(9)(A). Here, the wage index adjustments are simply based on the incorporation of the IPPS AWI, not on any adjustments specific to OPSS made under section 1833(t)(9)(A), so 1833(t)(9)(B) provides no authority for a budget neutrality adjustment.

Further, section 1833(t)(9)(A) allows adjustments “to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.” CMS has not explained how the increase to the AWI of the lower quartile hospitals at the expense of other hospitals is supported by this provision. Clearly, CMS cannot rely on changes in medical practice or technology, the addition of new services or new cost data. As to “other relevant information and factors,” CMS has failed to explain what these would be. As discussed above in connection with the exceptions provision under IPPS, this catchall phrase cannot be read to allow CMS to ignore the detailed wage index provisions in the Medicare Act in favor of implementing a policy of CMS’s own making. Such an approach would both be inconsistent with the Medicare Act and would involve an unfettered and impermissible delegation of Congressional authority to CMS.

C. A Larger Negative Adjustment to the Conversion Factor as Part of the OPSS Final Rule Is not a Logical Outgrowth of the OPSS Proposed Rule, and Without New Impact Files, Providers Do not Have the Ability to Meaningfully Comment on the Appropriateness of the Larger Adjustment Which Might Result from the IPPS Final Rule’s AWI Policy

In the proposed rule, CMS says it will make a budget neutrality adjustment to the “conversion factor” under OPSS to take into account the difference in the 2020 wage index as compared to the 2019 wage index by comparing OPSS payments using the 2019 wage index to projected payments using the proposed 2020 wage index (the “standard calculation”). CMS proposes a very modest budget neutrality adjustment of 0.9993, which includes a slightly positive adjustment of 1.0005 using the approach described above combined with a negative adjustment of 0.9988 to reflect the five percent cap on wage index decreases to ensure that the transition wage index is implemented in a budget neutral manner, consistent with the policy set forth in the IPPS rule.

It seems that the reason that the standard calculation is so small is that it incorporates the full IPPS wage index changes, as set forth in the IPPS FFY 2020 proposed rule, as opposed to the changes in the IPPS final rule. These proposed changes were designed to be budget neutral—the increase to the AWIs of the lowest quartile were offset by decreases to the AWIs in the highest quartile. However, after CMS finalized the IPPS rule, a reduction to the standardized amount for all IPPS hospitals is used, instead, to pay for the AWI increase for hospitals in the lowest quartile. Because CMS plans to adopt the IPPS final rule wage index for the OPSS wage index, it appears that the budget neutrality adjustment would have to be redone, becoming negative, since there is no longer a negative adjustment to the highest quartile of hospitals. Instead, it appears that there will have to be a downward adjustment to the conversion factor, which was not considered in the OPSS proposed rule. However, unlike the IPPS proposed rule where CMS considered various alternatives to the proposed wage compression policy, including the one ultimately adopted, CMS has not discussed any alternatives nor provided any clear roadmap as to what should happen to the OPSS payment rule concerning the wage index calculation. As such, our guess is that the conversion factor will be negatively adjusted downward as a result of the IPPS final rule’s low wage hospital assistance policy, which is not a logical outgrowth of the OPSS proposed rule.

Moreover, CMS has not posted any new impact files or anything else on the CY 2020 OPSS webpage to account for what will take place as a result of the IPPS final rule policy. Accordingly, CMS has not made clear how the very different AWI policy under the IPPS final rule will operate under the OPSS rule. It is unclear whether CMS will make a corresponding adjustment under Section 1833(t)(9)(B) and if so, how large it will be. Because CMS has not provided relevant data to validate any calculation to such potential adjustment, providers cannot meaningfully comment on what might be the larger negative adjustment to the conversion factor. Thus, not only is the larger negative adjustment to the conversion factor not a logical outgrowth of the OPSS proposed rule, but providers cannot meaningfully comment on such negative adjustment, making the application of any such changes impermissible.

OPSS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPSS final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at average sales price (ASP) minus 22.5%, instead of ASP plus 6%. In 2019, CMS continued this policy and extended it to apply to non-excepted off-campus PBDs. For 2020, CMS proposes to continue to pay ASP minus 22.5% for 340B-acquired drugs under the OPSS, as well as when furnished in non-excepted off-campus PBDs paid under the PFS-equivalent rate equal to 40% of the OPSS payment amount.

