Catholic Health Association of the United States

A Passionate Voice for Compassionate Care

September 17, 2021

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Room 445-G Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

REF: CMS–1753–P

RE: 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 Ms. Brooks-LaSure:

The Catholic Health Association of the United States (CHA) is pleased to submit these comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2022 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment rates. This proposed rule includes provisions related to payment for Part B drugs acquired under the 340B drug discount program, the inpatient only (IPO) list and two-midnight rule, criteria for when procedures may be added to the ASC covered procedures list, civil monetary penalties for non-compliance with price transparency requirements, coinsurance for screening colonoscopies, outpatient hospital and ASC quality reporting among other provisions.

We appreciate your staff's ongoing efforts to administer and improve the payment systems for outpatient hospital and ambulatory surgical services, especially considering the agency's many competing demands and limited resources. CHA offers the following comments on the proposed rule.

- **340B Payment Policies**

Since 2018, CMS has paid separately payable Part B drugs acquired under the 340B program at average sales price (ASP)-22.5 percent in place of ASP+6 percent in the hospital outpatient department. CHA objected to CMS' policy at that time it was proposed on legal and policy grounds. We reiterate our belief that CMS lacks authority to make this change, which has undermined the very purpose of the 340B program and caused harm to 340B hospitals, to the communities and

patients those hospitals serve, and to Medicare beneficiaries. Despite objections from CHA and others, CMS decided to finalize its policy for 2018 which it later continued for 2019 through 2021. CMS now proposes to continue the policy for 2022 pending review of the policy by the United States Supreme Court.

On December 27, 2018, United States District Court for the District of Columbia concluded the Secretary exceeded his statutory authority by adjusting Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for 2018 (see *American Hospital Association et al. v. Azar et al*). On May 6, 2019, the District Court ruled that the rate reduction for 2019 also exceeded the Secretary's authority. On July 31, 2020, the United States Circuit Court for the District of Columbia (the appeals court) entered an opinion reversing the district court's judgment. On July 2, 2021, the United States Supreme Court granted a petition for a writ of certiorari and directed the parties to argue whether the petitioners' suit challenging the 340B drug payment adjustment is precluded from judicial review.

As a matter of policy, savings generated by the 340B program allow hospitals to provide many types of assistance to low-income patients and communities, including access to free or reduced priced drugs for those who cannot afford their prescriptions; clinical pharmacy services; funding for services such as obstetrics, psychiatry, diabetes education, and oncology; and establish outpatient services to increase access. Given the purpose of the 340B program is to "maximize scarce Federal resources as much as possible, reaching more eligible patients, and provide care that is more comprehensive," **CHA continues to oppose these payment cuts and believes that CMS should return to paying for Part B drugs acquired under the 340B program at ASP+6 percent.**

In addition, 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 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. The threat of losing savings from the contract pharmacy program in conjunction with reduced reimbursement has created extreme financial vulnerability for 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.

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, PPS-exempt cancer hospitals, and critical access hospitals (CAHs). However, in 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." **CHA opposes any future efforts to expand the payment cuts to other 340B hospital types.**

- **Services Furnished in Off-Campus Provider-Based Departments**

Off-campus provider-based departments (PBDs) that opened after November 2, 2015 (non-excepted off-campus PBDs) are paid through the physician fee schedule (PFS) at a rate equal to 40 percent of the OPPS rate, pursuant to Section 603 of the Bipartisan Budget Act (BBA) of 2015 as implemented by CMS. In the BBA Congress specifically excepted from this new policy off-campus PBDs that existed prior to November 2, 2015 (excepted off-campus PBDs). However, in the CY 2019 OPPS final rule CMS adopted a policy to apply the PFS adjusted payment rate for clinic visits (HCPCS code G0463) in *excepted* off-campus PBDs and exempted this payment change from the required budget neutrality requirements that customarily apply to OPPS payment changes. CMS proposes to continue this policy for CY 2022, and notes that this policy was upheld by a federal circuit court in 2020 and that the Supreme Court recently denied certiorari. Nonetheless, **CHA continues to oppose this policy and urges CMS to reimburse excepted off-campus PBDs at the OPPS rate as we believe Congress intended.**

CHA hospitals provide services to low income and rural communities. Payment rates for non-excepted off-campus PBDs under section 603 are already affecting access to needed services by lessening hospitals' ability to move into these communities when physicians are leaving their practices. Additional payment reductions to hospitals' excepted PBDs that are neither required nor supported by the law negatively affect access to needed services in these vulnerable communities. CMS is not adequately taking into account the role off-campus PBDs play in the communities they serve as a crucial and often only point of access for health care services, nor does it acknowledge the key differences between physician practices and off-campus PBDs that result in higher overhead expenses for off-campus PBDs. **CHA continues to strongly oppose this policy and encourages CMS to restore payment for outpatient clinic visits in excepted off-campus PBDs to 100 percent of the OPPS rate.**

- **In-patient Only (IPO) List**

Services on the IPO list are not paid under the OPPS. For 2021, CMS adopted a policy to eliminate the IPO list over a transitional period beginning in 2021 and ending in 2024. For 2021, CMS removed 298 musculoskeletal procedures from the IPO list of 1,740 total services. In public comments on the 2021 OPPS rule, CHA indicated that it was premature to adopt a policy to eliminate the IPO list over three years. We urged CMS to continue with its standard process for removing procedures.

Services on the IPO list require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery. CHA believes the IPO list is a necessary safeguard for Medicare beneficiaries against invasive procedures being performed inappropriately in an outpatient setting.

CMS proposes to reinstate the IPO list as well as the prior criteria that CMS used for removing a procedure. After evaluating the 298 musculoskeletal procedures removed from the IPO list against these criteria, CMS proposes to add all of them back to the IPO list for 2022. **CHA supports abandoning the elimination of the IPO, reinstatement of the criteria and restoring to the list the procedures eliminated for 2022.**

When it made the proposal to eliminate the list, CMS noted that medicine is constantly evolving and that clinical judgement, taken together with consideration of a beneficiary's specific needs, should not be unduly constrained by inflexible regulatory structures. While we support the continuation of the IPO list, CHA agrees it should evolve as practice standards evolve. CMS requests public comment on the future of the IPO list including how to make updates that will allow services currently performed inpatient to be paid when performed on an outpatient basis. We agree that the list should be consistent with current standards of practice and the appropriate role of clinical judgement. We believe the process previously used for removing procedures from the list remains pertinent and suggest CMS could consider setting general criteria for removal based on peer-reviewed evidence, patient factors including age, co-morbidities, social support, access to care and other factors relevant to positive patient outcomes.

- **Two-Midnight Rule**

Under the two-midnight rule, an inpatient admission is considered reasonable and necessary when the physician expects the patient to require a stay that crosses at least two midnights. Procedures on the IPO list are appropriate for inpatient hospital admission regardless of the expected length of stay. Once a procedure is removed from the IPO list, it is subject to medical review for compliance with the two-midnight rule by a Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIO). BFCC-QIOs may refer cases for further review by a Recovery Audit Contractor (RAC) if the hospital has high denial rates, consistently fails to adhere to the two-midnight rule or fails to improve after BFCC-QIO educational intervention.

In 2020, CMS finalized a policy to exempt procedures that have been removed from the IPO list from referral to the RACs for noncompliance with the two-midnight rule for the two calendar years following their removal from the IPO list. Procedures removed from the IPO list would not be considered by the BFCC-QIOs in determining whether a provider exhibits persistent noncompliance with the two-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for patient status. In conjunction with eliminating the IPO list, CMS replaced this two-year exemption with an indefinite time period until the procedure is more commonly performed outpatient (50 percent or more of the time) than inpatient.

In conjunction with its proposal to reinstate the IPO list, CMS also proposes to reestablish the two-year exemption from review of patient status by the BFCC-QIOs and referral to the RACs. The two-

year exemption would be in place of the indefinite exemption until a procedure is routinely performed outpatient.

In the past, CHA has urged CMS to consider an exemption period of longer than two years and to identify procedures that should be permanently exempted from BFCC-QIO review of patient status and referral to the RACs. Consistent with our prior suggestions, **CHA urges CMS to retain the indefinite exemption from BFCC-QIO review for patient status and referral to the RACs until such time as a procedure removed from the IPO list is performed outpatient at least more than 50 percent of the time.**

- **Ambulatory Surgical Center (ASC) List**

Prior to 2021, CMS regulations only allowed a procedure to be included on the ASC list of covered procedures when the procedure would not be expected to pose a significant safety risk and the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Surgical procedures were also excluded from the ASC if they:

1. Result in extensive blood loss;
2. Require major or prolonged invasion of body cavities;
3. Directly involve major blood vessels;
4. Are generally emergent or life-threatening in nature;
5. Commonly require systemic thrombolytic therapy;
6. Are on the IPO list;
7. Can only be reported using a CPT unlisted surgical procedure code; or
8. Are excluded from Medicare coverage (preventive exams, eye exams, custodial care, dental services, etc.).

Beginning in 2021, CMS eliminated both the inclusion criteria and the first five of the above exclusion criteria. CMS also added 267 codes to the ASC covered procedures list including services that were completely inappropriate to be performed in an ASC site of service. Such services included exploration of a penetrating wound (often billed when the patient has a gunshot or a stab wound). ASCs are for scheduled ambulatory surgical procedures. Clearly, treatment of a gunshot or a stab wound is an emergency and would not be a scheduled service.

CHA opposed CMS' policy to eliminate the ASC inclusion and exclusion criteria and add the 267 procedures to the ASC covered procedures list. For 2022, CMS proposes to reinstate the inclusion and exclusion criteria for a procedure to be on the ASC covered procedures list. CMS also proposes to remove the 258 of the 267 procedure codes added for 2021. **CHA strongly supports CMS' proposals to restore the ASC-list inclusion and exclusion criteria and to remove the 258 procedures from the list.**

Beginning with 2023, CMS further proposes to use to use a nomination process to add procedures to the ASC covered procedures list. Under this proposal, CMS would solicit recommendations for procedures to be added to the ASC covered procedures list from medical specialty societies and other members of the public. Nominations received by March 1 would be included in the following year's OPPS proposed rule. After considering public comments, CMS would make a decision in the OPPS final rule. This proposal is the same as one of two alternatives that CMS considered but did not adopt for 2021. CHA supported this alternative in our 2021 proposed rule comments. **CHA supports the public nomination process that CMS proposes.**

- **Price Transparency**

Effective January 1, 2019, CMS adopted a policy that required hospitals to post standard charges for all items and services in a machine-readable format. Effective January 1, 2021, CMS adopted a policy that further required hospitals to make public gross charges and payer-specific negotiated charges available for all items and services, and gross charges and payer-specific negotiated charges for 300 shoppable services.

While CHA supports policies that help patients access the information they need when making decisions about their care, including about potential out-of-pocket costs, we continue to question the usefulness of requiring hospitals to post this data and to have concerns about the enormous burden that would be imposed on hospitals. Hospitals spend considerable time and effort working to accurately inform patients about how much a hospital stay will cost them. These efforts give patients a reasonable expectation of their planned out-of-pocket expenses based on their insurance plan and minimize the potential for surprise bills. CHA believes patients are concerned about their out-of-pocket costs for hospital services and not the amounts negotiated with private payers.

Over our objections, CMS adopted these proposals and now proposes to increase civil monetary penalties (CMPs) associated with non-compliance. 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 and the considerable time and effort it takes to comply. **CHA opposes CMS' proposal to increase CMPs associated with non-compliance with the price transparency rules.**

CMS should work to align policies across the various existing price transparency rules and statutes in order to avoid patient confusion and duplication of efforts. We strongly recommend that CMS assess what changes are needed to better align these requirements with all 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 related to the overlaps in the No Surprises Act and transparency in coverage requirements,

but more is needed. **We urge CMS to work with stakeholders to ensure that transparency requirements are aligned** and to address, for example, 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 and 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.

Our member hospitals will continue to provide patients with needed information to avoid surprise bills or unexpected liability for any services provided during their hospital stay. In the interim, **CHA urges CMS to work collaboratively with the hospital community on lessening the burden of the price transparency rules.**

- **Coinsurance for Screening Colonoscopies that become Diagnostic**

Medicare pays 100 percent of the payment amount when a patient undergoes a screening colonoscopy. No patient cost sharing is due. However, if during the course of a screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, Medicare Part B will pay for a diagnostic colonoscopy and patient cost sharing must be charged. This policy is required by law. As a result, many beneficiaries face unexpected coinsurance charges because of events that occur while the patient is under sedation.

After many years, Congress is finally correcting this unfair policy. Unfortunately, the change in law transitions patient coinsurance to $0 over a period of 8 years. **While this policy is not within CMS' discretion, CHA nevertheless thanks CMS for its prompt implementation of the statutory provision through its 2022 regulations.**

- **Use of 2019 Utilization Data to Set the OPPS and ASC Relative Weights**

CMS normally uses the latest available claims data to the set the OPPS and ASC relative weights. For 2022, 2020 claims data would be the latest available to set the weights. However, CMS notes that 2020 claims data is atypical because of the COVID-19 PHE. CMS' analysis further concludes that these data would have an impact on the OPPS and ASC relative weights. To avoid using utilization data affected by the PHE, CMS proposes to use 2019 data instead of 2020 data to set the 2022 OPPS and ASC relative weights. **CHA agrees with this proposal.**

- **Hospital Outpatient Quality Reporting Program**

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

CMS proposes to add this process measure tracking the percentage of health care personnel in facilities including outpatient hospitals (but excluding long-term care facilities) who have received a

complete COVID-19 vaccination course to the Hospital OQR Program measure set, with reporting to begin January 1, 2022. **CHA supports the addition of this measure to the OQR program and other facility quality programs as a part of the overall CMS response to the COVID-19 PHE**. Data collected for this measure can aid facilities in assessing their individual strategies to combat COVID-19 and provide the public with important information to consider in making health care decisions during the PHE. While we would prefer that this measure be NQF-endorsed, it did receive conditional support for rulemaking from the Measures Application Partnership. Given the ongoing nature of the COVID-19 PHE, the recent surge of disease due to the Delta variant of the virus, and the likelihood that at least one vaccine booster dose will be needed to maintain full immunization status, CHA believes that the proposed measure is timely and its adoption should not be delayed.

Addition of Breast Screening Recall Rates

CMS proposes to add a new claims-based, facility-level, process measure beginning with CY 2023 payment determinations to track the percentage of patients who are recalled for further diagnostic breast imaging after review of their initial breast screening images. Preventing breast cancer through early detection and avoiding unnecessary imaging are both important public health concerns and we do not object in principle to this measure. **However, CHA does not support adoption of this measure for CY 2023 payment determinations at this time as this measure has not been submitted for NQF endorsement.** CMS has not included risk adjustment for social risk factors because it is concerned doing so could mask potentially important inequities. We appreciate CMS' attention to this possibility. Risk adjustment for sociodemographic factors should be carefully tailored to those for which there is a conceptual relationship with outcomes or processes of care and empirical evidence of such an effect, for reasons unrelated to quality of care. Differences in performance measure outcomes due to actual variation in the quality of care provided to subgroups of patients should not be tolerated. Given the existence of racial and ethnic health disparities in breast cancer mortality rates, CHA suggests that delaying adoption of this measure for NQF review could provide an opportunity to consider further whether there is appropriate adjustment for social risk factor adjustments that could be included.

Removal of Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival and Median Time to Transfer to Another Facility for Acute Coronary Intervention
Addition of ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

CMS proposes to remove two chart-abstracted measures that address aspects of optimal initial treatment of possible acute myocardial infarction to be replaced by a single electronic clinical quality measure (eCQM) focused on the same topic but more reflective of current treatment guidelines. The changes would be effective with the 2023 reporting period. The new measure if adopted would represent the first eCQM adopted into to Hospital OQR Program.

CHA agrees with CMS that the new measure more directly and completely captures the population of interest and better reflects current treatment guidelines. However, the proposed new measure has not been endorsed by the NQF yet**. We recommend that this package of related measure changes be delayed until the 2024 reporting period to allow for completion of NQF review of the new measure.** It seems particularly worthwhile that the new measure be sufficiently robust to earn NQF endorsement since it would be the inaugural eCQM of the OQR program. Alternatively, the new measure could be adopted for voluntary reporting in 2023 with mandatory reporting beginning in 2024, allowing hospitals to gain experience with the measure and time for NQF review completion.

Policies to Support eCQM Implementation in the Hospital OQR Program

CHA notes that CMS also proposes the addition of policies that would facilitate the implementation of the proposed STEMI eCQM measure, and any future eCQMs, as part of the OQR program's measure set, such as a data review and correction period and an extraordinary circumstances exception for significant hospital health information technology disruptions. **We support those policies for adoption on a timeline that matches whatever timing is finalized for adoption of the STEMI eCQM.** CHA notes the proposed gradual increase in the number of quarters of required data reporting for the STEMI eCQM and we strongly recommend a similarly phased approach be adopted for future OQR eCQMs.

Hospital OQR Program Data Validation Requirements

CMS proposes changes to the OQR program's data validation process beginning with the 2022 reporting period/2024 payment determination. The changes would align the OQR validation process with that of the Hospital IQR Program. CHA supports the changes as proposed and the continued alignment of measures and policies across the two programs wherever appropriate and feasible.

Request for Comment: Measures Addressing Transitions in Care Settings

CHA supports the renewed attention to patient safety and quality issues that has occurred related to recent changes in the IPO list. We fully support the propriety of the potential future adoption of measures that assess quality of care for services whose delivery is shifting from inpatient to HOPD settings. We note that the process for adoption of such measures would also provide a valuable opportunity to consider whether there could be inequities in patient access to procedures newly available in the HOPD setting. CHA generally believes that measures specific to the services that are transitioning will be a better approach to measure development rather than attempting to craft one-size-fits-all measures applicable to multiple, heterogeneous procedures.

Request for Comment: Patient Reported Outcomes after Primary Elective Lower Extremity Joint Replacement

CHA generally supports the importance of patient-reported outcomes performance measures (PRO-PMs) in providing information highly valued by beneficiaries in health care decision-making as well as feedback that is similarly valuable for provider quality improvement efforts. The frequency of lower extremity joint replacement operations in the Medicare population and the availability of validated outcome tools makes these procedures an appropriate focus for PRO-PM adoption into the OQR program.

CHA anticipates that the most significant lower extremity joint replacement PRO-PM data collection challenge will relate to the one-year postoperative assessment. We recommend that CMS first build upon lessons learned from the voluntary reporting of a similar measures under the Comprehensive Care for Joint Replacement Model (CJR). Patients should be offered multiple modes for responding, ranging from telephone to electronic submissions and special efforts may be necessary to reach populations with certain social risk factors (e.g., sensory disabilities, limited broadband access). Patient incentives may be necessary to achieve sufficient response rates.

Measure alignment across settings with results reporting stratified by setting as described by CMS seems a reasonable approach. We recommend that CMS consider proof-of-concept testing prior to adopting this or other approaches given the inherent burden of PRO-PMs for providers and patients and provide relevant data from the experience gained via the CJR model. CHA further notes the immediate and ongoing importance of beneficiary caregivers when joint replacement procedures are performed in the HOPD setting compared to the inpatient setting. Caregivers, most often family or friends, are critical to the safety and success of these procedures and developing a measure(s) to capture their involvement would seem appropriate.

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

General Considerations

CHA and our members are unconditionally committed to achieving equity in health care access and quality. Our mission is rooted in our respect for the dignity of each and every human person, created in the image of God. Access to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual. Our vision for health care calls for a system that achieves health equity by delivering the same level and quality of care to everyone in our nation without exception. Every day our members provide needed health care to all in their community regardless of age, gender, race, ethnicity, sexual orientation or sociodemographic characteristics. They have considerable experience with the delivery of culturally competent care and meeting the

special needs of patients whose social risk factors complicate their care, such as physical and sensory disabilities, housing and food insecurity, and limited English proficiency.

This commitment motivated the Catholic health ministry's initiative *We Are Called: Confronting Racism by Achieving Health Equity*. Through this initiative, CHA members have committed to working for health equity in COVID-19 testing, treatment and vaccination; putting our own houses in order; building just and right relationships with our communities; and advocating for policies to end systemic racism and health inequity.

We firmly concur with CMS that more can be done to use performance measurement systems to identify, understand, and eliminate health disparities. We appreciate the opportunity to respond to the Equity RFI, which poses numerous questions with a focus on three areas for potential future actions by the agency, including stratifying quality measures by social risk factors, improving demographic data collection, and creating a facility equity score.

As an introduction to our comments, we suggest the following as essential characteristics of measures focused on issues of health equity:

- Data-driven: Developed based upon well-documented outcome disparities with clear associations to well-defined social risk factors.
- Actionable: Designed to yield performance results for which change is possible.
- Have utility: In the near-term, process measures may be more feasible and could point the way to meaningful outcome measures.
- Give feedback: Constructed for timely performance scoring and meaningful feedback to providers.
- Feasible: Based on considerations of provider burden and CMS operational capabilities.
- Aligned: Standardized and aligned within CMS programs, across agencies and among stakeholders.

Specific Considerations

CHA echoes our previous support for the use of stratified performance measure results as a valuable tool to identify and reduce health disparities, and for use in tandem with risk adjustment for social risk factors where appropriate. Differences in performance measure outcomes due to actual variations in the quality of care provided to subgroups of patients should not be tolerated. Outcomes variation independent of quality of care, however, must be explored and reflected appropriately in measure development and risk adjustment. We support application of the CMS Disparity Methods to the Hospital OQR Program measures where appropriate after simulation or pilot testing demonstrates feasibility, accuracy, and reproducibility. The choice of social risk factors for stratification should reflect their distribution within a given quality program's patient population.

We agree that race, ethnicity, and dual eligibility status are reasonable initial candidates for results stratification but recommend that language preference and disability status also be considered.

CHA notes that stratification by race and ethnicity first requires standardized data element definitions. We favor the practicality of the Office of Management and Budget's standard minimum set of five racial and one ethnicity categories. To address the known gaps in race and ethnicity data CMS proposes to use a method of indirect estimation. We urge CMS to proceed cautiously. While we share with CMS the desire to move forward expeditiously using the data it has, we are concerned with the high risk of data inaccuracy and measurement bias. Patient self-reporting is widely acknowledged to be the best way to gather accurate sociodemographic data. We would prefer CMS to focus on efforts to improve access to directly collected self-reported race and ethnicity data.

CHA agrees with CMS that measure results stratified by race and ethnicity and/or dual eligibility status must first be confidentially reported to hospitals. Public reporting should not be pursued until sufficient time has elapsed for establishing processes for review and correction and for data validation, demonstrating that the imputed data and results based upon them are highly reliable and reproducible, allowing for emergence and identification of unintended consequences. Prior to public reporting, we recommend strongly that CMS undertake focus groups to test messaging and understanding of the data, so that the results reported are clear and actionable for patients, families, and caregivers. A broad outreach program to educate beneficiaries about stratified results should also be considered.

CMS reports having identified six OQR program measures as high-priority candidates for further exploration of disparities reporting stratified by dual eligibility: MRI Lumbar Spine for Low Back Pain (OP-8); Abdomen CT – Use of Contract Material (OP-10); Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13); Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32); Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35); and Hospital Visits after Hospital Outpatient Surgery (OP-36). CMS states that these measures were chosen based on analyses by CMS of known disparities, procedure volumes, and statistical reliability. CHA has no objection *per* se to further evaluation by CMS of these six measures for stratified reporting, but we urge CMS also to review them against the essential criteria for equity measures that we have outlined above.

CHA firmly agrees with CMS that improved data collection would allow better measurement of performance and outcomes with respect to individuals with social risk factors. Many of our members already deploy EHR capabilities that could facilitate improved collection, and routinely collect race, ethnicity, and language preference data; they are also already expanding their efforts to link their data to quality measurement. Our hospitals already have effective programs for training staff members to interact with patients and families in ways that are culturally competent and respectful when collecting sensitive information.

CHA appreciates the intrinsic appeal to quality measurement experts of collecting a standardized set of social, psychological, and behavioral data along with race and ethnicity for each patient to be shared interoperably to multiple users for a variety of purposes. However, we are worried about expanded data collection intruding into the facility's admission process on the day of service and delaying or disrupting patient care. Further, CHA is quite concerned by the privacy, burden, and cost implications of expanded data collection, most of which would fall on hospitals. Therefore, we reiterate our recommendation for initial small-scale, real-world, pilot testing prior to requiring expanded data collection in HOPDs.

CMS also suggests the development of a facility equity score. We believe this would be premature. We are also not convinced that a facility-level equity score would provide useful information for patients or hospitals. For example, an overall positive score could mask poor performance on particular measures and/or among certain subpopulations. While an appropriate sense of urgency should inform our work toward the goal of ending health inequity, the obligation to improve the health of our patients and communities demands that we ensure our tactics are well-tailored to achieving that goal.

- **Request for Information on Rural Emergency Hospitals (REHs)**

Our rural communities, home to approximately 46 million families and individuals, face significant economic and health challenges. Rural health care providers struggle to serve an increasingly vulnerable and diverse community stretched across a wide geographic service area, while also facing staffing shortages. The increased need coupled with the increasing cost and challenge of operating a full-service hospital facility in a rural community has left health care providers with difficult choices.

Acknowledging the difficulties face by these communities, Congress created a new Medicare provider type – Rural Emergency Hospitals (REHs) – effective for CY2023. Critical Access Hospitals (CAHs) and other small rural hospitals will have the opportunity to apply to become an REH, which can offer emergency department services, observation care, and certain outpatient services. The proposed rule includes a request for information on CMS' plans to establish standards and requirements for REHs.

CHA appreciates CMS' invitation for stakeholder input on the design of the REH provider type. In general, CHA urges CMS to consider the unique circumstances of small rural and critical access hospitals that may seek to convert to an REH, including their payer mixes, staffing difficulties, large number of uninsured patients, and geographic isolation it develops conditions of participation for the new program. We strongly recommend that CMS defer to flexibility in future rulemaking. Keeping these types of facilities open, operational, and high-quality will serve not only the

immediate needs of the community but also the Administration's commitment to improving health equity.

Scope of Services

REHs are required to provide emergency and observation services. They also may elect to 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.

Telehealth: Telehealth services can significantly benefit rural residents 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. CMS should reduce regulatory barriers to providing telehealth in the REH setting, encourage telepsychiatric care, and provide adequate reimbursement for these services. We also urge CMS to work with Congress to eliminate the geographic and originating site restrictions to allow REHs to serve as distant sites for telehealth delivery.

Provider Arrangements: Visiting physician services, time-sharing arrangements, or office leasing agreements can be a crucial tool for small and rural hospitals that may have limited clinical staff and/or rely on visiting physicians to provide specialty services. We ask that the agency provide clear language expressly allowing for such visiting agreements across a range of providers to share treatment space in order to offer a broader range of medical services and better meet patient needs.

Maternal Health Services: Access to maternal health care services is a significant challenge in many rural areas. CMS should maximize the ability to use telehealth for providing pre- and post-natal care and specialty care for mothers and infants. Similarly, allowing for the provider arrangements just described and creating regulatory flexibility to REHs for providers who wish to share treatment space would fill gaps in access to maternal health care.

Behavioral Health and Substance Abuse Treatment: 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. 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). Removing telehealth and virtual care limitations for REH patients would also reduce gaps in access to care.

Other considerations

Quality Measurement: CMS should focus on developing a small number of measures for REHs that are reliable, clinically relevant and appropriate for low-volume settings. The measures 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. We urge CMS to use the MAP process, as it does for almost all of its quality measurement and value programs, to obtain multi-stakeholder input on measures it is considering for REHs, and to work with the NQF Rural Health Workgroup.

Payment: We urge CMS to work within the confines of the statute to ensure that reimbursement is sufficient for REHs to create a viable option for rural hospitals. We also urge the agency to apply sequestration only to those payments that have not already been reduced to account for sequestration, as some of the payments used to calculate REH payments will have sequestration already applied while others may not. CMS should ensure that REH are not "double penalized" when applying sequestration.

In closing, thank you for the opportunity to share these comments on the proposed 2022 OPPS proposed rule. We look forward to working with you on these and other issues that continue to challenge and strengthen the nation's hospitals. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director, Public Policy, at 202-721-6300.

Sincerely,

Lisa A. Smith
Vice President
Advocacy and Public Policy