September 17, 2021

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

SUBJECT: CMS-1753-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (Vol 86, No 147), August 4, 2021

Dear Administrator Brooks-LaSure:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule updating the Medicare Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2022.

California's hospitals — like other hospitals across the nation — are still navigating the unprecedented challenges posed by the public health emergency (PHE). They are simultaneously providing care to those suffering from the latest surge in COVID-19 cases, collaborating with local partners to support COVID-19 vaccination efforts, and ensuring that capacity to provide non-COVID-19 emergent and non-emergent care remains available. We greatly appreciate the federal government's continued partnership and efforts to support hospitals during the PHE. This includes CMS-provided waivers offering flexibility and financial support through the Provider Relief Fund and Treasury programs to ensure that hospitals can continue operations, invest in the supplies and infrastructure necessary to effectively respond to the pandemic, and provide succor to those who need care.

Despite the flexibility and financial support provided, California's hospitals are struggling. Costs associated with maintaining health care delivery system capacity during the pandemic — particularly staffing costs and PPE — have increased significantly. At the same time, patient volumes (and revenue) declined due to the public's general hesitance to seek necessary care and intermittent moratoriums[1] on non-emergent procedures. A recent analysis by Kaufman Hall, a nationally renowned consulting firm,

[1] Nationally in spring 2020 and continuing in local hotspots through the current period.

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estimates that even after federal support, California's hospitals lost more than $8 billion in 2020. And additional losses during 2021 due to COVID-19 could exceed $2 billion, further jeopardizing the stability of the delivery systems that are essential in continuing efforts to respond to the ongoing pandemic.

In light of the pandemic, CHA appreciates that, in the OPPS proposed rule, CMS has taken necessary steps to further minimize the negative impact of the COVID-19 PHE on hospitals. We strongly support CMS' proposals to use alternative data for rate setting when the data sets CMS traditionally uses demonstrate aberrant utilization patterns that are unlikely continue into 2022. We also support CMS' efforts to ensure patient safety by rescinding the phase-out of the inpatient-only (IPO) list that was finalized in the CY 2021 OPPS rule. However, we are deeply concerned by continued, unjustified reductions in payments to 340B hospitals for separately payable Part B drugs and strongly oppose increasing the penalties related to the hospital price transparency requirements.

In summary, CHA:

- Strongly supports CMS' efforts to mitigate the impact of COVID-19 on OPPS rate setting by using 2019 Medicare Provider Analysis and Review (MedPAR) data and FFY 2018 Hospital Cost Report Information System (HCRIS) data to establish the relative weights and calculate the fixed loss outlier threshold.
- Opposes CMS' existing and proposed payment methodology for 340B-purchased drugs and respectfully requests that CMS restore payment for separately payable drugs acquired through the 340B program at average sales price (ASP) plus 6% in a non-budget neutral manner.
- Strongly opposes increasing the penalties related to the hospital price transparency requirement. Given the requirement has been in effect for less than a year, we believe it is premature to assert that the existing penalties are insufficient to compel compliance. Our members support taking steps to ensure that patients have resources to understand their out-of-pocket costs. However, compliance efforts have been challenged, as key IT and administrative resources necessary to implement the requirements have been focused on responding to the COVID-19 PHE.
- Respectfully encourages CMS to delay the start of the radiation oncology (RO) model until January 1, 2023, to allow time for health systems to upgrade their IT systems to participate. We also ask the agency to reduce the model's discount rate. The discount rate in the RO model is still far greater than those found in other APMs with similar risk profiles. Given the capital-intensive nature of RO services, CHA is concerned that an inappropriately inflated discount rate will result in longer wait times and reduced access to RO services for all patients — particularly those who face disparities in health outcomes.
- Strongly supports CMS' proposal to use a cost floor to establish partial hospitalization program (PHP) payment updates and urges CMS to consider more long-term approaches to addressing cost fluctuations in PHP services. We also urge CMS to extend its policies allowing for PHP services to be provided to patients in their home via telecommunications services beyond the COVID-19 PHE.
- Urges CMS to address several operational questions and concerns related to reporting on the proposed COVID-19 Vaccination Coverage Among Health Care Personnel quality measure, including reducing duplicative reporting requirements, and revising measure specifications to address booster shots and exemptions for sincerely held religious beliefs.

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

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

In the proposed rule, CMS proposes and clarifies several policies intended to improve compliance with the Hospital Price Transparency final rule requirements. Most notably, CMS proposes to increase civil monetary penalties (CMPs) for non-compliance, based on a sliding scale factor tied to bed counts. **CHA and its member hospitals are committed to price transparency and have long been committed to providing patients with information to understand their out-of-pocket costs. While we offer comments on CMS' specific proposals below, we urge CMS to consider some overarching feedback on the direction of overall price transparency proposals moving forward.**

In addition to the hospital price transparency final rule requirements, CMS finalized similar requirements for health plans under the transparency in coverage final rule, and Congress last year passed the No Surprises Act (NSA), which includes additional price transparency requirements for hospitals and plans. Notably, on August 20, the Departments of Labor, Health and Human Services (HHS), and Treasury issued guidance (multi-agency guidance) on both the transparency in coverage final rule and NSA implementation that acknowledged the significant burdens of compliance and delayed key deadlines. This includes delaying enforcement of the requirements that plans and issuers make public machine-readable files for in-network rates and out-of-network allowed amounts and billed charges by six months, until July 1, 2022. The guidance also states that regulations implementing NSA requirements for health care providers and facilities to provide a good faith estimate of expected charges for scheduled services will not be issued before the statutory compliance date of January 1, 2022, and thus enforcement will be deferred until regulations are promulgated and applicable. In addition, the guidance delays requirements that health plans provide an advanced explanation of benefits that would provide patients an estimate of their out-of-pocket costs for future services.

CHA thanks the agencies for appreciating the significant technical challenges faced by hospitals and health plans and strongly supports the delayed deadlines. We believe this delay will not only allow the agencies to work with stakeholders to develop the IT infrastructure necessary to operationalize these requirements, but provides HHS and CMS an opportunity to review its portfolio of overlapping transparency initiatives and develop a comprehensive strategy that will ensure consumers have ready access to the information they need to make more informed choices about their health care.

In light of the significant overlap, duplication, and interaction of various price transparency requirements, CHA urges CMS to consider its hospital price transparency requirements as part of its portfolio of transparency initiatives and work across agencies to better align the varying regulatory and statutory requirements. We believe that the recent multi-agency guidance underscores the opportunity to re-think how health care price information can be made public in ways most useful to policymakers, providers, payers — and most importantly, patients. Secondarily, CHA believes that by developing an overarching strategy, HHS and CMS have an opportunity to reduce the administrative burden across all stakeholders, which will ultimately translate into lower premiums for consumers and costs for patients.

For example, there is duplication in federal requirements for hospitals and health plans to provide out-of-pocket cost information to patients. Under the hospital price transparency final rule, hospitals are

required to publicly post a searchable display of standard charges[2] for at least 300 "shoppable" services[3] and a machine-readable file for all items and services provided by the hospital. Similarly, the transparency in coverage final rule requires health plans to make publicly available an internet self-service tool that allows patients to check the cost-sharing amount for shoppable services[4] and machine-readable files containing in and out-of-network rates for all covered items and services[5]. The recent multi-agency guidance notes that because the NSA includes largely duplicative requirements, the departments will exercise enforcement discretion on the existing regulation and propose rulemaking that could better align the requirements.

We urge the administration to harmonize its efforts to provide a comprehensive mechanism for patients and consumers to understand their out-of-pocket costs in advance of a service or procedure. Having an overarching, federal framework that allows consumers to request an estimate of their out-of-pocket costs in advance of a service or procedure will allow health plans, providers, and their respective technology vendors to develop a standardized, automated process to exchange the data and effectively communicate it to patients and consumers, while reducing administrative burden and associated costs.

In addition, we urge CMS to reconsider the usefulness of its hospital machine-readable file requirements. As researchers and media have reported on compliance with the existing regulation, many have found that even among hospitals deemed to be most compliant with the requirements, it is challenging if not impossible to compare prices within, and particularly across, hospitals. As was pointed out by CHA and other stakeholders in response to the hospital price transparency proposed rule, this is true due to many factors, such as differences in contracting practices and variation in the inclusion of facility and professional fees.

Overall, we urge CMS to continue working across the federal government and with stakeholders to determine what price information — and in what format — is most useful to patients in understanding their out-of-pocket health care costs, while aligning various federal requirements to reduce burdens on providers so they can remain focused on direct patient care.