There is No Basis for Paying Hospitals Less Than the Statutory ASP Plus 6%

Congress established the 340B Drug Pricing Program 25 years ago to provide safety-net hospitals financial relief from high prescription drug costs. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate share hospitals that serve low-income and indigent populations. **In California, 175 hospitals across more than 1,800 sites participate in the 340B program. These hospitals rely on 340B savings to not only reduce the price of lifesaving pharmaceuticals for vulnerable patients, but also expand additional health services throughout the community.**

CHA strongly opposes CMS' proposed continuation of the 340B payment cuts and extension of the payment cuts to non-excepted, off-campus PBDs. CHA respectfully requests that CMS withdraw these proposals from consideration, as they fundamentally undermine the program's intent and goals and will have devastating impacts on patients served by 340B hospitals and clinics. Furthermore, we disagree with CMS' assertion that 340B hospitals will move drug administration services for 340B-acquired drugs to non-excepted off-campus PBDs in the absence of this policy change. We urge CMS to study hospitals' drug administration behavior pre- and post-implementation of the 2018 OPPI final rule to confirm this presumption before finalizing such an extreme policy.

Congress intended for savings from the 340B program to help participating entities "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Many 340B hospitals are the safety net for their communities, and the 340B program generates valuable savings to reinvest in programs that enhance patient services and access to care.

CHA assures the agency that this type of payment cut is not sustainable and may force many of these facilities to reduce services or close. This is particularly concerning in rural and underserved areas where urban 340B hospitals operate off-campus clinics. The proposed policy would deter 340B hospitals from expanding off-campus clinics that primarily administer drugs, such as infusion therapy clinics, into rural and underserved areas.

For example, several 340B hospitals that operate infusion therapy centers in rural areas said that, without the 340B discount, they could not afford to keep these clinics open. Due to skyrocketing pharmaceutical prices, many physician practices cannot afford to own and operate infusion therapy clinics in California — meaning that some of the sickest patients undergoing chemotherapy treatment in rural California may have to travel 30 to 40 miles to the nearest infusion therapy center.

Similarly, inner city clinics operated by 340B hospitals are also financially unviable and depend greatly on savings generated from the 340B drug discount program. Many inner city clinics operate with the purpose of reaching patients suffering from diabetes, HIV, and Hepatitis C. If implemented, the proposed Medicare reimbursement rates for Part B drugs would require many California hospitals to

close these financially vulnerable clinics. As a result, the provision of routine, necessary care to these vulnerable patient populations would be severely compromised.

It is quite concerning that the continuation of this flawed 340B policy does nothing to address the unsustainable increases in the cost of drugs. If the average sales prices for pharmaceuticals in our country were reduced, the cost to the Medicare program and its beneficiaries would also be reduced. **CHA urges CMS to focus its attention on the underlying issue of rising pharmaceutical costs as opposed to unsustainable cuts to Medicare payments to a subset of safety-net hospitals.**

A Proper Remedy is Straightforward and Easily Administered

In the proposed rule, CMS addresses the continuing lawsuit *American Hospital Association et al. v. Azar et al.* CMS seeks public comment on potential remedies for the CY 2018 and CY 2019 payments, and for use in CY 2020 payments in the event the agency receives an adverse ruling by the U.S. Court of Appeals. CMS notes that devising a remedy will be complex because of the OPPS budget neutrality requirements and seeks comments on the most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy — including whether to make the relevant budget neutrality adjustment across multiple years. CMS also seeks public comment on the appropriate OPPS payment rate for 340B acquired drugs, including whether a rate of ASP plus 3% could be an appropriate remedial payment amount both for 2020 and for determining the remedy for 2018 and 2019.

In summary, we agree that the payment remedy is very straightforward and should result in the following:

Refund payments should be made to each affected 340B hospital and calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 hospital OPPS rules, and others not adversely impacted by the reductions should be held harmless. This remedy would not disrupt the Medicare program and is consistent with those for past violations of law. Our detailed comments follow.

Such a straightforward remedy that is easy to implement will not be disruptive, does not require new rulemaking, and is comparable to those the courts and agency have adopted to correct other unlawful Medicare payment reductions. Specifically, the agency can recalculate the payments due to 340B hospitals based on the statutory rate of average sales price (ASP) plus 6% provided by the 2017 OPPS rule. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and the amount they are entitled to, including ASP plus 6% plus interest. Claims that have not yet been paid should be paid in the full amount, including ASP plus 6%.

While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single

factor — which will be uniform across hospitals — to determine how much should have been paid and, thus, how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced, plus interest.

There is Ample Precedent for Full Retroactive Adjustments that are not Budget Neutral; ASP Plus 3% is an Unlawful Proposal

The Department of Health and Human Services (HHS) has previously demonstrated its authority to remedy the underpayments caused by its unlawful rule, including: *Cape Cod Hospital v. Sebelius* (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid); *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar* (D.D.C. 2018) (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required); and *Shands Jacksonville Medical Center v. Burwell* (D.D.C. 2015) (HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6%).

The remedy is not required to be budget neutral. The authority the agency cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, the agency does not consistently apply budget neutrality to fix its missteps and in other relevant instances. For example, HHS allows for retroactive correction of the wage index without any budget-neutrality adjustment if it makes the error and it was not something a hospital could have known or corrected. In addition, budget neutrality does not apply to changes in enrollment or utilization for drugs when the average sales price increases.

As previously stated, there is no basis for hospitals being paid less than ASP plus 6%. The OPDS mandates HHS reimburse hospitals for covered outpatient drugs at ASP plus 6%. This was the methodology used from 2013 to 2017. HHS has now requested comment on adjusting the payment for 2018, 2019, and 2020 from ASP plus 6% to ASP plus 3%. Although the agency has some authority to deviate from this law, it is attempting to use a policy rationale that is inconsistent with the law itself. Therefore, it would be unlawful to reduce payment to ASP plus 3%.

New Patient Co-Payments Are Not Required

Today, Medicare reimburses hospitals at 80% for covered outpatients, and the remaining 20% is collected from the patients or their insurance. Because HHS deviated from the lawful payment rate for 2018 and 2019 with a 30% reduction, in theory hospitals could collect from patients or their insurance companies the difference between 20% of the lawful payment rate and the 20% copay that was actually collected. HHS has requested comment on the “most appropriate treatment of Medicare beneficiary cost-sharing responsibilities.”

Although the agency has raised requiring patient co-payments to be adjusted retroactively as a possible remedy, CHA does not believe that there is any law that would require hospitals to collect

payments altered by the agency's illegal act. Neither the False Claims Act nor anti-kickback statutes would apply since patients would not have been induced to seek services. But more importantly, California hospitals do not believe in pursuing patients for additional copayments when patients believe they had fully paid for their portion of hospital care provided months, or in some cases years, prior. For California hospitals and Medicare beneficiaries, this is not a satisfactory remedy to a problem that the agency has unlawfully created. We urge HHS to state this clearly in the final rule.

The 340B program is vitally important to the nation's safety net. We believe that alternative approaches could address the issue of rising drug prices, and we will work with the administration and Congress in support of alternatives. **In the interim, CHA urges CMS to protect the 340B program and withdraw the proposal to not only continue the 340B payment cuts but expand the payment cuts to non-excepted, off-campus PBDs. Since 1992, this bipartisan program — which does not depend on taxpayer dollars — has allowed hospitals to access discounted drugs, enabling them to stretch scarce federal resources and provide more comprehensive services.** The cuts proposed by CMS are contrary to the program's statutory intent — to help covered entities and the vulnerable populations they serve. **Continuing this flawed policy or any other alternative other than current ASP plus 6 percent penalizes safety-net hospitals participating in the 340B program and severely impedes their ability to sustain vital services and care for patients in California's most underserved communities.**

Updates to the Inpatient-Only List

The inpatient-only list specifies services and procedures that Medicare will pay for only when provided in an inpatient setting. For CY 2020, CMS proposes to remove CPT code 27130—Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty (THA)) with or without autograft or allograft from the inpatient only list.

After reviewing the clinical considerations of THA and considering public comments in response to past rules, CMS believes that THA meets criterion for removal. For appropriately selected patients, CMS believes outpatient THA is appropriate. Several surgeons and other stakeholders believe that, with thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some Medicare beneficiaries. At this time, CMS does not propose to remove partial hip replacement (PHA) from the inpatient-only list, because it does not believe it meets the criteria for removal.

CHA disagrees with the stakeholder responses to the agency and strongly opposes CMS' consideration of removing THA from the inpatient-only list at this time. As stated in our CY 2018 OPPTS comments, we believe that THA is far more medically complex and invasive than total knee arthroplasty (TKA), and is often performed on an emergent, rather than elective, basis. The inherent risks of complications post-surgery are further enhanced due to the requirement of an inpatient qualifying stay in order to qualify for skilled-nursing facility (SNF) care. Therefore, if the patient receives THA on an outpatient basis, that stay is less than 24 hours. We believe a significant proportion of patients who perhaps do not need to be in the inpatient setting following surgery may need a level of SNF care for which they would no longer qualify. This puts patients at risk. Lastly, similar challenges remain for

comprehensive care for joint replacement (CJR) participants and bundled payments for care improvement (BPCI) advanced participants. These challenges have yet to be addressed despite the policies continuing to be advanced (and the implementation of TKA from the removal of the inpatient-only list in prior years). With that said, CHA supports CMS's prudent approach of no further action on PHA.

Impacts to Alternative Payment Models: CJR and BPCI Advanced

In California, there are more than 100 CJR model participants across three metropolitan statistical areas (MSAs) and numerous BPCI Advanced participants who have chosen joints as their clinical bundles. Absent clarification from CMS about how the agency will proceed in addressing the expected decrease in volume on the inpatient side and the subsequent effect on the target price for these providers, it is unacceptable to make such a change at this time. While we see advances in treatment in the traditionally insured commercial population, we are concerned that TKA and THA remain complex procedures, particularly for the Medicare population, and urge the agency to proceed with caution as it moves forward. Moreover, in the OPSS final rule implementing the move of TKA from the inpatient-only list, CMS explained that, although an increasing number of TKA cases may shift to the outpatient setting, it does not expect a large decrease in the volume of cases currently performed in the inpatient setting before the end of the CJR model in 2020. CMS also said it is monitoring outpatient TKAs to determine if it needs to change quality-adjusted target price calculations under the CJR model due to shifts to the outpatient setting. However, the agency recently released its Year 2 evaluation report of the CJR program and notes that the analysis is absent a review of this policy, as it was not in place at the time of the second performance year. At this time, we have no national data on the impact of these policies on these programs, leaving hospitals in great uncertainty. Therefore, CHA cannot support these policies.

If CMS proceeds in adopting the THA policy in addition to the current removal of TKA from the list, CHA urges CMS to act quickly to address concerns about the implications for CJR and BPCI Advanced. We suggest the agency propose through rulemaking a comprehensive risk-adjustment methodology for both programs. This would ensure that actual and historical episode spending is adjusted to reflect comparable patient populations. We have previously urged CMS to incorporate risk adjustment into the CJR program, but the pace of change is far too slow, as these programs are fully implemented.

In its analysis, CMS may want to evaluate including *outpatient* TKA in the CJR and BPCI Advanced programs. To do so, it could, for example, reimburse for this procedure at the outpatient ambulatory payment classification (APC) rate, but substitute the relevant inpatient Medicare-Severity Diagnosis-Related Group (MS-DRG) rate when calculating a participant hospital's actual episode spending. To ensure a level playing field, CMS also would need to specify that TKA could be performed in a hospital outpatient department only – not in an ambulatory surgical center (ASC). Many additional considerations also would need to be evaluated, such as which quality measures would apply to participant hospitals, and whether the outpatient claim would contain sufficient information to assign the appropriate MS-DRG (i.e., the Major Joint Replacement *with* Major Complications MS-DRG vs. the Major Joint Replacement *without* Major Complications MS-DRG).

One-Year Exemption from Medical Review

CHA supports CMS' proposal to establish a one-year exemption from medical review activities for procedures removed from the inpatient-only list beginning with CY 2020. While a step in the right direction, more can and should be done to not only allow time for provider education — but even more importantly, to ensure the CMS and its contractors, the Beneficiary Family Centered Care-Quality Improvement Organizations (BFCC-QIO), are aligned on medical review guidance for the field to follow.

CHA supports CMS' proposal to continue the BFCC-QIO reviews of short-stay inpatient claims for procedures that have been removed from the inpatient-only list within the first year. Such claims will not be counted against a provider in the context of the two-midnight rule. However, the challenge in these reviews that occurred when TKA was removed from the inpatient-only list caused a pause in all medical review and created significant confusion in the field. We are not confident that the medical review guidance questions have been fully addressed and believe additional time is needed for claims to process, and for contractors to gain experience in medical review in this area *prior* to putting hospitals at risk for recovery audit contractor (RAC) referrals.

We appreciate that these procedures would not be eligible for referral to RACs for noncompliance with the two-midnight rule and RAC "patient status" review within their first calendar year of removal from the list, but do not believe the time is sufficient. Information gathered when reviewing procedures that are newly removed from the inpatient-only list during the exemption period could be used to help inform guidance to the field in advance of medical reviews that would result in a claim denial. CHA urges CMS to consider the challenges that occurred on previous rollouts and afford itself and contractors additional time in this process to develop guidance that can be shared in advance for stakeholder input before finalization. That additional time should be extended to providers to ensure a seamless transition, clear and prudent guidance, and time for operational changes to occur.

Supervision Level for Outpatient Therapeutic Services

CHA strongly supports CMS' proposal to change the minimum level of supervision required for hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs, beginning January 1, 2020. CHA applauds CMS for removing this burdensome and unnecessary regulation.

Prior Authorization for Certain Hospital Outpatient Department Services

In an effort to control for what CMS deems "unnecessary increases in the volume of certain covered outpatient services," CMS proposes to implement a prior authorization requirement for several categories of services: blepharoplasty, botulinum toxin injections, panniculectomy rhinoplasty, and vein ablation. CMS notes that these are primarily cosmetic procedures, and the prior authorization process would ensure these services are only billed when medically necessary.

We remain extremely concerned with CMS' assertion – without clear and convincing evidence – of "unnecessary increases in volume of services for certain covered outpatient services" and urge the

agency to revisit its analysis of the claims data and present additional evidence of over utilization beyond increases above the national average. Such a narrow view is contrary to the agency's responsibility to ensure beneficiaries have access to high-quality health care services. Our perspective is supported by a similar view advanced by the Hospital Outpatient Advisory Panel, which recently concluded that there is a lack of evidence presented for the adoption of the site-neutral policies for clinic visits. Absent a robust analytical framework, including input from clinical experts and medical record reviews from which to assess unnecessary increases in the volume of services, the agency has provided no convincing evidence to support such a significant change in fee-for-service policy such as prior authorization. For instance, the FDA approved the use of Botox for treatment of migraine headaches in 2010. This additional medical indication could explain why CMS is seeing more use of Botox injections over time in recent years.

To address what CMS perceives as unnecessary increases in volume, CMS proposes to establish a process through which providers would request prior authorization for provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. CMS proposes to add regulations that establish the conditions of payment for covered outpatient department services that require prior authorization, establish requirements for the submission of prior authorization requests (including expedited review request), and permit suspension of the prior authorization process generally or for particular services. Finally, CMS proposes to implement the process for dates of service on or after July 1, 2020.

This proposal, as outlined, presents a number of challenges. First and foremost, we are perplexed as to why the agency has not focused prior authorization processes directly on Part B physician claims for these services. Is there evidence that the unnecessary utilization is occurring in greater instances in hospital outpatient departments than in the physician office setting? Patients consult with their doctors in determining their course of treatment. The continued approach of putting hospital administrators in the middle of that patient relationship with their clinician under a prior authorization process has not been well considered. Unlike most states, the vast majority of hospitals in California are unable to employ their doctors and, as such, must endeavor to navigate a complex regulatory framework in which to fully integrate. Policies like these, when applied to a hospital outpatient department setting but not the physician office setting, create misalignment, clinician frustration, and beneficiary confusion. **Moreover, CMS estimates it would take only one year to procure a contractor, educate staff, and prepare hospitals and physicians for implementation. We believe CMS has woefully underestimated the time it takes to establish a well-functioning, technologically efficient and provider/patient friendly method for prior authorization. Hospitals' less than satisfactory and often extremely frustrating and costly experience with managed care prior authorization processes across commercial and Medicare Advantage (MA) plans speaks volumes about the challenges that lie ahead if not more thoughtfully considered.**

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services published in September 2018 a report titled *"Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Services and Payment Denials."* Among the report's findings are:

- CMS audits found widespread and persistent problems related to denials of care and payment in MA, including insufficient denial letters, inappropriate denials related to insufficient outreach, and inappropriate denials related to making the wrong clinical decision. More than half of the MA contracts were cited for inappropriate denials.
- Incorrect or incomplete denial letters (seen in half of the audited Medicare Advantage organization contracts) may inhibit beneficiaries' and providers' ability to appeal.
- When MA beneficiaries and providers appealed, they were usually successful in getting denials overturned. Overturn rates at the initial (plan) level ranged from 0 to 100%, with a median of 77%.
- MA beneficiaries and providers rarely used the appeals process. The OIG notes that contract-specific rates of appeal varied widely.

Based on its findings, the OIG recommended that CMS enhance oversight of MAO contracts, including ones with high overturn rates and/or low appeal rates, address persistent problems related to inappropriate denials and insufficient denial letters, and provide beneficiaries with clear, easily accessible information about violations.

While CHA strongly opposes the implementation of a prior authorization policy in the CY 2020 OPSS for several reasons noted above, we are intrigued by the concept of prior authorization in a fee-for-service payment system. The motivations of such a process in a fee-for-service payment system are — and should be — different than the flawed incentives inherent in a managed care environment. CMS proposes to model the prior authorization process after the durable medical equipment (DME) process that was initially outlined in statute. Such legislative authority does not currently exist in the OPSS system. Notably, the DME prior authorization program was up and running after a pilot **and six years** of agency engagement with the MACs and suppliers before full implementation. In addition, it is our understanding that when a new piece of equipment is added to the list for prior authorization, the process is rolled out on a limited basis and then scaled nationally. CMS should proceed cautiously in permitting immediate nationwide applicability of prior authorization for DME as proposed for FFY 2020.

We understand that targeted probe and educate reviews, as well as post payment reviews, have decreased substantially for DME that is subject to prior authorization. **Conceptually, if a robust and meaningful prior authorization process was established for a limited number of services, there would be no need for pre- or post-payment reviews of those claims – including reviews by RACs. Not removing such policies and adding more complexity is the opposite of the agency's goals of reducing administrative burden; it will only add additional costs to an already costly claims processing process.**

CHA encourages CMS to begin the process of stakeholder engagement to solicit additional input and to lay a foundation for a meaningful dialogue about the opportunities and challenges a prior authorization process presents. We look forward to engaging in that dialogue.

Potential Revisions to Laboratory Date of Service Policy

Many hospitals rely on independent laboratories — especially for more technologically advanced tests such as molecular pathology and advanced diagnostic laboratory tests (ADLTs) — which, by definition,

are performed only at a single laboratory. However, Medicare date of service (DOS) requirements and “under arrangement” regulations often require that the hospital bill for these tests, requiring that the laboratories in turn seek payment from the hospital. CMS heard from hospitals and laboratories that its DOS policies have been administratively burdensome, and was also concerned that its 14-day rule created delays and barriers to patient access to necessary laboratory tests. In the CY 2018 OPPTS final rule, CMS established an exception to its DOS policies that allows independent laboratories performing certain molecular pathology and ADLTs to bill Medicare directly, as these tests are rarely performed by hospital laboratories.

The exception requires laboratories to bill Medicare directly for these tests if the following conditions are met:

- The test was performed following the date of a hospital outpatient’s discharge from the hospital outpatient department.
- The specimen was collected from a hospital outpatient during an encounter.
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter.
- The results of the test do not guide treatment provided during the hospital outpatient encounter.
- The test was reasonable and medically necessary for the treatment of an illness.

Many hospitals and laboratories have reported administrative difficulties implementing the DOS exception. As a result, CMS applied enforcement discretion – extended through January 2, 2020 – for the DOS exception to provide additional time for hospitals and laboratories to make necessary changes to their systems to bill for tests subject to the exception. However, hospitals continue to struggle to make the necessary system changes to provide the performing laboratory with several data elements that are needed for the laboratory to bill Medicare directly for the test. In response to these concerns, CMS is considering a number of changes to the current exception, which — while well intentioned — we believe fall short of addressing hospitals’ administrative concerns, and instead increase complexity and reduce the usefulness of the exception for laboratories.

First, CMS is considering changing the test results requirement to specify that if the other four requirements are met, the ordering physician can decide if the results of the test guide treatment provided during a hospital outpatient encounter. **CHA is concerned that this change will increase burden and confusion for hospitals and providers, as it is often unknowable to the physician how the result of a test will influence the site of care delivered in the future. Under such a policy, we believe the date of the specimen collection would be the default DOS, requiring the hospital to bill Medicare and the laboratory to seek payment from the hospital, significantly reducing the usefulness of the exception.**

Second, CMS is considering limiting the laboratory DOS exception to solely ADLTs, removing the exception for molecular pathology tests. **We do not believe this will reduce administrative burden.**

Rather, it significantly reduces the exception for laboratories, as ADLTs represent an extremely small number of laboratory tests. Finally, CMS is considering excluding blood banks and blood centers from the laboratory DOS exception, some of which perform certain molecular pathology tests. CMS notes that blood banks and centers primarily perform this testing to identify the most compatible blood product for a patient, and believes that this kind of testing is so connected to the treatment furnished to the patient during the hospital encounter that it must be considered a hospital service, requiring hospitals to bill and receive payment for the testing. **However, CHA believes this would add even more complexity to the exception, requiring hospitals to tease out different purposes for different molecular pathology tests. We urge CMS to rethink each of these proposals and refocus efforts on providing hospitals with the time and resources to develop the necessary system changes that will allow these laboratories to bill directly for the tests.**

Hospital Outpatient Quality Reporting Program

CMS proposes to remove the measure OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the hospital outpatient quality reporting (OQR) program beginning with 2022 payment under measure removal Factor 8: costs outweigh the benefit of continued use of the measure. **CHA agrees that this measure is administratively burdensome and supports its removal from the OQR program. CHA also believes it would be inappropriate to continue to include this measure, which is no longer being maintained by the measure steward, to ensure specifications are in line with clinical guidelines and standards. The measure lost its National Quality Forum endorsement in 2018.**

However, we ask CMS to clarify its proposal to no longer require reporting on the measure beginning with October 2020 encounters, rather than on January 1, 2020. CMS notes that it decided not to remove the measure beginning with the CY 2021 payment year out of concern that the reporting period is already under way — which for CY 2021 is CY 2019 — but it is unclear why CMS would continue to require hospitals to report on measure data from January 1 – September 30, 2020. **We urge CMS to clarify that reporting of the measure would no longer be required for the full CY 2022 payment year reporting period, beginning with January 1, 2020, encounters.**

CMS Requests for Information

Price Transparency Quality Measurement

CMS seeks public comment on a number of additional price transparency topics in two broad categories: improving access to quality information by entities developing price transparency, and improving incentives for providers to share charge information with patients. CHA strongly believes such a dialogue with CMS is a critically important one and that it must commence immediately. In review of the administration's most recent proposals related to price transparency, we believe there is a fundamental misunderstanding of hospital and payer contracting arrangements, how data are captured and retrieved in provider revenue cycle systems, and the multiple interactions of federal and state law and regulation — creating a challenge for our shared goals of making patient out-of-pocket costs more readily available to patients. CHA strongly believes that, if we are to advance this dialogue in a meaningful and

productive way that puts patients first, we must first have a common vocabulary from which to communicate. To date, we do not have such a common vocabulary or shared understanding of perspectives that bring about opportunities and meaningful problem solving. We urge the agency to begin this dialogue first and then, as a next step, we believe that additional information may be best gathered through future RFIs informed by CMS listening sessions, Medicare Technical Advisory Groups, and direct stakeholder engagement in small groups. We look forward to continued and active engagement in this process.

CHA appreciates the opportunity to comment on the CY 2020 OPPS proposed rule. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs