American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–1753–P: 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 Proposed Rule (Vol. 86, No. 147), August 4, 2021.

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2022.

A summary of our overarching concerns and comments follows.

Outpatient Clinic Visits in Excepted Off-campus Provider-based Departments (PBDs). For CY 2022, CMS proposes to continue to pay for the hospital outpatient clinic visit services in excepted off-campus PBDs at 40% of the OPPS payment amount. **The AHA continues to urge CMS to reverse this harmful policy and restore full OPPS payment for hospital outpatient clinic visits in excepted PBDs. By continuing to make this payment reduction, CMS has undermined clear congressional intent and exceeded its legal authority.**

Payments to 340B Hospitals. **The AHA continues to oppose the agency's deep OPPS payment cuts to 340B hospitals. These cuts directly harm 340B hospitals**

and their ability to care for their patients, contravening Congress' intent in establishing the 340B program. These cuts are the crux of the legal issue the U.S. Supreme Court will review in its upcoming term. For more than 25 years, the 340B program has helped participating hospitals stretch scarce federal resources to reach more patients and provide more comprehensive services. The continuation of this harmful policy, especially as the COVID-19 pandemic continues, will undoubtedly result in the continued loss of resources for 340B hospitals and exacerbate the strain on these hospitals and the patients they serve.

Proposed Changes to the Inpatient-Only (IPO) List. **The AHA strongly supports CMS' CY 2022 proposal to halt the elimination of the IPO list.** The IPO list was put into place to protect beneficiaries given that many medical and surgical services are complicated, invasive procedures with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period.

Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs. **The AHA supports a number of proposals related to the OQR and ASCQR Programs**. In addition, we have specific recommendations on how the agency should implement the measure on COVID-19 Vaccination among Health Care Personnel. We also have a number of concerns with CMS' proposals to adopt several measures that lack clinical and statistical reliability, and we urge the agency to reconsider these proposals in light of its goals for meaningful measurement.

Proposed Changes to the List of ASC-Covered Surgical Procedures. **The AHA strongly supports CMS' proposal to reinstate the criteria for adding surgical procedures to its ASC covered procedures list (CPL).** We also support its related proposal to remove 258 procedures it had added to the ASC CPL in CY 2021.

Proposed Updates to Requirements for Hospitals to Make Public a List Of Their Standard Charges. The AHA looks forward to working with CMS to improve the hospital price transparency rule, especially as it relates to better aligning these requirements with those in the transparency in coverage final rule and No Surprises Act. However, we strongly oppose increasing the penalties for non-compliance especially during the ongoing COVID-19 pandemic when the personnel required to implement this policy also are critical to helping hospitals manage this crisis. **We urge the agency not to finalize the proposed penalty increases and instead focus on aligning the various federal price transparency policies to better serve patients and reduce duplication of effort.**

Request for Information (RFI) on Rural Emergency Hospitals (REHs). **The AHA appreciates the opportunity to comment and provide feedback on the RFI for the newly designated provider type of REHs.** We held extensive discussions with our members and have a number of recommendations as CMS moves forward. We look forward to continuing to work with the agency to ensure that REHs are able to become a meaningful part of health care delivery in rural areas.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director for policy, at rschulman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

American Hospital Association
Detailed Comments on the OPPS and ASC Payment System Proposed Rule for CY 2022

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USE OF 2019 CLAIMS DATA FOR 2022 RATE SETTING

Typically, CMS uses the most recently available claims data for rate setting, which for CY 2022 rate-setting purposes would be CY 2020 claims data and cost report data from the most recent release. For CY 2022, this would be cost report data extracted from the Healthcare Cost Reporting Information System (HCRIS) in December 2020. However, because the CY 2020 claims data and cost report data include services furnished during the COVID-19 PHE, which significantly affected outpatient service utilization, CMS determined that CY 2019 claims data and the cost report data from the fiscal year (FY) 2018 HCRIS file would better approximate expected CY 2022 outpatient service utilization. As a result, the agency proposes to set CY 2022 OPPS payment rates using the most recent complete data available prior to the COVID-19 PHE.

The AHA supports CMS' proposal to use CY 2019 claims and FY 2018 HCRIS cost report data for CY 2022 rate setting and appreciates its recognition of the unusual nature of the CY 2020 data. That said, AHA's support of this methodology only pertains to the proposed CY 2022 rates and weights. The data used in future years' rulemaking should be revisited on a year-by-year basis.

CALCULATION OF THE OPPS UPDATE FOR HOSPITALS NOT MEETING THE OUTPATIENT QUALITY REPORTING REQUIREMENTS

CMS proposes that the reduced conversion factor for hospitals not meeting the outpatient quality reporting (OQR) requirements would be $82.810. However, if the full update of 2.3% (1.023) is reduced by 2.0 percentage points to 0.3% (1.003), the resulting conversion factor (CF) for hospitals that do not meet the OQR requirements would be $83.227. This discrepancy exists because CMS calculates the CF for hospitals that do not meet the requirements by multiplying the full conversion factor ($84.457) by a "reporting ratio" of 0.9805. The proposed rule does not explain the calculation of the reporting ratio. Ostensibly, it is the ratio of the reduced update to the full update considering all of the adjustment factors above. While $82.810 divided by $84.457 does equal 0.9805, it is not equivalent to the reporting ratio of 0.9846 that should result from dividing the correct reduced CF of $83.227 by $84.457. It appears that CMS is understating the CF used to pay hospitals that do not submit quality data by nearly $0.42. **AHA urges CMS to correct this erroneous calculation by either paying hospitals subject to the reduced update using a CF of $83.227 or raising the reporting ratio to 0.9854 ($83.227 divided by $84.457).**

OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

For CY 2019, citing "unnecessary" increases in the volume of outpatient clinic visits in hospital provider-based departments (PBDs) allegedly due to payment differentials driving the site-of-service decision, CMS finalized a policy to pay for clinic visits furnished in excepted (grandfathered) off-campus PBDs at the same rate they are paid in non-excepted (non-grandfathered) off-campus PBDs. Specifically, in the CY 2019 final rule, CMS adopted a policy to phase in over two years payment for excepted clinic visit services at 40% of the OPPS payment amount. This policy was implemented in a non-budget neutral manner, which the agency estimated would result in a CY 2020 reduction of $800 million in hospital payments under the OPPS.

For CY 2022, CMS proposes to continue pay for the hospital outpatient clinic visit services in excepted off-campus PBDs at 40% of the OPPS payment amount. **By continuing the cut, we believe CMS has undermined clear congressional intent and exceeded its legal authority, despite the U.S. Supreme Court, on June 28, declining to review the unfavorable ruling by the appeals court that deferred to the government's inaccurate interpretation of the law.**

The Growth in Outpatient Volume and Expenditures is not "Unnecessary." **This policy relies on the most cursory of analyses and policy rationales.** In its CY 2019 and 2020 rulemaking, CMS finalized its phased-in policy implementing a 60% cut in payment for a clinic visit, an essential hospital outpatient service, without presenting any of its own data analysis on:

- Clinic visit volume;
- Clinic visit expenditures;
- The "unnecessary" nature of clinic visit volume or expenditures;
- The "shifting" volume of clinic visits from physician offices to excepted off-campus PBDs due to payment differentials; or
- How a reduction in payment for the hospital outpatient clinic visit is a "method" that would lead to a reduction in the volume of "unnecessary" services in excepted off-campus PBDs.

Indeed, this complete lack of data, analysis and evidence did not go unnoticed. At the Aug. 19, 2019, meeting of CMS' Advisory Panel on Hospital Outpatient Payment, panel members expressed concern that CMS had not followed through on its 2018 recommendation that the agency *not implement* the proposal for reduction in payment for outpatient clinic visits and instead study the matter to better understand the reasons for increased utilization of outpatient services. Indicating their continued concern about

the lack of evidence to support CMS' clinic visit payment reduction and the policies' possible impacts on access to care, the panel voted unanimously to recommend that CMS freeze the payment policy for off-campus clinic visits at CY 2019 rates and evaluate whether beneficiary access has been compromised and whether the volume of outpatient services has decreased.

Further, blaming increases in OPPS expenditures on the "unnecessary" shifting of services from physician offices to PBDs in response to payment differentials ignores the many factors outside of hospitals' control that also result in increases in OPPS volume and expenditures. This includes such things as: changes in patient demographics and clinical needs, technological advances, the impact of other Medicare policies that are intended to increase the volume of services in PBDs, drug price inflation, or the fact that physicians often refer Medicare beneficiaries to hospital outpatient departments (HOPDs) for services they do not provide in their offices. We refer you to AHA's comments for the CY 2021 OPPS proposed rule for further description of the many factors that contribute to increases in OPPS volume and expenditures that are outside of hospitals' control.

Continued Cuts to Hospital Reimbursements for Clinic Visits are Excessive and Harmful, Especially during the Global COVID-19 Pandemic. As noted above, CMS proposes to continue to impose the 60% cut in payment for clinic visits furnished in excepted off-campus PBDs. **Continuing these cuts to outpatient payment for clinic visits, particularly in light of the devastating impact that the COVID-19 pandemic has had on hospital and health system financial health, would be excessive and harmful to patients and communities.**

Hospitals have been on the front lines since the start of the pandemic and have endured historic financial challenges due to revenue losses from forced shutdowns and a slow resurgence of non-emergent care, as well as increased costs associated with preparing for the pandemic and treating COVID-19 patients. In 2020, projected losses to hospitals were estimated at $323 billion[1], leaving nearly half of America's hospitals and health systems with negative operating margins by the end of 2020.[2] Despite the advent of multiple COVID-19 vaccines and a growing number of Americans who have been vaccinated, the pandemic continues to take its toll. Kaufman Hall recently projected that hospitals and health systems could lose an additional $53 to $122 billion in revenue in 2021.[3] This would bring the total estimated pandemic-related losses for the nation's hospitals and health systems to about $376.1 billion from 2020 through 2021. While, to date, the impact of COVID-19 has been significant, even with federal emergency funding, the financial damage is likely to continue. Adding to this financial impact is the recent fourth COVID-19 surge due to the delta variant and the future unpredictability of

[1] AHA Report: Hospitals and Health Systems Continue to Face Unprecedented Financial Challenges due to COVID-19, June 2020.
[2] Kaufman Hall, The Effect of COVID-19 on Hospital Financial Health, July 2020.
[3] COVID-19 in 2021: The Potential Effect on Hospital Revenues, Kaufman Hall, February 2021

COVID-19's trajectory, with the possibility of even more challenging COVID-19 variants. **Now more than ever, hospitals will need support from government for what is likely to be a highly challenging environment even as COVID-19 cases diminish.**

Continuing to impose a 60% cut on clinic visit services in 2022, on top of the dire financial impacts on U.S. hospitals and health systems due to COVID-19, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries.

Specifically, among all Medicare beneficiaries, relative to patients seen in physician offices, patients seen in HOPDs:

- Are more likely to have severe chronic conditions and more chronic conditions;
- Are more likely to have a prior hospitalization and have higher prior emergency department (ED) use;
- Are more likely to live in communities with lower incomes;
- Are 73% more likely to be dually eligible for Medicare and Medicaid;
- Are 52% more likely to be enrolled in Medicare through disability or end-stage renal disease (ESRD);
- Are 31% more likely to be non-white;
- Are 62% more likely to be under age 65 and, therefore, eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis; and
- Are 11% more likely to be over 85 years old.[4]

Among Medicare beneficiaries with cancer, the differences in the types of patients seen in HOPDs compared to physician offices is even starker. For example, relative to cancer patients seen in physician offices, cancer patients seen in HOPDs not only are more likely to have more chronic conditions and more severe chronic conditions, higher prior utilization of hospitals and EDs, and a higher likelihood of residing in low-income areas, but also:

- Are 123% more likely to be dually eligible for Medicare and Medicaid;
- Are 84% more likely to be enrolled in Medicare through disability or ESRD;
- Are 81% more likely to be non-white; and

[4] Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices, KNG Health Consulting, LLC, April 2021.

- Are 137% more likely to be under age 65 and, therefore, eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis.[5]

Furthermore, a recent analysis of Medicare fee-for-service (FFS) claims data highlights that, during the pandemic, HOPDs were even more likely to treat more medically complex individuals than physician offices. In general, independent physician office (IPO) volume tends to be greater than HOPDs. For instance, in 2019, Medicare volume at IPOs was 1.8 times greater than volume at HOPDs. However, according to the recent analysis[6], this trend was nearly the reverse for outpatient COVID-19 care. In 2020, the number of COVID-19 cases treated in HOPDs was 1.2 times that of the number of COVID-19 cases treated in IPOs. Moreover, in 2020, dual eligible beneficiaries were 1.4 times more likely to get care at HOPDs than at IPOs, the same proportion as in 2019. This indicates that HOPDs continue to treat higher percentages of dual eligible beneficiaries than do IPOs, even during the pandemic. However, that trend is even more pronounced when examining COVID-19 care for dual-eligible Medicare beneficiaries: dual-eligible patients with COVID-19 were 1.8 times more likely to receive care at an HOPD than at an IPO.

According to FY 2019 Medicare cost report data, Medicare margins for outpatient services were negative 15.5% in 2019. The Medicare Payment Advisory Commission (MedPAC) reports that overall Medicare margins were negative 8.7% in 2019.[7] Moreover, according to a 2021 analysis of the impact of the COVID-19 pandemic on hospitals, prepared by Kaufman, Hall & Associates LLC, even with the Coronavirus Aid, Relief, and Economic Security (CARES) Act funding in 2020, the estimated losses of $323 billion left nearly half of America's hospitals and health systems with negative operating margins by the end of 2020. Hospital operating margins decreased nearly 27% between December 2020 and January 2021, and 46% compared with the same period last year. Before COVID-19, the median hospital operating margin was a modest 3.5%.[8] For any organization, a positive operating margin is essential for long-term survival.

We are concerned that continued Medicare site-neutral payment reductions, together with the devastating impacts of COVID-19, will threaten beneficiary access to critical hospital-based "safety-net" services and undermine the ability of hospitals to adequately fund their 24/7 emergency standby capacity. **For better or worse, the hospital safety-net and emergency stand-by role are funded through the provision of outpatient**

[5] Comparison of Care in Hospital Outpatient Departments and Independent Physician among Cancer Patients, KNG Health Consulting LLC, April 2021.
[6] Dobson | DaVanzo analysis of Medicare fee-for-service claims under DUA RIF 54757.
[7] MedPAC Report to the Congress: Medicare Payment Policy. March 2021.
[8] https://www.aha.org/system/files/media/file/2020/07/KH-COVID-Hospital-Financial-Health_FINAL.pdf.

services. If CMS continues to erode this funding, so too will these critical services be eroded.

In fact, this erosion is already occurring, due in no small part to CMS' policies. As spurred by the steady decline in Medicare margins over the past two decades, and as documented by the North Carolina Rural Health Research Program, 138 rural hospitals have closed since 2010, 19 of them in 2020. While MedPAC and others dismiss these closures by noting that the hospitals were "small" or "near other facilities," the concern remains that these very vulnerable rural hospitals are the "canaries in the coal mine." They serve as the initial indicators that we are beginning to reach a tipping point where private payers are no longer willing to fund, and hospitals can no longer sustain, operations on the cost-shift that such considerable Medicare underpayments, particularly those under OPPS, necessitate.

Site-neutral Policies are Based on Flawed Assumptions. **Finally, the entire premise of CMS' site-neutral policies is based on the flawed assumption that Medicare physician fee schedule (PFS) payment rates are sustainable rates for physicians.** However, the truth is much different. AHA members tell us that when they acquire independent physician practices, it occurs because the physicians have reached a point where their practices are no longer financially viable – they are failing due to poor payer mix, increasing Medicare and Medicaid regulatory burden, and declines in Medicare and Medicaid reimbursement. Instead of allowing these physician services to be lost to the community, or in communities where there are already health care deserts, hospitals purchase the practices in order to ensure continued access to these services.

For all the reasons above, we urge CMS to reverse its harmful policy of reducing payment for outpatient clinic visits in excepted PBDs.

PAYMENTS FOR 340B

The AHA continues its steadfast opposition to payment cuts to 340B hospitals. We call on the Department of Health and Human Services (HHS) to end the punitive policy that unfairly and unlawfully targets 340B hospitals. Specifically, since 2018, CMS has paid for drugs purchased under the 340B program at a rate of Average Sales Price (ASP) minus 22.5%, as opposed to the original payment rate of ASP plus 6%. This represents an almost 30% payment cut. This policy has eliminated approximately $1.6 billion annually in payments to hospitals participating in the 340B program. In addition, this reduction has only exacerbated the financial pressures faced by 340B hospitals responding to the COVID-19 public health emergency.

On top of these mounting challenges, 340B hospitals have faced an onslaught of troubling actions by drug manufacturers seeking to limit the scope of the program. Over the past year, multiple drug companies have taken steps to restrict access to 340B drugs for 340B hospitals with contract pharmacy arrangements, despite directives from

the Health Resources and Services Administration (HRSA) finding these actions to be in clear violation of the law.[9] The threat of losing savings from the contract pharmacy program in conjunction with reduced payment as a result of the current OPPS payment policy has created extreme financial vulnerability for many 340B hospitals and the patients they serve. **In light of the pandemic, as well as other critical issues facing 340B hospitals, it is imperative for HHS to put an immediate end to this misguided policy.**

Seeking Relief from Payment Cuts through the Courts. While we urge the Administration to end this unlawful policy, we continue to seek relief in the courts. Specifically, the AHA, joined by member hospitals and health systems and other national organizations representing 340B hospitals, has challenged the agency's policy to levy an unprecedented cut in OPPS payments for 340B drugs of nearly 30% since the agency first proposed the policy in the CY 2018 OPPS proposed rule. These efforts led to a favorable decision by a federal district court that ruled the payment reductions were unlawful. However, in July 2020, two members of the three-judge panel of the U.S. Court of Appeals agreed to overturn that ruling, despite a spirited dissent questioning the majority's deference to the government's position, specifically the government's interpretation of the relevant statutes. These efforts now move to the Supreme Court of the United States as the court has agreed to consider the AHA's petition asking to reverse the federal appeals court decision. In the petition filed with the Supreme Court on September 3rd, the AHA and the other petitioners argue that: "Congress took particular care to constrain the agency's power to set rates for outpatient drugs, and the agency simply decided that it would prefer not to respect those limitations…. Here the agency has violated unambiguous statutory commands. That action cannot be defended under *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or on any other ground…."[10]

Unlawful Interpretation of the Statute. This proposed rule continues the flawed policy first established in the CY 2018 OPPS rule and expanded in subsequent rules to non-grandfathered (non-excepted) off-campus PBDs. **As clearly articulated in previous comment letters and legal briefs, the AHA continues to believe that CMS contrived this policy based on a flawed and unlawful interpretation of the statute and therefore lacks the necessary authority to impose a payment reduction of nearly 30% for 340B drugs**. In the Petition for a Writ of Certiorari, the AHA and other petitioners argued that HHS had "…violated a clear statutory directive when it set rates based on average acquisition cost, and did so for one hospital group but not others, without collecting and considering the acquisition cost survey data that Congress required."[11] The petitioners further contended that the modest "adjustment" authority in the statute "…does not permit such an end run around the unambiguous requirements

[9] https://www.hrsa.gov/opa/index.html
[10] AHA Opening Brief in Case Urging U.S. Supreme Court to Reverse Cut to 340B Program
[11] No PetitionForAWritOfCertiorari.pdf (aha.org)

Congress set forth."[12] As noted in the petition, the district court agreed that the "statutory scheme is clear," and while HHS has authority to make adjustments it cannot fundamentally rework the statutory scheme by applying a different methodology.[13] The federal appeals court, however, enabled these cuts through deference to the government's inaccurate interpretation of the law, which is the crux of the legal issue under consideration before the Supreme Court.

Failure to Provide Sufficient Analysis for the Continuation of the 340B Payment Policy. In addition, the proposed rule perpetuates HHS' failure to provide sufficient analysis for the continuation of the 340B payment policy. When the policy was first proposed by CMS, it stated that it used data to identify 340B hospitals that were actively participating at that time and made several assumptions about 340B claims volumes to estimate the amount of money that would be taken away from 340B hospitals as a result of the payment reduction. These data also were used by HHS to establish the appropriate adjustment to the OPPS conversion factor to ensure that the policy was implemented in a budget-neutral manner. However, the agency has never provided any level of transparency or sufficient access to data, methodology or analysis to allow the public to assess the validity of their original assumptions and replicate their analysis. The AHA has raised these concerns repeatedly in response to prior proposed OPPS payment rules, but they have largely been dismissed by HHS. It is especially egregious that HHS has not updated the budget-neutrality adjustment to the OPPS conversion factor. In fact, in response to this issue, HHS has incorrectly stated that it does not need to update this factor as the payment rate of ASP minus 22.5% has not changed since the policy was first implemented. However, in not updating this factor, it is clear that HHS has not taken into account any changes that have occurred in which hospitals are actively participating in the 340B program or any changes in utilization and volume since HHS first proposed changes to 340B payment policy in 2017. If the policy is to remain budget-neutral on annual basis as HHS has intended for the policy to be, then it must update the factor annually based on the most recently available data. This approach is consistent with other budget-neutral policies included in OPPS, such as wage index, outliers, rural sole community hospital (SCH) adjustment, and cancer hospital adjustment, for which adjustments are analyzed and made annually via the OPPS conversion factor. **On this point, the AHA strongly recommends that, if HHS is allowed to continue the current 340B payment policy, it should annually ensure that it remains budget neutral by recalculating the policy's impact to make certain the conversion factor is properly adjusted.**

Potential Expansion of Cuts to Other 340B Hospital Types. The proposed rule suggests the potential to expand the 340B payment policy to other 340B hospital types. Specifically, in prior rules as well as the current proposed rule, HHS has exempted certain 340B hospital types from its payment cut – rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, as well as critical access hospitals (CAHs). However, in

[12] Ibid.
[13] Ibid.

both the CY 2021 and CY 2022 OPPS proposed rules, CMS has stated that "We may revisit our policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking." **The AHA opposes any future efforts of CMS to expand the payment cuts to other 340B hospital types, as this would perpetuate an already flawed policy**. The 340B hospital types currently exempt from the policy are largely rural hospitals or hospitals that treat a specific patient population, whereby these hospitals rely heavily on the 340B program to maintain important services and programs for their patients, such as infusion centers for rural patients, pediatric diabetes management, and rural opioid treatment centers. In addition, many rural hospitals rely on savings from the 340B program to keep the doors of their facility open, which in and of itself enables them to fulfill the Congressional mission of the program of "reaching more eligible patients and providing more comprehensive services." Further, these hospitals have already faced tremendous hardship wrought by the ongoing COVID-19 pandemic as well as the ongoing threats from pharmaceutical manufacturers to eliminate 340B contract pharmacies, which are especially important for rural hospitals since many of them do not operate their own in-house pharmacy and rely heavily on the contract pharmacy program. For some hospitals, the combination of these issues, as well as a payment reduction of nearly 30% on their 340B drugs, could result in the shutdown of some vital programs, or worse, the facility itself. **Therefore, if the current payment policy is maintained, we urge CMS to not expand the policy any further to other hospital types in future rulemaking.**

For nearly 30 years, the 340B program has allowed participating hospitals to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve. Hospitals use savings from the program to provide free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs.[14] In 2018, tax-exempt 340B hospitals provided nearly $68 billion in total benefits to their communities, despite incurring billions in costs associated with uncompensated and unreimbursed care. 340B hospitals continue to serve as lifelines of their communities and the discounts they receive through the 340B program play an important role in allowing them to care for patients, especially as they have done during the COVID-19 pandemic.

CHANGES TO THE INPATIENT-ONLY LIST

The inpatient-only (IPO) list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Prior to 2021, CMS annually reviewed the IPO list to

[14] AHA Reply to Government Related to Petition for Cert At US Supreme Court Re: 340B Payment Reduction | AHA

identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using five criteria specified in regulation. However, in the CY 2021 rule, CMS finalized a policy to eliminate the IPO list over the course of three years. It began with the removal of 298 Healthcare Common Procedure Coding System (HCPCS) codes, including 266 musculoskeletal-related services in CY 2021.

The AHA strongly supports CMS' proposal in this rule to halt the elimination of the IPO list. The IPO list was put into place to protect beneficiaries. Many of its services are surgical procedures that are high risk – complicated and invasive procedures with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period, and which require the care and coordinated services provided in the inpatient setting of a hospital. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which could make these procedures even more complicated and risky if furnished in outpatient settings. We agree that halting the elimination of the IPO list and, instead, allowing these procedures to be evaluated using the criteria in place prior to 2021 would result in greater consideration of the impact removing services from the list has on beneficiary safety. It also would allow providers affected by the COVID-19 PHE additional time to prepare to furnish appropriate services safely and efficiently if some are removed from the IPO list.

The AHA also supports CMS' proposal to restore the 298 services removed from the IPO list in CY 2021. These procedures were removed from the list without data to support the appropriateness of their performance in the outpatient setting. Therefore, we agree with CMS' determination that there is inadequate evidence to demonstrate that any of the services removed in CY 2021 can be safely performed on the Medicare population in the outpatient setting, that most outpatient departments are equipped to provide the services to the Medicare population, or that the services are being performed safely on an outpatient basis. The appropriate setting for procedures should be determined with a focus on patient safety and peer-reviewed evidence.

CMS also requests comments about whether it should preserve the longer-term objective of eliminating the IPO list or if it should maintain the IPO list but continue to systematically scale the list back so that inpatient-only designations are consistent with current standards of practice. **The AHA supports the latter approach. In doing so, we urge the agency to, at least, continue with its pre-2021 process for removing procedures from the IPO list.** In fact, CMS could enhance determinations about individual procedures that could be safely removed from the IPO list by setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities, social support, and other factors relevant to positive patient outcomes.

Moreover, we believe that the goal of entirely eliminating the IPO list is unrealistic, unsafe and inappropriate, as the list includes some procedures that may never be appropriate to furnish in an outpatient setting. These include, for example:

- Current Procedural Terminology (CPT) code 33935 Transplantation heart/lung;
- CPT 32853 Lung transplant double;
- CPT code 19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation); and
- CPT code 3352 Coronary artery bypass, using venous graft(s) and arterial graft(s), six or more.

These services, as well as others among the more than 1,700 services on the IPO list, may never be able to be performed safely in hospital outpatient settings because of the complex and high risk nature of the procedure and the fact that they require far more than 24 hours of postoperative recovery and monitoring time before the patient can be safely discharged.

PAYMENT FOR THE BLOOD NOT OTHERWISE CLASSIFIED (NOC) CODE

Starting Jan. 1, 2020, CMS established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products before blood product-specific HCPCS codes are available. For CY 2021, CMS set the status indicator (SI) for HCPCS code P9099 from “E2” to “R” (blood and blood products, paid under OPPS). CMS made HCPCS code P9099 separately payable at a rate equal to the lowest paid separately payable blood product in the OPPS with a payment rate of nearly $8.00 per unit. CMS indicated that this was consistent with OPPS policy for other major categories of medical care where the payment rate for the unclassified service is based on the lowest-paying ambulatory payment classification (APC) for that category of service.

The agency proposes no change to this SI for CY 2022. **However, the AHA agrees with the Advisory Panel on Hospital Outpatient Payment recommendation that CMS assign an SI of “F” to HCPCS P9099, which would authorize A/B Medicare Administrative Contractors to pay HCPCS P9099 on the basis of reasonable cost.** Providers should receive separate reimbursement for new blood/blood products, as they incur a cost for these products well beyond the nearly $8.00 per unit currently paid. In addition, there are several new types of blood component products currently in development expected to be approved over the next several years that would be grossly underpaid if they remained at the current reimbursement level. Appropriate payment for new blood products would facilitate patient access to new products and encourage providers to offer these new blood products/components without an unacceptable financial loss.

Finally, we recommend that if SI of "F" is approved, CMS should develop simple and straightforward billing instructions that do not add undue administrative burden in order for hospitals to receive payment.

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

The AHA recommends that CMS revise the code descriptor of HCPCS code G0463, by inserting the word "or" between the words "outpatient" and "clinic," so that it would read, "Hospital outpatient or clinic visit for assessment and management of a patient." Many payers are erroneously categorizing G0463 as a clinic-only evaluation and management (E/M) code. That is, payers are refusing to pay for HCPCS code G0463 because in their assessment it only represents services provided in a PBD/clinic where the hospital also employs the physician and is split-billing for both the professional and technical component. As CMS is historically aware, there are legitimate instances where hospitals report G0463 for an outpatient evaluation visit only, on the order of, and under the supervision of, a physician, without also billing the professional component. For example, the physician may not be employed by the hospital and therefore the hospital would not bill the professional component. CMS' historical guidance to hospitals is to report G0463 if there is no other appropriate CPT or HCPCS code to describe the service provided.

Equitable Adjustment for Drugs, Biologicals and a Device Category with Expiring Pass-through Status

CMS notes that if it finalizes its proposal to use the CY 2019 claims data, instead of CY 2020 claims data, in establishing the CY 2022 OPPS rates, it would effectively remove approximately one year of pass-through data collection time for rate-setting purposes for drugs, biologicals and devices with pass-through status that will expire in CY 2022. Therefore, for CY 2022, CMS proposes to use its equitable adjustment authority to provide up to four quarters of separate payment for 21 drugs and biologicals whose pass-through payment status will expire on March 31, 2022, June 30, 2022, or Sept. 30, 2022, and six drugs and biologicals and one device category whose pass-through payment status will expire on Dec. 31, 2021. **The AHA supports this proposal. We agree that having a full year of claims data from CY 2021 to use for CY 2023 rate-setting and avoiding using CY 2020 data to set rates for these pass-through drugs, biologicals, and the device category for CY 2022 is the best way to ensure that adequate data for rate-setting purposes is available once these products' pass-through status expires**

COMMENTS ON TEMPORARY POLICIES FOR THE COVID-19 PHE

Direct Supervision by Interactive Communications Technology. In the April 6, 2020, COVID–19 interim final rule with comment period, CMS allowed providers to satisfy "direct supervision" requirements for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services to be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. Last year, CMS finalized the continuation of this policy through the later of the end of the calendar year in which the PHE ends or Dec. 31, 2021. In this rule, and in the CY 2022 PFS proposed rule, CMS seeks comment on whether it should make this flexibility permanent or if it should temporarily continue it beyond the current timeframe. **The AHA strongly supports the COVID-19 pandemic policy regarding direct supervision by interactive telecommunications technology**. We believe that this policy will continue to improve access for patients and reduce burden for providers after the end of the PHE. **We urge the agency to make this policy permanent and stand ready to assist in determining appropriate guardrails for its operation.**

However, we remain concerned about, and continue to urge CMS to revise, its clarification in the April 6, 2020, COVID-19 interim final rule indicating that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to "immediate availability," but rather requires the real-time presence via interactive audio and video technology throughout the performance of the procedure. Requiring real-time presence throughout the procedure, rather than "immediate availability," is inconsistent with the statutory and regulatory definition of "direct supervision." It is, in fact, more akin to "personal supervision." Under current regulations, as well as the statutory language that defines the required level of supervision for cardiac rehabilitation, pulmonary rehabilitation and intensive cardiac rehabilitation programs, "direct supervision" does not require the actual presence of the physician for the duration of the service; rather it requires only that the physician be "immediately available" to furnish assistance, as necessary, through the performance of the procedure.

Specifically, 42 CFR 410.28(e)(1), as updated by CMS' COVID-19 interim final rule, defines direct supervision as:

> "the physician must be *immediately available* to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in §400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider."

Further, Section 1861(eee)(2)(B) of the Social Security Act establishes that, for cardiac, intensive cardiac and pulmonary rehabilitation programs, "a physician is *immediately available* and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed." This statutory requirement is very similar to the requirement for direct supervision.

Neither definition of the direct supervision for these services mandates more than the *immediate availability* of the physician throughout the service. However, CMS' clarification is closer to the definition of personal supervision (42 CFR 410.32(b)(3)(iii)), which means that "the physician must be in attendance in the room during the performance of the procedure. A personal level of supervision is unnecessary for these services (which are only furnished to stable outpatients) and is inconsistent with the statutory requirement of direct supervision for cardiac, pulmonary and intensive cardiac rehabilitation services.

The AHA continues to urge CMS to allow the supervising physician to be *immediately available* to furnish assistance and direction throughout the service using audio/video real-time communications technology.

Specimen Collection for COVID-19 Tests. As result of the COVID-19 PHE, CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [covid-19]), any specimen source). HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures for the duration of the COVID-19 PHE, with a payment rate of $22.98 for 2020. HCPCS code C9803 is conditionally packaged, meaning that it will only be paid separately if it is the only service provided or it is billed with a clinical diagnostic laboratory test that is separately payable. CMS requests comments on whether and why it should keep HCPCS code C9803 active beyond the conclusion of the COVID-19 PHE and whether it should extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the COVID-19 PHE ends.

The AHA recommends that CMS retain HCPCS code C9803 and its current APC assignment and status indicator, as well as its payment rate, beyond the COVID-19 PHE. Even when the PHE ends, at a time when there is increased population immunity due to vaccination or full recovery from the infection, the novel coronavirus is expected to become endemic. While outbreaks will likely be rarer and smaller, they will still occur, particularly as immunity wanes among the vaccinated and recovered individuals and as immunologically naive babies are born. Additionally, new variants, even more aggressive than the delta variant, might emerge. **This means that specimen collection for COVID-19 testing still will be necessary. Hospitals will need to continue to provide higher level, and more costly, personal protective equipment (PPE), as well as continue other training and protocols necessary for**

the protection of those health care personnel who obtain these laboratory specimens.

The use of these enhanced protective equipment and protocols is recommended by Centers for Disease Control and Prevention (CDC) and mandated by the Occupational Safety and Health Administration (OSHA). That is, CDC's Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing state, "For healthcare providers collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended PPE, which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown." Furthermore, this testing should only be done by trained health care personnel. That is, for initial diagnostic testing for current SARS-CoV-2 infections, CDC continues to recommend collecting and testing an upper respiratory specimen using sterile swabs, which must be done by a trained health care provider. CDC notes that this is important both to ensure patient safety and preserve specimen integrity. OSHA's recently issued COVID-19 Health Care Emergency Temporary Standard (ETS), which is expected to become a permanent standard by the end of 2021, requires that health care employers must provide a respirator to each employee who has exposure to a person with suspected or confirmed COVID-19 and ensure that it is provided and used in accordance with OSHA's Respiratory Protection Standard. Employers also must provide each of these employees with gloves, an isolation gown or protective clothing, and eye protection, and ensure that the PPE is used in accordance with OSHA's PPE requirements.

LOW-VOLUME POLICY FOR CLINICAL, BRACHYTHERAPY AND NEW TECHNOLOGY APCS

In the past, CMS has selectively used the equitable adjustment authority to determine costs for low-volume services. CMS believes these policies, which have mitigated concerns regarding fluctuations in payment rates for low-volume new technologies and device-intensive procedures, should be expanded to all low-volume APCs with fewer than 100 single procedure claims available for rate-setting annually. Therefore, for 2022, CMS proposes to designate clinical APCs, brachytherapy APCs, and new technology APCs with fewer than 100 single claims that can be used for rate setting as low volume. For low-volume new technology procedures, CMS proposes to determine the higher of the procedure's cost based on the geometric mean, median, or the arithmetic mean to assign the procedure to a new technology APC. For clinical and brachytherapy APCs, CMS proposes to determine relative weight based on the higher of the APC's geometric mean, median, or the arithmetic mean. CMS will use up to four years of data to make these determinations when a new technology procedure, clinical APC or brachytherapy APC is designated as low volume.

The AHA supports CMS' proposed low-volume policy because it will help to mitigate annual payment fluctuations among these services and create better year-over-year predictability in Medicare revenue for hospitals providing these low-volume services.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS proposes a number of updates to the OQR measure set and requests feedback on several issues, including potential new measures, data on health disparities, and transitioning to digital quality measurement.

Adoption of COVID-19 Vaccination Coverage among Health Care Personnel (HCP) Measure. For the CY 2024 reporting period, CMS proposes to adopt this measure that assesses the percentage of HCP eligible to work in the hospital for at least one day during the reporting period who received a complete vaccination course against COVID-19. If finalized, hospitals and ASCs would be required to submit data through the CDC's National Healthcare Safety Network (NHSN) platform beginning Jan. 1, 2022, for the OQR and ASCQR. This measure was adopted for the inpatient quality reporting program in the FY 2022 inpatient prospective payment system (PPS)/long-term care hospital (LTCH) PPS final rule issued Aug. 2, 2021, as well as for the LTCH, inpatient rehabilitation facility, skilled nursing facility (SNF), and inpatient psychiatric facility quality reporting programs in their respective FY 2022 final rules.

In our comments on the proposed adoption of this measure in the FY 2022 proposed rules, we voiced support for CMS' efforts to encourage vaccination against COVID-19 among HCP; however, we raised concerns regarding some of the specifications of the measure as well as uncertainties regarding vaccination details and potential unintended consequences if the measure were adopted and performance on it publicly reported. Due to those concerns, we suggested that CMS delay adoption of the measure or implement it for voluntary reporting for at least the first quarter of the reporting period, if not the first year. While those concerns remain, the AHA Board of Trustees recently issued a statement strongly encouraging vaccination of all HCP, and voiced support for hospitals and health systems that adopt mandatory COVID-19 vaccination policies for HCP in their organizations. In turn, and because this measure has already been finalized for adoption in other settings, **we support CMS in its ongoing efforts to combat COVID-19 by encouraging vaccination of HCP, and will use these comments to raise certain issues with the measure that we urge the agency to address before the start of the reporting period.**

First, we ask CMS to clarify how booster shots would be incorporated into measure collection and calculation. While the protocol for administering booster doses has not yet been established, Francis Collins, M.D., director of the National Institutes of Health, stated Aug. 15 that "we may need boosters, maybe beginning first with health care providers." In response to this issue in the inpatient PPS final rule, CMS noted that it

believes "the numerator [of the measure] is sufficiently broad to include potential future boosters as part of a 'complete vaccination course' and therefore the measure is sufficiently specified to address boosters." We interpret this to mean that, once booster doses are recommended, hospitals and health systems will report in one data submission field the number of HCP who received their initial vaccination doses as well as their booster dose. By the time the final OPPS/ASC rule is issued, the CDC will likely have determined a course of action for administering boosters. **We urge CMS to develop plans to issue guidance regarding documentation of booster doses and reporting so that hospitals and health systems can easily incorporate this information once booster doses are recommended.**

In addition, the AHA remains concerned about the potential misalignment between exclusions in the measure's specifications and those allowed by the Federal Equal Employment Opportunity Commission (EEOC) guidance issued May 28, 2021. The measure denominator excludes only individuals with medical contraindications to the vaccine as established by the Food and Drug Administration (FDA) and CDC. However, the EEOC guidance allows employers to require vaccination against COVID-19 as long as the employer complies with certain provisions including Title VII of the Civil Rights Act of 1964, which requires an employer to provide reasonable accommodations for employees who refuse vaccination due to a sincerely held religious belief, practice or observance. **To maintain alignment across relevant federal guidelines, CMS should allow facilities to exclude HCP who decline vaccinations under the provisions outlined by the EEOC from the measure's denominator.**

Finally, we strongly encourage CMS to work with CDC and HHS to clarify and streamline the various COVID-19-vaccination-related data reporting requirements. An interim final rule issued in August 2020 established a Medicare Condition of Participation (CoP) requiring hospitals to report to HHS a vast array of COVID-19-related data points, building on a voluntary effort established in March 2020. This CoP requirement will remain in place for the duration of the COVID-19 PHE. Earlier this year, HHS added optional reporting fields to the CoP that ask for hospitals to report on the proportion of their workforce that has received the COVID-19 vaccination, and the volume of patients to whom the hospital has administered vaccinations. The HCP personnel data fields in HHS' reporting guidance differ significantly from CMS' proposed HCP vaccination measure. We are concerned about the potential for duplication of effort and confusion among hospitals, policymakers and the public that would result from CMS and HHS collecting two different sets of data on HCP vaccination rates.

We understand that data needs have evolved, and we appreciate that HHS is working to evaluate and potentially adjust required data fields and reporting cadences to account for developments in disease incidence and vaccination rates. However, given the importance of achieving a high level of vaccination coverage among HCP, there must be one "source of truth" that hospitals, policymakers and the public rely upon to evaluate progress. CMS has now adopted the NHSN-based HCP COVID-19 vaccination measure across multiple measurement programs, and, therefore, we

believe that measure is most appropriate as that source of truth. Thus, **we encourage CMS to work with HHS to phase out the HCP COVID-19 vaccination fields from HHS' hospital CoP reporting guidance.**

Adoption of Breast Screening Recall Rates Measure. CMS proposes to adopt this claims-based process measure beginning with the CY 2023 reporting period. The measure calculates the percentage of Medicare FFS beneficiaries who received a traditional mammography or digital breast tomosynthesis (DBT) screening study and then received a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging of the breast in an outpatient or office setting within 45 calendar days of the first image. CMS notes that while there are no clinical guidelines to indicate the optimal proportion of imaging recalls, CMS cites "evidence from the clinical literature" suggesting the appropriate rates "should fall between 5 to 12 percent." Providers recalling less than 5% of patients risk delayed diagnoses, while those recalling more than 12% may subject patients to superfluous radiation. The measure is not endorsed by National Quality Forum (NQF), and CMS does not mention any plans to submit the measure for endorsement.

Although it addresses an important topic, the AHA does not support the adoption of this measure because it lacks clinical evidence to demonstrate the measure's effect on outcomes, and is unlikely to be useful for patients. As currently specified, the measure would be reported as a percentage; without a benchmark informed by clinical evidence to compare the percentage to, this information is not useful. We urge CMS to consider the history of a similar measure, OP-9, Mammography Follow-up Rates, which was recently removed from the OQR because it no longer aligned with clinical guidelines; this measure also is not based upon current clinical guidelines, so if OP-9 is deficient, this measure also must be deficient.

In addition, the purpose of reporting recall rates may be difficult for a consumer looking to choose a provider to understand. While this measure would provide data on whether a provider does unnecessary (or insufficient) scans, it does not provide a complete picture of how accurately a facility detects breast cancer. Thus, we recommend that CMS work with measure developers to reconsider this concept in conjunction with other indicators of performance in breast cancer screening, such as positive predictive value.

Removal of Fibrinolytic Therapy Received within 30 Minutes of ED Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3) and Replacement with ST-Segment Elevation Myocardial Infarction (STEMI) Electronic Clinical Quality Measure (eCQM). CMS proposes to remove two chart-abstracted process measures (OP-2 and OP-3) from the OQR beginning with the CY 2023 reporting period and replace them with a new, more broadly applicable measure on the same topics (STEMI eCQM). The two measures currently used in the OQR assess whether patients receive timely care for STEMI in the ED, but the chart abstraction process is burdensome and the measures' populations are limited to patients receiving care in facilities that either provide fibrinolytic therapy or who are transferred to a facility

capable of percutaneous coronary intervention (PCI); these measure do not capture patients who receive PCI at a facility capable of performing the procedure, but the proposed new STEMI eCQM does.

In addition, the STEMI eCQM is designed to be calculated by hospitals' certified electronic health record (EHR) technology using patient-level data submitted to CMS. The agency asserts — and we agree — that this method of measure calculation would more efficiently and comprehensively measure timeliness of STEMI care while incorporating contraindications to enhance the clinical applicability of the measure. Finally, CMS proposes to phase in the new measure by adopting it for voluntary reporting in CY 2023 followed by mandatory reporting in CY 2024.

The AHA supports the replacement of OP-2 and OP-3 with the STEMI eCQM in the phased approach proposed. When reviewing the STEMI eCQM as part of the NQF's Measure Applications Partnership (MAP), AHA recommended that CMS replace the two chart-abstracted measures with the new STEMI eCQM. The topic of timely STEMI care is important and well assessed with a process measure; however, many process measures are based solely upon claims data and thus do not incorporate important clinical information that informs providers' decision-making. Appropriately specified eCQMs can provide a comprehensive picture of provider behavior and ensure that clinicians and their facilities are not being unfairly evaluated based on what was actually suitable performance. We also appreciate the phased approach to measure adoption that CMS proposes. This incremental implementation will allow hospitals time to change workflow as necessary to submit data.

In addition, by the time this measure is required for reporting, it will have gone through the NQF endorsement review process, as CMS submitted the measure for review in January 2021. The concerns we raised with this measure when we commented on it during the MAP process — specifically, whether there is enough of a performance gap to justify including this measure in a streamlined set as nationwide performance for the other STEMI-related measures has improved immensely in the past decade — are likely to be addressed in the endorsement process.

<u>Required Reporting of Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31 and ASC-11)</u>. CMS proposes to restart required reporting of this previously voluntary measure beginning with the CY 2023 reporting period for the OQR and ASCQR. The measure assesses the percentage of adult patients who had cataract surgery and had improvement in visual function within 90 days following the surgery. Improvement is evaluated based on pre- and post-operative surveys.

In the CY 2015 OPPS/ASC rule, CMS adopted the measure for voluntary reporting only due to several concerns, including:

- The measure is operationally difficult for hospitals to collect and report.

- The results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery.
- Clinicians used inconsistent surveys to assess visual function, as the measure allows the use of any validated survey.

The measure's specifications remain unchanged. Yet, CMS now believes that its "earlier concerns have been ameliorated," and thus the measure should be required for reporting beginning with the CY 2023 reporting period.

However, the AHA does not believe CMS has done enough to address the measure's shortcomings to begin mandatory reporting. First, the proposed rule gives no information to suggest CMS had made the measure any less operationally difficult for hospitals to collect and report; instead, the agency merely notes that "hospitals have had several years to familiarize themselves with OP-31, prepare to operationalize it, and opportunity to practice reporting the measure." However, the measure has been voluntary since the CY 2015 reporting period, and CMS notes that only "a small number of facilities" have actually reported on the measure. These data do not indicate that hospitals have overcome the operational difficulties in collecting it, nor are they any more prepared to implement the measure and the onerous operational logistics it entails.

CMS also notes that "research indicates that using different surveys will not result in inconsistencies, as the allowable surveys are scientifically validated." However, the study cited by the agency is hardly relevant to this measure. It assesses the administration of cataract surgery questionnaires completed six months after surgery (rather than 90 days, as is specified in the quality measure) in Australia and Sweden and the purpose of the study was only to investigate the responsiveness of 16 different questionnaires, not to compare the agreement among results. In fact, the study found that one survey in particular is ideal for measuring visual function outcomes — the outcomes relevant to the measure — while other instruments may be preferred to measure different constructs.

Unless and until CMS can demonstrate that the problems with this measure have been ameliorated, **we cannot support the required reporting of OP-31 and ASC-11 beginning in CY 2023 or any future year.**

Required Reporting of Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e and ASC-15a-e). CMS proposes to require reporting of the OAS CAHPS survey as well as five measures based on the survey beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period. These measures and the associated survey were delayed for mandatory

implementation in the CY 2018 OPPS/ASC final rule due to a lack of sufficient operational and implementation data. In that rule, CMS also noted that survey measures may not account for differing patient response rates based on the method of survey administration; in addition, administering the survey in the outpatient setting may result in high burden for providers, and national OAS CAHPS data may not be reliable. In our comments on the CY 2018 OPPS/ASC proposed rule, we agreed with CMS' proposal to delay implementation of the OAS CAHPS survey and related measures, and urged the agency to use the delay to address several critical implementation issues.

In this proposed rule, CMS states that it now believes "that patients are able to respond to OAS CAHPS survey questions, and that those responses are reliable," and that any burdens associated with administration of the survey are outweighed by the benefits of the measures. CMS proposes to incorporate two additional survey administration methods: If finalized, organizations would be allowed to administer the OAS CAHPS survey via mixed mode web with mail follow-up of non-respondents and mixed mode web with telephone follow-up of non-respondents in addition to the previously allowed methods of mail only, telephone only, and mail with telephone follow-up of non-respondents.

The AHA is encouraged by aspects of CMS' proposals for the OAS CAHPS survey, and agrees with the concept of using systematic, reliable approaches to capture patient perspectives on the care they receive. At the same time, we believe important work remains to ensure the OAS CAHPS accurately and meaningfully reflects hospitals' work to improve the patient experience. Getting the OAS CAHPS "right" is especially vital given the substantial resources it will take for hospitals to collect and report measure data. It is possible improvements can be accomplished by the time CMS proposes to require measure data collection and reporting in CY 2024. **However, given the complexity of the task, we ask that CMS consider retaining the OAS CAHPS measures for voluntary reporting until these important issues can be addressed**.

The AHA has long supported the use of rigorously designed surveys of patient experience of care, and we have engaged with CMS, the Agency for Healthcare Research and Quality (AHRQ) and several other stakeholders on work to improve CAHPS surveys. One of our longstanding recommendations has been for CMS to develop more economical survey administration approaches, like email or web-based surveys, which have more consistent response rates. **We applaud CMS for taking this important step in modernizing patient experience surveys; by allowing web-based survey administration, providers will be able to reach a wider patient population and receive more and timelier information they can use to improve patient experience.**

While we believe that adding web-based survey administration will improve response rates and decrease burden, we still have concerns about the reliability of the data produced by the survey. The CAHPS program already includes multiple, and potentially overlapping, survey tools. Correct attribution of performance results could be especially

problematic if a new survey for ASCs and HOPDs is implemented because two existing CAHPS surveys — the Clinician/Group CAHPS (CG-CAHPS) and the Surgical CAHPS — capture closely related information. These surveys evaluate providers on several issues, including access to appointments, physician communication with patients, courtesy of office staff, and follow up on testing results. Another survey relevant to outpatient surgical patients may result in patients receiving three separate but similar surveys for exactly the same care episode. CMS itself listed these and other issues in its rationale to delay implementation of the OAS CAHPS survey and related measures in previous rules.

In past comments, we suggested CMS ameliorate these issues by ensuring that survey administration protocols clearly identify which particular institution is being surveyed to help guarantee correct attribution of experience as the agency conducts analyses of the national survey data and plans necessary modifications. It does not appear that CMS has made any substantive changes to administration protocols, the survey, or the related measures to address any of its stated concerns outside of method of administration. In this proposed rule, the agency simply states that "we believe that patients are able to respond to OAS CAHPS survey questions, and that those responses are reliable based on our prior experiences collecting voluntary data for public reporting since CY 2016," and provides a link to the agency's provider data homepage — the agency does not provide any specific data demonstrating OAS CAHPS reliability. We agree that the survey and topics addressed by the related measures are important, but **we ask CMS to provide evidence of the survey's reliability before it requires survey administration.**

Finally, the OAS CAHPS survey measures are not endorsed by the NQF. Through the process of seeking endorsement, all stakeholders are given insight into whether the measures portray hospital performance in a fair and accurate manner. Given the significant resources needed to collect survey data, **we encourage CMS to pursue NQF endorsement of these measures before the OAS CAHPS is required of hospitals.**

eCQM Reporting Requirements. CMS proposes a number of updates to eCQM reporting requirements for the OQR that would bring them into alignment with the requirements for the IQR and Promoting Interoperability Program. In addition, CMS proposes exceptions for hospitals with few or no patients relevant to individual measures. **The AHA supports the alignment of these requirements,** as many facilities reporting data for the OQR use the same systems and staff to report data for their organization's IQR measures as well. In addition, **we support the proposed exceptions for hospitals that either do not offer a service evaluated by a quality measure or that have five or fewer applicable discharges per quarter**, as these facilities should not be held to the same quality reporting standards as facilities with larger volumes.

Requests for Information

Patient Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) Measure. CMS and many private payers are increasingly encouraging THA/TKA procedures to be done on an outpatient basis; CMS removed TKA from the Inpatient-Only List in the CY 2018 OPPS final rule and THA in the CY 2020 final rule, adding TKA to the ASC Covered Services List in the same rule. In order to better inform decision-making regarding care and for quality improvement efforts in the outpatient setting, CMS is considering a measure reporting the hospital-level risk-standardized improvement rate in patient-reported outcomes following THA/TKA procedures for Medicare FFS beneficiaries aged 65 and older. Improvement would be determined via pre- and post-operative assessments of hip or knee pain and functioning. The measure is endorsed by NQF for use in the inpatient setting, and CMS solicited comments on the potential future adoption of this measure in the IQR in the FY 2022 IPPS/LTCH PPS proposed rule; CMS would re-specify this measure for the outpatient setting.

We believe that the measure concept is appropriate for a CMS quality program because it addresses a common procedure that is performed nationwide on a variety of patients, making it relevant for a large population. In addition, non-emergent procedures like THA/TKA can be considered "shoppable" services, where prospective patients can use comparable performance information to make a choice on where to get care. Finally, the outcome of note (substantial clinical benefit) is comprehendible and aligned with patient values — more so than many currently used measures that provide clinical insight into complex issues that a layperson would have trouble understanding. These conceptual advantages coupled with the measure's NQF endorsement make it appropriate for consideration for a CMS quality reporting program; however, we encourage CMS to consider a few issues as the agency re-specifies the measure for use in the outpatient setting.

Because THA/TKA procedures are increasingly being offered in the outpatient setting, the patients receiving these services in a hospital-based setting (either inpatient or HOPD) will be the sickest and most complex (i.e., patients who will need access to the full resources of a general acute care hospital rather than an ASC or other outpatient facility). In addition, the time lag between care being delivered and data being reported is more substantial for this measure than for most as the postoperative assessment is not conducted until up to a year after the procedure. These issues undermine the usefulness of the measure by resulting in inappropriate comparisons. As CMS considers using the established measure in the outpatient setting, it should ensure it uses a risk adjustment methodology that takes into account differences in patient complexity in addition, the agency should investigate a reporting cadence that limits lag as much as possible.

The AHA is supportive of well-constructed and meaningful patient-reported outcomes (PRO) measures. However, while these measures provide helpful information, they are

inherently burdensome to patients, and we urge CMS to consider how this and other PROs will interact with (and potentially compete with) other patient surveys, like the OAS CAHPS survey. Patient response rates to the various surveys across the continuum of care are dropping, and the more tasks heaped upon patients, the less likely they are to complete them all. Thus we encourage CMS to be thoughtful in its implementation of this measure to ensure that it gleans sufficient data to inform quality improvement.

Health Equity and Data Collection. The AHA applauds CMS' commitment to advancing health equity, and we are pleased the agency seeks input on a range of potential policy actions intended to accelerate the nation's progress on this vital topic. Hospitals and health systems are working hard to identify and address health disparities and to close remaining gaps in quality performance across patient populations. Our ultimate goal is the same as CMS': to ensure that all patients feel valued and recognized, and that the care they receive does not vary due to race, ethnicity, gender, sexual orientation or other demographic or social risk characteristics.

General Considerations. Most of the policy ideas shared in the RFI focus on the collection, analysis and use of health equity-related data within the context of CMS' existing framework of quality measurement and value programs. We certainly understand this focus, given both the visibility and importance of CMS' quality measurement programs, and the vital need to have reliable, accurate and actionable data to both identify disparities and track progress over time. As CMS continues to work with the health care field to advance equity and considers advancing its use of equity data, our members have asked that CMS:

- Work to foster alignment and standardization of approaches to collecting, analyzing and exchanging demographic and social risk data. This includes a consistent approach across CMS itself, and across other federal agencies and programs. Given the breadth of health equity issues, and the wide range of stakeholders affected by it, CMS can help ensure that all stakeholders use consistent definitions and standards. Furthermore, such standards should be thoroughly field tested before broader implementation.

- Ensure that equity data use and collection efforts are aligned with CMS' broader goals and strategy related to health equity. In other words, the collection, use and analysis of data should not be done in isolation and should be linked to achieving specific goals in CMS' strategy.

- Identify and share more broadly data to which CMS itself may have access. For example, to the extent CMS is collecting demographic and social risk data during the time of Medicare enrollment, the agency should explore ways of determining whether this information could be linked to quality data. These steps could help provide additional data for CMS' efforts to identify disparities in performance and

outcomes.

- Be judicious in requests for new data and ensure any efforts to collect equity data achieve an appropriate balance of value to advancing health equity and administrative burden. As CMS notes in the proposed rule, "the development of consistent and sustainable programs to collect data on social determinants of health can be considerable undertakings." Indeed, data reporting often involves investments in systems and personnel, and redesigns of workflows to ensure data can be captured. However, certain types of data (e.g., living situation, sexual orientation and gender identify) also may be sensitive for patients to disclose. We encourage CMS to engage patients and providers extensively as it explores additional data collection.

Facility Equity Score. CMS recently developed — but has not yet implemented — an equity summary score for Medicare Advantage (MA) plans, which aggregates results from multiple quality measures and then assesses to what extent disparities in performance may exist among beneficiaries along the lines of race and dual-eligible status. CMS is interested in building a similar score for hospitals that would supplement the measure data already reported on the Care Compare website. The agency asserts that this summary score could provide easy-to-interpret information regarding disparities measured within individual facilities and across facilities nationally.

The AHA understands the conceptual appeal of an overarching "facility equity score." However, such a score would not be a helpful step in advancing health equity at this time; thus, we recommend that CMS prioritize other mechanisms for advancing health equity.

The AHA is concerned that a facility equity score may inadvertently lead to a reductionist approach to assessing provider efforts related to health equity. The facility equity score would assess for disparities only along the lines of race and ethnicity and dual-eligible status. Certainly, knowing whether disparities exist along those dimensions is important. At the same time, recent work around health equity also has highlighted the concept of "intersectionality;" that is, disparities often are driven by a confluence of multiple characteristics rather than just one or two. The drivers that matter the most to particular patients, communities and hospitals are likely to vary, and be interconnected. For example, other factors such as education, housing and access to healthy foods also can contribute to health disparities. As a result, judging a hospital's success or failure in addressing disparities through only the dimensions included in the facility equity score could result in an incomplete assessment.

Furthermore, we question whether a summary equity score would be actionable by hospitals, or meaningful to the public. As we understand it, the score blends together the performance for racial and ethnic subgroups along with those for beneficiaries who are eligible for both Medicare and Medicaid. Yet, a hospital wanting to improve its performance would be challenged to use a single summary score to identify the specific

quality measures and dimension of equity that drives their performance. Even more concerning is the prospect of hospitals or the public drawing either false comfort or false alarm from such "rolled up" results. For example, a high overall score may inadvertently obscure lower performance on particular quality measures, or among particular segments of a hospital's patient population.

Lastly, we are not sure that a composite score of only hospital-level process of care and outcome measures would give hospitals the information they need to help make a bigger impact on health equity in their communities. The difference in health outcomes and disparities in health are the results of longer-term processes that begin well before a hospitalization and extend until far after a patient is discharged from the hospital. Addressing them will require a common engagement of providers, public health experts, patients and families across the care continuum. Certainly, the stratification of individual hospital process of care measures by race/ethnicity or dual-eligible status can help hospitals ensure that the care provided to patients in these different groups is not different based on these characteristics. However, many of the most critical factors influence overall health during a person's whole life, not merely the few days they are a patient in our hospital. To truly understand and address disparities in health, we need to examine critical indicators of health experiences over time, alongside both hospital and longer-range health outcomes, and then engage with public health experts, other providers, community leaders and others to begin to address these issues.

Measure Stratification and Indirect Estimation. Instead of a summary facility equity score, we encourage CMS to prioritize further stratification of individual quality measures by race and ethnicity and dual eligibility. We would support providing hospitals with additional confidential reports, and believe this approach would result in data that are more actionable by providers and less susceptible to the methodological challenges of a rollup summary score highlighted above.

As we understand it, one of the methods CMS is considering for creating these stratified reports is indirect estimation. Given the gaps in available demographic data for Medicare beneficiaries, CMS is considering using data from existing sources like the U.S. Census and Medicare administrative data (e.g., first and last names, and the racial and ethnic composition of the patient's neighborhood) to "impute" (i.e., infer) the demographic composition of hospitals' patient populations.

While the AHA appreciates that CMS is trying to make the highest use of the data it has, we are concerned about the potential for indirect estimation to lead to measurement bias. As CMS notes, the "gold standard" for race, ethnicity and other demographic data is patient self-reported information. Furthermore, the quality of the indirect estimation model would be only as good as the data that go into it. To the extent CMS draws on data from the census, we expect the data could lag the actual demographic composition of a hospital's patient population by several years. This would limit the usefulness of analyses based on indirect estimation. At a minimum, we urge CMS not to use indirect estimation in any public-facing analysis of equity performance.

Digital Quality Measurement (dQM) and the Use of Fast Healthcare Interoperability Resources (FHIR). The proposed rule includes a request for comment on CMS' plans to advance the use dQMs and expand the agency's use of FHIR standards and Application Programming Interfaces (APIs) for both current eCQMs and future quality measures. CMS states that its goal is "to move fully to digital quality measurement" by 2025 and to enhance the interoperability of quality measure data.

The AHA agrees that a digital and interoperable quality measurement enterprise is a laudable long-term goal that could have positive and far-reaching impacts to quality of care and the provider experience. The AHA also sees significant potential in expanding the use of FHIR, as this standard is easier to implement and more fluid than many other available frameworks. At the same time, transitioning to only dQMs in CMS quality measurement programs will prove a staggeringly complex task. In this rule, CMS offers a working definition of dQMs and a long list of laudable attributes for dQMs. The agency also correctly identifies the need to work with multiple stakeholders. While all of these things are helpful and necessary, they are not by themselves enough to ensure a successful transition to dQMs. This also is why it is difficult for AHA to judge whether CMS' stated goal of transitioning to fully dQMs by 2025 is achievable; given the complexity of the task, we are skeptical.

For these reasons, we urge CMS to propose a clearer overarching plan and goals for its proposed transition to dQMs. CMS should specify what steps it expects for hospitals and other stakeholders to take, the sequencing and timing of those steps, and identify any interdependent steps and policies across CMS, the Office of the National Coordinator for Health Information Technology (ONC), and any other relevant federal agencies. We also believe that any new standards or processes that emerge from this plan would need to be adequately vetted and field-tested before they were made into regulatory requirements. The AHA and our members would be pleased to engage CMS in such a planning process.

Below we offer comment on several specific issues included in the RFI and offer additional recommendations to the agency.

dQM Definition. CMS' proposed definition of dQMs is very broad and lists a range of data sources, including administrative systems, clinical assessment data, case management systems, EHRs, instruments (e.g., wearable medical devices), patient portals, health information exchanges (HIEs), registries, and "other sources." Hospitals do not manage some of these sources themselves; yet, their performance on a dQM could be linked to such data. We are concerned that the accuracy and reliability of dQMs could be compromised by poor data quality from outside sources. For these reasons, CMS, ONC and other stakeholders may need to consider the development of source system verification and/or certification criteria.

dQMs as Self-Contained Tools. In the RFI, CMS offers a lengthy list of attributes and functionalities that dQMs could have. This ranges from simpler tasks like the ability to generate measure score reports, to considerably more complex tasks like being "compatible with any data source," and "having the ability to adopt to emerging advanced analytic approaches like natural language processing." The AHA encourages CMS to work across stakeholders to determine whether these attributes can be sequenced and scaled. We are skeptical that all of the attributes on CMS' proposed list would be achievable for even a single dQM by 2025, whereas certain attributes may be achievable by that point.

Public-Private Sector Collaboration. The AHA is pleased that CMS is considering the development of a "common portfolio" of dQMs that could be used across federal programs and agencies, and with private sector quality measurement programs. Hospitals have long aspired to an approach to quality measurement that enables them to report data only once and have it used for multiple purposes. Unfortunately, they continue to face discordant reporting requirements among federal, state and private sector quality reporting and value programs. Even when the measure topics are the same, often there are differences in measure design across programs that result in the need for duplicative data collection, excess costs and confusion. As CMS advances a plan for dQMs, we encourage the agency to prioritize the development of dQMs that are usable across the public and private sector.

Safe Use of Opioids – Concurrent Prescribing eCQM in the IQR and Promoting Interoperability Programs. In the FY 2020 IPPS/LTCH PPS final rule, CMS finalized the required reporting of this eCQM in the IQR and Promoting Interoperability Programs beginning with the CY 2022 reporting period. The measure assesses the proportion of inpatient hospitalizations for adult patients prescribed or continued on two or more opioids or an opioid and benzodiazepine concurrently at discharge. In this rule, CMS seeks input for potential measure updates as the agency prepares for NQF re-endorsement of the measure, and to potentially inform any future rulemaking regarding the measure.

When the AHA first had the opportunity to review this measure as part of the MAP process in 2016, we agreed with CMS that improving prescribing practices for opioids was (and continues to be) a top national priority. However, we noted in our comments to the MAP, as well as in our comments on the FY 2020 IPPS/LTCH PPS proposed rule in which CMS proposed to adopt this measure for the IQR and Promoting Interoperability Program, that we had concerns with the measure concept. The measure inherently presumes that all concurrent prescriptions of opioids and benzodiazepines are inappropriate, when in fact many patients rely upon the combination of, for example, methadone and buprenorphine as part of their evidence-based medication assisted therapy for opioid use disorder (OUD). Because this is a process measure, there is no risk adjustment; facilities that serve more complex and sicker patients or many patients with OUD would likely appear to perform below average on this measure.

While CMS acknowledges that providers are not expected to have a measure rate of zero, the agency is unable to provide a benchmark to which providers should compare themselves. Without the goal of an optimal percentage of concurrent prescriptions, providers may decline to recommend these medications when appropriate. **In order to balance the benefits and inadvertent risks of this measure, we recommend that CMS consider ways to narrow the patient population to exclude appropriate concurrent prescriptions from the numerator, and to allow facilities to choose this eCQM from the "menu" of available measures rather than require it as part of participation in the Promoting Interoperability Program.**

LIST OF ASC-COVERED SURGICAL PROCEDURES

In the CY 2021 OPPS/ASC final rule, CMS substantially revised the regulatory criteria the agency uses to determine which procedures can be added to the ASC covered procedures list (ASC CPL) by eliminating certain general standards as well as five of the general exclusion criteria. Instead, CMS added these criteria as non-enforceable "physician considerations." Based upon these revised criteria, the agency added 267 procedures to the ASC CPL for 2021. Finally, CMS added a new provision which established that CMS will add a surgical procedure to the ASC CPL either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the revised criteria.

ASC CPL Criteria for CY 2022. For CY 2022, as urged by the AHA, CMS proposes to reinstate the requirements for ASC covered surgical procedures that had been in place prior to CY 2021. CMS states that many of the procedures added in CY 2021 would be appropriate only for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary.

The AHA strongly supports CMS' proposal to restore these key criteria for determining which surgical procedures may be included on the ASC CPL. As has been demonstrated in recent years, criteria that were in place prior to CY 2021 have supported the ability of ASCs to safely furnish an expanding range of surgical procedures as innovations in surgical care occur. However, because ASCs are not subject to the same level of regulatory oversight as hospitals and are not equipped to manage emergencies that require lifesaving hospital inpatient capabilities, keeping the ASC general exclusion criteria in place prevent surgical procedures that pose significant threats to beneficiary safety and quality of care from being performed in ASCs.

Procedures Added to the ASC CPL in CY 2021 Which Would Not Meet the Proposed Revised CY 2022 Criteria. After evaluating the 267 surgery or surgery-like codes that were added to the ASC CPL in CY 2021, CMS clinicians determined that 258 of these surgical procedures may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC, and that nearly all would likely require active medical monitoring and care at midnight following the procedure. Thus, CMS proposes to

remove 258 of the 267 procedures that were added to the ASC CPL in the CY 2021 final rule. **The AHA supports CMS' proposal to remove these 258 procedures added to the ASC CPL in CY 2021.**

Nomination Process Proposal. For CY 2022, CMS proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. **The AHA supports CMS' proposed nomination process and agrees that it would allow for the expansion of the ASC CPL in a more gradual fashion, which would better balance the goals of increasing patient choice while also incorporating patient safety considerations.**

PACKAGING POLICY FOR NON-OPIOID PAIN MANAGEMENT DRUGS UNDER THE OPPS AND ASC PAYMENT SYSTEM

For CY 2022, CMS reports that it conducted its usual review of payments and utilization patterns for opioids and non-opioid alternatives in both the ASC and HOPD settings. As a result, the agency proposes to continue to pay separately for Exparel and Omidria in the ASC setting and to package payment for these non-opioid pain management drugs in the HOPD setting. CMS states that although packaging encourages efficiency and is a fundamental component of a PPS, its overriding policy objective to reduce financial disincentives for use of non-opioid products leads it to reconsider its policy for HOPDs. Therefore, CMS requests comment on whether it should expand to the HOPD its current ASC policy to pay separately, at ASP plus 6%, for non-opioid pain management drugs that function as surgical supplies. The agency also is interested in receiving information on any non-drug products that function as surgical supplies that commenters believe should be eligible for separate payment under this policy.

The AHA appreciates that CMS is engaging stakeholders to investigate novel strategies to address the opioid crisis. We continue to agree that stemming the tide of this epidemic must involve changes to how services are reimbursed so that financial incentives promote a full range of approaches to treating pain. **As such, we believe that the current packaged payment for such non-opioid alternatives in HOPDs presents a barrier to access care and therefore warrants separate payment under OPPS as well. Therefore, we continue to support the ASC proposal but also recommend that CMS similarly un-package Exparel, Omidria and other non-opioid pain management treatments in HOPDs.** Based on feedback from our members, the AHA agrees that this strategy has the potential to incentivize use of non-opioid pain management drugs in all settings in which outpatient surgery and other outpatient services involving pain management are furnished (such as in the ED). While certainly not a solution to the opioid epidemic, un-packaging appropriate non-opioid therapies like Exparel and Omidria is a low-cost tactic that could change long-standing practice patterns without major negative consequences.

Similarly, AHA continues to support un-packaging other non-opioid treatments including drugs, devices and therapy services that are not currently separately payable in either the ASC or HOPD setting. Specifically, we support separate payment for continuous infusion pumps, as our members suggest that this would be a helpful approach to increase the usage of these non-opioid therapies. For example, the "On-Q" pain relief system is a portable pain system that provides non-opioid local anesthetic medication to the site of the pain. Its purpose is the same as Exparel's: to deliver relief at the site of the pain rather than by a systemic pain reliever. It also prevents the side effects that many people experience from oral medications. Other drugs that should be considered for separate payment are intravenous (IV) Ibuprofen and Ofirmev (IV Acetaminophen). Our members also have suggested that CMS consider separate payment for Polar ice devices that use ice and water for post-operative pain relief after knee procedures. In addition, therapeutic massage, THC oil applied topically, acupuncture, and dry needling procedures are very effective therapies for relief of both post-operative pain and long-term and chronic pain.

Criteria for Eligibility for Separate Payment in ASCs for Non-Opioid Drugs that Function as Surgical Supplies. For CY 2022 and subsequent years, CMS proposes two criteria intended to identify non-opioid pain management drugs that function as supplies for which separate payment under the ASC payment system would be appropriate. The agency also requests comments on other potential policy modifications and additional criteria for revising payment for non-opioid pain management drugs. Specifically, CMS proposes the following criteria:

Criterion 1: FDA Approval and Indication for Pain Management or Analgesia. The drug must be approved by the FDA under a new drug application, a generic drug application or, in the case of a biological product, licensed under provisions in the Public Health Service Act. Also, the drug or biological must have an FDA-approved indication for pain management or analgesia.

Criterion 2: Cost of the Product. A drug or biological only would be eligible for a payment revision under the ASC payment system if its per-day cost exceeds the drug packaging threshold under the OPPS, which for CY 2022 is proposed to be a per-day cost of $130.

The AHA generally supports these criteria for determining eligibility for separate payment for non-opioid drugs that function as surgical supplies. However, we believe that the first criterion is too narrow and that non-opioid anesthesia drugs also should qualify for separate payment. For instance, we are aware of four common options for non-opioid anesthesia that can be used during and after surgery. Dexmedetomidine is a fast-acting sedative that is only given intravenously and can be easily titrated during surgery. Two non-opioid options that are typically used at the end of surgery are intravenous acetaminophen and ketorolac. Ketorolac is a non-steroidal anti-inflammatory drug that can be quite useful for controlling severe pain following

surgery, as well. Finally, ketamine is a type of sedative and hypnotic agent that works quickly during surgery and that can significantly improve post-operative pain. Unlike its opioid counterparts, ketamine actually opens up the airways to improve respiration. There are several clear benefits to using non-opioid anesthesia along with, or instead of, its traditional counterparts. For example, these drugs work better for patients who may have a long history of opioid use for chronic pain and who may have a high tolerance for these traditional drugs. In addition, non-opioid agents tend to result in fewer post-operative complications with breathing and decreased consciousness and can allow patients to get back to their baselines as quickly as possible.

ASC QUALITY REPORTING (ASCQR) PROGRAM

Restarting of Previously Suspended Measures. CMS proposes to once again require reporting of four patient safety measures that were previously adopted but whose reporting is currently suspended in the ASCQR. These measures include ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC-4: All-cause Hospital Transfer/Readmission. **While these events certainly merit surveillance, the AHA does not believe that re-starting these measures in the ASCQR would achieve CMS' goal of meaningful measurement.** Burns, falls, and wrong site/side/procedure/implants are described by CMS and others in the quality field as "never events": serious and costly errors in the provision of health care services that should never occur. Because these are preventable and serious, their incidence is rare. Thus, while CMS looks for ways to streamline and improve the measures used in its quality reporting programs, it does not make sense to add four measures that focus on rare events that are captured in surveillance otherwise.

In the CY 2019 OPPS/ASC proposed rule, CMS proposed to remove these measures because they were "topped out." In addition, the agency voiced concern about some of the data submitted for these measures due to the data submission method. CMS ultimately declined to remove the measures from the ASCQR, and instead suspended reporting on the measures while the agency developed reporting capabilities for the measures via the Hospital Quality Reporting platform.

Altering the data submission method — i.e., replacing submission of certain quality data codes on claims with data submission via modernized CMS web-based tool — may improve the completeness and accuracy of the data submitted, but we question whether that information is useful. We agree with CMS that it is imperative to monitor these types of events and prevent their occurrence to ensure that they remain rare. There are other ways to do this. The majority of states and the District of Columbia have mandatory reporting of never events, and most of these states also require facilities to conduct root cause analyses and submit corrective action plans. ASCs have their own extensive internal surveillance systems to identify errors and analyze them for opportunities for system change.

We also note that NQF endorsement for three of the four measures has been removed (and one never received endorsement). While CMS notes that endorsement "was allowed to lapse by the measure steward, not because they failed the endorsement maintenance process," we think this is a distinction without a difference: the four measures are not endorsed by the NQF and have not undergone recent updating to ensure that their specifications are reliable, valid, and in line with clinical standards, and thus they should not be used in a CMS program until and unless that occurs.

RFI: Future Development of a Pain Management Measure for the ASCQR. Due to the high national prevalence of chronic pain as well as the increased attention to pain management in the midst of the opioid epidemic, pain management services are increasingly being offered as a form of early intervention and more of these procedures are being performed in ASCs. CMS believes that a measure assessing pain management surgical procedures performed in ASCs would address a high priority topic not currently addressed in the ASCQR measure set, and seeks comment on the development of such a measure.

We agree that pain management is an important topic, relevant to a large proportion of the population and a straightforward indicator of outcomes that a layperson can understand. We also appreciate CMS' circumspect approach in developing quality measures on the topic, considering the intersection of pain management, use of controlled substances, and behavioral health. However, we believe we could provide more useful and specific comments if CMS was to first develop discrete concepts for measures and then approach the field for input.

For example, the federal task force created by the Comprehensive Addiction and Recovery Act of 2016 issued a report in 2019 that addressed pain management in five categories and goals that should serve as a starting point for measure development:

- Medications: suitable class, dosage, and duration of medication based on pain diagnosis, mechanisms of pain, and related co-morbidities.
- Restorative therapies: inclusion of multidisciplinary, multimodal acute and chronic pain care in treatment plan.
- Interventional procedures: appropriate use of diagnostic and therapeutic modalities considered alongside alternative approaches.
- Behavioral health approaches: attention to psychological, cognitive, emotional, behavioral, and social aspects of pain and function.
- Complementary and integrative health approaches: consideration of modalities including acupuncture, massage, movement therapies, and spirituality when clinically indicated.

Finally, while we understand CMS' rationale — that pain management surgical procedures are a significant portion of those performed at ASCs, and thus an applicable

measure would provide important quality of care information for a specialty not currently included in the ASCQR measure set — we also caution the agency against developing a broad measure that misses the nuances of pain management. As immediate past Chief Medical Officer of HHS and Pain Management Best Practices Inter-Agency Task Force chair Dr. Vanila Singh noted, "There is no one-size-fits-all approach when treating and managing patients with painful conditions. Individuals who live with pain are suffering and need compassionate, individualized and effective approaches to improving pain and clinical outcomes." An easy measure to specify and implement would be a claims-based process measure, but such a measure would likely fail to accurately evaluate person-centered care. We recommend that CMS take its time on this sensitive topic rather than moving quickly with the first available measure.

UPDATES TO REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES

CMS proposes changes to the hospital price transparency rule and requests comments to potentially inform policymaking in the future. **The AHA looks forward to working with CMS to improve the hospital price transparency rule, especially as it relates to better aligning these requirements with those in the transparency in coverage final rule and No Surprises Act.** The AHA continues to support policies that help patients access the information they need when making decisions about their care, including information about their potential costs. Hospitals have long been committed to providing patients access to this information, though earlier solutions required more cumbersome, manual processes with significant technical barriers, such as those related to obtaining cost-sharing information from insurers. We have seen the field overcome many of these barriers over the last several years, with patient price estimator tools now commonly available on both hospitals' and insurers' websites. Looking forward, patients soon will have access to even more financial information prior to care through the implementation of the other federal price transparency policies. To avoid patient confusion and duplication of efforts, alignment across these policies is critical. Any changes to the hospital price transparency rule should be focused on achieving this goal.

Our specific comments on the agency's proposals and requests for comment follow.

Increase in Civil Monetary Penalties for Noncompliance. CMS proposes to increase the civil monetary penalties for noncompliance with the hospital price transparency rule on a sliding scale based on hospital bed count. **The AHA strongly opposes increasing these penalties and urges CMS not to finalize this proposal.** CMS argues that increasing the penalty will encourage greater compliance, citing findings from their initial reviews and a number of external studies. However, there is no evidence that the current penalty amount impacted early compliance with this rule. In fact, to date, CMS has not actually issued any penalties. Hospital noncompliance is more likely due to competing priorities primarily related to the ongoing COVID-19 pandemic, something we

raised prior to the implementation start date of Jan. 1, 2021.[15] Compliance with this rule takes considerable time and effort – it is not simply a compilation of existing spreadsheets. Many personnel across multiple departments working alongside a number of hospital technology vendors must build and populate the machine readable files from scratch. As we have previously noted, because the negotiated rate information required by CMS does not actually exist for many services, hospitals must make decisions about how to populate these sheets with the most meaningful information available. All of this takes considerable time and resources, and the personnel required to comply with this rule have been overwhelmed with more pressing assignments, such as bringing hospital surge capacity online and assisting with the monitoring and tracking of vaccine distribution. As CMS notes in the proposed rule, "noncompliance [with the Hospital Price Transparency rule] is less serious than noncompliance that poses or results in harm to the public."[16] Hospitals made the same calculation in prioritizing COVID-19 preparation and care over preparing for compliance with this rule. CMS showed support for hospitals needing to prioritize COVID-19 over other federal requirements during this period, offering enforcement discretion for a number of federal requirements. The AHA continues to argue that such flexibilities should be granted for these policies as well. In lieu of these flexibilities, hospitals have been forced to make those resource allocation decisions on their own.

In addition, we urge CMS to not rely on external sources to estimate compliance with these requirements. Due to a lack of understanding around the complicated nature of these files, we have seen a number of studies that have misrepresented hospital compliance by assessing the files in a manner that does not align with the requirements in the final rule. As the sole arbiter of compliance, only CMS' review should be taken into consideration when determining whether and how hospitals are complying. To that end, we ask that instead of taking punitive actions at this point, CMS should use the findings from its initial audits to provide feedback and guidance to the field. For example:

- Are there certain issues with compliance that are occurring regularly, and if so, are these areas that warrant greater technical assistance from CMS?
- How often are the noncompliance issues identified actually a result of a misunderstanding about the data in the file, either by CMS or the public?

Given hospitals' need to continue focusing their efforts on caring for their communities in the midst of COVID-19, as well as the ongoing uncertainty about how CMS defines "compliance," this is not a time for CMS to impose such hefty

[15] AHA letter to Biden-Harris Transition Team on the Hospital Price Transparency Rule. December 12, 2021. Available at: https://www.aha.org/lettercomment/2020-12-21-aha-letter-biden-harris-transition-team-price-transparency-rule

[16] 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, 86 FR 42018 (Proposed August 4, 2021)

fees for noncompliance. Rather, we encourage CMS to use this initial implementation period to learn more in order to inform any future changes.

Most critically, CMS should assess what changes are needed to better align these requirements with the other federal price transparency policies. The departments of Health and Human Services, Labor, and Treasury began the work of reducing duplication and aligning price transparency policies in their recent FAQs,[17] which addressed overlaps in the No Surprises Act and transparency in coverage requirements. More is needed though to further align those requirements with the hospital price transparency rule requirements. As we have discussed previously,[18] patients now have multiple avenues for accessing information about their health care costs as a result of technological advances and federal and state policies. Depending on the source of the estimates and the inputs included (e.g. common ancillary services, other providers) these estimates will assuredly vary, and we continue to be concerned about how this misalignment will actually hinder, not help, patients' understanding of their cost obligations. **We urge the agency to take steps to align all of the federal price transparency requirements in order to minimize any confusing or conflicting information for patients**. Doing so also will help mitigate the substantial costs to the health care system of implementing each of these distinct policies.

This work may be part of the notice and comment rulemaking process related to the good faith estimates for insured patients and advanced explanation of benefits discussed in the FAQs. We urge the agency to ensure hospital price transparency rule alignment during that process. In preparation for those rules, we recommend the agency bring together a multi-stakeholder group, including hospital, insurer, and vendor technical experts, to determine:

- The best source(s) for patient cost estimates, such as the good faith estimates/advanced explanation of benefits, the machine-readable files, and/or the various online patient price estimator tools. If the group agrees that multiple sources are warranted, it also should plan for how to ensure consistency across the various platforms so that patients do not receive conflicting estimates.
- What, if any, value is created for the patient through the publication of the machine-readable files and whether the hospital and insurer files are both necessary.

[17] Departments of Health and Human Services, Labor, and Treasury. FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49. August 20, 2021. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs%20About%20ACA%20%26%20CAA%20Implementation%20Part%2049_MM%20508_08-20-21.pdf

[18] AHA letter to CMS on the No Surprises Act – Good Faith Estimates and Advanced Explanation of Benefits. June 2, 2021. Available at: https://www.aha.org/lettercomment/2021-06-04-aha-cms-re-no-surprises-act-good-faith-estimates-and-advanced-explanation

Finally, we reiterate our earlier assessment that CMS cannot legally increase the penalties for noncompliance as it lacks authority to impose penalties on hospitals that fail to comply with the hospital price transparency final rule in the first place. CMS relies on section 2718(b)(3) of the Affordable Care Act for its authority to enforce the requirement that hospitals make their standard charges public. That reliance is completely misplaced. CMS' enforcement authority is limited to section 2718(a) and (b)(1). To conclude otherwise is contrary to Congress' clear intent and flies in the face of the enactment history and structure of section 2718. It also is inconsistent with HHS' prior view of the ambit of section 2718(b)(3).

Section 2718 contains several disparate provisions under the section heading "Bringing down the cost of health care coverage."

- Subsection (a) applies to reporting requirements (for what is frequently termed medical-loss ratio (MLR) information) by health plans on the health exchanges.
- Subsection (b) requires health plans on the health exchanges that fail to meet MLR requirements to provide premium rebates to enrollees and requires states to take certain steps to further the policy objectives of the MLR requirements.
- Subsection (c) requires the National Association of Insurance Commissioners (NAIC) to establish definitions and methodologies needed for health plans to comply with subsections (a) and (b).
- Subsection (d) gives HHS authority to adjust the rates of health plans in the exchanges.
- Subsection (e) requires hospitals to make public their standard charges.

Until CMS published the 2020 OPPS proposed rule, the agency never said that it had authority to enforce through penalties the requirement in section 2718(e) that hospitals make public their standard charges. We believe there is good reason for that: CMS knew that section 2718(b)(3) does not authorize enforcement of section 2718(e). Indeed, HHS implicitly acknowledged the narrow scope of section 2718(b)(3) when it implemented the MLR requirements in 2010 and said that the regulations promulgated "implement enforcement authority in section 2718(b)(3) and provide for enforcement of the reporting obligations set forth in *section 2718(a) and rebate requirements in section 2718(b)*."[19] HHS did not even suggest that section 2718(b)(3) might apply to section 2718(c). Rather, HHS correctly recognized that section 2718(b)(3) authorizes enforcement of the requirements in only subsection (a) and paragraph (1) of subsection (b) of section 2718. That is, the MLR rebate requirements applicable to health plans.

Patient Price Estimator Tools. CMS also offers clarification regarding the use of a patient price estimator to fulfill the shoppable service requirement, noting that for a tool to be compliant it must provide the patient a single amount, tailored to their circumstances, and based on benefit information received directly from the patient's insurer (if applicable). **The AHA supports the use of patient price estimator tools**

[19] 75 Fed. Reg. 74,864, 74,889 (Dec. 1, 2010).

and commends CMS for permitting hospitals to use these tools to comply with a portion of the rule. The patient-specific cost estimates generated by these tools provide the information that patients most often request when preparing for the financial aspects of their care. Many hospitals were already implementing these types of online search tools prior to publication of the hospital price transparency rule, or were considering doing so in the near future. To assist members with this decision, the AHA developed a member toolkit, which includes an issue brief on implementation considerations and lessons learned from early adopters, as well as member case studies. With the inclusion of this option in the final rule, we saw an increase in both the pace of implementation, as well as the availability of vendor support which further enabled hospital adoption.

As discussed previously, a critical next step for the field is ensuring alignment across the various options for patients receiving cost estimates prior to care. The AHA is committed to working with CMS and other stakeholders to determine appropriate standards for developing pre-service patient cost estimates, whether they be done through online price estimator tools or as a good faith estimate as required by the No Surprises Act. **We once again urge CMS to work with stakeholders on the many technical considerations for these estimates and apply the same standards across all types of patient cost estimates.**

In addition, we want to bring to your attention some remaining technical issues that CMS should consider when determining compliance. Specifically, we want to alert you to ongoing issues with some insurers' responses to eligibility requests, which are necessary for the patient estimator tools to incorporate a patient's health insurance information from the plan. Because some plans do not provide real-time out-of-pocket information to providers, some providers have had to build workarounds into their online tools to allow for patients to input their own benefit information. This is of course not the ideal state, but can be a necessary option for hospitals to include in their tools in instances when not all insurers in their markets reliably respond to eligibility transaction requests with a patient's cost-sharing information.

We also want to clarify that it is not only "unusual or unforeseeable circumstances" that may change the final cost of care. Rather, there are factors that are just unknowable prior to a health care visit and that cannot be accurately estimated using existing algorithms. For example, based on what a provider observes during a patient visit, the provider may order several different lab tests to inform next steps. It is not unusual or unforeseeable to do so, but which tests need to be ordered are unknowable until after examination. Depending on the mix of tests, the final price for the visit may vary. This is why some hospitals have chosen to include detailed disclaimers on their patient estimator tools: they want to ensure patients have the best available information about the expected cost of their care, even if that information is explaining why the final amount may be hard to predict ahead of time.

Exemplar Hospitals. CMS requests comment on ways to identify and highlight hospitals that are "embracing and exemplifying the spirit of consumer price transparency," and offers a number of possible options that CMS is considering. The AHA is proud of our members that have taken steps to improve their patients' access to cost information. However, given our ongoing reservations that the hospital price transparency rule does not provide the best pathway for patients to get accurate cost estimates, we do not believe that a designation based on these regulations is appropriate. In addition, we are particularly concerned by CMS' suggestion that price transparency could be incorporated into the hospital quality measures. **It is essential that quality measure focus solely on issues that directly impact patient quality. The AHA recommends that CMS not move forward with this, or other, options being considered to highlight exemplar hospitals.**

"Plain Language" Definition. CMS finalized requirements for the shoppable service requirement in the CY 2020 hospital price transparency final rule, including a "plain language" description of each shoppable service. At the time, CMS did not establish plain language standards and instead left it up to each individual hospital to develop their own plain language descriptions. In this proposed rule, CMS seeks comment on whether it should require specific plain language standards, and if so, what those standards should be.

The AHA urges the agency to allow more time with the hospital price transparency rule in effect before implementing any new type of standardization. Significant work has already been done to implement the shoppable service requirements as currently stated in regulation. **Prior to introducing new standards, we encourage CMS to convene a multi-stakeholder group consisting of hospitals, insurers, and patient representatives to identify what is working and determine whether any further standardization is necessary.** As discussed previously, such standards should then be used across the various price transparency policies, including those in the transparency in coverage final rule and the No Surprises Act, to ensure patients are seeing consistent language across all platforms. The AHA welcomes the opportunity to work with CMS to convene this workgroup.

Machine-Readable File Standardization. Hospitals, often in partnership with vendors, developed their machine-readable files based on their interpretation of the available guidance and to accommodate the hospitals' different types of privately negotiated contracts with insurers. CMS is now seeking comment on whether it should impose additional standardization on these files.

Hospitals have already dedicated significant resources toward complying with the machine-readable file requirements. They have done so despite continued skepticism of these data's usefulness to the patient and in spite of the immense strain to the health care system caused by the COVID-19 pandemic. Standardization at this point could negate much of the upfront work, requiring hospitals to start again in order to recreate their files in the new format. This would create excess administrative burden, once

again drawing resources away from more important hospital needs. Moreover, these regulations have not been in effect long enough to determine what attributes of existing files are most useful, if any. Finally, as discussed in the previous sections, more work is needed to align these requirements with those in the transparency in coverage and No Surprises Act. **The AHA urges the agency not to impose additional standardization until the work to align the three price transparency policies is complete.**

RADIATION ONCOLOGY MODEL

In this rule, CMS makes several proposals to prepare for a Jan 1, 2022, launch of the Radiation Oncology (RO) Model. **The AHA strongly supports CMS' efforts to transform the delivery of cancer care. We also support the original intent of the RO Model, which was to protect access to care by ensuring fair, predictable payment for radiation oncologists.** In a 2017 report to Congress, CMS explained that an alternative payment model (APM) could contribute to establishing this rate stability and ensuring access to high-value cancer care because it could offer a work-around to the difficulty of determining accurate prices for services that involve expensive capital equipment.[20]

However, this important and still relevant goal of the original RO Model has been marred by the incorporation of significant payment cuts and a substantial burden of participating in this mandatory model. **As such, the AHA urges CMS to revisit the original goals of the RO Model. We are concerned that the model no longer adheres to either those goals or the agency's own recent writings on allowing models to "define success as encouraging lasting transformation and a broader array of quality investments, rather than focusing solely on each individual model's cost and quality improvements."[21]** We also are concerned that implementing a model with significant payment cuts at a time when hospitals are already stretched to the brink is a misguided step in the fight against cancer. **In light of these worries, and the years of efforts by stakeholders to help CMS design a fair and effective model, the AHA urges the agency to consider the changes outlined below, including a one-year delay of the model start date and discount factors at or below 3%. We stand ready to work with you to improve the RO Model.**

Extreme and Uncontrollable Circumstances (EUC) Policy. In this rule, CMS proposes to adopt an extreme and uncontrollable circumstances (EUC) policy for the RO model, which would allow the agency to, in the event of an EUC, revise the model performance period; grant certain exceptions to RO model requirements to ensure the delivery of

[20] United States Department of Health and Human Services, "Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services," November 2017. *Available at* https://innovation.cms.gov/files/reports/radiationtherapy-apm-rtc.pdf.
[21] Chiquita Brooks-LaSure, Elizabeth Fowler, Meena Seshamani, and Daniel Tsai, "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years," *HealthAffairs* (August 12, 2021). https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/.

safe and efficient health care; and revise the RO model's payment methodology. **The AHA thanks CMS for proposing an EUC policy and strongly supports the agency finalizing this policy.**

CMS also proposes that if an EUC were to be nationwide and impact RO participants' ability to implement the requirements of the model at the start of the Performance Year (PY), the agency could delay the start date of the model performance period by up to one calendar year. **We strongly urge the agency to implement this policy in response to the current surge of COVID-19 cases and delay the model start date until Jan. 1, 2023.** With an average of over 100,000 new COVID-19 cases per day and deaths reaching a six-month high, the pandemic is certainly still a nationwide emergency circumstance. Implementing a mandatory model when radiation oncology practices are already struggling to find beds for cancer patients will make it extremely difficult for practices to succeed in the model – let alone stay open – and for the model itself to make a positive impact on radiation therapy care.

Delaying the model start date is especially important given the lack of data CMS has shared with participants and the burden of implementing this model even upon receiving that data. CMS states in the rule that it will not be able to provide case mix or historical experience adjustment data inputs to participating practices until after the final rule is issued. The data used to inform these inputs is from 2017 through 2019; this is the same data included in the data file published with the proposed rule. The final rule is expected in November, leaving participants less than eight weeks to understand the financial implications of their required participation in this model. **We urge CMS to supply these data inputs as soon as possible, in line with its recent statements about committing to "greater transparency and accessibility to Innovation Center data."[22]**

Even once CMS does supply participants with these data inputs, the burden of implementing the RO model remain astronomically high. Nearly all RO practices have a separate RO management system that sits on top of the practice's EHR. There are only two vendors nationwide that provide these RO systems. They are extremely expensive and require many months to make the upgrades that will be needed to comply this this model. These vendors then must train all users on the upgraded system, and there is already a long queue for their expertise. Like all health care businesses, these vendors are short-staffed due to COVID-19, and that staff has been repeatedly diverted to COVID-19 data collection and submission and other related projects. And, none of the burden of compliance with this model has been placed on the vendors to redesign their software systems; rather hospitals and other participants – already stretched thin due to COVID-19 and other factors – are having to manage both their own compliance and the software changes that are the vendors' expertise. **There simply is not enough**

[22] Chiquita Brooks-LaSure, Elizabeth Fowler, Meena Seshamani, and Daniel Tsai, "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years," *HealthAffairs* (August 12, 2021). https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/.

manpower to put this model in place in the two months' time between the expected date of the final rule and Jan. 1, 2022. We urge CMS to delay the model start date to Jan. 1, 2023 to give the model and its participants the best chance to truly improve cancer care and patient outcomes.

Included Cancer Types. In this rule, CMS proposes to remove liver cancer from the list of 16 cancer types included in the model. In doing so, the agency notes that treatment of liver cancer with RT services continues to develop, with limited guidance for first line use of radiotherapy. Therefore, liver cancer does not meet the inclusion criteria because it is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines. **The AHA appreciates and supports this proposal to remove liver cancer from the disease sites included in the model.**

However, we continue to be concerned that with 15 cancer types remaining, the model is still too broad for a mandatory program. Hospitals and health systems are at many different points along the transition to value. To succeed in the RO model, they would have to make significant changes to the care processes and policies they have built around current regulatory payment structures. For example, many providers would need to upgrade their technology and machinery to provide lower and more precise fractions of RT. They will need to build upon their current infrastructure for health information technology, patient and family education, treatment planning, and care management. This is no small task; it will require significant investments of time, effort and finances. It would be particularly costly for technical participants that deliver the capital-intensive portions of RT. As discussed above, with the reimbursement cuts that would result from the discount factors and withholds in this model, some may not have funds left for investments of this magnitude. **We therefore urge CMS to include only those cancers for which there is strong clinical evidence for a range of treatment alternatives, such as prostate cancer, breast cancer, and lung cancer.**

Proposed Discount Factor. In the RO model final rule, CMS adopted discount factors of 3.75% for the professional component (PC) and 4.75% for the technical component (TC). These discount factors represented a 0.25% decrease from the discount amounts CMS had originally proposed. In light of proposals in this rule to remove brachytherapy and liver cancer from the model, the agency proposes to reduce the discount factors by an additional 0.25% each, which would result in a 3.5% discount factor for the PC and 4.5% for the technical component TC. **Despite this minor reduction, we remain deeply concerned about the amount and application of these discount amounts and the uneven playing field they create both within the model and between participants and those excluded from the model.** They are the largest discounts we have seen CMS set forth in any bundled payment model. They are particularly concerning given that the agency also proposes to build in significant savings for itself through the withholds, require down-side risk immediately and, make the model mandatory for providers.

The level of the discount amounts also creates unnecessary competition between those required to participate in the model and those exempted from it, which could produce misaligned incentives that do not benefit patient care. Additionally, we remain puzzled as to why the TC discount factor is higher than the PC discount factor. It is quite concerning to us given that hospital TC providers have little ability to impact the treatment plan/episode cost and make all of the capital investments for RT, yet, at the same time, cannot earn a 5% advanced APM bonus under the Quality Payment Program (QPP) through participation in this model, unlike PC providers. The payment methodology in this model often has some vague calculations, offering little transparency into its methodology. **We urge CMS to release the assumptions upon which their actuaries rest their analysis, as well as the analysis itself, so that stakeholders can understand how they arrived at their calculations.**

More importantly, we strongly urge CMS to set both the PC and TC discounts at 3% or less to ensure all patients retain access to RT services. Reducing these cuts to 3% would still generate significant savings for Medicare and better align the RO model's discount factors with those of other APMs. Indeed, after years of cuts, and with more on the way, radiation oncology practices are hanging on by a thread. As described in our comments to the CY 2022 physician fee schedule proposed rule, the proposed clinical labor pricing changes and conversion factor reduction would result in an 8.75% cut across all radiation oncology services – even before this model begins. This comes at a time when nearly all specialists have lost billions of dollars due to the COVID-19 pandemic. Specifically, RO revenues declined 8% in 2020[23] and cancer care will only become more complex and expensive due to foregone care during the PHE. According to the American Society for Radiation Oncology, if the PFS cuts are finalized, radiation oncology will have experienced a cumulative 10-year reduction in PFS payments of 25%, for a total of $300 million. These PFS cuts trickle down into the RO model due to the model's trend factor, which uses the PFS and the OPPS to update the national base rate amounts each year. Slapping radiation oncology services with additional 3.5% and 4.5% discounts on top of that will absolutely cause a reduction in the availability of radiation oncology services.

The cuts also are particularly problematic for practices already operating on thin margins, such as those serving rural or historically marginalized populations. For these practices, which often have high Medicaid volume, their ability to utilize all available resources to optimize patient treatment will dwindle or disappear if they suffer the additional significant cuts proposed in this model. All RO practices require multimillion dollar investments in capital equipment and ongoing support of the highly skilled staff they need to operate. If they suffer additional cuts, practices with historically low reimbursement will struggle to invest in the human and technological infrastructure to

[23] Kurt Gillis, PhD, "Policy Research Perspectives: Changes in Medicare Physician Spending During the COVID-19 Pandemic," American Medical Association (2021). *Available at* https://www.ama-assn.org/system/files/2021-03/prp-covid-19-medicare-physician-spending.pdf.

provide high quality, state-of-the-art care. Should these practices close in areas where there is no other RO department, patients would need to travel long distances for their care, which many of them cannot do because, for example, they do not own a car or cannot afford to take time off of work.

CMS' stop-loss policy that applies only to participants with 60 or fewer episodes during the baseline period is concerning. We do not understand this limitation – the number of episodes a participant performs is unrelated to case complexity, for which stop-loss policies are designed to account. We are worried that under this policy, outlier patients could lose access to services either at their home facility or at highly specialized locations to which they travel for care. This is due to the fact that the large cuts in this model will lead to significant revenue cuts for complex patients. For example, one of our members modeled their 2019 bone metastases episodes and found that had those episodes been paid under the model, the hospital would have seen a 66% rate reduction for that cancer type. No hospital can repeatedly endure a nearly 70% pay cut and still have the resources needed to treat those patients. Thus, even patients with access to efficient RO practices or facilities that care for the most complex patients could be in jeopardy.

Quality and Clinical Data Reporting. In the CY 2021 OPPS/ASC final rule, CMS delayed quality measure requirements until the second performance year. In this rule, CMS proposes that Professional and Dual participants submit quality measure data as well as certain clinical information not available in claims or quality measures starting Jan. 1, 2022 (PY1), regardless of when during the year the proposed model performance period begins. For PY1, Professional and Dual participants would be required to submit data for three pay-for-performance measures: Plan of Care for Pain, Screening for Depression and Follow-up Plan, and Advance Care Plan; these participants would also be required to report data for one pay-for-reporting measure, Treatment Summary Communication—Radiation Oncology; data reported for this measure would be used to propose a benchmark to re-specify it as a pay-for-performance measure in PY3.

We remain concerned about the selection of these quality measures and the burden of reporting they would present. First, the Treatment Summary Communication measure is neither endorsed by the NQF — its endorsement was removed in 2017— nor used in any other CMS program. We encourage CMS to use only measures endorsed by the NQF, but if the agency moves forward with the inclusion of this measure, we suggest CMS wait until the measure steward provides new specifications that better meet the RO model's needs, and then observe reporting of this measure in a "dry run" before using it in the aggregate quality score (AQS) calculation.

We further encourage CMS to consider calculating the AQS using pay-for-reporting on all four quality measures for the first year of the model before transitioning to a performance-based calculation. This model would require a significant shift for many providers in how they report quality metrics and they therefore need time to make that shift without being penalized for it. In theory, forgoing the quality

withhold may be more cost effective for participants than complying with these requirements for the very small portion of the quality withhold they could earn back. In addition, as with other CMS programs, we recommend that the agency provide confidential feedback reports with performance information to participants to give them the opportunity to review and correct their quality data before it is used in payment determinations or public reporting.

We also continue to be concerned about the requirement in this model to report basic clinical information that is not available in claims or captured in the four quality measures due to the significant burden we expect this requirement would create. In the RO model final rule, CMS finalized a requirement for providers to report data items such as cancer stage, disease involvement, treatment intent, and treatment plan. These requirements will be burdensome without much benefit to patients or use to CMS, especially as the requirements apply for non-Medicare beneficiaries as well. Providers already incorporate much of this information in their care; manually abstracting it from a chart and reporting it in a separate portal will add a significant amount of administrative work to already busy staff schedules. Experience has demonstrated that these portals (1) are frequently unreliable and logistically challenging; (2) contain limits on who can log into them; (3) crash due to the volume of data inputted; and (4) make feedback reports difficult to download. Moreover, CMS has not provided the precise information fields it would require in connection with the clinical data reporting, making it impossible for providers to plan or determine whether those data elements are already in use in their electronic health records (EHRs). Finally, many professional participants do not have adequate staff to perform this abstraction.

RO Model Billing Requirements. In a recent webinar, 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.” AHA 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. We are concerned that this could distort the Medicare cost-to-charge ratio (CCRs) for radiation oncology services for RO model participating hospitals.

As the agency is aware, the CCRs for participating hospitals along with the CCRs for non-participating hospitals will be used as part of the APC weight setting process in future years. Given CMS has designed the model to include 30% of all RO services nationally, the number of hospitals and the volume of services included in the model 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 radiation oncology services in future years but also increasing Medicare payments for all other services paid using the APC schedule given the weighting system's inherent budget neutrality. **Therefore, we ask CMS to take appropriate steps to ensure that a distortion of APC weights does not occur as a result of the RO model. The AHA stands ready to work with the agency on finding a solution to this challenge.**

COMMENT SOLICITATION ON RURAL EMERGENCY HOSPITAL PROVIDER TYPE

The millions of Americans living in rural communities depend upon their hospital as an important, and often the only, source of care. The nation's nearly 2,000 rural community hospitals frequently serve as the anchor for their area's health-related services, providing prevention and wellness services, as well as community outreach and employment opportunities. However, these rural communities and their hospitals face many challenges. Rural hospitals often struggle with their remote location, limited workforce and constrained resources. Many of these hospitals are fighting to survive – potentially leaving their communities at risk for losing access to local health care services.

Recognizing these difficulties for rural communities, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs), which would allow a facility to provide emergency hospital services for Medicare payment without the need to furnish acute care inpatient services. The proposed rule includes a request for information (RFI) on CMS' plans to establish standards and requirements for REHs. Below, we offer comments on several specific issues included in the RFI and provide additional recommendations for the agency to consider.

Type and Scope of Services. REHs are required to provide ED and observation services. They also may, at their own election, provide other outpatient medical and health services. CMS describes four such services in the RFI – behavioral health, telehealth services, opioid treatment programs, and maternal health services – and seeks comment on what it should consider as additional eligible services.

The REH designation was designed to allow rural hospitals to continue providing emergency and certain outpatient services, and thus remain as access points for care in their communities. Yet, the specific care needs in rural communities are diverse and opportunities may change over time. Thus, it will be important for CMS to allow for flexibilities when determining eligible outpatient and other medical services to account for shifts in care delivery, advances in knowledge and practice, and other changes and developments in both the health care field and in specific communities. **Therefore, the AHA recommends that CMS establish a minimum set of required services that can be furnished by providers with diverse operational sophistication and consider the wide ranging needs of the communities they serve. In addition, to**

the extent that REHs can demonstrate safe and effective methods of furnishing additional services on an outpatient basis, CMS should allow them to do so. This would allow REHs to best serve the needs of their communities, especially as demographics and health needs continue to evolve in rural communities. Creating such flexibilities also would allow REHs to work and coordinate with other providers in the community to meet the care needs of the population.

With our recommended flexibility in mind, we highlight several services that should be included in a minimum set of required services. We also highlight other critical services that we urge CMS to specifically denote as eligible for all REHs to furnish on an outpatient basis, and the barriers and challenges rural hospitals currently face in providing those services.

Required Services. By statute, REHs are required to provide emergency and observation care to its community. We recommend that CMS focus its efforts in establishing a minimum set of services that help support these emergency care needs and allow for flexibilities in requiring other outpatient and medical services. For example, in order to fully support its ED needs, REHs also may provide or arrange to provider laboratory, radiology, and pharmacy services.

Telehealth. Rural health care can benefit profoundly from robust telehealth services, given the longstanding challenges rural communities face in provider recruitment/retention, low patient volume, and geographic isolation. Telehealth also may be especially important for providing care in specialties that are not well represented in rural areas. For example, behavioral health services remain limited in rural communities, where 94% of the 734 counties classified as entirely rural have no licensed psychologists.[24] While the COVID-19 public health emergency has led to an increase in the adoption of telehealth services during the pandemic, barriers still remain for rural communities. **We therefore strongly support CMS' proposal in the CY 2022 PFS rule to add REHs to the Medicare list of approved telehealth originating sites, as required under law.**

Moreover, permanently removing certain limitations on telehealth for REHs would allow for less expensive and more convenient care options for rural patients. **Specifically, we urge CMS to work with Congress to eliminate the geographic and originating site restrictions in Section 1834(m) of the Social Security Act and allow REHs to serve as distant sites for telehealth delivery.** Having access to high quality and continuity of care remains a challenge for patients in rural communities. These changes would allow patients to receive all telehealth services in their homes, residential facilities, and other locations, and to remain connected to their REH providers if they are unable to leave their homes or if it is unsafe to do so. Given the importance of continuity of care in achieving positive patient outcomes, we also urge CMS to make every effort to extend

[24] Whelan C. (2019). Addressing the Healthcare Crisis in Rural America. https://www.huronconsultinggroup.com/insights/healthcare-crisis-rural-america

access to telehealth and other communications technology-based services to patients of REHs. This includes working with Congress to remove limitations on the types of health care professionals that can furnish telehealth services to include all those that are eligible to bill Medicare for their professional services, such as to physical therapists, occupational therapists, and speech language pathologists, among others, and authorizing REHs to provide services via audio-only telecommunications technology and/or consultation with specialists.

Visiting Provider Services. We urge CMS to allow REHs to engage in certain arrangements, such as visiting physician services, time-sharing arrangements, or physician leasing agreements. In rural areas, hospitals may lease space to visiting specialists several days per month to make certain services locally available. These types of agreements are crucial for those small and rural hospitals that may have limited clinical staff and/or rely on visiting physicians to provide specialty services (e.g., cardiology, oncology) that would otherwise require patients to travel long distances in order to obtain such care. REHs should have an arrangement in place with visiting specialists to ensure necessary patient information is shared with the specialist in the instance that a patient needs to receive care outside of the REH. **We ask that the agency provide clear language expressly allowing for such visiting agreements across a range of providers such that they may share treatment space in order to offer a broader range of medical services and better meet patient needs.**

For example, visiting provider agreements are crucial for small and rural hospitals that face workforce shortages in rural areas and may have limited clinical staff and/or rely on visiting physicians for maternal services, such as obstetricians/gynecologist (OB/GYNs) and pediatric specialists. Specifically, the use of midwives, especially in these underserved areas, can improve access and outcomes.[25] The ability to build flexible, multi-disciplinary maternal health care teams is important for many rural practitioners.

In addition, rural communities have not been adequately equipped to address the unique behavioral needs of their communities. These crucial services include a spectrum of acute and chronic mental health and substance use disorder services, such as services provided by trained psychiatric nurses and other professionals. We encourage the agency to provide such flexibilities so that co-location arrangements can enable REHs to serve their patients in a more efficient and effective manner and encourage adaptable care teams that meet the workforce realities in rural communities.

Maternal Health. Maternal health care remains a significant challenge for many rural providers as they continue to face financial and operational burdens in providing such services. Rural communities also struggle to recruit and retain health care providers. The telemedicine and visiting provider services mentioned above can be specifically useful in creating care opportunities for these services, including providing pre- and

[25] Campbell, O.M. (2018). Might Midwives Help Fill Rural Maternity Care Gaps? http://ruralhealthquarterly.com/home/2018/07/09/might-midwives-help-fill-rural-maternity-care-gaps/

post-natal care, specialty care for mothers and infants, and improve overall birth outcomes in rural communities. For example, utilizing telehealth for prenatal care can save long travel times and reduce in-person visits. Telemedicine may also include provider-to-provider communications. For rural practitioners, this may include electronic consults with specialists, such as maternal fetal medicine physicians, who may not practice locally. Additionally, creating regulatory flexibility to REHs for providers who wish to share treatment space would fill gaps in access to maternal health care. Support from other practitioners in this way is important for rural clinicians who may not see the same patient volume as larger communities. By removing these telehealth and co-location limitations for REHs, as described above, these providers can employ innovative initiatives and approaches to promote access, increase quality of care, and improve outcomes for mothers and babies that best fit their communities.

Behavioral Health and Substance Use Treatment Services. Behavioral health concerns – including mental illness, emotional distresses and substance use disorders – have long affected the American population nationwide, and in particular, some of these conditions disproportionately affect rural communities.[26] For example, a 2017 study found that suicide rates have been consistently higher in rural areas for nearly two decades.[27] Additionally, as the entire country continues to confront the opioid crisis, rates of drug overdose deaths in rural communities are notably on the rise.[28] These trends are especially alarming in light of the fact that more than 60% of mental health Health Professional Shortage Area (HPSAs) are rural or partially rural.[29]

Therefore, we recommend that CMS implement policies to allow better integration and coordination of behavioral and substance use treatment services with health care providers, entities, or organizations with which an REH routinely works, such as rural health clinics (RHCs) and federally qualified health centers (FQHCs). For example, referral and co-location arrangements would expand access and increase continuity of care to behavioral and substance use treatment services in remote and marginalized communities. While working together, rural hospitals and FQHCs may be able to share access to patient care records, which would allow for greater synergy and integration of behavioral health care, as well as other primary care services. In addition, removing telehealth and virtual care limitations for REH patients, as described above, also would fill gaps in access to behavioral and substance use treatment services for rural communities.

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[26] Shawnda S. (2017). Rural Behavioral Health. Rural Health Research RECAP. https://www.ruralhealthresearch.org/assets/658-1990/rural-behavioral-health-recap.pdf
[27] Centers for Disease Control and Prevention. (2018 March 22). Suicide Policy Brief: Preventing Suicide in Rural America. https://www.cdc.gov/ruralhealth/suicide/policybrief.html
[28] Centers for Disease Control and Prevention. (2018 February 28). Drug Overdose in Rural America. https://www.cdc.gov/ruralhealth/drug-overdose/index.html
[29] Centers for Disease Control and Prevention. (2018 March 22). Suicide Policy Brief: Preventing Suicide in Rural America. https://www.cdc.gov/ruralhealth/suicide/policybrief.html

Other Considerations. We also recommend that CMS consider the following to be expressly eligible services for REHs:

- To allow for drugs administered by infusion or injection in the outpatient setting as an eligible medical and health service. Providing access for the safe administration of chemotherapy and other services remain to be an important factor among rural communities, where these outpatient services are important health care access points in more remote areas and in particular, communities that serve structurally and historically marginalized communities. For example, an AHA study found that cancer patients receiving care in outpatient departments are more likely to be enrolled in Medicare through disability or ESRD, dually-eligible, from lower income areas, and have more chronic conditions.[30]

- To allow ambulatory surgery service as an eligible service to be furnished by REHs. Rural patients oftentimes have to travel long distances to receive care for ambulatory surgical services in outpatient departments or ASCs.[31] They also are less likely to receive care in an ASC; thus, maintaining access to surgical services is an important feature for rural residents.

Health and Safety Standards. Ensuring the delivery of high quality and effective care to patients is the top priority for America's hospitals and health systems. To achieve that goal, our members recognize the important role that health and safety standards play, which is why the AHA appreciates the agency's interest in determining whether specific safety-focused standards should be established for REHs. **We are confident the CoPs currently in place for CAHs will be sufficient for REHs as well.** However, we recognize CMS may have interest in creating additional standards specifically for REHs beyond the CAH CoPs. Should the agency take those additional steps, a critical piece in determining what those standards should entail requires a recognition of the unique set of circumstances attached to hospitals seeking REH designations. Specifically, these hospitals face significant staffing challenges and are subject to a variety of geographic limitations. In addition, we urge the agency to recognize that many states will have to revise current licensure requirements to allow for REHs. This may take time and guidance from CMS to facilitate a process that will reduce turbulence for those providers applying for REH status.

As the agency considers additional requirements that should be applied to REHs, the AHA strongly encourages CMS to take these challenges and limitations into account during its decision-making process. Specific examples of the need for flexibility follow.

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[30] American Hospital Association. (2021). Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices among Cancer Patients. https://www.aha.org/system/files/media/file/2021/04/KNG-Health-AHA-HOPD-and-IPO-Comparison-CANCER-COHORT.pdf

[31] MedPAC. (2019). Ambulatory Surgical Center Services: Assessing Payment Adequacy and Updating Payments. http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf

Staffing Challenges. Hospitals seeking REH designation likely will be entities already facing difficult situations in securing permanent staff. Given the size of these hospitals, many have limited medical staff on-hand and must rely on the utilization of staffing agencies to fill open slots to provide care to patients. **In recognizing these unique challenges, we urge the agency to look to more innovative approaches to ensure that necessary privileging functions can be carried out without jeopardizing the ability of hospitals to receive REH designations.** For example, CMS could examine the opportunity to allow for the establishment of multi-provider coalitions aimed at providing appropriate performance reviews and recommendations for privileging of staff without negatively impacting the opportunity for hospitals to be designated REHs. While staffing coalitions represent only one potential solution that can be employed, **we urge the agency, through coalitions or another mechanism, to provide substantial flexibility in its approach to privileging requirements for REH staff.**

In addition, under most circumstances, for a transfer of a patient to move forward, a physician member of the medical staff must provide final approval, which could prove difficult for many hospitals applying to be REHs. **We urge CMS to consider allowing other medical professionals, like certain nursing professionals, to sign off on the transfer of a patient to another provider to ensure the efficient and timely care of patients.**

Transfer Agreements. We recognize that the establishment of REHs is aimed at addressing the needs of individuals in traditionally underserved, rural communities. In seeking the REH designation, there should be an understanding that REHs likely will not be able to provide complex levels of trauma care when necessary, which means transfer agreements with nearby trauma centers will be vital. **While we support the need for transfer agreements for REHs, we urge the agency to recognize the geographic limitations of many of these providers.** For example, given the geographic location of certain REH applicants, the nearest level I or II trauma center may be hundreds of miles away. While we understand the need for transfer agreements, **it seems appropriate for the agency to consider whether a transfer agreement with a level III or IV trauma center, rather than with a level I or II trauma center is permissible based upon the services that a specific REH provides.** Transfer agreements certainly play a vital role in ensuring those individuals who need more immediate, complex and specialty care will receive it; however, those agreements are most beneficial when they are grounded in realistic need. Further, it is important to note that CAHs currently have agreements in effect to transfer patients needing more complex levels of care. As such, building off of current arrangements and implementing a more flexible approach, taking into account geographic location, services offered, and access to specialty care, may be a more practical tactic for hospitals seeking a REH designation.

Patient Observation Care Requirements. In determining the annual per patient average of 24 hours in an ED and observation care setting, we urge CMS to consider instances

where patients are unable to be transferred in a timely manner. We recommend that CMS consider the ability for REHs to provide flexibility on observation bed lengths of stay, in the event that a patient cannot be transferred in a timely manner. For example, our members have stated that, in particular during the COVID-19 pandemic, local hospitals often face capacity issues that prohibit timely transfers of patients. Additionally, psychiatric and rehabilitation cases also may be difficult to transfer in rural communities. Allowing for flexibilities when determining the annual per patient average of 24 hours in ED and observation care would ensure that patients can be effectively and efficiently transferred, without jeopardizing the clinical needs of patients. It also is worth noting that providing this flexibility would not rush REH decision-making and would take into recognize important patient considerations related to transfers, such as distance from the patient's home and significant financial implications.

Other Considerations. Below are other examples of flexibilities that CMS should consider from CAH CoPs that may apply differently to REHs.

- The CAH CoPs life safety codes anticipate that many patients would be inpatients and likely sick enough to be unable to move out of danger from fire or other threats on their own, but the patients cared for in an REH may largely be ambulatory. Something more akin to the life safety requirements for ambulatory surgery centers may be better.
- Similarly, the CAH CoPs have requirements for meeting dietary requirements of patients, but given the more time-limited stay for most patients at an REH, perhaps those expectations should be scaled back.
- Relatively recently, CMS instituted criteria that were intended to demonstrate that CAHs and other hospitals were providing primarily inpatient care, as required in the Medicare statute. These inpatient criteria would not be applicable to REHs. We anticipate that CMS will want to consider whether it should have criteria for REHs that demonstrate that REHs are meaningfully being used as emergency hospitals. For example, will CMS have an expectation that a certain percentage of visits will result in the transfer of patients for inpatient care? Or that a proportion of patients seeking care at the REH would present with symptoms that a reasonable layperson would agree to constitute as reason for seeking emergency treatment? We recommend that CMS engage with stakeholders for further comment and feedback.
- Similarly, the CAH CoPs have a requirement for patient visitation policies. REHs also may need patient visitation policies, but they should be significantly scaled back from those of a hospital due to the more limited amount of time most patients will spend in the REH.
- CAHs also are required to have organ donation programs and plans for encouraging donation and working with local organ procurement organizations. Whether such a program should exist at or should exist in a scaled back way in a REH depends on the anticipation of how many patients who might qualify to be donors would be treated at an REH versus how many would be transferred to an

acute care hospital, where such life decisions would be addressed. It is hard to know the answer to this question now, but we urge CMS to consider minimizing the burden on these providers by scaling back the requirements for an organ donation program to simply sharing information with the patient and/or the health care proxy on their opportunity for organ donation and then connecting them with the organ procurement organization in the event that they are interested.

Care Coordination. In order for CMS and other federal agencies to encourage collaboration and coordination between an REH and other area health care providers, we urge CMS to remove the various regulatory barriers on care collaboration that we described above and expand its opportunity to provide waivers in certain circumstances. While there is no single, one-size fits all strategy, rural hospitals around the country are employing solutions that align their communities' needs with available support structures and resources. These relationships provide critical medical expertise and a learning opportunity for rural providers. It is especially important for REHs who may focus on providing emergency services and look to other providers and entities in the community to provide more primary and other medical services. In rural communities, these partnerships provide patients the opportunity to know and feel comfortable with providers and maintain continuity of care.

Quality Measurement. Given the novelty of the REH program, and the nature of care delivery and quality measurement in rural and low-volume settings, CMS faces unique challenges in identifying a small set of important, impactful, reliable, accurate and clinically relevant measures for REH providers. As CMS develops an approach to implementing REH quality measurement and reporting requirements, we offer several overarching recommendations.

First, we encourage CMS to be data driven as it selects measure topics and specific measures. The measures included in an REH measurement program should reflect the types of services and care delivered most frequently in that setting, along with areas of care where there may be inappropriate variation or potential quality of care challenges. CMS may wish to use some empirical modeling to project what types of services may be offered, and then identify whether there are any existing measures that reasonably align with important quality issues for those services. It is essential that low volume rural hospitals invest their efforts in measuring aspects of care that are truly important and relevant for the patients they serve and the care they provide. This is especially true given that they often face significant resource constraints, and that quality measurement efforts will be potentially more likely to divert finite clinician time away from the direct provision of care in these settings.

In addition, we urge CMS to use the MAP process both to review the initial list of REH measures, and to add new measures to the program in future years. For almost all of its quality measurement and value programs, CMS uses the MAP to obtain multi-stakeholder input on measures it is considering for future rulemaking. We understand that the statute does not require CMS to use the MAP in selecting REH program

measures. However, we feel the potential benefits of using the MAP outweigh the time and resources required to go through the process. The MAP's input can help ensure the measure align with the broader suite of CMS measurement programs, and provide CMS with perspectives on the potential unintended consequences of using a measure. We believe this input will be especially important given CMS' stated desire to continue its Meaningful Measures initiative to streamline and focus on measures that assess the most important aspects of care.

We also urge CMS to be mindful of the significant methodological challenges with measurement in rural and low-volume settings. Measure reliability and validity often hinges on having a sufficient volume of cases to ensure the reported rates are not just statistical "noise." Yet, rural providers often struggle to achieve sufficient volumes. Determining appropriate approaches to addressing low-volume measurement issues will be imperative as CMS considers the public reporting of REH data. As CMS considers existing measure, the agency may wish to model how many REH facilities could achieve sufficient measure volume to achieve reliability. CMS also could consider other recommendations for addressing low volume that that the NQF provided in its MAP Rural Technical Expert Panel 2019 report. This includes measuring over longer timeframes to aggregate sufficient data.

Lastly, our members have expressed some concern about the potential use of "time-based" quality measures. Such measures are sometimes used to assess whether referrals to higher levels of care or to other providers are performed in a timely way. Given the geographic isolation of many rural facilities, and the fact that the degree of geographic isolation is not uniform across the country, it could prove highly problematic for one REH to score better or worse on a time-based measure simply because of their geographic location.

Health Equity. The AHA thanks CMS for its interest in understanding how the new REH model could help advance health equity. In the OQR section of this letter, we offer several general recommendations on the collection, use, and reporting of health equity-related data, and we believe those recommendations also apply to REHs. As CMS continues its health equity-related work, we encourage the agency to ensure its approach is consistent across programs and settings.

Payment Provisions. By statute, starting Jan. 1, 2023, REHs will be paid 105% of the OPPS rate for covered outpatient services, plus an additional facility payment. The annual additional facility payment for 2023 is calculated as the excess of the actual total amount paid to all CAHs in 2019 for inpatient hospital, outpatient hospital, and SNF services, over what would have been paid had payments been made under the applicable PPSes, divided by the total number of such hospitals in 2019. For 2024 and subsequent years, the facility payment would be increased by the hospital market basket percentage increase.

In order to calculate the additional facility payment, CMS would need to, first, calculate the actual payments made to CAHs in CY 2019; second, estimate the amount that would have been paid under the applicable inpatient, outpatient and SNF PPS; and third, compare these two payments to arrive at the annual additional facility payment amount. CMS seeks comments on issues the agency should consider when calculating the estimated payment under the PPS. Further, CMS is seeking feedback on whether the claims forms used by CAHs to report inpatient hospital services, outpatient hospital services, and SNF services contain all of the necessary information such that the claims could be processed by the applicable CMS prospective payment systems.

The AHA strongly recommends that CMS use 100% Medicare FFS claims data to calculate the additional facility payment. Specifically, the AHA recommends that CMS use the CY 2019 100% Medicare inpatient, outpatient, and SNF standard analytic files (SAF). These claims data capture the full breadth of services and payments provided and are the most appropriate source of data for purposes of calculating this additional facility payment. The AHA also recommends that, as CMS proceeds with rulemaking, it sets forth its detailed methodology for calculating the additional facility payment for public comment. It is critical that stakeholders be able to replicate and comment on a proposal for further consideration.

Sequestration. In 2019, Medicare payments to CAHs were subject to a 2% reduction due to sequestration. The reduction led to CAHs being reimbursed roughly 99% - rather than 101% – of their allowable costs. CMS will need to consider the impact of this sequestration when determining the additional facility payment amount. Since CMS would need to compare the actual payments made to CAHs with an estimate of the amount that would have been paid under PPS, the agency will need to separately consider how, if at all, the sequestration amount is reflected in each payment method in order to accurately make the comparison.

Specifically, the sequestration reduction is already reflected in the claims data that will be used to calculate actual payments to CAHs. That is, the actual payments made to CAHs already reflect the 2% reduction. However, CMS' estimated PPS payments will not inherently include sequestration. **Thus, in order for the agency to create an apples-to-apples comparison of actual cost-based payments and estimated PPS payments, we recommend that CMS apply the 2% sequestration only when it estimates payments that would have been made under the inpatient, outpatient, and SNF PPS.**

Additional Data Sources. Although the 2019 Medicare inpatient, outpatient, and SNF SAFs contain sufficient information to calculate the actual cost-based payment paid to a CAH for a certain claim, the SAFs alone do not contain enough information to estimate what payments would have been under the applicable PPSes. For example, to estimate an inpatient PPS operating payment for a claim for a given provider, CMS would need

information that is not contained in the inpatient SAF file. This includes, but is not limited to:

- Publicly released MS-DRG weight table for the applicable FY to obtain the MS-DRG service intensity weight;
- Publicly released payment rates;
- Hospitals' wage index and cost-of-living adjustments;
- Hospitals' indirect medical education (IME) adjustments;
- Hospitals' disproportionate share hospital (DSH) adjustments and uncompensated care payments per claim; and
- Hospitals' cost-to-charge ratios.

For hospitals paid under the inpatient PPS, this information is available in the inpatient provider specific file (PSF), in related "impact files," or in other public use files (PUF) that CMS publishes annually with each inpatient PPS rule. The inpatient PPS PC PRICER software program uses the PSF and other relevant files to calculate claim-level payments under the inpatient PPS. However, to the best of our knowledge, no analogous inpatient PSF, impact file, or related PUFs exist for CAHs. Therefore, CMS will need to create these files in order to estimate, for a given claim for a given provider, what the payment would have been under the inpatient PPS. Similarly, the outpatient and SNF SAFs alone also do not contain sufficient information needed to estimate what payments would have been under the outpatient and SNF PPS. CMS also will need to create similar types of PSF, impact files and/or PUFs for outpatient and SNF in order to estimate the amounts that would have been paid. **We strongly urge CMS to publish any file the agency creates and uses to estimate the additional facility payment, along with a detailed methodology, to allow stakeholders to replicate and comment for further consideration**.

In addition, we recommend that when creating any new PSF, impact files, and other related PUFs for CAHs, CMS uses the same or similar time periods that the agency utilized to calculate payments for those hospitals paid under the inpatient, outpatient, or SNF PPS. For example, if the 2017 Medicare cost report was used to calculate a parameter needed by the inpatient PPS PC PRICER to determine a payment made to an inpatient PPS hospital for a 2019 claim, then the 2017 Medicare cost report for a CAH should also be used to calculate this parameter when creating the CAH PSF impact file, or PUFs to determine what the CAH's payment would have been under inpatient PPS in 2019.

Inpatient Services. In order to calculate the actual inpatient cost-based payments that CAHs received in CY 2019, we recommend that CMS use the 100% Medicare FFS inpatient SAF claims data file and sum the relevant variables in the data file, including the Medicare Trust Fund as well as beneficiary portions.

In order to estimate the payment that would have been paid under the inpatient PPS, CMS would need to use the same inpatient PPS policies and rates in place during CY 2019. Since the inpatient PPS is paid on a FY basis, we recommend CMS use the FY 2019 policies to estimate the inpatient PPS payments from Jan. 1 through Sept. 30, 2019, and the FY 2020 policies to estimate the inpatient PPS payments from Oct. 1 through Dec. 31, 2019.

Outpatient Services. In order to calculate the actual outpatient cost-based payments that CAHs received in CY 2019, we recommend that CMS use the 100% Medicare FFS outpatient SAF claims data file, extract the associated line level data from each claim and sum the actual cost-based payment, which should include the beneficiary portion and the payer portion. The line-level data should distinguish whether the procedure code is payable under the OPPS versus a separate fee schedule or payment system (i.e., physician fee schedule, ambulance fee schedule, etc.). CMS should only consider those line level data that are paid under the OPPS.

In order to estimate the payment that would have been paid under the outpatient PPS, we recommend CMS use the OPPS policies and rates in place during CY 2019. Again, we recommend that CMS exclude line level data not paid under the OPPS, based on the HCPCS code, special modifiers, and the payment policy in effect for CY 2019.

We urge CMS to consider several unique features of the CAH outpatient payment methodology that would apply when calculating actual outpatient cost-based payment and the estimated OPPS payment. Effective Jan. 1, 2014, hospitals reimbursed under the OPPS were required to bill clinic evaluation and management (E&M) visits using HCPCS code G0463 in place of codes 99201 through 99205, and 99211 through 99215. However, providers not paid under the outpatient PPS (i.e., CAHs) were required to continue to bill under the original clinic codes instead of G0463. In order to accurately calculate actual payments paid to CAHs, we recommend CMS include these outpatient visits to CAHs that used the original clinic codes. The agency also should consider these visits when estimating the OPPS payment. We strongly urge CMS to consider if there are any other codes or special modifiers for which this situation arises, and that it should take those codes and special modifiers into consideration when calculating actual cost-based and estimated outpatient PPS payments.

Skilled Nursing Services. CAHs may have SNF distinct part units and/or offer swing bed services. SNF distinct part units under CAHs are reimbursed under the SNF PPS while their swing bed services are paid under the cost-based method. Because the comparison to calculate the annual additional facility amount is made between actual payment and estimated PPS payment, the comparison for SNF distinct part units would yield no payment difference since the actual payment was also under PPS. We focus the following discussion for calculating the additional facility payment on swing bed SNF services only.

In order to calculate the actual cost-based payments that CAHs received in CY 2019 for SNF swing bed services furnished during a Part A covered stay, we recommend that CMS use the 100% Medicare FFS SNF SAF claims data file. Payments should include both the beneficiary and payer portions.

In order to estimate the payment that would have been paid under the SNF PPS, since the SNF PPS is paid on an FY basis, we urge CMS to use the FY 2019 policies to estimate the SNF PPS payments from Jan. 1 through Sept. 30, 2019, and the FY 2020 policies to simulate the SNF PPS payments from Oct. 1 through Dec. 31, 2019. In addition, on Oct. 1, 2019, CMS changed its SNF PPS payment methodology from the Resource Utilization Group version IV (RUG-IV) method to the Patient Drive Payment Model (PDPM). Therefore, when estimating SNF PPS payments from Jan. 1 to Sept. 30, we recommend CMS use the RUG-IV methodology, and the PDPM methodology when estimating payments from Oct. 1 through Dec. 31, 2019.

In addition, we urge CMS to consider several additional issues when estimating what would have been paid under SNF PPS payments for CAHs. First, CAHs are not required to submit Minimum Data Set (MDS) 3.0 assessments for their SNF swing bed patients. These assessments are required under the SNF PPS, but because CAH swing bed services are paid under cost-based reimbursement, such assessments are not completed. The MDS 3.0 assessments are the primary basis for determining case mix groupings under the SNF PPS. As a result, CAH swing bed claims data do not contain all the relevant patient groupings required to estimate SNF PPS payments. Therefore, CMS will need to estimate what the case mix categories would have been under the SNF PPS for swing bed services furnished by CAHs.

In doing so, we recommend that CMS estimate case mix groupings using both diagnostic and service utilization characteristics from the SNF claim and preceding hospital claims. We believe that it is important for CMS to consider the clinical profile of swing bed patients. In particular, our analysis indicates that swing bed patients may be more clinically complex and use less therapy than non-swing bed patients, and thus not accounting for both diagnosis and utilization may bias RUG-IV and PDPM case mix categories. As well as accounting for the higher complexity of SNF swing bed patients, it is particularly important to include the utilization of physical, occupational, and speech language therapy, which are coded as revenue center lines on SNF claims, when estimating case mix categories. While therapy coding on claims may not be as accurate as those on MDS assessments, our analysis indicates they do serve as markers with significant predictive power in predicting RUG-IV and PDPM case mix categories. Not accounting for therapy utilization and clinical complexity differences would create biases in the estimation of SNF PPS payments, and therefore the REH lump sum payments to CAHs. **That said, we strongly urge CMS not to require CAHs to submit MDS assessments for their swing bed services. It would be impossible for CAHs to complete MDS assessments for swing bed patients who were discharged 18 months or more in the past, as these assessments involve**

complex mobility, self-care, and cognitive clinical assessments that must be performed on the patient during their stay.

Second, SNF SAF claims do not include SNF stay identifiers, which are important for correctly calculating the per-diem payment adjustments applied under PDPM. This would be required to implement the SNF interrupted stay policy when estimating SNF PPS payments. While the SNF stay grouping logic for PDPM is implemented and available in CMS' internal data systems, we strongly recommend that CMS publishes its methodology for public comment so that stakeholders can replicate and comment on CMS' implementation of simulated RUG-IV and PDPM SNF CAH swing bed payments using the publicly-available limited data set (LDS) SAF files. Similarly, while predictive algorithms can be difficult to document (e.g., documenting the "parameters" inside machine learning algorithms), we strongly encourage CMS to document their logic in sufficient depth so that stakeholders can replicate CMS's methodology on the LDS claims data and comment accordingly.

Other Considerations. Finally, we also recommend that CMS pay REHs for ambulance services that qualify on the 35-mile drive requirement at a cost-basis method. That is, for an ambulance service that is the only provider within a 35-mile drive of the REH or is more than 35-mile drive but is the closest ambulance provider to the REH, CMS should pay 101% of reasonable costs as it has done for CAHs.

Enrollment Process. The statute requires eligible facilities to submit an application to enroll as an REH, which would contain an action plan for initiating REH services, including a detailed transition plan that lists the specific services that the facility will retain, modify, add and discontinue. In addition, eligible facilities also must provide information regarding how it intends to use the additional facility payment, including a detailed description of the services that the additional facility payment would be supporting.

The AHA recommends that CMS take all reasonable steps to streamline the enrollment process. In particular, we recommend that CMS establish a similar enrollment process for REHs, including the initial enrollment and changes in enrollment information, as the agency has previously done in establishing other designations, such as the CAH designation. One member indicated that the conversion process to a CAH designation and the process to work with the State Offices of Rural Health has been an effective and efficient enrollment model. **We also urge CMS to keep in mind that eligible facilities are diverse in size, location, and complexity and, hence, the formality and sophistication of services that the facility intends to furnish will be dictated by those characteristics.** Accordingly, we ask that CMS refrain from including rigid and complex requirements that may preclude eligible facilities from converting to REHs and subsequently, preclude REHs from providing and billing services in a timely manner.

We recommend that CMS consider the following as it establishes a streamlined and efficient enrollment process:

- Eligible facilities should enroll using the Medicare Enrollment Application for Institutional Providers (CMS-855A).
- Ordered or referred Medicare Part B services furnished directly by a REH should be billed using the Uniform Bill (UB-04) format.
- CMS should provide Medicare contractors with a reasonable time frame for processing enrollment applications.
- CMS should develop a REH Technical Assistance (TA) Program that can offer resources and guidance to help providers develop plans and language for the application process. In the future, the TA program could offer guidance about budgeting, reimbursement, working with states, and offer opportunities for community stakeholders to discuss REH issues.

Finally, we seek clarification on the following related to the enrollment process:

- Per statute, an enrollment as a REH remains effective until the facility either elects to convert back to its prior designation or is determined to no longer meet the requirements applicable to maintain as a REH. Given that the statute allows for facilities to convert back to their prior designation, we urge CMS to provide a streamlined pathway for facilities to do so. In particular, CMS should establish a clear process for a necessary provider CAH that converted to a REH to revert back to its necessary provider status.
- In addition, we urge CMS to clarify that REHs do not qualify as hospitals when other hospitals are calculating mileage requirements to be, for example, a CAH or sole community hospital. Under CMS guidance, for these purposes, the agency considers as hospitals those facilities that primarily provide inpatient or rehabilitation services, but are not primarily engaged in providing skilled nursing care. REHs clearly do not meet these criteria because, by definition, they do not provide any acute inpatient or rehabilitation services.
- Per statute, a REH may be considered as a hospital with less than 50 beds for the purposes of determining payment limit exception for RHCs. Therefore, we urge CMS to definitively state that provider-based RHCs that meet the requirements under Section 130 of the Consolidated Appropriations Act of 2021 would retain their grandfathered status after the hospital converts to a REH provider type. Retaining such status would maintain access to critical health care services in rural communities.
- Finally, we ask CMS to ensure that, once enrolled, nothing in the regulations related to the REH will prevent these facilities from receiving crucial payments, such as Medicaid DSH payments, or their ability to use “Method II” to bill and receive payment for physician services. Individuals under age 65 who live in rural areas are more likely to be uninsured and high rates of uninsured and governmental payers as part of a hospital’s payer mix is frequently cited as one

of the key drivers of rural hospital closure.[32] These payments play a vital role in ensuring the financial sustainability of hospital-based healthcare services in rural areas.

[32] American Hospital Association. (2019). Rural Report: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality Affordable Care. https://www.aha.org/system/files/2019-02/rural-report-2019.pdf