Proposed Increase to Civil Monetary Penalties (CMPs)

CMS has established a process for enforcement of the requirements under the hospital price transparency final rule, which includes issuance of a written warning notice to the hospital of the specific violation, submission of a corrective action plan from the hospital, and imposition of CMPs — not to exceed $300 per day — on the hospital if it fails to provide or comply with its corrective action plan. In early 2021, CMS began auditing hospital compliance and issuing warning letters to those found to be out of compliance. To date, CHA is not aware of any hospitals that have been assessed CMPs. **CHA appreciates CMS' appropriately measured compliance approach to date.**

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[2] Standard charges are defined as the gross charge, payer-specific negotiated charge, de-identified minimum and maximum negotiated charges, and discounted cash price.

[3] This requirement can also be satisfied by posting an out-of-pocket cost estimation tool that provides real-time cost estimates tailored to the individual.

[4] Effective beginning on January 1, 2023, for the 500 most common services.

[5] Effective beginning on July 1, 2022.

CHA notes that the hospital price transparency requirements had been in effect for less than eight months at the time the proposed rule was published. Despite current enforcement efforts being in their infant stages, in the proposed rule CMS says that it is "concerned by what appears to be a trend towards a high rate of hospital noncompliance," and proposes to increase the maximum CMP using a scaling factor to establish the CMP amounts. Specifically, CMS proposes to establish hospital bed counts — as specified on the Medicare cost report — as the scaling factor for assessing CMPs. Under the proposal, hospitals with 30 or fewer beds would remain with a maximum daily penalty of $300; hospitals with 31 to 550 beds would be assessed at a maximum daily penalty of $10 per bed; and hospitals with more than 550 beds would be subject to the maximum daily penalty of $5,500. Thus, the annual maximum penalty for hospitals would be significantly increased from $109,500 to $2,007,500.

CHA strongly opposes this proposal and believes it is inappropriate for CMS to increase CMPs at this time. Hospitals are working in good faith to comply with the price transparency regulations, while at the same time the COVID-19 PHE continues to demand the hospital and health system IT and administrative resources that are also necessary to comply with the hospital price transparency requirements. Further, we urge the agency to provide additional education and technical assistance as it assesses hospital compliance and provide transparent information on its ongoing enforcement efforts. **Given the impact of the COVID-19 PHE on a hospital's compliance efforts and need for additional CMS support of hospital efforts to implement these technical requirements, we believe it is premature to consider an increase in the CMPs associated with the hospital price transparency requirements.**

Additional education and technical assistance is needed to support hospital compliance. Despite best efforts to comply with the hospital price transparency final rule requirements, many hospitals continue to be challenged in understanding whether the price information they have made available would be deemed compliant by CMS. For example, hospitals often report that different vendors will suggest differing file formats to meet the machine-readable file requirements, and it can be unclear which, if any approach, would be deemed compliant.

While CHA greatly appreciates the educational resources that CMS has provided to date, they have not been comprehensive, up-to-date, or provided in abundance. We note that the FAQ document CMS has posted has not been updated since January 15, 2021, so it does not incorporate any issues CMS has identified by its enforcement efforts[6], and the agency has made available just two "how-to" documents[7,8,9] that merely summarize the material already available in the hospital price transparency final rule. Hospitals continue to have significant questions that have not yet been addressed in these documents — in particular, how to report standard charge information in cases where multiple contracted rates for a single service may exist depending on certain information only determined at the time of service or as a result of the outcome of the service. In addition, there is confusion about how to report contracted rates under value-based agreements and capitation, which is common in California.

CHA urges CMS to expand upon its existing guidance documents — in particular, detailing how CMS views compliance with the machine-readable file requirements, taking into consideration the

[6] https://www.cms.gov/files/document/hospital-price-transparency-frequently-asked-questions.pdf
[7] https://www.cms.gov/files/document/steps-machine-readable-file.pdf
[8] https://www.cms.gov/files/document/steps-making-public-standard-charges-shoppable-services.pdf
[9] CHA notes that neither of these documents has been materially updated since they were first published.

complexities of hospital contracting — and provide further education to hospitals. Notably, on August 11, CMS held a National Stakeholder Webinar on Price Transparency. This webinar provided hospitals with additional instruction on how to comply with the machine-readable file requirements, and we applaud CMS for providing additional clarity in its presentation. Feedback from CHA's members suggests that hospitals would benefit from additional sessions and encourage CMS to continue these efforts as well as offer regularly scheduled "office hours" sessions to discuss implementation issues with CMS staff. In addition, we urge the agency to provide hospitals with technical assistance in addressing specific instances of non-compliance identified in audits.

CMS should provide transparent information on enforcement efforts. In the proposed rule, CMS cites its own "sampling and reviews to date," along with several independent studies to support its concerns with high rates of non-compliance with the price transparency requirements. However, even among independent studies, wide variation in hospital compliance was found, and several studies mentioned limitations in evaluating compliance. **CHA urges CMS to provide transparent information on its compliance audits, including but not limited to how many hospitals have been found to be compliant, how many are found insufficiently compliant, common issues identified, and examples of successful corrective action plans. We believe it is premature to increase CMPs prior to a more complete picture of hospital compliance within the first year of implementation.**

Impact of COVID-19 PHE on hospital compliance. As noted throughout this letter, California hospitals remain significantly challenged by the COVID-19 PHE. With each additional surge, hospitals have faced new challenges, and many of the staff who are responsible for implementing price transparency requirements have had to shift their focus to ensuring that the capacity and resources necessary to provide care to those suffering from COVID-19 in their communities are available. For example, the same IT and administrative staff who would have begun working toward compliance were responsible for building out systems to support surge capabilities, including opening alternate care sites and increasing telehealth utilization. Notably, California experienced its most significant surge during the fourth quarter of 2020 (November and December) and first quarter of 2021 (January and February), just as the regulations were coming into effect. Many of these same hospital staff were tasked with the mandated daily reporting of COVID-19 information to local, state, and federal systems, as well as standing up systems to support vaccination administration in their communities and tracking the vaccination status of their staff. The resources involved in these various projects cannot be underestimated, and we urge CMS to recognize that hospitals have been operating under crisis conditions for almost 18 months while working to comply with the price transparency requirements. We urge CMS to retain its existing CMP amounts and re-evaluate the impact of current CMPs on hospital compliance at least 12 months after the end of the COVID-19 PHE.

Patient Price Estimator Tools

Under the hospital price transparency final rule, hospitals can satisfy the requirements to make available consumer-friendly price information on common "shoppable services" by utilizing an internet-based price estimator tool. In the proposed rule, CMS clarifies that for a tool to be compliant, it must provide the patient a single amount, tailored to their circumstances, and — if applicable — based on benefit information received directly from the patient's insurer. CHA strongly supports the use of patient price estimator tools. Even prior to the issuance of the hospital price transparency final rule, many California

hospitals offered these tools to help patients understand their expected costs, and we strongly support their use as an option to comply with the price transparency requirements.

As CMS audits hospital compliance, we ask the agency to be aware of several technical challenges. For example, these tools rely on health plan and insurers' responses to eligibility requests. However, hospitals report that some plans to do not provide real-time, out-of-pocket information to providers, and as such, have had to build in workarounds that require patients to input their specific information — such as co-pays or annual out-of-pocket limits — into the tool. We also note that, while hospitals do their best to provide accurate estimates of an episode of care, there are many unknowable factors, such as additional labs or imaging services ordered to inform next steps, that CMS may not view as "unusual or unforeseeable circumstances" and that change the cost of care following an estimate.

Definition of "Plain Language"

CMS states that its reviews of hospital compliance with the price transparency requirements indicate that not all hospitals appear to be using what could reasonably be considered "plain language" to describe shoppable services. While CMS recommends using federal plain language guidelines, it does not require it. CHA urges CMS not to adopt existing federal plain language guidelines in the context of the hospital price transparency requirements. We remain concerned that CMS does not fully understand hospital contracting and billing practices, and certain "plain language" terms would not translate to a standard definition in health care. As CMS works to improve the usefulness of this information to patients and the public, we urge the agency to engage a broad group of stakeholders to inform any future language to describe shoppable services.

OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP minus 22.5%, instead of ASP plus 6%. In 2019, CMS continued this policy and expanded it to apply to off-campus provider-based departments (PBDs) that are subject to section 603 of the Bipartisan Budget Act of 2015 and paid under the physician fee schedule (PFS)-equivalent rate equal to 40% of the OPPS payment amount. The 340B payment policy does not apply to rural sole community hospitals, children's hospitals, or PPS-exempt cancer hospitals.

For CY 2022, CMS proposes to maintain its policy and pay for separately payable drugs acquired through the 340B program at ASP minus 22.5%. **CHA strongly opposes CMS' proposed payment methodology for 340B purchased drugs and respectfully requests the agency restore payment for separately payable drugs acquired through the 340B program at ASP plus 6%. Further, we ask that, if CMS rescinds its current 340B payment policy and reverts back to paying ASP plus 6% for separately payable drugs acquired under the 340B program, it work with Congress to do so in a non-budget neutral manner.** We believe additional funding is necessary in the OPPS given that the average PPS hospital Medicare margin is negative 8.7%[10].

As it stands, CMS' current and proposed payment rates fundamentally undermine the program's intent, subvert Congress' goals, and will continue having a devastating impact on patients served by 340B hospitals and clinics. Safety net hospitals and clinics participating in the 340B program benefit today because pharmaceutical manufacturers are required to sell outpatient drugs at discounted prices. These

[10] http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_ch3_sec.pdf?sfvrsn=0

discounts are vital for 340B providers, as they provide care for the majority of uninsured and low-income patients. **Specifically, in California, 175 safety net 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. In fact, a recent analysis by the American Hospital Association found that in 2018 — the most recent year for which this information is available — tax-exempt hospitals participating in the 340B program provided $64.3 billion in total benefits to their communities.**

Continuing these cuts runs contrary to congressional intent of the 340B program. While we acknowledge there are open issues currently awaiting hearing by the U. S. Supreme Court, hospitals continue to be concerned that these proposed payment reductions will directly threaten access to care, especially in rural and other vulnerable communities.

CMS' proposed continued cuts to the 340B program come at a time when the entire health care system is facing ongoing, unprecedented challenges as a result of COVID-19. For over 18 months, California's more than 400 hospitals have been responding to an evolving global pandemic that threatens millions of lives around the world. In response, CHA's members are intermittently canceling non-emergent procedures to ensure sufficient capacity to provide care for surges of COVID-19 patients while still ensuring access for those needing emergent care, purchasing and maintaining large quantities of personal protective equipment, retrofitting facilities, and collaborating with their communities to support ongoing vaccination efforts. These ongoing activities significantly increase operating costs. A recent report by Kaufman Hall finds that the COVID-19 pandemic resulted in 254 California hospitals (58%) finishing 2020 with negative operating margins. It is projected that as many as 206 California hospitals (47%) will have negative operating margins in 2021[11]. This is not sustainable. If these policies are continued, they will have a significant negative impact on Medicare payments for separately payable Part B drugs to 340B hospitals, further threatening the financial viability of California's already weakened safety net hospitals.

Partial Hospitalization (PHP) Services

CMS proposes payment updates for hospital-based and community mental health center (CMHC) PHP services under its existing methodology using geometric mean per diem costs. However, because the geometric mean per diem costs CMS calculated for both CMHC and hospital-based PHP would decline in CY 2022 compared to CY 2021, the agency proposes to instead use a cost floor for both types of PHP providers. **CHA strongly supports this proposal and urges CMS to consider more long-term approaches to addressing cost fluctuations in PHP services, as well as provide more stable payment rates to ensure access to these important services.**

In addition, CMS reminds providers that under its April 30, 2020, interim final rule,[12] hospital and CMHC staff may furnish PHP services, incident to a physician's services, to beneficiaries in temporary expansion locations (including the beneficiary's home), and that these services can be furnished using telecommunications technology if the beneficiary is registered as outpatient. **While these policies are currently in place for the duration of the COVID-19 PHE, we urge CMS to extend this policy until at least December 31, 2023 — in alignment with its proposals related to maintaining temporary telehealth services as proposed in the CY 2022 physician fee schedule proposed rule — and consider**

[11] https://www.kaufmanhall.com/sites/default/files/2021-04/kh-cha-financial-forecast-ebook_final.pdf
[12] CMS–1744–IFC

future policies to permanently allow patients to receive PHP services in their home via telecommunications technology.

Inpatient-Only (IPO) List

In the 2021 OPPS final rule with comment period (85 FR 86084 through 86088), CMS adopted a policy to eliminate the IPO list over three years. As part of the first phase of eliminating the IPO list, CMS removed 298 codes from the list beginning in 2021. The removed procedures were not assessed against the agency's longstanding criteria for removal.

After further consideration of the policy and the concerns stakeholders have raised since the final rule was issued, CMS proposes to halt the elimination of the IPO list beginning in 2022. CMS also believes that the criteria for removing a procedure from the IPO list should be reinstated, which it proposes to do beginning in 2022.

CMS further evaluated the 298 procedures removed from the IPO list in 2021 against the proposed reinstated criteria and determined that none of the removed procedures met the criteria for removal from the IPO list. For this reason, CMS proposes to add all 298 procedures back to the IPO list for 2022.

CHA strongly supports CMS' proposal to rescind its policy to phase out the IPO list and return the 298 procedures to the list for CY 2022. Further, we do not believe that it should be a "policy goal" of CMS to phase out the IPO list. The list exists for a reason — to protect patients and ensure high-quality outcomes. And we believe that the annual review of the services — using the five criteria reinstated in the proposed rule — on the IPO list provides an appropriate process and framework to evaluate procedures for potential removal on a case-by-case basis as anesthesia, surgical techniques, and post-operative management protocols evolve.

Medical Review of Certain Inpatient Hospital Admissions

As discussed above, CMS adopted a policy to eliminate the IPO list over three years in the CY 2021 OPPS final rule. In conjunction with that policy, CMS adopted a policy to indefinitely exempt procedures removed from the IPO list after January 1, 2021, from site-of-service claim denials, eligibility for BFCC-QIO referrals to recovery audit contractors (RACs) for noncompliance with the two-midnight rule, and RAC reviews for "patient status." This exemption would last until Medicare claims data indicate that the procedure is more commonly performed outpatient than inpatient.

Now that CMS is proposing to return to its prior policy of selectively removing procedures from the IPO list, the agency believes that an indefinite exemption from medical review activities related to the two-midnight rule may no longer be warranted. Accordingly, CMS proposes to rescind the indefinite exemption and apply a two-year exemption from two-midnight medical review activities for services removed from the IPO list on or after January 1, 2021.

CHA asks CMS to maintain an indefinite exemption of the two-midnight rule for procedures removed from the IPO list in the future. While we have previously supported a two-year exemption from review under the two-midnight rule, we believe the complexity of the services remaining on the IPO list — as evidenced by the results of CMS' review of the 298 services the agency proposes adding back to the list — merits the need for an indefinite exemption. Even after reverting back to a policy where individual

procedures are reviewed for removal on a case-by-case basis, we believe a higher percentage of Medicare beneficiaries will require the services removed from the IPO list on an inpatient basis than is typical for services heretofore removed from the IPO list. Therefore, we ask CMS to allow hospitals additional time to develop criteria to identify which patients are appropriate to perform a recently removed IPO list procedure on in the outpatient setting, and which patients — due to underlying health issues and contributing social factors — should still receive the service in an inpatient setting.

Low Volume Policy for Clinical, Brachytherapy, and New Technology APCs

CMS proposes to continue its policy (with modification outlined below) established in CY 2019 OPPS final rule that created a different payment methodology for services assigned to new technology ambulatory payment classifications (APCs) with fewer than 100 claims. This methodology may use up to four years of claims data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for assigning services to a new technology APC.

However, CMS proposes to utilize this policy through a proposed universal low volume APC policy that is similar to the current new technology APC low volume policy but applies to clinical APCs and brachytherapy APCs in addition to new technology APCs. It also uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. If the universal low volume APC policy is finalized CMS will end the separate new technology APC low volume policy. **CHA strongly supports CMS' proposal to expand its low volume policy to low volume clinical APCs and brachytherapy APCs. We believe the proposed policy will address the longstanding issue of payment rate instability for APCs with fewer than 100 claims.**

Packaging Policies and Non-Opioid Treatment Alternatives

For CY 2022, to address the decreased utilization of non–opioid pain management drugs and encourage their use rather than that of prescription opioids, CMS proposes continuing to unpackage, and pay separately at ASP plus 6%, the cost of non–opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting (and not pay separately for these drugs when furnished in the hospital outpatient payment department [HOPD] setting).

CMS believes that it may be appropriate to establish a similar payment methodology for drugs furnished in the HOPD setting and, therefore, is requesting comment on expanding the policy to HOPDs. CMS is further investigating whether products should be treated the same depending on if they are furnished in an ASC or HOPD. **CHA appreciates the agency's continued work on the negative impact of packaging policies on the use of non-opioid treatment alternatives in hospital outpatient settings. Our members believe that the current packaging of non-opioid alternatives continues to present a barrier to their broader usage and, therefore, these treatments should be paid for separately.**

We support CMS' proposal to continue unpackaging Exparel and Omidria when they are provided in ASCs and encourage CMS to adopt a similar policy when they are provided in an HOPD. CHA also encourages CMS to consider unpackaging other non-opioid treatments including drugs, devices, and therapy services that are not currently separately payable in both the ASC and HOPD setting. Based on feedback from our members, examples of other non-opioid treatments include the "On-Q" pain relief system, IV Ibuprofen and Acetaminophen, devices that use ice water for post-operative pain relief for knee procedures, therapeutic massage, and dry needling procedures.

Use of 2019 Claims Data for 2022 Rate-Setting

CMS normally uses the MedPAR file from the second year preceding the rate-setting year (e.g., 2020 for 2022). CMS also typically uses cost reports from the HCRIS dataset beginning three fiscal years prior to the year that is the subject of the rulemaking (2019[13] for 2022). However, CMS believes that CY 2020 outpatient utilization has been significantly affected by the COVID-19 PHE. In the proposed rule, CMS offers compelling evidence that the claims data from the 2020 MedPAR file are atypical. These trends are not expected to continue into 2022. Additionally, in the proposed rule CMS presents an analysis that concludes there would be a material effect on OPPS rate setting from using atypical 2020 outpatient utilization rather than continuing to use the more typical utilization patterns from 2019.

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

Extending Expiring CY 2021 Pass-Through Payment for CY 2022

As discussed above, CMS proposes to use 2019 claims data in establishing the 2022 OPPS rates. The CY 2019 data will not reflect a full three years of pass-through payment for products with expiring pass-through payments after 2021. Therefore, CMS is proposing to continue separate payment for the remainder of 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021, and September 30, 2022.

Extended pass-through payment would apply to one device and 21 drugs, three of which would be packaged after pass-through expires. Table 38 in the proposed rule lists drugs, biologicals, and the device that will receive extended pass-through payment. **CHA supports CMS' proposal to continue pass-through payments for the drugs and devices listed in Table 38 of the proposed rule.** We believe this will allow CMS appropriate time to collect the necessary data to accurately set APC weights that incorporate these technologies once pass-through payment status expires.

Hospital Outpatient Quality Reporting (OQR) Program

COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

CMS proposes to add a new process measure to the Hospital OQR Program beginning with the CY 2024 payment determination to track the percentage of health care personnel who receive a complete COVID-19 vaccination course. CMS proposes to require an initial data reporting period of January 1, 2022, through December 31, 2022, for the CY 2024 payment year, with data reported for at least one week of every month in the reporting period using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) web-based surveillance system. Notably, CMS has finalized the addition of this measure in the inpatient QRP, skilled-nursing facility QRP, inpatient rehabilitation facility QRP, and inpatient psychiatric hospital QRP beginning with the FFY 2023 payment year, with the reporting period beginning October 1, 2021.

[13] Many FY 2019 cost reporting periods actually end in 2020.

California's hospitals strongly support the nation's COVID-19 vaccination efforts and have been leaders in vaccinating their communities. In the time since CHA submitted comments on this measure for inclusion in other settings of care, several factors have altered the COVID-19 vaccination landscape, including full Food and Drug Administration (FDA) approval of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 and older. In addition, on August 5, California issued a state public health officer order[14], requiring all employees, staff, and vendors in health care settings — including hospitals, psychiatric hospitals, skilled-nursing facilities, and others — to complete a full course of COVID-19 vaccination by September 30. Finally, the FDA amended emergency use authorizations for Pfizer and Moderna's COVID-19 vaccines to allow for the use of a third, additional dose for certain immunocompromised individuals, and the CDC announced plans to begin offering COVID-19 booster shots to all individuals, pending FDA authorization.

In light of these factors and continued concerns with the operational burdens of reporting COVID-19 data across local, state, and federal systems, CHA offers the following specific comments and recommendations.

Duplicative reporting requirements should be eliminated. Currently, hospitals voluntarily report COVID-19 vaccination rates for health care personnel to the Department of Health and Human Services (HHS) through weekly COVID-19 Hospital Data Reporting via the HHS Protect portal. Though this reporting is voluntary, it is part of a broader set of daily reporting requirements, which must be collected and reported as a condition of participation (CoP) for hospitals that participate in Medicare. Notably, the fields required to capture health care personnel vaccination data under the CDC/NHSN specifications require additional information that is more detailed than what is submitted via HHS Protect. In addition to requiring more time and effort to collect, reporting conflicting data elements can be confusing to hospitals and requires more time and effort to collect. In its response to comments as part of the FY 2022 IPPS final rule, CMS stated that it does "recognize that this measure may lead to duplicative reporting if hospitals voluntarily report COVID-19 health care personnel vaccination information to other data reporting systems in addition to this measure requirement via the NHSN, and we are collaborating with other HHS agencies, including the CDC to minimize reporting burden to the extent feasible." **We urge CMS to work swiftly across HHS agencies to eliminate duplicative reporting requirements and consider additional actions to reduce COVID-19 data reporting burden.**

CMS should clarify the impact of booster shots on measure specifications. As currently specified, the numerator of the proposed measure includes "the cumulative number of HCP eligible to work in the health care facility for at least one day in the submission period and who received *a complete vaccination course* against SARS-CoV-2." As previously noted, a third dose of vaccination is currently approved under EUA for immunocompromised individuals, and it is expected that a third dose will be authorized for all individuals. While including a third dose within the definition of a "complete vaccination course" may seem straightforward, it will be challenging for hospitals to track where each individual health care personnel fall with that definition on any given day. For example, some health care personnel may be immunocompromised, and thus already eligible for a booster short, while others may become eligible for a booster shot six- to eight-months following their second dose, depending on FDA approval and CDC recommendations. This means that any health care personnel who was eligible for inclusion in the

[14] https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Health-Care-Worker-Vaccine-Requirement.aspx

numerator of the measure with two-doses could fall out eight months after their second dose. Tracking this information for vast numbers of health care personnel included in the denominator for the purposes of reporting on a monthly basis will be a challenging task. **We urge CMS to clarify the definition of a "complete vaccination course" to address booster shot recommendations and authorization.**

Measure specifications should reflect exclusions for religious exemptions. The proposed measure specifications exclude from the denominator only those health care personnel determined to have a medical contraindication to the COVID-19 vaccine, as described by the CDC. However, under Equal Employment Opportunity Commission (EEOC) guidelines, employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice, or observance prevents them from receiving the vaccination. Notably, California's state public health officer order on health care personnel COVID-19 vaccination also exempts workers from the requirements due to a sincerely held religious belief. **CHA urges CMS and the CDC to revise the measure exclusions to align with the EEOC guidance. Doing so will reduce data collection and reporting burdens as hospitals work to comply with all state and federal regulations.**

Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e)

The OAS CAHPS survey set includes five measures designed to assess a patient's experience with care following a procedure or operation performed in a hospital outpatient department. The set was first adopted into the OQR Program in the 2017 OPPS final rule, for use beginning with the 2020 payment determination. However, CMS delayed implementation to allow time for further accrual of operational experience and implementation data from the National OAS CAHPS voluntary reporting program that began in 2016. CMS now proposes to implement the OP-37a-e measure beginning with voluntary reporting for the 2023 reporting period/2025 payment determination and begin mandatory reporting beginning with the 2024 reporting period/2026 payment determination. Notably, CMS proposes to add two new web-based data collection modes, with either mail or telephone follow-up of non-respondents.

CHA strongly supports CMS' proposal to add two web-based data collection modes for OAS CAHPS survey administration. CHA has long advocated that CMS develop web-based options for patient experience surveys, and we urge the agency to extend this proposal to other CAHPS surveys, including the HCAHPS survey. We believe this is a strong step in the right direction toward improving response rates and data reliability; however, we are still concerned that several longstanding concerns remain unaddressed.

In the proposed rule, CMS says that its review of the national OAS CAHPS voluntary reporting program data has found that patients are able to respond to OAS CAHPS survey questions, and that those responses are reliable. CHA urges CMS to provide additional details on its analysis of reliability under the voluntary program, and in particular address stakeholder concerns that the multiple and potentially overlapping patient surveys — such as the Clinician/Group CAHPS (CG-CAHPS) and the Surgical CAHPS — may lead to patient confusion about which provider is being evaluated upon survey. Finally, we note that the survey measures are not endorsed by the National Quality Forum (NQF). **We urge CMS to seek and obtain NQF endorsement of the OAS CAHPS survey measure prior to requiring mandatory reporting under the OQR program.**

Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program

Similar to its request for information on Closing the Health Equity Gap in CMS Quality Programs as part of the FFY 2022 IPPS proposed rule, CMS seeks comments on addressing health equity in the Hospital OQR Program, including expansion of its current disparities methods to stratify performance results on certain OQR measures by dual eligibility, using indirect estimation to identify the race and ethnicity of Medicare beneficiaries where this information is missing, and possibility of hospital collection of standardized demographic information to support quality reporting and measure stratification.

California hospitals are committed to improving health equity and eliminating disparities in health care outcomes, and we applaud the administration for its continued commitment to addressing these significant issues through the federal quality programs. We reiterate that overcoming obstacles to health equity will require a long-term, systemic approach with collaboration across all levels of government and institutions. Knowing that hospitals are uniquely positioned to help advance health equity and reduce disparities, many of our members have already invested in efforts to improve data collection on race, ethnicity, language preference, and other sociodemographic data, and we offer several comments for CMS to consider as it engages in this long-term work:

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

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

Stratification of quality measure results and indirect estimation of race and ethnicity: CHA supports providing hospitals with confidential hospital-specific reports on OQR measures stratified by dual eligible status as a first step in exposing significant disparities. However, we encourage CMS to look beyond dual eligibility as a proxy for social risk and work with stakeholders to understand how additional systemic factors — such as housing instability, access to healthy foods, and community violence — contribute to inequities in our health system. We urge CMS to explore how it could provide hospitals with actionable data on these factors that allow them to work with community partners in advancing health equity in their communities.

Finally, CMS discusses further expanding stratified reporting to include race and ethnicity, initially using a statistical modeling technique called "indirect estimation," to identify the race and ethnicity of Medicare beneficiaries where this information is missing. CHA echoes the concerns of the agency that algorithms used to indirectly estimate race and ethnicity could unintentionally introduce measurement bias. **We urge CMS to support health system efforts to improve the collection of self-reported data, which CMS acknowledges as the gold standard for collecting race and ethnicity data. As CMS works toward these goals, we ask that indirectly estimated stratified measure reports not be publicly reported.**

Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR)

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

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

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

RFI: Hospital Inpatient Quality Reporting (IQR) Program and Promoting Interoperability Program - Safe Use of Opioids eCQM

CMS requests input on potential measure updates for the Safe Use of Opioids Concurrent Prescribing eCQM as it prepares for National Quality Forum re–endorsement in 2022. Under both the hospital IQR and promoting interoperability programs, hospitals are required to report three self–selected eCQMs and the Safe Use of Opioids eCQM beginning with the 2022 reporting period.

CHA appreciates that CMS is seeking feedback on this existing policy and urges the agency to modify the eCQM reporting requirements for both programs through future rulemaking. Specifically, while

we do not oppose the Safe Use of Opioids Concurrent Prescribing eCQM as an option in the eCQM measure set, we continue to believe hospitals should have the flexibility to choose to report the eCQMs that are most appropriate to their specific quality improvement priorities. We urge CMS to rescind its policy that requires hospitals to report the Safe Use of Opioids eCQM beginning with the 2022 reporting period but maintain the measure as an option for hospitals that wish to self-select. In addition, as the measure is reviewed by NQF for re-endorsement, we suggest that measure exclusions be refined to better address patients with appropriate concurrent prescriptions.

Request for Information (RFI) on Rural Emergency Hospitals (REHs)

Section 125 of the Consolidated Appropriations Act (CAA) of 2021 establishes REHs as a new Medicare provider type that will furnish emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, seven days a week. In addition, a REH may elect to furnish other medical and health services on an outpatient basis, as the Secretary may specify through rulemaking. REHs may not provide acute care inpatient services, with the exception of skilled-nursing facility services that are furnished in a distinct part unit. In the CY 2022 OPPS proposed rule, CMS requests information to inform policy making on the development of the REH model. **CHA greatly appreciates CMS' efforts to seek feedback from stakeholders as it looks to develop the regulatory framework for this new, important provider type. Below, please see comments from CHA's members.**

Types of Services

The RFI seeks information about the additional services that are appropriate for a REH to provide to improve access to care for Medicare beneficiaries in rural areas.

Telehealth: **CHA's members believe that telehealth will be an important component of the REH model.** Therefore, we believe CMS must provide REHs with the flexibility to ensure that they can provide access to virtual services (including services provided by specialists in urban areas) and receive payment for those services. We believe a key part of this will include ensuring that the patient's home (and other locations that are not at the REH) may be considered a reimbursable originating site. Further, given the challenges related to high-speed internet access in many rural areas, we ask that CMS ensure that audio-only visits will be considered covered services when they are provided by a REH. **If CMS does not have the regulatory flexibility to ensure broad access to telehealth services is available after expiration of the PHE, we ask the agency to work with Congress to address this flaw in the model.** Based on CHA's members' experience during the PHE, we strongly believe that telehealth flexibility will be a crucial tool that REHs can use to provide access to services to members of rural communities. This is particularly true for mental health services.

Maternal health: Critical access hospitals (CAHs) and other hospitals that could qualify as an REH typically have low annual newborn delivery volumes. As a result, they have struggled to recruit obstetrical and gynecology providers and nurses to rural areas. **While CHA believes that it is important that REHs have the *option* to provide maternal health services. We do not believe that it would be appropriate to require REHs to deliver maternal health services beyond having the capability to provide emergency labor and delivery services in the emergency department.**

Other services: CHA believes that REHs should be allowed to provide any other type of service that is available in a hospital outpatient department. These services should include but not be limited to imaging

and other diagnostic services, emergency surgeries, surgeries performed in an ambulatory setting, infusion services, therapy services (physical, speech, and occupational), and behavioral health services.

Licensure, Certification, and other Requirements

A REH must have a transfer agreement in effect with a level I or level II trauma center and meet other conditions, including certain licensure requirements, emergency department staffing requirements, staff training and certification requirements, and CoPs applicable to hospital emergency departments and CAHs for emergency services. REHs must have an annual per-patient average of 24 hours or less in the REH.

Transfer agreement: Many CAHs and small rural hospitals also maintain transfer agreements with level III and IV trauma centers as well as other hospitals in urban and exurban areas without a trauma center designation. **We ask CMS to confirm that hospitals that have a transfer agreement(s) in place with level III and/or IV trauma centers and other hospitals without a trauma center designation can maintain those agreements after they convert to a REH.**

Average patient stay: CHA's members are concerned about the requirement that REHs have an annual per-patient average stay of 24 hours or less. CHA's members (like other rural hospitals) report significant challenges transferring patients in mental health crisis to an inpatient psychiatric hospital due to the lack of beds — even in urban and exurban areas. Further, during the PHE, many rural hospitals have struggled to transfer acutely ill patients to facilities that can provide the appropriate level of care due to a lack of inpatient capacity at hospitals in nearby urban and exurban areas. **Therefore, CHA asks that CMS remove any patient who is transferred (or expires awaiting transfer) from the calculation of an REH's length of stay.** Otherwise, we are concerned that some hospitals that initially qualify as an REH may not be able to maintain the designation by failing to meet the average patient stay requirement.

Equity

CMS seeks input on how REHs can help address health equity with respect to the scope and type of services offered. CHA supports CMS' continued efforts to address issues that result in disparate outcomes. The scope of services necessary to address the drivers of inequitable health outcomes will be unique to each community. Therefore, CHA does not believe it would be appropriate for CMS to attempt to define a set of specific services that a REH must provide to ameliorate the issues that have resulted in disparate outcomes. While we believe REHs have the opportunity to address disease-specific issues to improve outcomes related to chronic diseases such as diabetes, congestive heart failure, depression, and substance use disorder, we encourage CMS to allow REHs the flexibility to address upstream opportunities that could improve the health of the entire community if (and only if) the REH is uniquely positioned to do so in its community.

Therefore, CHA asks CMS to provide flexibility allowing (but not requiring) REHs to use a portion of their monthly lump sum payment to address a wide range of issues that impact health equity. This will likely require CMS to allow REHs to use Medicare funds to invest in items and services that the program has traditionally not covered. In addition to addressing community issues, this may also include providing support services to patients requiring in-patient care at a facility outside of the local community. One example of this might be providing transportation services (or vouchers) to allow a

family to visit (or stay with) a patient receiving inpatient hospital care at a facility that is not in the local community or to bring the patient home once they are discharged from the distant hospital.

CMS also seeks feedback on how the agency could measure the impact of a REH on health equity in the communities it serves. **Please see CHA's comments in the prior section in response to the RFI on health equity.**

Finally, CHA notes that counties in California — like in many states — have a broad responsibility to provide social and behavioral health services. We ask that CMS carefully construct any requirements for REHs related to health equity and mental health services. If these requirements are not carefully defined, CHA's members are concerned that localities may attempt to shift their responsibilities to REHs. This would diminish, instead of expand, the overall resources available in the community to ameliorate the issues that create disparate health outcomes.

Quality

CMS seeks broad input on a range of issues relating to quality measurement for REHs, including quality reporting requirements and specification of quality measures. As CMS is well aware, one of the challenges facing rural providers related to quality measures is the low volume of services they provide. This makes it challenging to develop reliable measures that accurately gauge a rural provider's performance. This is fundamentally why CAHs are allowed to voluntarily report measures to the IQR program. Additionally, REHs are a unique provider type. From a quality measurement standpoint, they are best thought of as a low-volume emergency department that may also provide ambulatory clinic visits and outpatient procedures with supporting diagnostic services (e.g., lab, x-ray) in the same location.

CHA fundamentally believes that the measures CMS selects should reflect the type and scope of services REHs provide. Further, these measures should focus on patient outcomes (or processes that are indicative of patient outcomes), that are within a REH's ability to control and are not administratively burdensome to measure.

Finally, CHA strongly emphasizes that given the issues related to low volume and the immaturity of quality measurement related to REHs, it would be inappropriate for CMS to deploy a pay-for-performance model for this provider type in the near-to-mid-term. Only after CMS has a sound measure set that accurately reflects the patient care activity that occurs at REHs and overcomes the measurement challenges presented by low-volume settings of care should CMS consider moving to a pay-for-performance model.

Payment Provisions

CMS solicits stakeholder input regarding the payment provisions established for the REH provider type, which will go into effect for items and services furnished on or after January 1, 2023. CHA's members are concerned about a REH's ability — once a hospital converts — to receive essential rural specific payment provisions that ensure access to providers and the safety-net payments that partially offset the costs of providing care to the uninsured and underinsured.

Rural provider payment provisions: **CHA asks CMS to confirm that CAHs that convert to a REH will still be able to use "Method II" to bill and receive payment for physician services provided at the REH.**

Further, we ask that CMS confirm that provider-based RHCs that meet the requirements under Section 130 of the CAA will retain their grandfathered status after the hospital converts to a REH provider type. Without the retention of these important provider payment methodologies, CHA is concerned that converting to a REH will limit access to health care services instead of creating a sustainable platform from which to expand access.

Safety net payments: Individuals under age 65 who live in rural areas are more likely to be uninsured than residents of urban areas. Approximately 12.3% of people in completely rural counties lacked health insurance compared to 10.1% for mostly urban counties[15]. Further, those who are insured are less likely to have coverage through a commercial health plan. This is due in part to lower labor-force participation and greater employment in jobs that do not offer insurance[16]. High rates of uninsured and coverage by governmental payers as part of a hospital's payer mix are frequently cited as key drivers of rural hospital closure[17] (and the need for models like REHs to maintain access to health care in rural communities). In California, the Medi-Cal global payment, federal disproportionate share hospital (DSH), and private DSH replacement programs play a vital role in ensuring the financial sustainability of hospital-based health care services in rural areas. **CHA asks CMS to ensure that nothing in the regulations related to REHs will prevent these hospitals from receiving these crucial payments that support safety net hospitals.** If these payments are not preserved, it is unlikely that rural hospitals in California will be able to take advantage of the REH model to ensure access to services.

Enrollment Requirements

California law limits emergency services to licensed emergency departments (EDs), which, as interpreted by the California Department of Public Health (CDPH), requires the ED to be located in a hospital building that includes inpatient and other basic services required for licensing. There appears to be legal authority under Health and Safety Code Section 1798.175 for a free-standing, non-hospital operated emergency service, but this model remains untested. Given these state-specific legal limitations, CHA is concerned that without changes to state law, rural hospitals in California will not be able to take advantage of the REH model. We are aware that state-specific licensure requirements preventing an otherwise qualifying hospital from converting to a REH are not unique to California. **Therefore, we ask CMS to work closely with the National Governors Association and the National Conference of State Legislatures when it develops the regulations related to the REH model. We ask that, to the extent possible, the regulations be crafted such that the federal definition of a REH is sufficiently broad to meet the facility licensure requirements in as many states as possible.**

The CAA requires that a qualifying hospital that seeks to convert to a REH must have been in existence as of December 27, 2020. **CHA asks CMS to grandfather any hospital that was in existence prior to December 27, 2020, but ceased operations as an acute care hospital due to a natural disaster.** As an example of the need for some form of grandfathering or other regulatory flexibility, a California hospital that — assuming state licensure issues are resolved — is an ideal candidate for the REH model would not qualify if the December 27, 2020, date is strictly applied. The facility was closed in 2018 due to wildfire damage and is currently not operating as an acute care facility.

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

Finally, CHA also asks CMS that it confirm that a CAH that converts to a REH can convert back to its prior provider type.

Radiation Oncology Model

Section 133 of the CAA of 2021 included a provision prohibiting the RO model from beginning before January 1, 2022. In the CY 2022 OPPS rule, CMS proposes that the model performance period would begin on January 1, 2022, and end December 31, 2026.

CHA notes that Congress, in Section 133 of the CAA, provided CMS and the Center for Medicare and Medicaid Innovation (CMMI) the flexibility to delay the start of the RO model further. The statute prohibits CMS from starting the model "before January 1, 2022." However, the statute does not require CMS to start the RO model on January 1, 2022. In doing this, Congress recognized both the highly uncertain nature of the COVID-19 PHE and the significant time and resources hospitals and physician practices will need to invest in implementing the reporting requirements necessary to participate in this model. **In light of the ongoing pandemic and the limited time CMS has provided for participants to upgrade their IT systems to meet the model's billing and data collection requirements, CHA respectfully asks that the agency delay the model until January 1, 2023.** We believe a 12-month delay in the start date will provide sufficient time for the necessary systems upgrades. It will allow for additional individuals to become vaccinated, reducing the severity of future COVID-19 surges, giving the administrative and clinical resources necessary to implement the model the bandwidth to do so.

Over the past 18 months, hospitals and health systems have been on the front lines fighting the COVID-19 pandemic. This work has involved (and continues to involve) making significant adaptations to deliver safe patient care, including staffing changes, physical space changes, and IT system changes in response. Those changes will need to remain in place and continue indefinitely, as the "peak" of the fourth COVID-19 surge is not anticipated to occur until late in the fall of 2021. Further, CMS is not anticipated to finalize the OPPS rule (and the related RO model changes until late October or early November). This means that hospitals and physician practices will have approximately two months to implement the policies and systems necessary to successfully participate in the RO model. And these efforts to implement the RO model will coincide with what is projected to be the peak of the fourth COVID-19 hospitalization surge. Now is not the time to ask hospitals and physician practices to divert their attention from COVID-19 to implementing an incredibly complex model for which CMMI itself is still finalizing many pertinent details.

Further, a delay will allow for CMS to provide the radiation oncology community (and its EHR vendors) the specifics necessary to automate and comply with the monitoring requirements at Section 512.220(a)(2). CHA is concerned that EHR vendors need time to develop the fields for the requested data elements, as they may be captured in clinical notes or external systems, but not in EHRs. While vendors can build something to be compliant, a new build can take between 12 and 18 months. Once the build is complete, practices must then implement and incorporate it into workflows, taking even more time. Compounding this, there are a limited number of vendor IT support staff whose services are necessary to facilitate these upgrades. The limited bandwidth of support staff will be taxed and exceeded — further delaying implementation for some RO model participants — given the number of facilities and group practices CMS is requiring to participate.

If CMS does not further delay the RO model start date as requested, we ask that compliance with these requirements — particularly the Clinical Data Elements — be voluntary until after specific guidance is issued by the agency, EHR vendors have had sufficient time to modify their products to collect the necessary data, and practices/facilities have been able to implement these changes into their existing EHRs. Given the amount of time CMS has had to issue these specifications, practices and facilities should not be forced to implement manual workarounds to collect these data or be penalized for not being compliant on day one due to a lack of guidance from the agency.

Included Cancer Types

CMS proposes to remove liver cancer from the RO model as an included cancer type. CMS notes that there is insufficient evidence to support radiotherapy as a first-line therapy for the most common type of liver cancer, hepatocellular carcinoma. **Given the lack of evidence-based guidelines that support radiotherapy for treatment of the most common liver cancer, CHA strongly supports the proposal to remove liver cancer from the list of cancer types included in the RO model.** Further, we commend the RO model team at CMMI for their continued literature reviews and conversations with radiation oncologists. We share CMMI's belief that the best available clinical evidence must drive the design of alternative payment models.

CHA believes that a prospective bundled payment methodology is appropriate for cancers with strong evidence-based treatment guidelines. During conversations, CHA's members raised concerns that the evidence base for guidelines related to treatment of bone and brain metastasis are not as robust as they should be for inclusion in a bundled payment model. Treatment of both cancers can vary widely in terms of the approach and technology used depending on the specific patient and disease progression. Therefore, we believe it is inappropriate to include these types of cancers in a prospective bundled payment methodology. **CHA asks CMS to re-evaluate the existing evidence-based guidelines to ensure that a prospective bundled payment will adequately cover the cost of therapy for these types of cancers.**

Included Modalities

CMS proposes to remove brachytherapy as an included modality in the RO model. In proposing to remove brachytherapy from the list of included services, stakeholders had expressed concern that RO episode-based payment does not adequately account for multimodality care. Specifically, concerns were raised about cases where the RO model participant furnishing the external beam radiation therapy is different from the RO model participant providing brachytherapy. **CHA strongly supports the removal of brachytherapy from the list of included RT services.** Given the RO model's episode payment methodology does not account for multimodality care, we believe it would be inappropriate to include brachytherapy. CHA notes that much of the anticipated reconciliation activity in the RO model was a result of brachytherapy. **Therefore, CHA respectfully asks CMS to eliminate the "incorrect payment withhold" from the RO model payment calculation.**

The proposed rule states that CMS will continue monitoring brachytherapy usage and consider adding it back if it developed a methodology to adjust pricing for cases where multi-modal therapy is deployed. **Given the complexity of the RO model's pricing and payment mechanism, CHA strongly discourages CMS from adding brachytherapy back during the model's initial five years.** As the payment methodology is currently designed, it will require significant additional administrative resources for

hospitals and radiation oncology practices to manage the current iteration. CHA strongly opposes any additional changes that increase the model's complexity. We are concerned about both unintended consequences for patient access and the increased administrative burden foisted on providers and facilities.

Finally, CHA is concerned that that the RO model does not specifically have a process, beyond the trend factor component of the annual update, to update the bundled payment for each episode to reflect changes in evidenced-based treatment guidelines and changes in technology. We are concerned that in the later years of the five-year model (or if the model is expanded beyond the initial five years) that payments calculated using the baseline (claims from 2017–19) and updated by the trend factor will not adequately cover the costs of care delivered under future evidence-based treatment guidelines. **Therefore, we ask the agency to engage with stakeholders to develop an ongoing process to ensure that episode payments in the RO model are sufficient to cover the costs — including for new technologies — associated with delivering cancer treatments grounded in updated evidence-based guidelines.** If RO model payments are not sufficient to cover the costs of new technologies as they are incorporated into evidence-based guidelines, it will be harder for facilities and practices to sustain the investments necessary to ensure access to care for the communities they serve.

Proposed Discount Factor

CMS proposes to lower the discount factor for the professional component (PC) from 3.75% to 3.5% and the discount factor for the technical component (TC) from 4.75% to 4.5% as a result of its proposals to remove brachytherapy from the list of included modalities and liver cancer from the included cancer types. **CHA appreciates and strongly supports the proposal to lower the RO model's discount factors. However, we urge CMMI to reduce the discount factor still further.** CHA notes that significant steps already have been taken to implement evidence-based guidelines that promote efficiencies and improve patient outcomes. This model should not penalize such practices and facilities with excessive cuts to achieve Medicare savings. We remain concerned that when these adjustments are combined with the payment reductions (discussed further below) already built into the pricing model, they may render providers and facilities unable to reasonably achieve savings. This will force efficient providers to find savings where none exist.

RO is a capital-intensive service line. One CHA member estimates that 85% of their costs are equipment and technology related. Beyond upfront capital investment in equipment, hospitals incur significant on-going costs related to software upgrades and equipment calibration. These costs continually outpace overall medical inflation. The high-upfront investment costs and the proprietary nature of the equipment pose an insurmountable barrier to switching vendors. And even if switching wasn't cost prohibitive, there are only two primary vendors for the technology necessary to deliver RO services. Therefore, there are limited opportunities for facilities and providers who are already adhering to evidence-based treatment guidelines to generate additional savings through internal cost reduction efforts.

CHA is deeply concerned that CMS' proposed discount factor, coupled with other facets of the payment model, will reduce patient access to radiation therapy by creating significant financial challenges for facilities that provide radiation therapy services. These access issues will be disproportionately borne by those communities with higher proportions of Medicare fee-for-service (FFS) beneficiaries and those that serve rural or socioeconomically disadvantaged populations requiring greater resource expenditures.

Additionally, CHA also notes that even with the proposed reduction, the discount factors for the PC and TC are still much higher than those found in similar CMMI programs. For example, the discount factor in both the Bundled Payment for Care Improvement-Advanced and Comprehensive Care for Joint Replacement (CJR) models is no more than 3%. In CJR, hospitals that exhibit superior quality outcomes will have their discount factor reduced to as low as to 1.5%. Similarly, in the Oncology Care Model the discount factor for the two-sided risk model is 2.75%.

CHA asks CMS to ensure that access to RO services is not harmed by the RO model. We ask the agency to reduce the discount factor to no more than 3% — on par with CMMI models that carry a similar amount of financial risk. Further, if CMS implements the model during the COVID-19 PHE, we ask that the agency gradually phase in the discount factor to allow time for facilities that provide RO services to implement the systems necessary to succeed under the model, retain the resources necessary to respond quickly to the ever-evolving PHE, and reinvest in a capital-intensive service line to ensure that access to these life-saving therapies can be maintained.

Case Mix Adjustment

CMS is considering removal of CY 2020 data from the calculation of any applicable baseline period or trend factor. However, CMS is not considering the exclusion of 2020 data from the case mix adjustment at this time. CMS justifies this by stating that the case mix episodes are weighted equally, and the case mix adjustment does not rely on the volume of RT services delivered.

CHA thanks CMS for analyzing the 2020 data and seeking feedback on possible modifications to the RO model as a result of the PHE. While we appreciate that the case mix is equally weighted for the rolling three-year period included in the payment model's adjustment factor, we are concerned that the six factors[18] included in the case mix do not include any indicator of patient acuity. **CHA has always believed that an indicator of patient acuity was sorely lacking in the RO model.** The addition of this type of adjustment is more important than ever given that many patients — as a result of the PHE — are experiencing delayed diagnosis and presenting for treatment with more advanced tumors. This requires a different, more resource-intensive treatment regimen than was typical in the baseline period (2017–19). Because the baseline remains constant during the RO model, the additional costs associated with providing care to those with advanced disease due to COVID-19-related delays in diagnosis and treatment are not captured in the current payment methodology, putting further financial pressure on RO model participants. **CHA respectfully asks CMS to incorporate a case-mix adjustment into the RO model to address the increased resource use required by many patients who now present with advanced tumors as a result of the COVID-19 PHE.**

Trend Factor

CMS applies a trend factor to each of the national base rates. The trend factor is intended to adjust these rates to reflect current trends in utilization and payment updates to the OPPS and PFS rates for radiation therapy services. While CHA conceptually supports CMS' proposal to modify the volume component to address shifts in utilization as a result of the COVID-19 PHE, we continue to have deep concerns about blending the annual PFS and OPPS update factors to derive an update factor to adjust hospital RO model payments for Medicare pricing changes.

[18] Cancer type, age, sex, presence of major procedure, death during episode, presence of chemotherapy

Volume component: CMS proposes, as part of its extreme and uncontrollable circumstances policy, to modify the volume component of the trend factor calculation to address significant shifts in utilization. When RO participants nationwide experience aggregate utilization disruptions that cause the cancer/component type trend factor to change by more than +/-10% compared to the prior year's trend factor, then CMS may modify that trend factor. **CHA is generally supportive of a mechanism to modify the trend factor to address changes in utilization that result from the PHE or other unforeseen circumstances beyond the control of RO model participants. However, CMS should not apply an arbitrary threshold to determine when it needs to modify data from an impacted year. Instead, CMS should use data from the most recent unaffected year to calculate the trend factor for any year that overlaps with the COVID-19 PHE.**

As a result of the PHE, treatments have been interrupted prior to completion due to COVID-19 infection and/or local quarantine requirements. The full extent of these unavoidable disruptions to treatment is impossible to estimate on both costs and patient outcomes. Any attempt to use impacted data to determine a trend factor will artificially underestimate the true cost of care under ordinary circumstances.

Pricing Component: CMS proposes that the numerator of the trend factor be the product of (a) the component's FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming performance year (PY) and (b) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished three years prior to the CY used to determine the FFS payment rates. The denominator of the trend factor would be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period and (b) the corresponding FFS payment rate for the most recent year of the baseline period.

CHA is deeply concerned about the impact of inappropriately blending the payment update factors in the OPPS and PFS to create an update factor that is applied to the baseline episode payment amount to calculate the current PY payment for the technical component for RO services to HOPDs that are compelled to participate in the model. As illustrated in Table 79 in the OPPS proposed rule (reproduced below), while physician group practice-allowed charges for RO model participants increase an average of 5.5% from 2022 to 2026, CMS projects that they will decrease by 9.6% for HOPD participants over the same time-period.

Radiation Oncology Model PGP vs HOPD Allowed Charge Impacts 2022 to 2026

% Impact	2022	2023	2024	2025	2026	2022 to 2026
PGP	1.80%	3.50%	5.20%	6.80%	8.50%	5.50%
HOPD	-7.20%	-8.30%	-9.30%	-10.40%	-11.30%	-9.60%

CMS attributes the impact on HOPDs and PGPs to a combination of the RO discount combined with the RO trend factor, which blends changes in the OPPS and PFS payment rates. Based on statute, PFS rates are subject to a 0% update from 2022-25. And in 2026 the maximum update will be .75%, limited to physicians participating in an Advanced Alternative Payment Model. However, OPPS rates are expected

to increase annually based on the adjusted hospital market basket update. Blending these two together results in an average increase expected for PGPs and an average decrease for HOPDs.

CHA does not believe it is appropriate to apply — in part — the rate of growth in physician payments to payments for services provided in the HOPD, as CMS intends to do in the RO model. When Congress passed MACRA, it no more intended to apply the annual PFS update factor of 0% to payments made under OPPS for the years 2020 through 2025 than it intended to apply the multi-factor productivity adjustment reduction (to which hospitals are subject) to physicians when it passed the Affordable Care Act (ACA). **Therefore, we ask that CMS correct this issue by calculating one pricing trend factor for the technical component of services provided in the freestanding setting using the change in PFS payments and one for the technical component of services provided in an HOPD using the change in OPPS payments.**

As discussed above, the RO model's pricing methodology will exacerbate access issues, as payment rates will fall well short of the cost to provide RO services in an HOPD. We reiterate that the brunt of these access issues will be borne by those communities with higher proportions of Medicare FFS beneficiaries and those that serve rural or socioeconomically disadvantaged populations requiring greater resource expenditures. For many of these communities, hospital-based clinics provide the only local access to life-saving RO services.

Patient Experience Withhold-CAHPS Cancer Care Radiation Therapy Survey

Starting in PY 3, RO model participants will be accountable for patient experience via the patient reported Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Radiation Therapy survey administered by a CMS contractor. TC payments — including HOPDs — will be subject to a 1% patient experience withhold. Under the reconciliation process, CMS will calculate the amount of patient experience withhold earned back by RO participants based on the beneficiary-reported CAHPS survey. Any portion of the withhold that is earned back will be distributed in an annual lump sum after the reconciliation process.

Prior to the pandemic, many RO providers offered patients a wide range of support services designed to make treatment as comfortable as possible. In response to the COVID-19 PHE, almost all RO providers curtailed these services to reduce infection risk and mitigate the further spread of the disease. However, it is likely that RO providers in areas with higher vaccination and lower infection rates will resume these support services before areas with lower vaccination and higher infection rates. CHA is concerned the availability of support services in some areas (due to low COVID-19 infection rates) while lack of availability of these same services in other areas (due to high COVID-19 infection rates) may skew CAHPS scores and repayment of the withhold in the RO model. **We believe this is yet another reason to delay the model for 12 months. Further, we ask the agency to monitor the data for any evidence of skewing based on COVID-19 infection rates. If evidence presents, we ask that CMS return the patient experience withhold to all RO model participants.** Alternatively, CMS could proactively take steps to address this issue by lowering the withhold to .5% or less for any year that overlaps with the COVID-19 PHE.

Low Volume Opt-Out

A physician practice, free-standing radiation therapy center, or HOPD may choose to opt-out of the RO model for a given PY if it has fewer than 20 episodes. Episode volume is based on the most recent claims data available, which CMS states will be from two years prior to the PY. At least 30 days prior to the start of each PY, CMS will notify RO participants eligible for the low volume opt-out for the upcoming PY. If the RO participant wishes to opt out, it must attest that it intends to do so prior to the start of the upcoming PY.

CMS also proposes that during the model performance period, an entity would not be eligible for the low volume opt-out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation. CHA strongly supports allowing low-volume providers to opt out. **However, we have concerns about the prospective nature of the low-volume opt-out requirement. Therefore, in addition to the prospective opt-out methodology included in the RO model, we ask CMS to also provide a mechanism where a RO participant that had 20 or more episodes over the course of a year two years prior to the PY in question can retrospectively request that it opt out of the model if it provided fewer than 20 episodes at the end of the current PY.** In this instance, a participant that retrospectively opts out would have its payments adjusted based on the FFS amount the participant would have been paid had it not been included in the mandatory model.

Participant Historical Data

In the proposed rule, CMS states that it will not provide case mix or historical experience adjustment data to participating practices until after the final rule is issued. This will leave participants with less than two months to analyze the data to understand how the participant might improve their performance and understand the full financial impact participating in this mandatory model. CHA notes that the data used to inform these inputs are from 2017-19 — the same vintage of data included in the file published with the proposed rule. **CHA asks CMS to supply these data to RO model participants immediately.**

RO Model Billing Requirements — Potential OPPS Rate Setting Impact

CHA asks CMS to clarify how the RO model billing requirements will impact the data CMS uses for rate setting in the OPPS. In a recent webinar[19], CMS instructed hospital RO model participants to "verify that RO Model HCPCS codes do not have a charge less than the fee amount" for the beginning and end of episode claims for the technical component. Additionally, RO model participants were instructed to submit no-pay claims once the start of episode claim has been processed, "using their typical coding and billing schedules and processes for Medicare services." CHA interprets "billing schedules and processes" to mean the no-pay claims should be billed with "full" charges from the hospital's chargemaster. If that is correct, what CMS is in essence asking hospital RO model participants to do is bill the charges for the technical component twice (once to receive payment, and once with the no-pay claim). As a result, hospitals could report the charges twice on their cost report while only reporting the costs once. This could distort the Medicare cost-to-charge ratio (CCRs) for RO services if the agency doesn't clarify how charges for RO model participants are to be billed and reported.

CMS has not discussed whether the CCRs for participating hospitals will be used along with the CCRs for non-participating hospitals as part of the APC weight setting process in future years. Given CMS has

[19] https://innovation.cms.gov/media/document/ro-model-coding-billing-pricing-webinar-aug21

designed the model to include 30% of all RO services nationally, the number of hospitals included in the model and the volume of services will distort the data used to set APC weights if charges submitted on claims for payment and no-pay claims are not appropriately accounted for by participating hospitals and the agency during the billing, cost reporting, and APC weight setting processes. This could not only result in under-reimbursing RO services in future years but also increase Medicare payments for all other services paid using the APC schedule, given the weighting system's inherent budget neutrality. Therefore, we ask CMS to clarify its billing and cost reporting instructions and take appropriate steps to ensure that a distortion of APC weights does not occur as a result of the RO model.

CHA appreciates the opportunity to comment on the CY 2022 OPPS proposed rule. If you have any questions, please contact me at cmulvany@calhospital.org or (202) 270-2143, or Megan Howard, vice president of federal policy, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy