

June 16, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Submitted electronically: http://www.regulations.gov

RE: Fiscal Year 2023 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule and Request for Information

Dear Administrator Brooks-LaSure:

Every American deserves affordable, comprehensive coverage that allows them to access affordable, equitable, and high-quality care. Americans should also have the personalized health care information they need, when they need it, to make better, more informed decisions before they seek and receive care. With this shared commitment in mind, AHIP¹ appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Fiscal Year (FY) 2023 Hospital Inpatient Prospective Payment System (IPPS) proposed rule (87 Fed. Reg. 28108).

We appreciate CMS's ongoing efforts to create temporary policies to account for the impacts of the COVID-19 public health emergency (PHE). COVID-19 created unprecedented impacts across the health care system, and AHIP appreciates CMS's work to ensure quality measurement does not interfere with the health care system's response to the pandemic. We ask that you consider the impact of COVID-19 on CMS's entire portfolio of quality measurement programs, including the Medicare Advantage Stars Ratings and the Qualified Health Plan Quality Rating System. The factors that influenced hospital performance and that are taken into account here are also likely to affect health plan performance.

Achieving health equity is a priority for AHIP and our health insurance provider members. We believe that investing in performance measures will help detect disparities in care and outcomes,

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¹ AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.

identify social determinants of health with which patients need assistance, and promote equitable care. AHIP applauds CMS's efforts to leverage its quality programs and support its goals as articulated in the request for information. However, investments and advances in the data infrastructure are needed to realize the full potential of measurement efforts such as the development of content and exchange standards. There are also few measures of equity, stratified clinical measures, or incentives to focus on reducing social determinants of health and disparities in care in Medicare payment systems. We greatly appreciate CMS's ongoing partnership in the Core Quality Measure Collaborative (CQMC) and hope to continue our joint efforts to align the public and private sectors through the Health Equity Workgroup. We believe that through this work, great strides can be made in overcoming these challenges in a way that not only improves patient outcomes but also does not impose undue burden on providers.

AHIP also appreciates CMS's leadership in transforming the practice of measuring quality health care to digital measurement. Digital measurement offers the opportunity to assess novel concepts while reducing provider and payer burden. We also encourage CMS to foster alignment on the adoption and approach to digital quality measurement across the industry. CMS should work with the National Committee for Quality Assurance (NCQA) and other measure developers to ensure synergistic approaches to adopting Fast Healthcare Interoperability Resources (FHIR). CMS should also work with the CQMC and health insurance providers to advance alignment of the use of digital quality measures (dQMs) across public and private payers. We wholeheartedly support the transition to digital measurement, it must be implemented in a way that protects patient privacy and considers the challenges of limited electronic health record use by some clinicians. CMS should explore ways to leverage the Trusted Exchange Framework and Common Agreement (TEFCA) as well as the Interoperability and Information Blocking Rules to promote information sharing across the health care industry that could support better care and allow for better quality measurement.

Thank you for the opportunity to comment on these important issues. AHIP stands ready to engage collaboratively with the Administration and other health care stakeholders to find solutions that decrease prices and costs for everyone that simultaneously protect health care quality, choice, value, and privacy for the hardworking individuals we serve. If you have any questions, please contact Danielle Lloyd at (202) 778-3246 or at dloyd@ahip.org.

Sincerely,

Danielle A. Lloyd Senior Vice President, Private Market Innovations & Quality Initiatives

V. H. Hospital Readmissions Reduction Program (HHRP): Proposed Updates and Changes

The HHRP requires a reduction to a hospital's base operating diagnosis related groups (DRG) payment to account for excess readmissions for selected appliable conditions. CMS proposes several changes to this program, as detailed in respective sections.

COVID-19 Policies

CMS previously finalized suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 program year due to the impact of the COVID-19 public health emergency (PHE). CMS now proposes to resume use of the measure beginning with the FY 2024 program year, with an exclusion of patients with principal or secondary COVID-19 diagnoses from both the denominator (cohort) and the numerator (outcome).

Additionally, CMS seeks to modify all six condition/procedure-specific readmissions measures to include a covariate adjustment for history of COVID-19 within one year preceding the index admission, beginning with the FY 2024 program year.

Recommendations:

AHIP appreciates CMS's efforts to mitigate the effects of the COVID-19 pandemic on hospitals' performance in the HRRP. We also agree that such mitigation should be balanced with incentivizing quality and value. We agree that resuming use of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) with an exclusion of patients with principal or secondary COVID-19 diagnoses from both the cohort and the outcome would balance these concerns. We support CMS's proposal to resume use of NQF #0506 in the HRRP in FY 2024.

We agree that the varying prevalence of COVID-19 cases and changes in policies and procedures to address COVID-19 could skew performance on the readmission measures. Moreover, the science around COVID-19 continues to emerge and the long-term effects on a person's health are still not fully clear. As such, we support CMS's proposal to modify all six condition/procedure-specific readmissions measures to include a covariate adjustment for history of COVID-19 within one year preceding the index admission, beginning with the FY 2024 program year, and suggest that CMS monitor for the potential need for a longer adjustment. CMS should continue to analyze the results of the measure to determine if the one-year time frame is sufficient. We also recommend CMS work with NCQA, the measure developer for the Plan All-Cause Readmissions measure (NQF #1768) to determine if a similar adjustment should be made to this measure as COVID-19 would have a similar impact on health plan performance under other federal quality programs including Medicare Advantage (MA) Star Ratings and the Quality Rating System.

Request for Public Comment on Possible Future Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

CMS seeks public comment on promoting health equity through possible future incorporation of hospital performance for socially at-risk populations into the HRRP. The HRRP currently uses beneficiaries' dual eligibility for Medicare and Medicaid as a proxy for their social risk and uses dual eligibility, as required by the statute, to divide hospitals into peer groups for comparison under the program.

Through the FY 2023 proposed IPPS rule, CMS seeks comment on variables associated with or measures of social risk and beneficiary demographics that are already collected, as well as broader definitions of dual eligibility, such as those who are enrolled in a Medicare Savings Program (MSP) (programs to provide financial assistance with Medicare premiums for beneficiaries with limited assets or income) or the Medicare Part D Low Income Subsidy (LIS), that could be included in the HRRP in addition to dual eligibility. CMS notes that initially, the agency would use such variables to stratify results within Hospital Specific Reports (HSRs) as confidential feedback to hospitals.

Recommendations:

AHIP agrees that health disparities must be identified and addressed and that value-based care arrangements such as the HRRP offer powerful levers to promote equity. However, it is essential that measurement and value-based care (VBC) do not inadvertently penalize clinicians or health insurance providers that serve vulnerable populations. This is especially crucial in a program like the HRRP that incentivizes through payment penalties only. Penalizing providers for factors outside their control risks worsening access problems and causing negative consequences for patients.

We appreciate CMS's ongoing work to ensure penalties from the HRRP are fair and based on true differences in quality and account for important differences in the underlying health of a patient populations. We support CMS conducting analyses comparing the impact of adjustments based on MSP, LIS, and self-reported sociodemographic data to the existing dual-eligible stratification and urge CMS to publicly share the results to enable informed commentary on the options by stakeholders.

However, stratification by dual-eligible status is a blunt proxy for identifying underlying differences in community capacity to address social determinants of health. As such, we recommend CMS explore additional ways to account for factors outside a provider's control that can influence readmission rates. For example, the social needs and risks of a patient population vary by location, as does the capacity of a community to action on social determinants of health (SDOH). Communities have different resources and the presence or absence of community-based organizations to support patients as they transition from the hospital is not uniform. In addition to the current peer group comparison approach, CMS should consider potential

appropriate risk adjustment to ensure that providers that serve more complex populations are not unfairly penalized. Value-based incentives should reward true differences in performance, not underlying differences in the region's social service capacity. It is vital that if CMS considers the development of measures that specifically assess readmission rates for socially at-risk populations that they be adequately risk-adjusted, and that the impact of payment penalties thoroughly analyzed before use in a program such as HRRP.

As CMS considers the expansion of approaches like stratification and directly risk adjusting measures, the accuracy of the underlying data on patient risk is an important factor. We believe that self-reported sociodemographic data is the most accurate; however, we caution its use for payment adjustments until there is sufficient, standardized data collected across hospitals to ensure statistically sound comparisons. While imputed methods can fill gaps in self-reported data, the extent of variability and lack of alignment in such methods should preclude its use for public reporting or payment purposes as it risks inaccurately penalizing hospitals. We support CMS exploring use of the Area Deprivation Index (ADI) to support quality measurement efforts and stratification to provide a composite view of social risk factors and geographical disparities. The NQF is developing guidance on the appropriate use of the ADI and other social risk factors for quality measures for inclusion in their forthcoming report on when and how to adjust quality measures using social risk factors that could prove useful. CMS should conduct thorough testing and analysis of the impact of these alternative approaches on the measures as well as on results of the program and seek stakeholder feedback prior to implementing any changes in the HRRP.

V. I. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

The hospital VBP program is a budget-neutral program funded by reducing participating hospitals' base operating DRG payments each fiscal year by 2%, redistributing the entire amount back to the hospitals as value-based incentive payments.

COVID-19 Policies

CMS proposes to continue several policies implemented in the FY 2022 IPPS final rule intended to address impacts of the COVID-19 PHE. CMS proposes to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and five Hospital Acquired Infection (HAI) measures, for the FY 2023 Program year. As a result, less than half of the Hospital VBP Program measures would be available for accurate national comparison. Thus, CMS proposes to remove the financial stakes associated with the program for FY 2023 and only calculate measure rates for public reporting purposes where feasible.

Recommendations:

AHIP agrees with CMS that the COVID-19 pandemic continues to impact the validity of the measures used in the VBP program. We agree with CMS's proposal to continue using the revised

the scoring and payment methodologies for FY 2023 and to suppress the HCAHPS and the HAI measures. We recommend that CMS not publicly report the results of any measure suppressed because of the impact of the COVID-19 PHE. Such data is likely to be too skewed and inaccurate to support stakeholder decision making.

We would also like to note that our member plans are reporting significantly lower response rates to the 2022 CAHPS survey. As we near the end of the data collection period, health insurance providers and our vendor partners are struggling to meet the required minimum response rates. While responses have been declining for several years, this year's data is particularly worrisome. Health insurance providers have worked with CAHPS vendors to combat declining response rates by oversampling. However, despite such efforts, early analysis of 2022 response rates by several member health insurance providers show a 2.5 to 5 percentage point decline in initial 2022 response rates compared to 2021 response rates. Thus, we believe CMS may need to make accommodations related to the incorporation of CAHPS in the MA Stars program as well.

Moreover, we think it is time for CMS to rethink its approach to patient experience reporting in general. The pandemic is certainly the cause of some, but not all, of the decline in CAHPS response rates. However, this compounds an underlying downward trend where several members have noted double digit declines in response rates. These declines have been across all product lines, and, to some extent reflect the changing way in which we interact with our enrollees. Health insurance providers and our CAHPS vendors have found that consumers are increasingly less likely to open unsolicited mail or answer phone calls from unfamiliar numbers. At the same time, virtually all health insurance providers now have apps and web-based platforms to interact with enrollees.

We urge CMS to continue working with AHRQ to research longer-term solutions to improve the CAHPS survey and response rates including reducing its length, revising the questions to better reflect the use of telehealth, and creating a web-based response option. As noted in our comments on the 2023 Medicare Advantage and Part D Advance Notice, we very much appreciate CMS' work to improve the CAHPS survey with the testing of a web-based tool. A web-based tool would align with how consumers want to respond to the survey. Allowing a web-based or other online format could make responding more convenient and less burdensome. We include this here, in our IPPS comments, as we strongly support alignment of quality measures across plans and providers. Thus, we think this fresh review of CAHPS should be applied across the board to all of the versions, including HCAHPS.

NHSN Healthcare-Associated Clostridioides difficile Infection and Hospital-Onset Bacteremia & Fungemia Outcome Measure

CMS also requests information on the potential future adoption of the National Healthcare Safety Network (NHSN) Healthcare-Associated Clostridioides difficile Infection Outcome Measure and the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure in the Hospital VBP program. CMS notes that this request for information (RFI) supports the agency's goal of

moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs.

Recommendations:

AHIP appreciates CMS's efforts to advance patient safety and agrees digital quality measurement has the potential to enable measurement of new areas while reducing the burden of measurement. We agree that the Healthcare-Associated Clostridioides difficile Infection Outcome measure and Hospital-Onset Bacteremia and Fungemia Outcome measures address important aspects of patient safety. We also agree that the digital version of the C. difficile infection measure could be more valid and reliable than the lab reported version as the digital version requires both microbiologic evidence of CDI in stool and evidence of antimicrobial treatment could better identify cases. We also believe the Hospital-Onset Bacteremia and Fungemia Outcome measure could serve as an important complement to the NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome measure and NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome measure.

However, hospitals will have varying ability to report using a digital version of the measure and while we appreciate the CDC's work to allow reporting using alternatives to Fast Healthcare Interoperability Resources (FHIR®) such as Health Level 7 (HL7) Clinical Document Architecture (CDA), it is unknown how using different versions of the measure would impact results. Moreover, the revisions to the specifications from the lab-reported to the digital versions could impact results having nothing to do with hospital performance. CMS should perform testing to understand how the versions of the measure compare (e.g., compare FHIR reported to CDA reported and lab-reported). CMS should not publicly report the results of these measures until it is understood how results would compare. In doing so, CMS should start by implementing these measures as voluntary measures in the IOR program and provide hospitals with confidential feedback on their results. Publishing results with variation due to the measure itself rather than provider performance risks confusing and misleading consumers and other stakeholders that depend on the results published on Care Compare. Moreover, CMS should not adopt these measures for the HVBP program or HAC reduction program until hospitals can consistently report using FHIR or testing confirms comparable results using different reporting methods.

V.J. Hospital-Acquired Conditions (HAC) Reduction Program: Proposed Updates and Changes

The HAC Reduction Program creates an incentive for hospitals to reduce the incidence of hospital-acquired conditions by reducing payment by 1% for applicable hospitals that rank in the worst performing quartile on select measures of hospital-acquired conditions.

COVID-19 Policies

CMS proposes to suppress the HAC measures and thus the penalties associated with the program in FY 2023. CMS will publicly and confidentially report the CDC NHSN HAI measure for FY 2023, but it will not calculate or report measure results for the CMS PSI 90 measure due to misaligned data periods. In addition, CMS proposes to suppress the CY 2021 CDC NHSN HAI measures data from the FY 2024 HAC Reduction Program.

CMS also proposes to make a technical update the CMS PSI 90 measure specifications to risk-adjust for COVID-19 diagnosis beginning with the FY 2024 HAC Reduction Program Year.

Recommendations:

AHIP and its members appreciate CMS's consideration of the challenges COVID-19 could create in fairly assessing hospital performance. We agree that the COVID-19 pandemic could have disproportionate impacts on hospital performance given geographic and temporal variation in surges of cases. We support CMS's proposal to suppress the HAC measures, and thus the penalties associated with the program in FY 2023.

We agree with the proposal to continue providing hospitals confidential reports of their scores on all measures in the program. However, we have significant reservations about CMS publicly reporting the results of any measure suppressed under the cross-program measure suppression policy. We do not believe this information will be accurate enough for stakeholder decision making and CMS should perform analyses to ensure the reliability and validity of the results of each measure before reporting them publicly. If CMS does choose to report the results of a measure based on data from the PHE, the agency should consider strategies to ensure the accuracy of the information provided to consumers such as using data from before the PHE, excluding data from 2020 and 2021, and assessing performance changes to ensure new results track with historical performance. Additionally, CMS should provide appropriate caveats and education to clarify the results are based on data from the PHE.

While we support CMS's efforts to protect access to care and ensure healthcare providers can maintain operations, we recommend CMS consider ways to protect patient safety and promote infection control practices to ensure patients are not exposed to COVID-19 while hospitalized. AHIP supports efforts to encourage vaccination against COVID-19 for staff and patients as well as the adoption of effective infection control practices. As a start, CMS could consider leveraging the HAC policy per the Deficit Reduction Act that prevents certain medical conditions that a patient develops during a hospital stay (not present on admission (POA)) from moving the DRG from a no Complication or Comorbidity (CC) tier to a CC or a Major Complication or Comorbidity (MCC) tier. CMS should also ensure that hospitals do not receive the Medicare add-on payment of 20% outlined by the Coronavirus Aid, Relief, and Economic Security (CARES) Act for those cases that were not POA. As a general matter, we note that we

do not support the extension of the 20% add-on payment for COVID-19 patients beyond the expiration of the PHE, consistent with the authorizing statutory language.

CMS could also explore ways to leverage the HAC Reduction Program in the future to incentivize hospitals to adopt policies to avoid iatrogenic COVID-19 infections. While there are not yet measures of rates of COVID-19, we encourage CMS to work with the CDC to develop a NHSN measure that could be adopted for use in the IQR and HAC Reduction programs.

NHSN Digital Measures

CMS seeks information from stakeholders on the potential future adoption of two digital NHSN measures: the NHSN Healthcare-associated Clostridioides difficile Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure. CMS also requests information on overarching principles for measuring health care quality disparities across CMS Quality Programs.

Recommendations:

AHIP appreciates CMS's efforts to advance patient safety and agrees digital quality measurement has the potential to enable measurement of new areas while reducing the burden of measurement. We agree that the Healthcare-Associated Clostridioides difficile Infection Outcome measure and Hospital-Onset Bacteremia and Fungemia Outcome measures address important aspects of patient safety. We also agree that a digital version of the C. difficile infection measure could be more valid and reliable than the lab reported version as requiring both require both microbiologic evidence of CDI in stool and evidence of antimicrobial treatment could better identify cases. We also believe the Hospital-Onset Bacteremia and Fungemia Outcome measure could serve as an important complement to the NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome measure and NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome measure.

However, CMS should not adopt the two new digital NHSN measures until it is clear that using different reporting mechanism will not impact results, and then should implement on a staggered basis. Hospitals will have varying ability to report using a digital version of the measure and while we appreciate the CDC's work to allow reporting using alternatives to FHIR such as Health Level 7 (HL7) Clinical Document Architecture (CDA), and potentially other formats it is unknown how using different versions of the measure would impact results. Moreover, the revisions to the specifications from the lab-reported to the digital versions could also impact hospital performance. CMS should perform testing to understand how the versions of the measure compare (e.g., compare FHIR reported to CDA reported and lab-reported). CMS should implement these measures as voluntary measures in the IQR program as a starting place and provide hospitals with confidential feedback on their results. CMS should not publicly report the results of these measures until it is understood how results would compare across version of

the measure. Publishing results with variation due to the measure itself rather than provider performance risks confusing and misleading consumers and other stakeholders that depend on the results published on *Care Compare*. Moreover, CMS should not adopt these measures for the HVBP program or HAC reduction program until hospitals can consistently report using FHIR or testing confirms comparable results using different reporting methods.

IX. A. Assessment of the Impact of Climate Change and Health Equity—RFI

CMS includes an RFI on how to better prepare for climate threats and how to handle the intersection of climate change and health concerns. Its' focus is on how hospitals, nursing homes, hospices, home health agencies, and other providers can best prepare for climate change's effect on beneficiaries and consumers, and how CMS can support them. CMS also seeks to understand how environmental inequities can impact communities' health, and how environmental dangers can affect hospitals' ability to meet community needs.

Recommendations:

AHIP and our member health insurance providers recognize the link between physical and emotional wellbeing and the health of the environment. We know that environmental hazards such as air and water pollution can lead to greater health risks and that vulnerable communities are often put most at risk. While AHIP is grateful for the opportunity to share our views on how best to prepare the healthcare system to address the effects of climate change on the health of the individuals and communities we serve, we do so with the knowledge that these are large-scale, systemic problems that cannot be effectively addressed by a single actor or group of actors. Rather, they require the energy and attention of a broad-based, multidisciplinary public-private partnership. We appreciate CMS's focus on this issue and the opportunity to consider ways in which CMS can support provider preparedness in addressing these challenges.

Health insurance providers and other "covered entities" subject to the Health Insurance Portability and Accountability Act (HIPAA) are required under HIPAA to have in place contingency plans to keep operations running in emergencies. Covered entities are required to undertake planning and business continuity activities in preparation for anticipated emergencies (e.g., hurricane-prone and flood-prone areas, wildfires or air quality concerns, earthquakes). Existing HIPAA regulations provide a solid basis for planning and preparing when responding to disasters and other emergency situations. However, disasters have increased five-fold over the past 50 years according to the World Meteorological Organization (WMO) due in part to climate change. It can be difficult effectively anticipate both the type of emergencies to be prepared for and how to prepare—as evidenced by the COVID-19 pandemic. Thus, the federal government

¹WMO, "Weather-Related Disasters Increase Over Past 50 Years, Causing More Damage But Fewer Deaths," (Aug. 31, 2021); available at: https://public.wmo.int/en/media/press-release/weather-related-disasters-increase-over-past-50-years-causing-more-damage-

fewer#:~:text=The%20number%20of%20disasters%20has,deaths%20decreased%20almost%20three%2Dfold.

could play a key role in educating providers, plans, and other stakeholders about the potential impacts of climate change, whether those impacts are already identified or are unidentified.

AHIP also agrees that addressing and mitigating the impacts of climate change is necessary to improving health outcomes and promoting health equity. Climate change is an equity issue as communities of color are disproportionately exposed to environmental pollutants. For example, the Environmental Protection Agency has linked asthma in Black and African children to the disproportionate exposure to environmental pollution in these communities.²

Health insurance providers are actively working to reduce health disparities in the communities they serve, including those caused by climate change, through innovative ways efforts designed to address social factors that negatively impact health. Across the country, health plans are partnering with local communities to innovate and create new service delivery models to deliver critical resources to vulnerable communities, such as safe and affordable housing, healthy food, and safe drinking water. Health insurance providers are also directly addressing the impacts of climate health is through pledges to reduce greenhouse gas emissions or become carbon neutral.

However, while health insurance providers are committed to participating in a multi-stakeholder response to climate change, ongoing pressure to control premium costs as well as federal and state rules regulating what "counts" as a medical expenditure for the purposes of establishing medical loss ratios applicable to most types of health insurance means that health insurance providers have limited available resources to invest in mitigating the impact of climate change and the health-related social factors climate change exacerbates.

We encourage CMS to partner with inter-governmental agencies to address this issue holistically. This is a complex issue that will require many resources outside of CMS and HHS to be impactful.

IX. B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—RFI

CMS is seeking comment on considerations the agency can take into account when advancing the use of measurement and stratification as tools to address health care disparities and advance health care equity. CMS seeks comment on key considerations in five specific areas that could inform its approach: (1) Identification of goals and approaches for measuring health care disparities and using measure stratification across CMS quality programs; (2) Guiding principles for selecting and prioritizing measures for disparity reporting across CMS quality programs; (3) Principles for social risk factor and demographic data selection and use; (4) Identification of meaningful performance differences; and (5) Guiding principles for reporting disparity results.

² EPA, "Children's Environmental Health Disparities: Black and African American Children and Asthma," available at: https://www.epa.gov/children/childrens-environmental-health-disparities-black-and-african-american-children-and-asthma

CMS also seeks comment on additional disparity measurement or stratification guidelines suitable for overarching consideration across quality programs.

Recommendations:

AHIP strongly supports the goals of this RFI and considers health equity a priority of its own. For far too long, discrimination and systemic racism have served as barriers to health equity for minority and underserved communities. Health insurance providers agree that mitigating these barriers to care is key to an equitable health care system and are actively promoting health equity by taking concrete steps to reduce disparities.

AHIP applauds CMS's efforts to leverage its' quality programs to promote health equity. Performance measurement and value-based care are underutilized levers to incentivize the health care system to become more integrated and cross-sectoral to eliminate healthcare disparities. AHIP has established several workgroups devoted to reducing disparities in healthcare including one that focuses specifically on identifying ways in which to measure disparities within value-based arrangements.

As CMS seeks to implement disparities reporting in its quality program, we urge CMS to consider several factors to ensure reporting is fair and drives the healthcare system to promote equity. First, it is essential that disparities reporting convey differences based on provider performance and not underlying factors outside a provider's control. CMS should ensure that performance measures as well as methods for stratifying results account for underlying differences. Next, additional work is needed to clarify how disparities are defined. CMS should work with stakeholders to develop and test metrics for identifying measure-specific disparities. The field needs to develop science and analytics to understand if a difference in performance on a given measure is a true disparity in care that is statistically significant. Finally, CMS should ensure that disparity reporting does not cause fragmentation or reinforce care silos. Reducing disparities and promoting health equity will require all healthcare stakeholders to work together. Disparity reporting should encourage collaboration across a care team to address equity in a comprehensive way.

We commend CMS for its work to evaluate how these powerful tools can best be used to promote health equity. To support that work we have developed recommendations for each of the five areas.

Area one: Identification of goals and approaches for measuring health care disparities and using measure stratification across CMS Quality programs

CMS notes the that one of the agency's goals is to give healthcare providers actionable and useful results. By quantifying healthcare disparities (for example, through quality measure stratification), CMS aims to provide useful tools for healthcare providers to drive improvements and notes that stratified disparity information could drive system-wide improvements. There are

multiple approaches to stratifying measures including within-provider and across-provider comparisons. CMS notes concerns about the potential for measurement bias including algorithmic bias and selection bias due to inadequate representation of subgroups of patients in measure cohorts.

Recommendations:

Achieving health equity is a priority for AHIP and its members. We believe key investments in performance measurement will allow for the identification of disparities in care and promote equitable care. COVID-19 has shown the urgency of reducing healthcare disparities and promoting health equity. Racial and ethnic minorities, individuals with disabilities, individuals who have low incomes, individuals who live in rural or inner urban areas, and individuals with other social risk factors are more likely to face barriers to care and receive lower quality care.

Performance measurement is increasingly serving as a driver of healthcare payment through the adoption of value-based care and alternative payment models. However, few of these performance measures focus on reducing disparities or advancing health equity. Performance measurement offers a powerful and underutilized tool to better understand if patients are receiving suboptimal care because of their social risk factors and to incentivize healthcare providers to improve quality.

AHIP has identified quality as a crucial aspect of our framework to promote health equity. Our work centers on using stratified measures to identify disparities, reducing disparities in quality, and ensuring providers use evidence-based interventions to reduce disparities. In furtherance of this goal AHIP has convened a Health Equity Measures for Value-Based Care workgroup to explore ways to leverage performance measurement to promote health equity and reduce healthcare disparities. This workgroup is reviewing currently available measures that directly promote actions to address equity, determining which current cost and quality measures should be prioritized for stratification, and identifying concepts where measure development is needed.

To realize the full potential of efforts to measure health care disparities and utilize measure stratification, stakeholders must accept and trust the results of both performance measure and disparity reporting. Ensuring stakeholders are aligned on the goals of measurement and the approaches use to measure disparities will encourage buy-in and incentivize action. With this perspective in mind, we encourage CMS to consider the following goals for measuring healthcare disparities across CMS programs.

Select Meaningful Measures

As outlined below, AHIP's Health Equity Measures for Value-Based Care Workgroup has developed selection principles for equity measures. Our work has focused on both stratifying existing performance measures to identify disparities and implementing measures that directly assess health equity and the use of interventions to achieve it. We have also noted the need to differentiate between programs focused on quality reporting and those that have financial

implications. Measuring disparities and incentivizing equity in a manner that directs resources away from healthcare providers or health insurance providers that serve vulnerable populations will only serve to make a bad situation worse. As such, our work has established two sets of measure selection criteria: one set of criteria for more challenging, innovative measures intended solely for use in quality reporting and improvement and another set of more established and tested measures for use in value-based care arrangements. We detail these criteria in response to section two below as we believe they are a complement and enhancement to the criteria CMS outlines in this RFI.

Identify Meaningful Differences in Performance

As noted above, additional work is needed to define healthcare disparities and better understand when variation in performance represents a statistically meaningful disparity. As noted above, CMS should test measures and analyze results to understand if those results actually evidence a true disparity in care.

Additionally, it is essential that disparities reporting convey differences based on provider performance and not underlying factors outside a provider's control. We recommend CMS identify and consider ways to address geographic variation and the potential influence of a healthcare provider's location and patient population on its score. In addition, we ask that CMS consider appropriate risk adjustment to ensure that providers who serve more complex populations are not unfairly judged or financially penalized.

CMS should consider how information on disparities will be used when determining the best approach to adjust for social risk factors. Use in a penalty only payment program requires a greater degree of certainty in performance than use in a program that incentivizes through bonus payments. For example, while CMS has chosen to focus on peer group comparisons to risk adjust the HRRP, there may also be a need to include social risk factors in the risk adjustment models of some measures. We recommend CMS continue to perform analyses to determine the need to include social risk factors in the risk adjustment models applicable to individual measures and sets of measures across its suite of programs to ensure these measures identify meaningful differences in performance and do not unfairly penalize healthcare or health insurance providers serving vulnerable populations.

Provide Actionable Information

A key challenge to using quality measurement to address disparities will be understanding how to incentivize and reward both attainment and improvement. We recognize the inherent challenges of serving socially vulnerable populations; however, we must ensure quality is improving for everyone who accesses our healthcare system.

Ensure Valid and Reliable Results

Measures prioritized for stratification should be valid, reliable, and assess concepts that provide meaningful information on the quality of care for a care setting or practice area. We appreciate

CMS's efforts to test and validate the measures used in its quality programs. We encourage CMS to ensure multi-stakeholder buy-in on measures selected for stratification and to encourage alignment in measures used and stratified across public and private payers. We support CMS's consideration of the issue of measurement bias and encourage CMS to consider the issues of statistical validity and reliability caused by stratification where a given provider may only have a small number of patients for whom a given measure is relevant. This will be a critical issue when selecting measures and publicly reporting stratified results. As detailed in our response to section two of the RFI, our work has noted the role that stratifying upstream measures of prevention can play to both address important healthcare disparities and ensure denominators large enough to produce valid and reliable results.

Encourage Alignment

Synthesizing efforts across the field reduces the burden of measurement and keeps efforts to measure disparities and promote health equity focused. To promote measure alignment, AHIP and CMS convened the Core Quality Measures Collaborative (CQMC) to identify priority measures for use across public and private payers. As a first step to alignment, the CQMC identified 10 core sets of measures in clinical areas known to have high costs, variations in quality, and misaligned measures. This year the CQMC convened a new workgroup focused on health equity to identify priority measures for stratification among other work. CMS could look to the work of the CQMC to identify current measures to prioritize for stratification. Additionally, AHIP's Health Equity Measures for Value Based Care Workgroup is currently selecting a set of health equity measures that could be prioritized for voluntary use across private sector payers. We would be happy to share the results of this work with CMS when it is finalized.

Use Accurate Data

Performance measurement depends on the availability of accurate data. As CMS considers options to address equity through its quality programs, we recommend continued consideration of the challenges of sociodemographic data collection and the importance of ensuring data on sensitive issues such as race, ethnicity, sexual orientation, and gender identity is collected in a trusted relationship and with the minimum amount of burden to the consumer. Building consumer trust and understanding of the purpose and use of data collection is essential to the success of efforts dependent on improving data on demographics and social risk. CMS should work with healthcare providers to promote patient privacy and provide guidance on best practices for data collection and storage. We also ask CMS to consider the challenges to both imputed and currently available self-reported data when choosing how to publicly display stratified results. Our concerns are detailed in section three of our response. Finally, CMS should consider ways to leverage technology and interoperability to improve data sharing. Improved data sharing could support quality measurement and ensure healthcare and health insurance providers have the necessary information to facilitate care while minimizing the response burden on patients.

Area two: Guiding principles for selecting and prioritizing measures for disparity reporting across CMS quality programs

CMS notes it is considering expanding the agency's efforts to provide stratified reporting for additional clinical quality measures, provided they offer meaningful and valid feedback to healthcare providers on their care for populations that may face social disadvantage or other forms of discrimination or bias. To support these efforts, CMS solicits feedback on several principles by which it could prioritize measures for disparity reporting across quality CMS programs:

- Existing Clinical Quality Measures
- Measures with Identified Disparity in Treatment or Outcomes for the Selected Social or Demographic Factor
- Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons
- Outcome Measures and Measures of Access and Appropriateness of Care

Recommendations:

Overall, AHIP supports the principles for selecting and prioritizing measures for stratified reporting across CMS quality programs. We agree that these principles balance fair and accurate comparisons with providing important information about healthcare disparities.

Existing Clinical Quality Measures

As noted above, we agree that measures prioritized for stratification should be valid, reliable, and assess concepts that provide meaningful information on the quality of care for a care setting or practice area. We recommend that CMS consider taking an incremental approach and start with a small, parsimonious set of measures to stratify to not only test and validate the concept but to also help center an organization's focus rather than spread finite resources over lots of different areas in a "boil the ocean" approach. Having a parsimonious set of measures focused on upstream issues will hopefully lead to meaningful and impactful efforts that build community trust and avoid performance disparities that evidence resource differentials between providers and communities rather than level of effort or engagement in the work of meaningfully addressing health equity. As noted above, aligning measures across programs and public and private payers could ensure consistent, focused use of existing clinical quality measures to identify disparities. We encourage CMS to look to the work of the CQMC as well as AHIP's Health Equity Measures for Value Based Care Workgroup.

<u>Measures with Identified Disparity in Treatment or Outcomes for the Selected Social or Demographic Factor</u>

We also agree that CMS should explore stratifying measures that address conditions with known disparities. We suggest that CMS explore measures addressing maternal health, cancer, cardiology, chronic kidney disease and End Stage Renal Disease. CMS should also consider measures that address upstream prevention and promote population health as addressing disparities in prevention upstream can reduce disparities in treatment downstream and promote better outcomes for patients. CMS could also explore stratifying process measures that address conditions with known disparities. Ostensibly, process measures are more in the control of providers, thus concerns about inadequate risk adjustment is minimized.

Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons

We strongly support CMS's principle to prioritize measures with adequate sample size to allow for reliable and valid comparisons. Stakeholders must trust the results of stratification if real change is to be achieved and reducing potential bias from small numbers can help ensure results are actionable and believable. AHIP has convened a Health Equity Measures for Value-Based Care workgroup to identify measures to prioritize for stratification. Our work has found that larger sample sizes is another reason to prioritize upstream prevention measures. As healthcare data becomes more interoperable, CMS could also explore ways to leverage digital quality measures (dQMs) and the potential pooling of data. That effort could be facilitated by the Trusted Exchange Framework and Common Agreement (TEFCA).

Outcome Measures and Measures of Access and Appropriateness of Care

Finally, we support CMS's principle to prioritize outcome measures for stratification. While we agree there are important roles for structure and process measures, outcome measures assess what matters most to patients and health insurance providers. AHIP agrees important disparities could be identified by stratifying additional outcome measures currently used in CMS's quality reporting programs. We recommend CMS consider stratifying all-cause and condition-specific mortality measures as well as HCAHPS and other patient experience measures. Mortality is an essentially important outcome and unfortunately disparities exist in this area.

Patient experience surveys could be leveraged to better understand experiences of discrimination and impacts of structural racism. We also recommend that CMS consider ways to utilize its current patient experience surveys such as CAHPS, the Health Outcomes Survey, and the Qualified Health Plan Enrollee Satisfaction Survey to address equity. These tools could be tailored to better identify and understand the experiences of consumers who experience discrimination. To ensure consumers respond, CMS could consider revising these surveys to remove extraneous items that may be duplicative or have poor reliability.

We also agree that stratifying access measures could help illuminate important disparities. While limited in the current hospital quality program measure sets, CMS could also explore stratifying access measures if such measures are developed and implemented in the future. Some potential concepts that could be explored include emergency room utilization, preventable health service utilization, and medication adherence. We also recommend that CMS consider stratifying cost measures such as the Medicare Spending Per Beneficiary measure and the risk-standardized

payment measures as stratifying cost measures could serve as a protection against potential stinting of care as Black patients are found to have lower total costs, potentially due to access challenges.

Enhanced Criteria Based on AHIP's Work

As noted above, AHIP's Health Equity Measures for Value-Based Care workgroup is exploring ways to leverage performance measurement to promote health equity and reduce healthcare disparities. This group has developed measure selection criteria as part of this work. We believe these criteria could be a complement to the work CMS has done to advance health equity and serve to promote alignment across public and private payers to ensure that we are working together to achieve the best possible outcomes for all consumers. We would be happy to share more detailed results of this work with CMS.

Based on our work identifying and developing measurement domains to promote health equity, we recommend the following principles for selecting and prioritizing measures for quality and disparity reporting:

- Measures meaningfully advance health equity or reduce healthcare disparities;
- Measures are unlikely to promote unintended adverse consequences;
- Measures provide a person-centered and holistic view of quality, including consideration of Social Determinants of Health (SDOH) and experience of care;
- Measures provide meaningful and usable information;
- Measures incentivize work on disparities reduction and improvement rather than penalize providers and payers who serve more socially disadvantaged patients;
- Measures are tailored to specific community needs and socioeconomic circumstances and focus on improvements within those populations rather than exist as flat standards to meet;
- Measures can be impacted by an intervention; and
- Data exists and is readily accessible to accurately support measurement.

If measures will be used in value-based care, we recommend the following principles for selecting and prioritizing measures for value-based care:

- Measures meaningfully advance health equity or reduce healthcare disparities with strong level of evidence necessary to include in value-based pay arrangements;
- Measures are unlikely to promote unintended adverse consequences;

- Measures are fully developed, accepted, and implemented measures (e.g., NQF-endorsed, in use by health plans and/or CMS/states, used by NCQA or other similar entities);
- Measures should represent a balanced mix of process, outcome, structural measures;
- Measures should be implementable in value-based purchasing or alternative payment models;
- Measures should be within the locus of control of the measured entity;
- Measures should incentivize the reduction of disparities while protecting the safetynet; and
- Measures should balance between innovation and feasibility while minimizing burden.

Area three: Principles for social risk factor and demographic data selection and use

CMS notes there are many social risk factors that can impact patient outcomes. However, identifying and prioritizing specific indicators of social risk or demographic variables to consider for stratified analyses and measure reporting can be challenging due to the large number of variables identified in the literature as potential risk factors for disparities in health care and poorer health outcomes. Moreover, the limited data available for many self-reported social risk factors and demographic factors across the healthcare sector can confound efforts to measure disparities.

CMS expects to continue evaluating patient-reported sources of social risk and demographic information. CMS is also considering three sources of social risk and demographic data that would allow the agency to report stratified measure results:

- Billing and Administrative Data;
- Area-based Indicators of Social Risk Information and Patient Demographics; and
- Imputed Sources of Social Risk Information and Patient Demographics.

Recommendations:

AHIP supports adding stratification by race, ethnicity, and other demographic and social risk factors to hospital's confidential reports to identify disparities in care. We agree that this additional information could help hospitals better understand where efforts are needed to improve care and provide necessary supports and the impact that structural and socioeconomic factors have on outcomes and disparities.

We believe self-reported sociodemographic data is the highest quality data but given the limited availability of self-reported sociodemographic data, we caution against its use for

disparity reporting and stratification at this point in time. We recommend that CMS establish minimum denominators that are statistically significant for fair comparisons on reducing disparities before self-reported data is used for disparity reporting and stratification. We also request CMS set reasonable timelines to transition to self-reported data. It will take time to build trust and understanding with consumers. It will also take time to build the necessary technological infrastructure and standardized data elements and codes to ensure standardized and codified data storage that has the appropriate privacy and security protections in place. We appreciate CMS acknowledging the challenges of collecting selfreported data and the limitations of the data shared from the Social Security Administration. Thus, CMS should understand that overcoming historical and technological barriers will require time and be an iterative process. We appreciate the need to urgently address issues of health equity and as such, recognize NCQA's leadership in this area through data collection requirements and stratification of HEDIS measures. However, overly aggressive timelines could jeopardize work to build trust with consumers and ensure data is accurate. We recommend CMS work with NCQA and other stakeholders to develop reasonable goals and timelines for collection of self-reported data.

We are supportive of efforts to enhance self-reported data collection. Improved interoperability holds promise to facilitate the collection of self-reported data. By sharing data across stakeholders, we can improve the availability of information and minimize the burden on consumers who may be repeated asked to provide demographic information. The inclusion of demographic and social needs data elements in the United States Core Data for Interoperability (USCDI) will improve data standardization and allow data to be shared more easily across disparate information systems. Moreover, the TEFCA processes are being implemented and stand to allow a transformative change for data sharing once the infrastructure is in place and operational. This will include Individual Access Services for individuals, as well as to realize the benefits for consumers and to reduce the burden with data sharing in siloed and non-integrated processes.

We also recommend CMS work with stakeholders to share best practices on consumer-centered data collection approaches and workflows to expand and improve available options for demographic and social risk data collection. We also recommend that CMS start with a small set of demographic or social risk factors so organizations can focus their efforts and more feasibly implement self-reported data collection methods. Consumers may not feel comfortable disclosing data in all situations, leading to potential discrepancies and underreporting. Therefore, consumers should be provided multiple opportunities to share their demographic information privately to help overcome challenges with data fidelity and validation. We also request CMS adopt policies across its programs to improve the collection of self-reported data on race, ethnicity, and social risk. This includes Original Medicare. CMS should work with the states to improve the availability of data available through Medicaid enrollment to further enhance data availability and to integrate data collected from other state-administered health and social programs.

As organizations transition to self-reported data, imputed data should serve as a bridge in order to advance work on equity. We agree with the use of imputed data to allow stratification of hospital quality measures by race and ethnicity for the purposes of confidential feedback reports for quality improvement but argue against its use for public reporting. Imputed data is less accurate, especially as America becomes more diverse and increasing numbers of Americans identify as more than one race or ethnicity. Moreover, this data may lack face validity with consumers and other stakeholders who distrust imputed data and fear it could mask disparities.

We also recommend that CMS work with regulators and private payers to coalesce around a standardized imputed method that would be used across the industry. The variability and lack of alignment in imputed methods could lead to comparisons that are not apples to apples, which would mislead improvement efforts. The extent of variability and lack of alignment in imputed methods should preclude its use for public reporting or payment purposes as it risks inaccurately penalizing hospitals.

We request that CMS develop appropriate guardrails to ensure accuracy of indirect data and ensure imputed data not add burden to consumers or providers nor distract from efforts to transition to self-reported data. Similar principles should be applied to self-reported data, establishing minimum denominators that are statistically significant to ensure that no individual could be inadvertently identified. Indirect data methods, in particular, may struggle to appropriately segment populations with statistical significance as the volume of individuals belonging to certain populations (such as Native American, Alaska Native, Asian American, Native Hawaiian, Pacific Islander) is too low. CMS should use strong, vetted algorithms for indirect data attribution (e.g., over 80% validity when compared to known self-reported race and ethnicity data).

To ensure imputed algorithms do not have potential harmful biases, we recommend CMS work with stakeholders to develop better definitions and approaches to measuring bias while supporting greater transparency of how imputed algorithms are calculated. This is important to maintain consumer trust and confidence. If algorithms are found to have biases that skew data and lead to inaccuracies, consumers may be even more hesitant to provide self-reported data in the future.

Finally, we recommend CMS update the Notice of Privacy Practices associated with the collection and use of self-reported data on demographic and social risk factors to ensure that consumers are aware of the reasons why the data are being collected, that the process is voluntary, and no adverse action will result for failing to provide the data (i.e., no loss of health benefits or access to services), and how it can be used, shared, and disclosed. The notice should cover the entire process of data collection, reporting, and data sharing. For example, an holistic view of data handling would strengthen consumer trust while ensuring sensitive data are accurate and protected. Health insurance providers that are HIPAA covered entities can also update their Notices of Privacy Practices to seek alignment with the federal effort.

CMS should also consider opportunities for consumer education and notification on the importance of self-reported data. Any entities that will be collecting and using this data should also be prepared to address the privacy and security of the data in line with HIPAA and the HITECH Act requirements via business associate contracts. At present, we await future regulations from HHS/OCR to direct HIPAA covered entities on the permitted uses and disclosures of protected health information for care coordination and similar purposes (e.g., to assist with obtaining housing, food services, etc.). Until such regulations are issued, HHS should address ways to avoid unintended consequences, including the potential the risk of discrimination from misuse of sensitive data. For example, non-HIPAA organizations should have appropriate policies for privacy, data sharing, and data governance, and data breach in line with the HIPAA and the HITECH Act requirements. Organizations that are not regulated by HIPAA or HITECH should be governed by these requirements or brought under a similar regulatory framework (e.g., the FTC regulating entities with "HIPAA-like" requirements). Informing care, population health management, and quality measurement are important functions that should occur with appropriate protection and security of sociodemographic data.

Area four: Identification of meaningful performance differences

CMS expects to consider different approaches to identifying meaningful differences in performance. Stratified results can be presented in several ways to describe to providers how well or poorly they are performing, or how they perform when compared to other care facilities. CMS notes that the agency aims to use standardized approaches where possible but also expects that decisions about how to identify meaningful differences in performance would ultimately be tailored to each individual program. CMS seeks feedback on several potential reporting methods:

- Statistical Differences;
- Rank Ordering and Percentiles;
- Threshold Approach; and
- Benchmarking.

Recommendations:

AHIP appreciates CMS's efforts to ensure disparities reporting identifies meaningful differences across providers. We recommend that CMS conduct analyses to compare the results of different methods and put the results of these analyses out for stakeholder review and public comment. This will ensure recommendations are based on not only sound statistical evidence, but also do not result in unintended consequences for healthcare providers based on location and characteristics of their patient population. Details of the analysis should include how the calculations were conducted for each approach and how the approach differs from the other approaches (e.g., how a provider's results would change). CMS should work closely with AHIP and its members as well as other stakeholders to review these analyses.

As part of these analyses, we recommend that CMS create a minimum threshold of acceptability from a statistical standpoint of what would constitute a disparity. We urge the adoption and use of metrics for which success is not solely based on percentage point improvement as this may incentivize bias in the selection of members and inappropriately reward efforts that have minimal actual impact on population level disparities in care. Moreover, a reduction in disparities should be measured against total quality of care. Providers with low quality for all patients may not demonstrate disparities in care; however, low quality should not be inadvertently rewarded.

Additionally, we recommend CMS consider ways to balance the accuracy of the information conveyed via disparities reporting with the needs of stakeholders to understand provider performance related to health equity. If information about disparities is made public, health insurance providers would be better able to better understand which health care providers in their networks were taking action to improve health equity. Private sector payers could enhance efforts by CMS and other public sectors payers to incentivize change and encourage consumers to use hospitals that provide high-quality, equitable care. However, CMS should ensure information that is publicly reported is accurate and understandable. As noted above, we do not support the public reporting of data based on indirect or imputed methods to determine a consumer's demographics. CMS could consider disparities reporting in the future if self-reported data is available and the method for determining differences is found to be evidence-based, valid, and reliable through a multistakeholder, consensus-based review. If results are publicly reported, CMS should make data conveyed via disparities reporting synergistic with the information currently reported on the *Care Compare* website to avoid conflicting or misaligned information.

Area five: Guiding principles for reporting disparity results

CMS notes the agency is exploring whether it would be prudent to first confidentially report all stratified measure results, where adopted into a quality reporting program, to give healthcare providers an opportunity to understand those results so they can begin to implement programs to reduce disparities before results publicly are publicly reported. CMS also believes it is important to report stratified measure data alongside overall measure results. Review of both overall measure results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing important information to drive quality improvement.

Recommendations:

AHIP is supportive of disparity reports but recommends CMS begin with providing confidential stratified disparity reports before moving to public reports. This would ensure health care providers and health plans have an opportunity to review results and make improvements in care delivery. It would also ensure that healthcare providers and health plans have an opportunity to review and provide feedback on the accuracy of the results before they are posted publicly. We believe this is a critically important step in the process as measures should be accurate and reflect the quality of care provided, especially when used for accountability purposes such as public reporting or value-based purchasing. As mentioned

previously, we support the use of imputed data for the purposes of identifying disparities for quality improvement but not for public reporting, given the extent of variability and lack of alignment across imputed methods used in estimating population demographics.

As CMS implements public reporting of stratified data, patients should be made aware of how data collected will be used in a way that is consistent with HIPAA. Patients may not be comfortable with public reporting due to concerns that doing so might inadvertently exacerbate existing disparities and other unintended consequences. We encourage CMS to act thoughtfully and with consumer buy-in as efforts to expand demographic data and report stratified results based on such data are implemented.

Finally, we recommend that public posting of health plan data only be done in conjunction with the public posting of government-run program data (e.g., Original Medicare, Medicaid in states without managed care, etc.) to provide relative comparisons of disparities that may occur across populations rather than populations specifically served by health plans as doing so would harm consumers seeking to compare the quality and equity of care available to them across the spectrum of available care delivery models.

AHIP and our members look forward to engaging with CMS on this important initiative.

IX. C. Continuing to Advance to Digital Quality Measurement and the Use of FHIR in Hospital Quality Programs-RFI

To supplement CMS' RFI in the FY 2022 IPPS/LTCH PPS final rule, and as part of CMS' modernization of its digital quality measurement enterprise, CMS includes an RFI to gather comment on continued advancements to digital quality measurement and the use of the FHIR standard for electronic clinical quality measures (eCQMs). In this RFI, CMS focuses on data standardization activities related to leveraging and advancing standards for digital data and approaches to transition to FHIR eCQM reporting in the future, as initial steps in the agency's transition to digital quality measurement.

In the FY 2022 IPPS/LTCH PPS final rule, CMS stated the agency's goal of moving to digital quality measurement for all CMS quality reporting and value-based purchasing programs (86 FR 5342). In this RFI CMS clarifies that it plans to transition incrementally, beginning with the uptake of FHIR API technology and shifting to eCQM reporting using FHIR standards. CMS reiterates its aim to achieve a quality measurement system fully based on digital measures.

In this RFI CMS seeks comment on:

- Revisions to the potential future definition of dQMs;
- Data standardization activities to leverage and advance standards for digital data; and
- Approaches to achieve FHIR eCQM reporting across quality reporting programs, and specifically for the Hospital IQR Program.

Recommendations:

Technology holds promise to further reduce the burden of reporting quality data while enhancing the information on quality available to all stakeholders. Digital measures and the electronic exchange of information through formats such as APIs could reduce the time and resources required to extract data from patient charts, surveys or other forms used to generate patient-reported outcome measures. Moreover, digital quality measurement (dQM) could allow novel concepts that could not previously be assessed due to data limitations.

Ongoing work by HL-7 such as the C-CDA and DaVinci Implementation Guides can lay the groundwork for better exchange of the data needed to support digital measurement. However, the necessary standards and implementation guides must be sufficiently tested and mature before widespread implementation is possible. Testing and maturity of the standards will be essential to the scalability and feasibility of digital quality measurement.

There is also a need for ONC and CMS to ensure certified EHR vendors build the data elements required for dQMs into their products. ONC and CMS must also incent providers to share data with health insurance providers electronically to ensure feasibility and alignment across payers. Using technology in this fashion will reduce provider burden while simultaneously creating information on provider value for consumers, payers, and purchasers.

We also encourage CMS to foster alignment on the adoption and approach to digital quality measurement across the industry. CMS should work with NCQA and other measure developers to ensure synergistic approaches to adopting FHIR resources. CMS should also work with the CQMC and health insurance providers to advance alignment of the use of dQMs across public and private payers.

AHIP appreciates CMS's leadership in the transformation to digital measurement and offers the following comments to facilitate this work.

Refined Definition of dQMs

In the FY 2022 IPPS/LTCH PPS final rule, CMS defined a dQM as software that processes digital data to produce a measure score or measure scores (86 FR 45342). In this proposed rule, CMS clarifies that dQMs are quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. CMS reiterates that data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources.

Finally, CMS notes it is considering how eCQMs, which use EHR data, can be refined or repackaged to fit within the dQM umbrella. CMS notes that eCQMs are a subset of dQMs and states that it considers the transition to FHIR-based eCQM reporting the first step to dQM reporting, and a potential model for how future digital reporting can occur. CMS states that while eCQMs meet the definition for dQMs in many respects, limitations in data standards, requirements, and technology have limited their interoperability. CMS also notes that currently there are multiple standards that must be supported (for example, Health Quality Measurement Format (HQMF) and Quality Reporting Document Architecture (QRDA) for eCQM data collection and reporting. Furthermore, mapping EHR data can be challenging and burdensome for providers as there is often novel data collection occurring to support quality measurement.

Do you have feedback on the potential refined definition of digital quality measures (dQMs)?

AHIP appreciates CMS's clarification that dQMs are "quality measures, organized as self-contained measure specifications and code packages..." Precise specifications are essential to ensuring the reliability and validity of a measure and to ensure it is feasible to use. We encourage CMS to ensure dQMs are reliable, valid, and fill the needs of all stakeholders by seeking multi-stakeholder feedback on candidate dQMs through processes such as the CQMC as well as through multi-stakeholder reviews such as the NQF endorsement process. However, electronic specifications in and of itself is not enough; both the inputs and outputs should be in electronic form and exchanged electronically among stakeholders. While claims-based measures are not ideal, they are dQMs and there will continue to be a role for them. Thus we also support the notation dQMS "use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems."

<u>Do you have feedback on potential considerations or challenges related to non-EHR data sources?</u>

AHIP recognizes the potential of digital measures to reduce burden and promote innovative measurement by leveraging new data sources and using data from sources other than EHRs. We agree that digital measures should be able to use data from multiple sources. Combining different types of data and data from different care settings will allow a broader scope of measurement and allow measurement of outcomes across providers and settings of care.

While incorporating non-EHR data sources could allow for measurement of novel concepts that we are currently unable to evaluate and facilitate quality improvement efforts in areas that have previously been unassessed, there are several potential challenges that must be addressed before dQMs will be able to use non-EHR data sources for performance measurement. First, it is essential that these data sources can be sufficiently standardized to support performance measurement. AHIP supports efforts to make measurement more person-centered and to ensure quality reporting and value-based payment programs assess what truly matters to patients. While we agree that sources like person-generated health data (PGHD) have the potential to provide a wide-ranging picture of a person's health and healthcare outcomes, we are concerned that the level of standardization, data quality, and data integrity may not be sufficient to support reliable

and valid quality measurement at this time. For example, there could be challenges in confirming patient-specific data. While FHIR-based data standards can provide the necessary infrastructure to share data from point-to-point, these standards do not offer a way to validate data quality. We strongly recommend CMS consider ways to maintain data integrate and address unintended consequences of inadequate data quality as the agency considers the use of more non-EHR data sources.

As one solution to these issues, we suggest CMS focus on efforts to create digital patient-reported outcome measures and leverage emerging technology such as APIs to alleviate the burden of collecting this data. Incentivizing the collection of patient-reported outcomes would allow greater understanding of outcomes from the consumer's point of view and advancement of person-centered care. We also recommend CMS work with stakeholders to discuss alignment, where applicable, with initiatives such as the FDA's consideration of use of and guidance around PGHD.

Secondly, CMS should consider how to support the aggregation of data from multiple sources. Such aggregation could alleviate the burden of measurement while providing better information to assess quality of care. To this end, there may be a role for HIEs and Health Information Networks or other models for sharing and storing this information. We believe this exchange requires additional thought and consideration, and in the context of TEFCA. However, we are concerned that payers or providers could be required to purchase certain software or be forced to pay to join registries or HIEs. Such requirements could inadvertently increase the cost and burden of measurement.

Data Standardization Activities to Leverage and Advance Standards for Digital Data

CMS notes it is considering implementing eCQM quality reporting via FHIR-based APIs based on standardized, interoperable data. Advancing data standardization is a critical step for this implementation, and for long-term digital measurement strategies. CMS notes its belief that standardized data and FHIR APIs are important pathways for advancing interoperability and notes its goal is for data to be sent and received via trusted exchanges, and for patients to have access to their data. CMS also states that operations activities (for example, prior authorization) are also dependent on standardized, interoperable data. Additionally, standardization is necessary across implementation guides, or rules for how a particular interoperability standard should be used, and across value sets that organize the specific terminologies and codes that define clinical concepts.

CMS states that commenters suggested, and CMS agrees with the use of data elements for quality measurement that are consistent with ONC's USCDI standard, where possible. To advance the use of standardized data, models, implementation guides, and value sets in quality measurement, CMS continues to focus on leveraging the interoperability data requirements for standardized APIs in certified health IT, set by the ONC 21st Century Cures Act final rule and any future updates made in rulemaking, as a vehicle to support modernization of CMS quality

measure reporting. CMS also notes it is collaborating with ONC to build requirements to support data standardization and alignment with requirements for quality measurement. For example, a USCDI+ quality measurement domain currently being explored would support defining additional data specifications for quality measurement that harmonize, where possible, with other Federal agency data needs and inform supplemental standards necessary to support quality measurement.

CMS also notes it is considering how to leverage HL7 implementation guides, including the following:

- US Core Implementation Guide;
- Quality Improvement Core (QI Core) Implementation Guide;
- Data Exchange for Quality Measures (DEQM) Implementation Guide; and
- Quality Measure (QM) Implementation Guide.

CMS also states it is considering if CMS specific implementation guides may be necessary.

Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?

The use of common open HL7 FHIR standards would ensure data is consistent and allow the exchange of the data with CMS and other quality programs. However, content and technical standards as well as implementation guides must be fully developed and sufficiently tested for successful implementation of truly interoperable sharing and transparency. Mature standards should be a precursor to implementation. Ongoing work by HL7 such as the C-CDA and Da Vinci Implementation Guides can lay the groundwork for better exchange of the data needed to support measurement.

However, other information will be necessary in addition to the implementation guides to promote data standardization and consistent implementation of FHIR-based measures. CMS should also make the code sets for FHIR-based measures available for stakeholder review to ensure feasibility and consistent use.

Approaches to Achieve FHIR eCQM Reporting

CMS lists activities it continues to undertake to support the reporting of FHIR-based eCQMs and dQMs such as converting current Quality Data Model (QDM)-based eCQMs to the FHIR standards and testing the implementation of measures respecified to FHIR.

CMS notes that commenters expressed concerns about infrastructure readiness and notes it is interested in data flows that support using the same data for measurement and to provide

feedback to providers at multiple levels of accountability, such as at the individual clinician, group, accountable care organization and health plan levels, as are used for patient care and other use cases (for example public health reporting).

Are there additional venues to engage with implementors during the transition to digital quality measurement?

AHIP has partnered with CMS and the National Quality Forum (NQF) to convene the Core Quality Measures Collaborative, a coalition of healthcare leaders working to advance quality measure alignment across public and private payers. While we agree that transitioning to dQMs presents an opportunity to reduce the burden on healthcare providers, reporting is only one aspect of the measurement enterprise. Burden can also be introduced when healthcare providers are required to report different measures to different payers and when they receive conflicting reports on the quality of care they provide.

AHIP and its members support exploring opportunities to further align measures across public and private payers. We agree that digital measurement provides new potential for further alignment on not just the measures themselves but the full measurement model from the collection of data elements through reporting and calculation of the measures, and back to the providers for near real-time feedback and clinical decision support at the beside.

To this end, the CQMC has undertaken work to support the transition to digital quality measurement as well as to identify ways to further align quality measurement models. The CQMC digital quality measurement workgroup is focused on promoting greater adoption of dQMs in the CQMC core measure sets, increasing the use of dQMs across payers, better understanding the barriers to digital quality measurement, and identifying areas that could most benefit from a transition to digital measurement. The CQMC measure model alignment workgroup is tasked with defining a quality measurement model and exploring opportunities to promote alignment across the measurement enterprise such as the potential for centralized data reporting and best practices for how measure results are communicated to healthcare providers and other stakeholders.

The CQMC offers a unique forum for CMS to engage with measure implementers to facilitate the transition to digital quality measurement. We look forward to continuing the partnership with CMS to improve care for all Americans through these efforts.

What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?

While we agree that FHIR-based quality reporting has the potential to reduce burden, the necessary standards and technology must be readily available to promote widespread adoption. CMS should continue to invest in HL7's Da Vinci Project to advance additional quality related use cases. Furthermore, CMS and ONC should ensure certified EHR vendors build digital measures into their products and incent providers to use them. Finally, CMS and ONC should

leverage interoperability to promote data sharing across the healthcare system. Encouraging sharing of data between healthcare and health insurance providers could promote better patient care and improve quality measurement. Using technology in this fashion will reduce the burden on providers while simultaneously creating robust information on provider value for consumers.

While FHIR-based quality collection and reporting may potentially reduce the effort involved in measurement in the longer term, there are several precursor steps that need to be taken as setting up this capability will be burdensome for health IT vendors and providers. First, some paper measures have been translated into machine-readable eCQMs, those that exist do not cover nearly enough care processes and outcomes to replace the current, manual quality measurement process. In addition, those that exist are not truly automated and interoperable from end to end (that is from data extraction to submission). Thus, in order to truly advance the goal of digital quality measurement additional measure development must be prioritized and that development process must include field testing to avoid the challenges that have plagued current eCQMs.

Second, mature standards must be in place for both content and exchange. While HL7 initiatives have been working feverishly, there are only a handful of example use cases that have been fleshed out regarding the exchange of quality data between providers and payers. Third, in order to support the efficient scaling of eCQMs and dQMs as a whole, there are necessary infrastructure components that must be built and tested. For example, for providers to seamlessly share data with payers beyond CMS, national solutions for accurate provider and payer directories must be available and tested. In addition, the APIs are currently configured to share a single patient's data at a time at their request per the ONC requirements. Additional changes will need to be made to the APIs to allow for bulk exchange with payers.

Are there other critical considerations during the transition?

First and foremost, we believe that data exchange and tools must protect patient privacy and the security of health information. As the healthcare ecosystem and its related information technology have evolved, there continue to be both new opportunities and new threats to patient privacy. While AHIP and its member health insurance providers wholeheartedly support moving to a health care system where data flow seamlessly among stakeholders to achieve improved wellness and better health outcomes, we remain concerned about policies that could result in sensitive information being shared with entities that are not covered by HIPAA or a similar, equally protective, regulatory paradigm.

Technology holds promise to allow quality measurement to leverage new data sources such as person-generated health data and reduce the burden of collecting patient-reported outcome data. However, dQMS that utilize these novel data sources could require potentially sensitive patient data to be sent through third-party apps or other unregulated entities. Moreover, the potential for quality measurement data to be part of the USCDI and to be shared as part of the Information Blocking and Interoperability regulations risks such data being accessed by bad actors and potentially exposed to security breaches.

AHIP requests that CMS work with Congress to fill the gap in the national privacy framework by developing robust federal privacy laws and regulations applicable to organizations that obtain health care data but are not subject to HIPAA. In addition, HHS and the Federal Trade Commission (FTC) should work together to find an effective stop-gap measure that can be implemented to protect potentially personally identifiable information that could be shared via APIs.

Second, CMS should ensure that dQMs do not inadvertently increase the burden of measurement. Quality improvement depends not only on the measures used but also how they are collected, calculated, reported, applied and displayed. To achieve improvements in care, measurement must be associated with the right incentives and lead to the ability to analyze and utilize results effectively. dQMs also have the potential to further splinter quality measurement and add burden for providers by encouraging additional third parties to apply quality measures based on the data shared with them but without direct agreements with the providers being measured. This could result in measurement of providers (or plans) without agreement regarding which measures will be used, how they will be displayed, etc. AHIP requests that CMS and stakeholders work collaboratively to include sample use cases that provide examples of how dQMs would be defined, measured against the data sources, reported, and utilized.

Defining a dQM in technical terms does not address the way in which the measure fits into the measure system or how it will be implemented.

Third, CMS should consider the infrastructure challenges as the agency considers its transition to dQMs. Many payers and providers do not have the infrastructure or resources needed to successfully report and exchange electronic data. HHS should further invest in the DaVinci Project's standards development and the ONC FHIR at Scale Taskforce (FAST) to identify scalable solutions to speed adoption. Furthermore, to safely share information across parties—known and unknown—and efficiently scale connections, there must be agreed upon rules of the road. We believe that TEFCA holds potential to address these concerns and ask CMS to consider a potential quality measurement use case under TEFCA. Without the expanded acceptable uses under TEFCA, the uses of the legacy content standards for quality programs have faced issues of adoption on national networks. Without TEFCA as a framework to build trust, new FHIR-based networks could be hampered by well-intentioned but varied limitations designed to protect privacy and enhance security.

Additionally, there is still a significant gap in EHR use by clinicians and even bigger gap in their ability to exchange data with plans. Individual providers and small group practices with minimal or no EHR use may not be able to report using dQMs. Plans have expressed difficulty getting provider buy-in on current digital approaches such as NCQA's ECDS measure reporting. Clinicians who are meaningfully using EHRs may be reluctant or unwilling to share information contained in those records with public or private sector payers.

Next, CMS should promote data sharing across the healthcare system as current one-side requirements could limit the ability of health insurance providers to implement dQMs and risks causing further misalignment of measurement. Misaligned measures have been a source of extra

burden on the healthcare system. One reason performance measures are not aligned across stakeholders is the varying ability to calculate a measure. For example, private payers do not have access to the clinical data necessary to calculate current measures that use paper medical records or EHRs as data sources. The transition to digital measures presents a new opportunity to ensure all stakeholders can use the same measure; thus, reducing variation in measure specifications and the use of related measures by different payers.

We appreciate CMS's vision to leverage existing technology such as the APIs required by the Interoperability and Cures Act Final Rules to implement digital quality measurement. However, the current one-sided requirements could inhibit the potential of dQMs to reduce burden if they cannot be used by all healthcare stakeholders. Currently, plans in federal programs are required to share data via APIs under the Interoperability regulations. However, CMS and ONC's previous proposal only required plans to share information but providers. The current regulations do not require providers to reciprocate as the Cures Act Final Rule and Interoperability and Patient Access Final Rule did not include provisions requiring information sharing with payers. Without commensurate data sharing requirements on healthcare providers, private payers have limited ability to use dQMs that leverage data from EHRs or other clinical sources not available to payers. CMS should work with ONC to implement consistent data sharing requirements that could promote the adoption of aligned dQMs across the healthcare system.

Finally, we urge CMS to consider the potential impact on health equity as it transitions to dQMs. A transition away from paper-based reporting to dQMs, and the necessary attendant data exchange capabilities will require significant effort and cost. We urge CMS to consider the potential implications of this transition on health equity and access to care. It is of the utmost importance that providers who serve disadvantaged populations and who may be less well-resourced not be penalized by policies promoting digital measurement. Transitioning to FHIR-based eCQMs and dQMs will require resources and investments. As noted above, a number of provider types have historically lagged in EHR adoption including post-acute and long-term care facilities and clinicians practicing in smaller groups, rural areas, and certain specialties such as behavioral health. AHIP members have noted the challenges these providers have in using eCQMs and currently available dQMs. Assuring universal EHR adoption and utilization will be critical to the success of digital quality measurement and safety-net providers and those serving disadvantaged populations will need support to fully participate in digital measurement.

Additionally, some providers such as those in rural areas may not have sufficient broadband access to support the exchange of dQMs. Finally, in areas served by HIEs ensuring all providers are able to effectively exchange dQM data with their HIE will be critical to effective implementation. Overcoming these infrastructure and equity challenges will take time. While we appreciate CMS's clarification in this rule that the transition to digital measurement will be incremental, we urge CMS to establish a roadmap for this transition that applies across all of its quality programs and to establish milestones along the way that act as gates from step to step. At each step we strongly encourage CMS to seek input from stakeholders including health insurance providers to encourage alignment across the public and private payer landscape.

IX. D. Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)– RFI

In addition to programs focused on providers, CMS notes its interest in opportunities to encourage exchange under TEFCA through CMS regulations for certain health care payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. As an example, CMS notes it believes there may be opportunities to encourage information exchange under TEFCA to support recently finalized requirements for these payers to make information available to patients and to make patient information available to other payers as beneficiaries transition between plans in the Interoperability and Patient Access final rule. Finally, CMS is considering future opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes.

Recommendations:

We appreciate CMS's efforts to improve health care data access and interoperability and recognize the important role of payers in those efforts. AHIP and its members wholeheartedly support moving to a health care system where data flows seamlessly among appropriate stakeholders to achieve improved wellness and better health outcomes for all Americans. AHIP supports efforts to promote nationwide interoperability of health records. We fully support the TEFCA initiatives and are committed to working toward a better infrastructure for medical records that place patients at the center and promote availability and access while protecting privacy and security.

At this stage, the TEFCA processes are voluntary, and much analysis is taking place by those entities who may see value in participating. The next year will show whether there is enough support and participation to move forward with more complete and interconnected systems and processes. While we applaud the advances ONC and the Recognized Coordinating Entity (RCE) have made to stand up TEFCA, there are still outstanding questions about how this network will come together. TEFCA has the potential to advance interoperability and improve data access for all stakeholders. Once implemented, TEFCA will lay out important rules of the road and allow the creation of a nationwide network of networks.

TEFCA depends on widescale adoption to be successful. However, questions remain regarding how health plans could participate in TEFCA. AHIP and its member plans strongly believe that TEFCA participation must remain voluntary at this time as it is challenging to determine the full impact and potential use cases until the process is finalized and it is known which organizations will be serving as QHINs. In addition, and stakeholders must see clear value in participating. ONC and CMS should ensure the inclusion of use cases in TEFCA that will make participation attractive not only to healthcare providers but to payers as well. For example, to encourage adoption and ensure TEFCA realizes its potential, CMS and ONC should advance use cases that address unmet needs or could leverage technology to reduce burden. By meeting these needs,

ONC and CMS could foster desire by health insurance providers and other stakeholders to join TEFCA and facilitate nationwide data sharing. Below we outline potential use cases that could incentivize health insurance providers to participate in TEFCA.

Longitudinal Health Records

We believe that consumers should have easy access to health information that is personalized and actionable, that they should be able to seamlessly share this information with others. In addition, we believe that the health information shared at the request of the consumer should be safely protected. We agree that payers can play an important role in ensuring consumers have access to their health information. In addition to the plans in federal programs implementing the Patient Access APIs, the majority of health insurance providers have web-based tools to share a variety of health information directly with their enrollees. Health insurance providers are continuously enhancing these tools to better meet their members' needs. However, for that information, as well as user trust, to be protected as it is exchanged across the ecosystem, all actors – providers, payers and third parties – must be held to consistent privacy and security standards.

We believe CMS should shift its approach to ensure that any large-scale exchange of consumer data (e.g., full clinical and claims records) is consumer-mediated and results in easy and meaningful access to comprehensive data. Consumer data beyond that which is needed for care coordination among payers is, and should remain, a component of the Patient Access API rather than the payer-to-payer exchange.

Impacted payers have already made full-scale claims data available to consumers through the Patient Access APIs. Through this technology, a consumer can already access their data and share it with an app of their choosing. Plus, they can do the same with their clinical information based on the comparable ONC information blocking requirements provisions on healthcare actors, as defined in the regulation. These investments and capabilities should be built on, not superseded by TEFCA. In addition, large scale data exchange should be supported by a secure entity that can integrate claims and clinical data, along with other sources such as patient-reported outcomes, to create actionable information and easy-to-use information for consumers. A solution, such as patient-centered data aggregation, should be part of a longer-term roadmap developed in collaboration with the industry.

By leveraging TEFCA to help consumers build their health records, CMS could protect patient privacy and security while streamlining data flow for all stakeholders. Payers and providers could share data through TEFCA while consumers could leverage it to facilitate the process of connecting records from multiple entities. Moreover, the flow-down provisions of the Common Agreement could fill an important gap in privacy as many third-party apps are not covered by HIPAA.

We offer the following as potential voluntary use cases that could hold value for health insurance providers. However, it is essential that CMS does not mandate participation in TEFCA under

these potential uses. Health insurance providers have invested significant resources in meeting the requirements of the current interoperability requirements. While TEFCA holds promise as a pathway to promoting interoperability, it is unreasonable to mandate major modifications so soon after the initial implementation of these requirements. Instead, we make these recommendations as options that ONC and CMS could implement to encourage health insurance providers to participate in TEFCA.

Payer-to-Payer Data Exchange

Interoperability holds great promise in allowing health insurance providers to facilitate better care for members and to take a more active role in care coordination. The payer-to-payer exchange specifically provides the opportunity to diminish potential disruptions for consumers who are changing plans and to help ensure continuity of care. However, sharing large amounts of unnecessary data can have the opposite effect, requiring the new health insurance provider to sift through (and store) large amounts of irrelevant information looking for the facts necessary to effectively deliver benefits and care. By focusing the payer-to-payer data exchange mandate on sharing information that will facilitate the consumer's transition from one impacted payer to the next, CMS could facilitate a successful implementation of this policy. To support this, CMS should focus on a subset of key coverage, clinical, demographic, claims (excluding payment rates), and encounter data exchanged in a standardized form and format, which can be easily integrated into the new payer's systems. To facilitate CMS's goal of enabling longitudinal records, CMS and Department of Defense (DoD)/Veterans Administration (VA) should also be required to participate in the payer-to-payer data exchange so consumer can transfer their relevant coverage data across all payers they may use across their care journey.

As CMS reconsiders the payer-to-payer exchange and develops new rulemaking, TEFCA could also play an important role. CMS should work with ONC and the RCE to ensure that TEFCA includes a voluntary payer-to-payer exchange use case early in its developmental roadmap. CMS then could permit the option of payers meeting the requirements of the payer-to-payer data exchange through TEFCA. By sending data through qualified health information networks (QHINs), payers would not have to build out extensive point-to-point connections, making the payer-to-payer data exchange more efficient and reducing the burden of implementation. This could also alleviate some of the current technical challenges such as a lack of digital endpoints and accurate patient matching. Given that the RCE expects to onboard QHINs in 2022, it may benefit all parties to delay the payer-to-payer exchange implementation deadline to enable payers to leverage TEFCA to meet these requirements.

Quality Measurement

Technology holds promise to further reduce the burden of reporting quality data while enhancing the information on quality available to all stakeholders. Digital measures and the electronic exchange of information through formats such as APIs could reduce the time and resources required to extract data from patient charts or other forms such as the surveys used to generate patient-reported outcome measures. As noted in our response above to the RFI on Continuing to

Advance to Digital Quality Measurement and the Use of FHIR in Hospital Quality Programs, we believe TEFCA could reduce the burden of quality measurement while enabling the measurement of new concepts that could not previously be assessed. We believe that TEFCA holds potential to facilitate adoption of digital quality measurement and enable the safe sharing of information across parties.

We ask CMS to consider a potential quality measurement use case under TEFCA. Without the expanded acceptable uses under TEFCA, the uses of the legacy content standards for quality programs have faced adoption challenges on national networks. Without TEFCA as a framework to build trust, new FHIR-based networks could be similarly hampered by well-intentioned but varied limitations designed to protect privacy and enhance security.

IX. E. Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a pay-for-reporting quality program that reduces payment for hospitals that fail to meet program requirements. Through the FY 2023 proposed rule, CMS proposes to adopt 10 measures, refine two current measures, make changes to the existing eCQM reporting and submission requirements, remove the zero-denominator declaration and case threshold exemptions for hybrid measures, update eCQM validation requirements for medical record requests, and create reporting and submission requirements for patient-reported outcome-based performance measures (PRO-PMs). CMS also seeks comment on the potential future adoption of two Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) measures.

First CMS proposes to adopt three measures addressing health equity:

- Hospital Commitment to Health Equity measure beginning with the CY 2023
 reporting period/FY 2025 payment determination, a structural measure that requires a
 hospital to attest activities across five domains, including strategic planning, data
 collection, data analysis, quality improvement, and leadership engagement.
- Screening for Social Drivers of Health measure and Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination.

Recommendations:

AHIP applauds CMS's efforts to leverage its' quality programs to promote health equity. For far too long, discrimination and systemic racism have served as barriers to health equity for minority and underserved communities. Health insurance providers know that ending these barriers to care is key to an equitable health care system. AHIP and its members agree with the

importance of promoting health equity and are actively taking concrete steps to reduce disparities.

AHIP strongly supports the goals of these measures as health equity is a priority of our own. Performance measurement is an underutilized lever to incentivize the health care system to become more integrated and cross-sectoral to eliminate healthcare disparities. AHIP established several workgroups devoted to reducing disparities in healthcare including one that focuses on identifying ways in which to measure disparities to create a more equitable healthcare. We commend CMS for its work to evaluate how these powerful tools can best be used to promote health equity. As such, we support the addition of the Hospital Commitment to Health Equity measure. We agree this measure assesses important aspects of a hospital's commitment to equity.

While we acknowledge the potential administrative burden of structural measures, we believe this measure could serve as an important first step towards measuring health equity. AHIP and its members have convened a workgroup to identify potential performance measures for value-based purchasing; however, at this time, there are few measures of health equity. In our work, we have identified developing a culture of equity, quality, data, access, accountability, community partnerships, and member experience as the priority domains for equity measurement.

We support the concept of assessing a hospital's commitment to equity and believe it could be well-aligned with our framework. A structural measure assessing priorities such developing an organizational commitment to reducing disparities, collecting demographic data, and training staff on best practices for data collection could allow hospitals to implement best practices for identifying and eliminating healthcare disparities. We would encourage CMS to consider measuring additional priority concepts developed by AHIP's Equity Measures for Value-Based Care Workgroup such as access, community partnerships, and patient experiences centered on identifying discrimination and structural racism.

We agree that when appropriate the results of this measure should be reported on Care Compare. We also encourage CMS to develop process and outcome measures assessing health equity.

While we agree with the value of the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures, there are a number of implementation concerns that should be addressed prior to the adoption of these measures in the IQR program. We urge CMS to implement these measures carefully and over a longer time period to ensure that resources to support equity initiatives are used in a way that improves patient outcomes and ensures the healthcare system does not accidentally erode trust with consumers.

First, we are concerned that these measures are conceptual similar but not fully aligned with NCQA's Social Need Screening and Intervention (SNS-E) proposed for adoption in HEDIS. We risk fragmenting efforts to address social risk if health plans and health care providers are measuring differently and accountable for different outcomes. Moreover, we are particularly concerned that a version of the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures were included in the April 2022 materials for the Medicaid

Core Set workgroup's annual review. Having two misaligned measures at the health plan level will cause confusion and waste resources that could be better utilized to help consumers rather than meet duplicative performance measures. CMS and NCQA should harmonize the specifications of these measures through a multistakeholder process, such as the NQF endorsement process. By harmonizing the measures, one consistent measure could be applied across the healthcare system to ensure clinicians, hospitals, and health plans are working in tandem to identify and address social needs. CMS should also work with the CQMC to promote alignment of health equity measures across public and private payers.

Next, CMS should ensure that these measures align with the Gravity Project's standards. Interoperability is essential to avoid burden on patients and reduce missing data. Interoperability could ensure that consumers are not asked multiple times for the same information. Given the delicate nature of the site of service, we would suggest that, when possible, CMS leverage interoperability requirements and other ways to connect with a person's record from their primary care provider to retrieve the information. However, we note that CMS and the measure developers should not be overly prescriptive on which screening tool to use. Healthcare and health insurance providers have already begun work to implement social needs screenings and the Gravity Project has developed its standards to be agnostic to the screening tool used.

Third, we ask CMS to work with hospitals to ensure social needs screenings are done in a respectful and person-centered way. We encourage CMS to educate and build trust with consumers on why hospitals are collecting this data, how it will be used, how it will not be used, and how it will be protected. We also encourage CMS to work with NCQA and other organizations doing similar work address social needs to develop frameworks, workflows, guidance, and best practices to collect this data at scale in patient-centered and respectful ways. We would recommend that stakeholders work together to address data collection, storage, and communication with patients and families.

There may also be negative reaction to the collection of this data if the timing seems inappropriate or if the data collection seems irrelevant to what the patient is experiencing at that moment; for example, collecting social needs data in the Emergency Department may not be the most appropriate time or location to collect this data if the individual is experiencing an emergency or stressful, emotional, or traumatic experience. CMS could also work with hospitals to consider utilizing non-clinical staff (e.g., social workers or community health workers) who may be better trained to build trust in short periods of time.

Additionally, we urge CMS to ensure these measures can be implemented consistently and allow fair comparisons across providers and regions. We are concerned that different hospitals may have different abilities and resources to address social services and that social needs and the availability of resources may differ by region. We are also concerned that some of the indicators may have small denominators, leading to potentially inaccurate or biased results. Moreover, the specifications of the measure are vague and could lead to inconsistent implementation and reporting. CMS should submit these measures for NQF review and endorsement to ensure their feasibility and scientific acceptability.

CMS should also consider the technical challenges to documenting social needs screening and if the results of these screenings have been addressed. CMS should work with ONC to standardize documentation across EHRs and add the capability to screen for social needs and document the results to the ONC HIT Certification Program.

Finally, we ask to clarify how the results of the screen positive rate would be displayed. AHIP is concerned that if these results are not communicated carefully, public reporting could cause unfair harm to a provider's reputation. A hospital serving a socially at-risk population may provide excellent care for all patients; however, reporting that the hospital had a high rate of positive screens could be interpreted negatively by consumers. Hospitals depend on having a balanced case mix to ensure adequate revenue flows and patients who do not perceive themselves to be at social risk or need social services may choose to avoid facilities with a high rate of positive screens.

CMS should finalize the proposal to adopt the Hospital Commitment to Health Equity measure. CMS should harmonize the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures with NCQA's Social Need Screening and Intervention (SNS-E). A consistent measure across the healthcare system could ensure health plans, hospitals, and clinicians are working together to address social needs. CMS should work with the CQMC and through the NQF endorsement process to identify a consistent, aligned approach to social needs screening measurement.

CMS should ensure the harmonized measure aligns with the Gravity Project's standards and uses interoperable data and is adequately risk adjusted to account for differences underlying populations and regional resources. CMS should provide guidance to hospitals on how to implement social risk screening to ensure it is done in a person-centered way.

Cesarean Birth and Severe Obstetric Complications eCQMs

CMS proposes to adopt two perinatal eCQMs—Cesarean Birth and Severe Obstetric Complications—available for self-selection beginning with the CY 2023 reporting period/FY 2025 payment determination followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination.

Recommendations:

Health insurance providers are committed to improving maternal health and have implemented several initiatives aimed at improving outcomes for people who are pregnant and babies. We strongly support the adoption of these two perinatal measures to improve outcomes and reduce complications for pregnant people.

CMS should finalize the proposal to adopt the Cesarean Birth and Severe Obstetric Complications—available for self-selection beginning with the CY 2023 reporting period/FY

2025 payment determination followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination.

Total Hip Arthroplasty and Total Knee Arthroplasty eCQMs

CMS proposes to adopt two measures addressing total hip arthroplasty (THA) and total knee arthroplasty (TKA). First, CMS proposes to adopt the Hospital-Level Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) PRO-PM (NQF #3559) beginning with two voluntary reporting periods (July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025), followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination. Second, CMS proposes to adopt the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA measure (NQF #1550) beginning with the FY 2024 payment determination. This measure was removed from IQR in 2018 but retained in VBP; CMS proposes to adopt an updated version with an expanded outcome. The measure has been revised to include additional ICD-10 codes for mechanical complications.

Recommendations:

AHIP supports the adoption of the Hospital-Level THA and/or TKA PRO-PM (NQF #3559), including CMS's proposal for a phased implementation to allow hospitals time to develop data collection mechanisms and gain familiarity with the measure. We also suggest that CMS consider the expansion of the measure to other sites of care such as ambulatory surgery centers and hospital outpatient departments to allow comparisons across facilities and settings and support consumer choice. We recommend that CMS consider the potential data collection burden and ways to leverage technology to minimize reporting burden on consumers and the implementation burden on providers. AHIP supports greater use of patient-reported outcomes-based performance measures (PRO-PMs) as an essential component of moving to value-based care. PRO-PMs will be essential to understanding if VBP models are delivering improvement on the outcomes that matter most to consumers.

AHIP also supports the adoption of the revised Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA measure (NQF #1550). Given the elective nature of these surgeries, it is essential for consumers to understand outcomes and potential risks. This measure could help consumers understand important differences between facilities and support their choice about where to seek care.

CMS should finalize the proposal to adopt the Hospital-Level THA and/or TKA PRO-PM (NQF #3559), including CMS's proposal for a phased implementation of the measure. CMS should finalize the proposal to adopt the revised Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA measure (NQF #1550).

Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e)

CMS proposes to add Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e), an outcome measure focusing specifically on opioid-related adverse events during an admission to an acute care hospital by assessing the administration of naloxone. This measure would be available for self-selection beginning with the CY 2024 reporting period/FY 2026 payment determination.

Recommendations:

AHIP supports the addition of the Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e). We appreciate CMS's efforts to reduce medication errors and improve patient safety.

Medicare Spending Per Beneficiary—Hospital Measure (NQF #2158)

CMS proposes to add the Medicare Spending Per Beneficiary—Hospital measure (NQF #2158) beginning with the FY 2024 payment determination (proposing adoption of an updated version of the measure). CMS had removed a prior version of this measure but proposes to adopt an updated MSBP measure. CMS has made three changes to the measure:

- Include all readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence;
- Add an indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to episode start date; and
- Revise the one step in the measure calculation from the sum of observed costs divided by the sum of expected costs (ratio of sums) to the mean of observed costs divided by expected costs (mean of ratios).

Recommendations:

We support the adoption of the revised MSBP measure. The revised specifications will encourage greater care coordination and shared accountability for avoidable readmissions and their associated costs.

Refinements to Existing Hospital IQR Measures

CMS proposes refinements to two measures that are currently part of the Hospital IQR Program measure set beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-

Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA (NQF #3474) and (2) Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) (NQF #2881).

Recommendations:

We support the proposed refinements to the Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA (NQF #3474) and (2) Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) (NQF #2881).

Digital NHSN Measures

CMS requests comment on the potential future inclusion of two digital NHSN measures: (1) Healthcare-Associated Clostridioides difficile Infection Outcome measure and (2) Hospital-Onset Bacteremia and Fungemia Outcome measure.

Recommendations:

AHIP appreciates CMS's efforts to advance patient safety and agrees digital quality measurement has the potential to enable measurement of new areas while reducing the burden of measurement. We agree that the Healthcare-Associated Clostridioides difficile Infection Outcome measure and Hospital-Onset Bacteremia and Fungemia Outcome measures address important aspects of patient safety. We also agree that digital version of the C. difficile infection measure could be more valid and reliable than the lab reported version as requiring both require both microbiologic evidence of CDI in stool and evidence of antimicrobial treatment could better identify cases. We also believe the Hospital-Onset Bacteremia and Fungemia Outcome measure could serve as an important complement to the NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome measure and NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome measure.

However, CMS should adopt a stepwise approach to implementing and utilizing these two digital NHSN measures. Hospitals will have varying ability to report using a digital version of the measure and while we appreciate the CDC's work to allow reporting using alternatives to FHIR such as Health Level 7 (HL7) Clinical Document Architecture (CDA), and potentially other formats it is unknown how using different versions of the measure would impact results. Moreover, the revisions to the specifications from the lab-reported to the digital versions could also impact hospital performance. CMS should perform testing to understand how the versions of the measure compare (e.g., compare FHIR reported to CDA reported and lab-reported). CMS should implement these measures as voluntary measures in the IQR program as a starting place and provide hospitals with confidential feedback on their results. CMS should not publicly report the results of these measures until it is understood how results would compare. Publishing results

with variation due to the measure itself rather than provider performance risks confusing and misleading consumers and other stakeholders that depend on the results published on *Care Compare*. Moreover, CMS should not adopt these measures for the HVBP program or HAC reduction program until hospitals can consistently report using FHIR or testing confirms comparable results using different reporting methods.

Establishment of a Publicly Reported Hospital Designation on Maternity Care

CMS proposes to establish a hospital quality designation that it would publicly report on a CMS website beginning Fall 2023. This designation would be awarded to hospitals based on their attestation of the components of the Maternal Morbidity Structural measure previously finalized for adoption in the Hospital IQR Program. This measure is designed to determine hospital participation in a state or national Perinatal Quality Improvement (QI) Collaborative and implementation of patient safety practices or bundles through that QI initiative. The Maternal Morbidity Structural measure is specified to capture whether hospitals are:

- Currently participating in a structured state or national Perinatal QI Collaborative;
 and
- Implementing patient safety practices or bundles as part of these QI initiatives.

Under this proposal, CMS would award this designation to hospitals that report "Yes" to both questions in the Maternal Morbidity Structural Measure.

Recommendations:

AHIP and our members are committed to improving maternal, newborn, and infant health outcomes for all Americans. Health insurance providers are committed to ensuring that our members receive high-quality care during pregnancy, childbirth and after delivery. In order to improve the birth outcomes of both mothers and their babies, maternity care must be safe, guided by sound medical evidence, and affordable. To support these goals, health insurance providers require hospitals in their networks to adhere to peer-reviewed medical guidelines for maternity care.

We support the creation of this designation to help consumers, health insurance providers, and employers and purchasers better understand a hospital's commitment to providing high quality maternity care. AHIP applauds CMS's efforts to leverage the IQR program to improve care for pregnant people and babies. This program could help consumers better understand where to seek maternity care and health insurance providers to design high-quality networks.

We encourage CMS to add additional quality measures addressing maternity care to the IQR program and to incorporation them into this designation. In order to assure that mothers are getting the recommended care at the recommended times, insurance providers rely on an array of quality measures, such as the rate of early elective deliveries, the rate of cesarean deliveries, and the rate of high-risk deliveries. Early elective deliveries can have serious consequences for the

mother and baby. Births delivered via cesarean section result in surgeries that have the potential to create additional risk to the patient. CMS could consider adding the PC-01 Elective Delivery measure and the PC-02 Caesarian Birth and Severe Obstetric Complications measures (if adopted for IQR) to this designation program to help stakeholders better understand a hospital's performance on these essential outcomes.

We encourage CMS to continue use the IQR program to address maternity care and to explore additional measures that could be added to the program measure set. The CQMC brings together health insurance providers, clinicians, employers, consumers, and regional collaboratives to align measures for use in value-based care programs and includes obstetrics and gynecology consensus core measures that address key clinical concepts in maternal and fetal medicine. CMS could look to the CQMC obstetrics and gynecology core measures set as a source for additional measures to improve the quality of maternity care and to advance maternal health equity.

IX. H. Proposed Changes to the Medicare Promoting Interoperability Program

The Medicare Promoting Interoperability Program encourages eligible hospitals and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT). CMS proposes several programs to the Medicare Promoting Interoperability Program. Specifically, CMS proposes to:

- Make mandatory the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure, expand to include Schedule II, III, and IV drugs and maintain the associated points at 10 points;
- Add a new Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure under the Health Information Exchange (HIE)
 Objective as a yes/no attestation measure, beginning with the EHR reporting period in CY 2023, as an optional alternative to the three existing measures under the HIE Objective;
- Add a new Antimicrobial Use and Resistance (AUR) Surveillance measure and require its reporting under the Public Health and Clinical Data Exchange Objective, beginning with the CY 2023 EHR reporting period;
- Beginning with the CY 2023 EHR reporting period, CMS proposes to reduce the active engagement options for the Public Health and Clinical Data Exchange Objective from three to two options;
- Beginning with the CY 2023 EHR reporting period, CMS proposes requiring submission of the level of active engagement, in addition to submitting the measures for the Public Health and Clinical Data Exchange Objective;
- Institute public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period;

- Beginning with CY 2023 EHR reporting period, CMS proposes to increase the Public Health and Clinical Data Exchange Objective from 10 to 25 points, to increase the points associated with the Electronic Prescribing Objective from 10 to 20, to reduce the points associated with the Health Information Exchange Objective from the current 40 points to 30 points, and to reduce the points associated with the Provide Patients Electronic Access to Their Health Information from the current 40 to 25 points;
- Adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM
 measure set beginning with the reporting period in CY 2023, and two new eCQMs
 beginning with the reporting period in CY 2024 in alignment with proposals for the
 Hospital IQR Program; and
- Modify the eCQM reporting and submission requirements to increase eCQM reporting from four eCQMs (one mandatory and three self-selected) to six eCQMs (three mandatory and three self-selected) beginning with the CY 2024 reporting period in alignment with proposals in the Hospital IQR Program.

Recommendations:

AHIP supports initiatives and incentives that foster participation in interoperability and nationwide data exchange. Supporting participation in TEFCA under the HIE objective as an alternative will encourage greater participation and help reach the intended goals of data exchange. As such, we appreciate CMS's work to include TEFCA as an option to meet this objective and support the proposal to adopt the Enabling Exchange under the TEFCA measure.

The COVID-19 pandemic has shown the need to improve public health reporting and surveillance systems. Improved data sharing could allow earlier identification and coordinated responses to future PHEs. We support CMS's proposal to modify the Promoting Interoperability scoring to increase the weight of the Public Health and Clinical Data Exchange Objective. We believe this represents an important step to improving our nation's public health information infrastructure.

AHIP supports CMS's continued efforts to align quality measures across its public reporting programs. We support these proposed additions and increase in reporting requirements to Promoting Interoperability program pending finalization of changes to the IQR program.

IX. E. Additional Activities to Advance Maternal Health Equity—RFI

CMS seeks comment to explore how the agency can address the U.S. maternal health crisis through policies and programs, including, but not limited to, the Conditions of Participation and through measures in its quality reporting programs.

Recommendations:

As noted above, AHIP and our members are committed to improving maternal, newborn, and infant health outcomes for all Americans. Health insurance providers are committed to ensuring that members receive high-quality care during pregnancy, childbirth, and after delivery. In order to improve the birth outcomes of both pregnant individuals and their babies, maternal care must be safe, guided by sound medical evidence, and affordable. We strongly support the goals of this RFI and applaud CMS for leveraging its programs and policies to advance maternal health equity.

To support these goals, health insurance providers require hospitals in their networks to adhere to peer-reviewed medical guidelines for maternity care. Clinical guidelines and quality metrics for maternal and infant care are set by independent experts, provider professional societies, government agencies, and credentialing/accreditation entities. These include clinical guidelines promulgated by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), recommended preventive services from the U.S. Preventive Services Task Force (USPSTF), and the Joint Commission's accreditation and certification standards.

Quality measurement is an essential tool to help understand if providers are following clinical guidelines. We recommend encouraging the use of consistent quality measurement, data collection, and reporting related to child and maternal health care; and supporting the use of innovative payment models for care delivery. As a start, CMS should explore ways to expand the measures in the IQR program to include additional measures that address maternal and infant health. The CQMC has developed a core measure set intended to identify prioritized measures for use in value-based care programs and includes obstetrics and gynecology consensus core measures that address key clinical concepts in maternal and fetal medicine. CMS could look to the CQMC obstetrics and gynecology core measures set as a source for additional measures to improve the quality of maternity care and to advance maternal health equity.

Health insurance providers are increasingly conscious of the racial disparities in birth outcomes and their implications for maternal health. Recognizing these disparities, our members are working collaboratively with provider partners to deliver culturally competent care and to utilize state of the art research and analytics to identify potentially high-risk pregnancies. Quality measurement is an increasingly important way to identify disparities in care. AHIP has convened a Health Equity Measures for Value-Based Care workgroup to identify the measurement domains that should be addressed to promote health equity. This workgroup (constituting of member health plans) is using an evidence-based and stakeholder-driven process to review currently available measures that directly promote actions to address equity, such as experiences of discrimination, patient-provider communication, accessibility and appropriateness of services, whether cultural preferences are taken into account, and more. The group is also determining measures that should be prioritized for stratification (such as maternal health quality measures) and identifying concepts where measure development is needed. We would be happy to share the results of this work with CMS. We encourage CMS to explore ways to stratify current measures to identify disparities in care.

We also encourage CMS to support measure development to create new measures that fill gaps in understanding the current quality of maternal care as well as measures that directly assess

activities that promote maternal health equity. The CQMC has identified a list of priority maternal and perinatal measurement gaps, including:

- Maternal morbidity and mortality;
- Time of decision for c-section and surgery start time (i.e., measurement of "decision to incision" start times);
- Behavioral health and substance use measures, including opioid use disorder screening, tobacco, smoking, and vaping measures for pregnant and/or post-partum women;
- Comprehensive post-partum visits and post-partum follow-up;
- Measures that consider healthy lifestyle behaviors throughout reproductive years;
- Decision-making measures for neonatal care; and
- Measures addressing neonatal morbidity and mortality (e.g., appropriate care for infants with Appar scores <7 at 5 minutes after birth).

We also encourage CMS to explore ways to leverage its value-based care programs to incentivize maternal health equity. The predominant fee-for-service (FFS) reimbursement system does not incentivize high-quality, affordable care. For this reason, AHIP shares CMS's goal of transforming the health care payment environment and moving away from paying for volume and toward paying for value. Payment reform can create strong economic incentives to drive high-value, cost effective care.

Health insurance providers are launching innovative payment and delivery models that support maternal and infant health outcomes, ensuring that pregnant individuals, new parents, and babies receive high-quality, affordable care.³ If CMS were to add measures of maternal health to programs such as HVBP, it could help to align efforts across the public and private sectors. However, such efforts should be appropriately balanced with access concerns to ensure quality measurement and VBC do not inadvertently worsen access challenges.

In order to facilitate clinical quality improvement efforts, CMS should consider supporting public-private partnerships to encourage initiatives that address the needs of different across communities and payers and disseminate best practices for caring for pregnant and postpartum individuals, including obstetric emergency protocols. CMS should also support research to determine the effectiveness of centering of care and integrating paraprofessionals into the preand postpartum care process (including the use of community health workers, midwives, and doulas in safe and effective models of care) and the effect this could have on maternal health equity.

Underscoring current maternal health disparities is the cultural competency of our health care institutions. Cultural competency is a reflection of how clinicians, health insurance providers, and other organizations are delivering health care services to meet the social, cultural, and linguistic needs of their patients. Research shows that racial and ethnic minorities are often disproportionately burdened by chronic illness and disease. Health insurance providers

 $^{^3}$ <u>https://www.ahip.org/news/press-releases/new-ahip-resource-improving-maternal-health-through-value-based-care.</u>

understand that every patient has different needs, and our member companies continue to invest in strategies to improve health outcomes for all the people they serve.

CMS and other stakeholders must provide culturally competent programs for expectant and postpartum individuals, in collaborations that work across providers, payers, and communities. CMS should explore ways help providers and their staff can identify and address unconscious bias in their care settings. Additionally, strategies to identify and address the highest risk pregnancies and engage through these culturally informed programs can help provide women the medical and social supports they need to achieve a healthy pregnancy. CMS should consider developing quality measures that assess patient experience with provider bias as well as measures that assess if an expectant mother is receiving care that is culturally informed. CMS should also explore ways to mitigate the effect of social risk on pregnant people and new mothers. Pregnant people and new parents may have trouble accessing care from doctors and hospitals that are in short supply in rural areas.

Telehealth could hold promise to help patients overcome challenges like access and other barriers to care, such as transportation. CMS and HHS should implement policies that give insurance providers the flexibility needed to best meet the needs of their members. As recently finalized policies for certain SDOH-offsetting services for people with chronic diseases who choose Medicare Advantage plans, HHS should implement policies that allow all types of insurance providers to incorporate activities to address SDOH into the numerator of the medicalloss ratio (MLR) calculation, as opposed to considering these activities as non-medical, administrative work.

CMS and HHS should support multi-state licensure compacts to ease licensure barriers to telehealth adoption; designate telehealth as a means of satisfying insurance network adequacy, quality measurement and risk adjustment requirements; and permit first-dollar coverage of telehealth services in HSA-eligible health plans. CMS and HHS should work with states to encourage policies that facilitate use of telehealth while allowing for flexibility -- not mandates for reimbursement, payment parity, site-specific use, prior visit requirements, or specific technology use, each of which limits the abilities of insurance providers to deliver care via telehealth.

Finally, CMS and HHS should promote the expansion of proven health and wellness programs and community-based efforts to address the issues faced by expecting or recent mothers and their children, including investments to increase the capacity of community-based organizations to address SDOH.

X.C. Request for Public Comments on IPPS Payment Adjustment for N95 Respirators that Are Wholly Domestically Made

In recognition of the costs associated with National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 respirators, CMS is considering whether it is appropriate to adjust payments to hospitals for the purchase of these respirators when they are wholly domestically made.

Recommendations:

AHIP supports domestic products where possible in health care to improve health security and availability of supplies. We learned from the pandemic that global supply chains can prove inadequate for emergencies, high-demand trends, and during geopolitical conflicts.

We have learned that respirators are vitally important, but so are other essential pharmaceutical components of drugs and essential drugs, medical gases, saline, and other life-saving and baseline supplies. Lessons learned during past hurricane and disaster situations evidence a need to "shore up" domestic inventories. This work should continue in conjunction with the federal agencies such as HHS/ASPR and others who monitor and contribute to policies for the national drug and similar healthcare readiness stockpiles, including the National Strategic Stockpile.

AHIP participated in the Health Leadership Council's Summit which discussed a variety of issues related to global and regional supply chains. It should be noted that concerns have been raised related to the cost effectiveness of domestic production for certain medical supplies that are not in high demand absent an emergency or crisis. It should also be noted that any known shortages can result in hoarding behaviorism which exasperates shortages and availability. These issues should be discussed in a final rule because while incentives are a good start, there are a myriad of issues (beyond payment rates) that can compound availability of supplies in emergency situations.

X. B. RFI on Social Determinants of Health Diagnosis (SDOH) ICD-10 Codes

CMS solicits comment on how the reporting of ICD-10 diagnosis codes that describe SDOH may improve its ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS-DRGs. CMS is interested in input on whether to require the reporting of certain Z codes, and if so, which ones.

Recommendations:

AHIP has and continues to support use of ICD-10 diagnosis codes that describe SDOH (Z codes) on claims, however this is not a long-term solution to ensuring access to up-to-date information on a person's social needs. This information is needed during the course of care and by disparate stakeholders. While use of these codes is not currently pertinent to payment, it is relevant for purposes of retrospective population-based research claims collection permits. We encourage CMS to consider ways to leverage interoperability and health information technology to foster data flow on social risk.

AHIP and its members believe that there may be a role for increased sharing of information to promote health equity. However, to truly address social needs and reduce health care disparities, we need national data and exchange standards that permit stakeholders from across the health

care industry to report and exchange information. Moreover, such information should ideally be available in real-time and at the point of care, not only when a claim is submitted.

CMS and ONC should explore how to leverage the USCDI and TEFCA to facilitate the exchange of data on social needs. ONC has continued to build on the USCDI and has added several new data classes and data elements related to SDOH in the USCDI v.2 and in the proposed USCDI v3. These additional data elements could be useful in understanding a member's social risks and needs. This includes an enrollee's SDOH assessment, SDOH goals, SDOH problems, and SDOH interventions. However, before these elements are mandated, more work needs to be done to standardize SDOH related data. AHIP and its member plans are actively working with HL7's Gravity Project to move toward standardized data collection and exchange as quickly as possible. We believe such information is pivotal to identifying health disparities and ensuring care is delivered in a more equitable manner. ONC and CMS could also explore ways to use USCDI+ to facilitate the collection and exchange of sociodemographic data. ONC and CMS should also explore ways to encourage a broad range of organizations to participate in TEFCA and exchange necessary information on a patient's social needs and risk. TEFCA could facilitate a flow of information to all parties with a role in supporting a patient. For example, data on social risk could be available to a health care provider planning a care transition for a patient, to a case manager at a health insurance provider outlining what supports a member may need, or to a community-based organization receiving referrals for social supports.

Finally, CMS and ONC have not placed similar requirements for health care providers to share USCDI with health insurance providers. By developing parallel requirements for providers to share data with payers and payers to share data with providers, CMS could ensure that data flows across the system to support patient care. By incorporating payers in data sharing efforts, health insurance providers could help to manage a person's social needs and facilitate interventions to address them. Demographic and data on a person's social needs could help health insurance providers take a more active role in addressing their members' needs. CMS and ONC should also require providers to share such data with payers to allow payers to take a more active role in assisting with social needs.

We recognize that it will take time to fully transition to an interoperable health care system. In the interim, administrative data plays an important role in facilitating information exchange. Using Z codes would allow providers to better define the SDOH needs of patients, standardize this data, and facilitate interoperable data exchange between health care providers, payers, and other relevant stakeholders to better collaborate and provide the necessary support and interventions. This information could be used to better understand the quality of health care provided and how it may lead to disparities, which would further enable quality improvement activities and engagement with consumers.

ICD-10 Z codes have potential to drive better documentation of SDOH, but additional changes are necessary to make codes meaningful in addressing health-related social needs. As such, CMS should overcome challenges to Z code utilization before requiring reporting. Provider use of Z codes is low for several reasons, including lack of awareness and concerns about how the code

information is used. Increasing awareness through education campaigns will take time, effort, and communication.

Technological and information sharing barriers also contribute to low utilization of Z codes. For example, many EHRs do not have easy pathways to add a Z code to the problem or diagnostic list, which hinders providers' ability to report them. While Z codes are documented by providers and care teams, it is important that these codes be shared with health insurance providers and other relevant service providers (such as human and social service providers) who can use their data analytics to identify population-level trends and disparities and inform care and services. CMS should consider other standardized codification systems (such as LOINC and SNOMED) that can be documented and shared by more entities, such as providers, payers, labs, and researchers as additional way to document and share SDOH in ways that improve quality and inform care.

Additionally, the electronic billing systems currently constrain the number of diagnosis codes that can be placed on a claim. The 837i permits 25 diagnoses, but payers often truncate this at 10 or 15. If CMS and CDC continue to add ICD-10 Z codes and determine that the claim form is the best avenue for transmission, then CMS will need to work with NUBC to identify a convention that permits capturing more codes than what the current claim form allows.

Finally, in addition to operational issues, the existing codes themselves may require review and additional codes are still needed to to fill gaps. For example, new Z codes for food insecurity, housing instability, and education status were just created in October 2021, and codes for material hardship, loneliness, lack of social support, and other issues were proposed in December 2021 and are still awaiting approval. Codes for transportation insecurity, legal needs, and other key health-related social needs are still lacking. Codes should also be created to document that a patient has been screened for health-related social needs but that no socioeconomic needs were identified to help track that SDOH assessments were administered. There may also be a need to revise the language associated with these codes to ensure it is not biased to ensure clinicians feel comfortable asking and consumers feel comfortable responding to the necessary questions. The language used in Z codes can also be judgmental or blame the individual and should be revised to ensure codes are neutral and patients and providers feel comfortable asking and responding to necessary questions. This challenge is made more acute by the recent enforcement of Cures Act Final Rule which requires providers to make information available to consumers through Application Programming Interfaces (APIs). As such, clinicians may be hesitant to add a code that includes potentially sensitive language if there is a chance that code could be seen by the patient when they access their records through APIs. CMS should focus on filling in gaps and facilitating use of Z codes before requiring the reporting of Z codes.

Lastly, in response to CMS's request for input on which codes would be important to document, we suggest the following:

- Z59.0: homelessness:
- Z59.81: housing instability;
- Z59.82 transportation insecurity;
- Z59.41: food insecurity;

- Z56.0: unemployment;
- Z60.4: social isolation;
- Z55.5: less than high school education;
- Z59.1: inadequate housing;
- Z56.82: military deployment status;
- Z65.2: problems related to release from prison;
- Z65.3: problems related to other legal circumstances;
- Additional code under Z59.64 for inability to pay or access transportation (proposed in December 2021 but awaiting approval);
- Additional code under Z58.8 for material hardship due to inadequate physical environment with sub-codes to denote inability to obtain internet service or electricity due to inadequate physical environment (proposed in December 2021 but awaiting approval);
- Additional code under Z59.8 for material hardship due to limited financial resources
 with sub-codes to denote inability to obtain adequate clothes, utilities, childcare, and
 other basic needs due to limited financial resources (proposed in December 2021 but
 awaiting approval);
- Additional code under Z60.8 for lack of social support (proposed in December 2021 but awaiting approval); and
- Additional code under R45.89 for loneliness (proposed in December 2021 but awaiting approval).

Additional Matters

AHIP has had inquiries from members regarding a provision in the recent CY 2023 final rule for Part C and D (CMS-4192-F) related to accounting for Medicaid payments and unpaid amounts in the calculation of enrollees' maximum out-of-pocket (MOOP) limit and its impact on disproportionate share hospital (DSH) payments. As CMS considers adjustments to DSH payments resulting from MOOP or other final policies, we would welcome the opportunity to engage with the agency on this issue to better understand and anticipate how the change in MOOP accounting will affect DSH payments in future years.