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June 28, 2021

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

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

RE: Fiscal Year 2022 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, AHIP[1] appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Fiscal Year (FY) 2022 Hospital Inpatient Prospective Payment System (PPS) proposed rule (86 Fed. Reg. 25070). While our response primarily focuses on the two requests for information and quality measure proposals, we also provide comment on the market-based weights and the New COVID-19 Technology Add-on Payment (NCTAP).

Achieving health equity is a priority for AHIP and our health insurance provider members. We believe that investing in performance measures will help identify of disparities and promote equitable care. We must proceed committment and transparency, but also cautiously to achieve the universal goal of equitable care, without undermining Americans' trust.

The lack of demographic data makes it challenging to truly understand and correct potential disparities in health care and outcomes. The health care industry, including CMS as a payer, must work together develop a blueprint to build consumer trust, share information, and ensure all stakeholders are acting collaboratively and consistently to mitigate bias and improve care. **This**

[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.

includes ensuring that all actors in the health care ecosystem are operating based on mature data and privacy standards. While we agree we must move swiftly to to identify disparities and promote health equity, we are concerned about the use of imputed data to support public reporting. Imputed data has questionable accuracy and publishing stratified measure results based on unreliable data may detract from consumer trust, jeopardize work toward the gold standard of self-reported demographic data, and draw bad conclusions about provider quality.

AHIP and its members also strive to move to digital quality measures (dQM) to improve data, advance insight, reduce administrative burden, and target innovative solutions that will truly improve Americans' health. As just one example of this commitment, CMS and AHIP are working together on the Core Quality Measure Collaborative, a multistakeholder effort to align quality measures across the public and private sectors.

While dQMs hold promise, the implementation process will require significant investments across stakeholders and take time to implement. Transitioning to dQMs by 2025 may not be feasible. To encourage speed in the transition, we recommend CMS develop a long-term plan on digital measurement in conjunction with the long-term plan on equity. Bringing these two workstreams together will help improve both plans and achieve their combined goals. The input that both plans will receive from multiple stakeholders will better inform milestones necessary to protect patient privacy, how to build the required infrastructure (e.g. the necessary technical standards for both content and exchange and issuance of the Trusted Exchange Framework and Common Agreement rule), and necessary measures. Such a collaborative and transparent process will also ensure widespread stakeholder engagment as we work together to , and mitigate disparities in outcomes and experiences.

AHIP appreciates CMS's efforts to ensure quality measurement does not interfere with the health care system's response to COVID-19, and we generally support CMS's proposals. We ask that you consider the impact of COVID-19 on CMS's entire portfolio of quality measurement programs, including the MA Stars Rating and the Qualified Health Plan Quality Rating System as the factors that influenced hospital performance and are taken into account here are likely to affect health plan performance as well.

We applaud CMS' attentiveness throughout the pandemic to ensuring regulations do not pose a barrier to ensuring patients with COVID-19 get the care they need when and how they need it. We support CMS's proposal for a limited extension of the temporary NCTAP beyond the expiration of the public health emergency (PHE) as a transitionary measure for those technologies that are newly authorized to treat COVID-19 and thus do not yet qualify for the traditional add-on payment. However, 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.

Finally, we appreciate and strongly support the proposal to repeal the market-based data collection requirement and market-based MS-DRG relative weight methodology that was finalized in the FY 2021 inpatient PPS rule. We wholeheartedly support the stated goals of the policy to inform individuals in advance about the cost and quality of health care services, promote choice, and encourage cost-conscious decisions to lower overall health care costs. **However, we do not believe the finalized approach will accomplish these aims.** The data collected and reported under the finalized approach has no relationship to patient cost sharing and uses the arcane, massive hospital cost reports, which are not readily accessible to or understood by patients. Moreover, we do not believe that using this data to calculate MS-DRG weights starting in FY 2024 will result in any savings to Medicare or result in a market-based payment system, as it merely shifts payments from one service to another. We opposed this policy when it was incepted and encourage the agency to finalize the proposal to repeal it.

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 dlloyd@ahip.org.

Sincerely,

Danielle A. Lloyd

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

ATTACHMENT

II.F. Proposed Add-On Payments for New Services and Technologies for FY 2022 (86 Fed. Reg. 25395)

CMS proposes to extend the New COVID-19 Treatments Add-on Payment (NCTAP) for eligible products through the end of the fiscal year in which the COVID-19 public health emergency (PHE) ends. Thus, if the PHE ends between October 1 and December 1, 2021, the policy would extend until September 30, 2022. If the PHE ends in calendar year 2022, then the policies would end September 30, 2023.

CMS established the NCTAP in November 2020 to mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE by providing higher reimbursement for eligible inpatient cases that use certain new products with current Food and Drug Administration (FDA) approval or emergency use authorization (EUA) to treat COVID-19 when the cost of treatment exceeds the payment rate of the assigned MS-DRG. The NCTAP was finalized as a modified, streamlined version of the longstanding New Technology Add-on Payment (NTAP) and differs from the NTAP in a number of ways.

Eligibility criteria for the NTAP pathway requires, inter alia, that the product receive FDA approval or marketing authorization by July 1 of the year prior to the year in which the application is being considered. Through preamble language, CMS has specifically stated that FDA "approval" and "marketing authorization" do not include authorization for emergency use.[1] In contrast, products authorized for emergency use for purposes of COVID-19 treatment can qualify for the NCTAP.

The payment formula for the NCTAP is also different. NCTAP is the lesser of: (1) 65% of the operating outlier threshold for the claim; or (2) 65% of the amount by which the costs of the case exceed the standard MS-DRG payment, including an additional 20% adjustment.[2] The 20% adjustment was codified in section 3710 of the CARES Act for discharges involving a patient diagnosed with COVID-19 for the duration of the PHE. Furthermore, the NCTAP amount is made in addition to the outlier amount whereas the NTAP decreases the outlier amount a hospital receives.

Through the FY 2022 Inpatient Prospective Payment System (IPPS) proposed rule, in addition to requests for comment on extending the NCTAP, CMS seeks input on how data reflecting the costs of a product with an EUA should be considered for purposes of NTAP eligibility criteria and whether the newness period should begin with the date of the EUA. The manufacturers of two of the three therapies currently approved for NCTAP (Olumiant and Remdesivir) submitted applications for NTAP for FY 2022. Even under these considerations, we recognize that new products intended to treat COVID-19 may not have had the ability to acquire FDA approval by July 1 and may have only obtained an EUA. While the three products currently authorized for NCTAP had the opportunity to apply for NTAP, additional products (e.g., Sotrovimab) may only

[1] 86 Fed. Reg. 25070, at 25394; CMS, 2021 Inpatient PPS Final Rule, 85 Fed. Reg. 58432, at 58742 (Sept. 18, 2020).
[2] NTAP is the lesser of: (1) 65% of the costs of the new technology; or (2) 65% of the amount by which the costs of the case exceed the standard MS-DRG payment.

receive an EUA and thus miss key deadlines required for the NTAP pathway. Therefore, we support maintaining a limited pathway for obtaining NCTAP for additional COVID-19 products with only an EUA that did not have the opportunity to apply for the NTAP this rulemaking cycle but retaining the existing policy for full FDA approval under the NTAP for all other products going forward.

While AHIP appreciates the availability of the NCTAP during the response stages of the COVID-19 pandemic as a means to mitigate any financial disincentive to provide certain treatments, given the significant advances the health care system has made to ameliorate the risk of COVID-19 infection under this Administration's leadership, we question whether it is necessary to continue the 20% add-on payment beyond the expiration of the PHE. Congress codified the 20% add-on payment only for the duration of the PHE, implying it envisioned special payment policies to last only throughout this period rather than beyond its expiration. Therefore, while we support for a limited extension of the NCTAP beyond the expiration of the PHE as a transitionary measure, we oppose the extension of the 20% add-on payment for COVID-19 patients beyond the end of the PHE consistent with the authorizing statutory language.

Finally, with respect to the NTAP and permitting products with only an EUA to qualify, we encourage CMS to retain its existing policy regarding what constitutes FDA approval or marketing authorization. We believe a full FDA review process is in the interest of patient safety and clinical efficacy rather than expanding eligibility criteria to include products under the expedited EUA process.

Recommendation:

- CMS should not extend the NCTAP beyond its current expiration date for the existing treatments that had an opportunity to apply for the NTAP.
- CMS should consider whether any treatments for which authorization is newly granted this calendar year should receive the NCTAP until the treatment may apply for and be granted NTAP status. The agency should evaluate safety, cost, and utilization data gathered since the NCTAP's inception to assess the financial impact and clinical outcomes of this policy to inform the decision on whether to grant NTAP status.
- The agency should maintain the current approval criteria for the NTAP rather than expand eligibility to include products with an EUA. The risk/benefit analysis of introducing new treatments during this historic pandemic should not be applied outside of the extraordinary circumstances of the COVID-19 pandemic. In the interest of patient safety, CMS should defer to and uphold FDA approval authority.
- CMS should not extend the 20% adjustment codified in section 3710 of the CARES Act for discharges involving a patient diagnosed with COVID-19 beyond the duration of the PHE.

V.G. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 through 412.154)

The Hospital Readmissions Reduction Program (HHRP) requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected appliable conditions. In this proposed rule, CMS proposes several additional policies to mitigate the impact of the COVID-19 pandemic on the results of the HRRP. These policies build on an Interim Final Rule published on September 2, 2020 that stated CMS would not use any first or second quarter CY 2020 claims data in the agency's calculation of performance for the applicable fiscal years. Therefore, results for FY 2022 will be calculated with a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data from the COVID-19 PHE.

CMS proposes to adopt a cross-program measure suppression policy to prevent hospitals' from being unfairly penalized under the HRRP during the COVID-19 pandemic. If the agency determines that the suppression of a HRRP measure is warranted for an applicable period, it would propose to calculate the measure's rate for that program year but would not apply it to Medicare payments. In the HRRP, this policy would have the effect of temporarily weighting the affected measure at 0% in the program's scoring methodology until adjustments are made, the affected portion of the performance period for the measure is no longer applicable to program scoring, or the measure is removed entirely through rulemaking. CMS would still provide feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they are made aware of the changes in performance rates that were observed. CMS would also publicly report suppressed measures' data with appropriate caveats noting the limitations of the data due to the COVID-19 pandemic.

Under this policy, CMS proposes to temporarily suppress the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (National Quality Forum (NQF) #506) for the FY 2023 program year. CMS performed analyses that demonstrate the clinical proximity of COVID-19 to the focus of this measure could negatively impact its validity. Additionally, CMS found that a substantial portion of the measure cohort includes admissions with a COVID-19 diagnosis. In addition, almost all the admissions with a COVID–19 diagnosis had a principal diagnosis of sepsis; observed mortality rates for these admissions are extremely high and are substantially higher than admissions without a COVID-19 diagnosis. CMS notes concern that these factors could distort the data used to support the pneumonia readmission measure.

Due to the impact of the COVID-19 on the measures used in the HRRP, CMS proposes to update the remaining five condition/procedure-specific readmission measures to exclude COVID-19 patients from the measures, beginning with FY 2023.

CMS also requests public comment on possible future stratification of results by race and ethnicity for condition/procedure-specific readmission measures and on the expansion of standardized data collection on additional social factors such as language preference and disability status. Specifically, CMS requests comment on 1) The possibility of confidentially reporting stratified results using indirectly estimated race and ethnicity in addition to the

currently reported results stratified using dual eligibility, for the six condition/procedure-specific readmission measures, and by expansion of standardized data collection to additional social factors, such as language preference and disability status; (2) the possibility of publicly reporting stratified results using both indirectly estimated race and ethnicity, and dual eligibility, publicly on Care Compare, after at least one year of confidential reporting and further rulemaking, for the six condition/ procedure-specific measures; and (3) on possible mechanisms of incorporating other demographic characteristics into analysis that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

AHIP appreciates CMS's efforts to mitigate the effects of the COVID-19 pandemic on hospitals' performance in the HRRP. 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. As such, we support CMS's proposal to suppress the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #506) for the FY 2023 program year. We also agree with adding an exclusion criterion for a secondary diagnosis of COVID-19 for the remaining measures.

We have significant reservations, however, 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 to support stakeholder decision making. If CMS does seek to report the results of the RSRR following Pneumonia Hospitalization measure, the agency should perform analyses on options such as excluding data from 2020 and doubling up the 2019 data, excluding data from 2020 and using only two years of data, and, in future years, excluding data from 2020 and using three years that span before and after it (e.g., 2018, 2019, 2021). CMS could then compare the results to determine which is the most reliable and valid as well as what most closely tracks with historical performance.

We thank CMS for the support the agency has provided across the healthcare system in responding to the COVID-19 pandemic. AHIP agrees the entire healthcare industry must maintain its focus on mitigating the pandemic. The factors that impact provider performance will in turn impact plan and issuer performance. Consistent with this view, we encourage CMS to consider the impact of COVID-19 on its entire portfolio of quality and value-based purchasing programs, including the Qualified Health Plan Quality Rating System and the Medicare Advantage Star Ratings. We encourage CMS to similarly review those measurement programs to determine if measures within those sets may similarly require suppression or technical updates to account for the impacts of COVID-19.

AHIP agrees that health disparities must be identified and addressed. Stratifying performance measures offers an opportunity to understand if outcomes vary for different populations. As such, we would support additional stratification of the HRRP measures. We agree with the use of indirect methods of calculating race and ethnicity for the purposes of stratifying measures for confidential reporting. However, we do not support the public reporting of stratified results using imputed data on race and ethnicity. There is a lack of alignment in imputed methods and too

much variability in results to use information based on imputed methods for public reporting or payment purposes. Reporting such data publicly risks misinforming the public. We would support publicly reporting results stratified by dual eligibility or by self-reported race and ethnicity. AHIP would supports the collection of additional data elements to allow further stratification of the HRRP measures.

Recommendations:

- CMS should adopt the cross-program measure suppression policy and suppress the 30-day RSRR for pneumonia for the FY 2023 program year.
- CMS should modify the remaining readmissions measures to add an exclusion criterion for COVID-19.
- CMS should not publicly report the results of any measure suppressed under the cross-program measure suppression policy. If CMS seeks to report the results of the RSRR following pneumonia hospitalization, it should run analyses on options to mitigate the impact of the data from during the PHE and identify the most accurate and valid method that tracks with historical performance and provides consumers with the most reliable information.
- CMS should consider additional stratification of the readmissions measures; however, results based on indirect, impute methods should not be publicly reported.

V.H Hospital Value-Based Purchasing (VBP) Program: Proposed Updates and Changes (§§ 412.160 through 412.167)

The hospital VBP program is a budget-neutral program that redistributes 2% of participating hospitals' base operating DRG payments each fiscal year based on each hospital's relative performance or improvement on a set of quality indicators. CMS proposes to adopt a policy for the duration of the COVID-19 PHE that would give CMS flexibility to suppress the use of data for a number of measures if it determines that circumstances caused by the COVID-19 PHE have affected those measures and the resulting Total Performance Scores (TPS) significantly. CMS would calculate measure rates for all measures, including the measures the agency proposes to suppress.

CMS proposes to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (NQF #0166) for the FY 2022 Hospital VBP Program Year. CMS analyses show a significant deviation in performance during the COVID-19 pandemic and the agency believes utilizing the measure results could unfairly penalize hospitals that treated many COVID-19 patients.

CMS also proposes to suppress the Medicare Spending per Beneficiary (MSPB) measure for the FY 2022 program year. Based on the agency's analysis, CMS has found that hospitalizations involving COVID-19 tend to have higher overall mortality rates, longer lengths of stay, and

higher observed, payment-standardized costs than hospitalizations without COVID-19. Based on this analysis, CMS believes that these rapid changes in patient case mix have significantly affected the MSPB measure. Under this proposal, CMS would calculate hospitals' MSPB measure rates, but would not use these measure rates to generate achievement or improvement points.

Additionally, CMS proposes to suppress the five Healthcare Associated Infection (HAI) Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2022 program year due to significant deviation in national performance on the measures. CMS is concerned that the COVID–19 PHE affected measure performance on the current HAI measures such that the agency will not be able to score hospitals fairly or reliably. CMS would calculate hospitals' five HAI measure rates but would not use these measure rates to generate achievement or improvement points for these measures.

CMS proposes to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) Measure (NQF #0468) for the FY 2023 Program Year. CMS has performed analyses that demonstrate the clinical proximity of COVID-19 to the focus of this measure could negatively impact its validity. Additionally, CMS found that a substantial portion of the measure cohort includes admissions with a COVID–19 diagnosis. In addition, almost all of the admissions with a COVID-19 diagnosis have a principal diagnosis of sepsis; observed mortality rates for these admissions are extremely high and are substantially higher than admissions without a COVID-19 diagnosis. CMS notes concern that this could distort the data used to support this measure.

The agency proposes to maintain the Clinical Outcomes Domain, and thus would calculate achievement and improvement scores as well as a domain score. However, because the domain is only weighted at 25% of the TPS, and the agency would have no other domain scores, it proposes not to calculate TPS for hospitals for FY 2022. Instead, CMS proposes to allow hospitals to retain the 2% of payments that are customarily redistributed.

Finally, CMS proposes to permanently remove the CMS Patient Safety and Adverse Events Composite measure (PSI 90) beginning with FY 2023 as they believe the costs associated with the measure outweigh the benefits.

AHIP agrees with CMS that the COVID-19 pandemic could impact the validity of the measures used in the VBP program. We support CMS's proposal to adopt a measure suppression policy to protect against disparate impacts on performance that could unfairly penalize hospitals. We agree with CMS's proposal to revise the scoring and payment methodologies for FY 2022 and to suppress HCAHPS, the MSBP measure, the 30-day pneumonia mortality measure, 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 agree with the goal of reducing the burden of measurement. We agree that variation in how measures are used in the scoring algorithms of different programs can lead to conflicting and

confusing results. As such, we support CMS's proposal to remove PSI-90 from the VBP set as it is used in the HAC Reduction Program.

We appreciate CMS's efforts to ensure hospitals that treated large numbers of COVID-19 are not unfairly penalized by distorted results of the measures in the VBP program. However, we have similar and 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 to support stakeholder decision making. CMS should perform analyses to ensure the reliability and validity of all measure results 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, or assessing performance changes to ensure new results track with historical performance.

AHIP agrees with CMS that the healthcare industry must maintain its focus on mitigating the pandemic. We would encourage CMS to consider the impact of COVID-19 on its entire portfolio of quality and value-based purchasing programs, including the Qualified Health Plan Quality Rating System and the Medicare Advantage Star Ratings to determine if other measures may require suppression or technical updates to account for the impacts of COVID-19.

Recommendations:

- CMS should adopt the cross-program measure suppression policy and revise the VBP scoring and payment methodologies for FY 2022 program year.
- CMS should suppress HCAHPS and the HAI measures for the FY 2022 program year.
- CMS should suppress the 30-day pneumonia mortality measure for the FY 2023 program year.
- CMS should not publicly report the results of any measures that are suppressed for the VBP program. If CMS chooses to report the results of any measure based on data from the PHE, the agency should consider strategies to ensure the accuracy of the information provided to consumers.

V.I. Hospital-Acquired Conditions (HAC) Reduction Program: Proposed Updates and Changes (§412.170)

The HAC Reduction Program incentivizes hospitals to reduce the incidence of hospital-acquired conditions by adjusting payments to applicable hospitals. The 25% of applicable hospitals with the worst performance are subject to a 1% payment reduction. CMS proposes to suppress affected measures for the FY 2022 HAC Reduction Program such that hospitals will not be scored using distorted quality measure data and will not receive Total HAC Scores based on those data. Under this proposed policy, if CMS determines that the suppression of a HAC Reduction Program measure is warranted for a program year CMS would calculate measure rates

for that program year but then suppress the use of those rates to generate Total HAC Scores. CMS would instead assign each hospital a 0% weight for any suppressed measures in the Total HAC Score calculation.

CMS would provide confidential feedback reports to hospitals on their FY 2022 and FY 2023 performance to ensure that they are made aware of the changes in performance rates that were observed. CMS would publicly report the FY 2022 and FY 2023 data with appropriate caveats noting the limitations of the data due to the COVID-19 pandemic.

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 certain HAC measures, if necessary, and assign those measures a 0% weight in the total HAC score calculation. 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 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.

Recommendation:

- CMS should adopt the cross-program measure suppression policy for the HAC Reduction Program.
- CMS should suppress any measures unduly influenced by the COVID-19 pandemic when calculating the Total HAC Scores for FY 2022.
- CMS should not publicly report the results of any measure that are suppressed for the HAC reduction program. If CMS chooses to report the results of the measure based on data from the PHE, the agency should consider strategies to ensure the accuracy of the information provided to consumers.

V.L. Market-Based MS-DRG Relative Weight—Proposed Policy Changes (§413.20) (86 Fed. Reg. 25527)

In the FY 2021 IPPS rule CMS finalized a policy requiring hospitals to report the median payer-specific negotiated charge by MS-DRG for each Medicare Advantage (MA) organization with which it has a contract for cost reporting periods ending on or after January 1, 2021. The agency

intended to use this data to calculate a new market-based methodology for estimating MS-DRG relative weights beginning in FY 2024.

CMS now proposes to repeal this policy. The agency also solicits public comment on alternative approaches or data sources for rate setting in future years, whether it should revise, rather than repeal, the market-based methodology and whether it should delay use of any new methodology beyond FY 2024. Should CMS finalize a delay, it would conduct further analysis based on median payer-specific negotiated charge data received through Medicare cost reports and provide further opportunity for public comment.

AHIP strongly supports the proposal to repeal the reporting, collection, and use of its market-based MS-DRGs using MA median payer-specific negotiated charge data to inform payment rates under the IPPS. We opposed this policy at its inception and maintain the position articulated in our FY 2021 IPPS comment letter that this policy is flawed. Simply put, we do not believe the market-based MS-DRG policy would accomplish its intended aims to increase transparency and establish a market-based IPPS, and moreover, believe it could result in unintended, negative consequences. Specifically, we are concerned that this policy: (1) does nothing to inform consumers about actual out-of-pocket costs; (2) will not reduce overall fee-for-service (FFS) beneficiary spending; (3) creates unnecessary burden on hospitals at a time when they are focused on moving from response to recovery from the COVID-19 pandemic; (4) has largely unknown consequences across the health care system, including MA benchmarks; and (5) has the potential to introduce new distortions and inaccuracies in MS-DRG rates.

Health insurance providers' primary goal is to ensure individuals have access to affordable, comprehensive health care. We wholeheartedly support informing people in advance about the cost and quality of health care services, enabling choice, and encouraging cost-conscious decisions to lower overall health care costs. However, the approach finalized in 2021 does nothing to provide Americans with timely, accurate, and actionable information on which to make decisions about health care, whether they are insured or uninsured. Instead, it provides a meaningless median with no relationship to patient cost-sharing, using an arcane report fed into a massive data file that cannot be practically accessed or readily understood by patients.

Altering the MS-DRG weights is this way will shift payments from one service to another. It will not impact beneficiary out-of-pocket costs that are based on a fixed deductible and per-diem cost-sharing for longer stays. And, on balance, will not result in any savings to the Medicare program as the rates must be budget neutral from year to year, except for the market-basket update and related policies.

Last year's rule included many policies that acknowledged the immense strain that the COVID-19 pandemic put on the healthcare system. However, finalizing this policy was conspicuously contrary to that refrain. Now is not the time implement a burdensome policy that fails to meet its intended goals and has the potential to result in unintended consequence.

Medicare MS-DRG weights and standardized amount are often used by MA plans and their network providers as a benchmark for contracted reimbursement rates. Moreover, MA plans are

required to reimburse at Medicare FFS rates for out-of-network services. Therefore, this proposed policy impacts not only FFS but also provider rates in MA. Additionally, the agency has not offered any analysis of whether the calculation finalized last year would result in any meaningful impact on the service weights (generally and specifically), nor whether the magnitude of those shifts would be substantial enough in certain geographic areas to impact MA benchmarks. Finally, forced disclosure of private, sensitive rates among competing providers can undermine negotiations and the effectiveness of selective contracting, a mechanism successfully used by MA plans to drive down health care costs, improve quality and enhance overall value in the delivery of health care services. This risk is all the more acute in markets with few providers or MA plans. As noted by the FTC, "[t]here is substantial risk that greater price transparency in concentrated health care markets may impede, rather than enhance, the ability of [health plans] to selectively contract with health care providers and to negotiate lower reimbursement rates."[3] In sum, the benefit of this transparency initiative for patients is significantly outweighed by the concomitant risk of sharing information with competitors.[4]

CMS has not adequately considered this policy's impact on alternative payment models (APM) and AHIP is concerned that the policy risks impeding APM adoption. Health insurance providers have embraced value-based payment models by investing substantial resources in developing and implementing APMs focused on high-quality, cost-efficient care. These APMs are often incomparable with the MS-DRG system, making it difficult to crosswalk such payments for purposes of reporting, and moreover, potentially distorting any calculations that include such payments. Rates paid under an APM are reflective of the broader goals of value-based payment reform, which may not reflect the actual market-based dynamics of unit prices.

AHIP supports CMS' stated goal of transitioning the Medicare FFS payment system to one that more closely reflects the actual cost of services in a true market. However, we believe better alternatives exist beyond the policies finalized in 2021. We believe CMS resources would be better invested in Center for Medicare and Medicaid Innovations (CMMI) models to test market-based policies. For example, we believe the Geographic Direct Contracting model, which would allow private payers to manage FFS beneficiaries within an APM structure could be used for this purpose.

AHIP welcomes the opportunity to further engage with CMS on our recommendations and to continue dialogue on other alternative approaches.

Recommendation:

[3] FTC Letter to MN State Reps Hoppe and Hortman (June 29, 2015).
[4] FTC, Price transparency or TMI? (July 2, 2015) (noting that, forced disclosure of competitively sensitive health care pricing information may result in anticompetitive consequences and this "risk is especially great if the information becomes accessible to competing health care providers in markets with only a few providers."); CMS, Notice of Benefit and Payment Parameters for 2021, 85 Fed. Reg. 29164, at 29194 (May 14, 2020) (declining to release information that can "reveal market conditions and issuers' private financial data" and noting that the agency believes that "it is important to protect information that contains trade secrets or confidential commercial or financial information" within the meaning of HHS's FOIA regulations).

- CMS should finalize its proposal to repeal the reporting, collection, and use of its market-based MS-DRGs using MA data to inform payment rates under the IPPS starting in FY 2024.

- CMS should not consider an alternative approach to revise and delay the policy. We do not believe implementing any of the alternatives discussed through previous rulemaking would resolve the inherent problems articulated herein and in our 2021 comment letter.

IX.A. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs – Request for Information

CMS reiterated its desire to move to digital measurement in its hospital quality programs by 2025. To support this transition, the agency is seeking information on:

- Clarifying the definition of digital quality measures (dQMs), including a potential definition for digital measures. CMS currently defines dQMs as "sources of health information that are captured and can be transmitted electronically and via interoperable systems" [5] but is seeking input on a future elaboration that would define a dQM as a "software that processes digital data to produce a measure score or measure scores". An electronic Clinical Quality Measure (eCQM) is the most common form of dQM. However, dQMs can include information generated from medical devices or digitized information from patient portals or similar modules.

- Using the Fast Healthcare Interoperability Resources (FHIR®) standard for eCQMs that are currently in the various quality programs. Currently multiple standards are used to report eCQMs which increases the burden using them.

- Standardizing data required for quality measures for collection via FHIR-based APIs;

- Leveraging technological opportunities to facilitate digital quality measurement;

- Better supporting data aggregation; and

- Developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.

Response:

Performance measurement is an essential tool to assess and improve the quality and value of healthcare delivered to Americans. Quality measures allow consumers to understand the value offered by a provider and can serve as important protections against stinting of care by ensuring performance is judged by successful outcomes and appropriate processes, not on cost alone. This is an especially important protection for some patients, such as those who may be members of racial and ethnic minorities, who have historically experienced access challenges that can

[5] CMS-1752-P; FY 2022 IPPS Proposed Rule

skew cost data in the absence of information about quality. The increased reliance on performance measures to support quality reporting and value-based payment models has, however, led to a proliferation in the number of measures and a commensurate increase in burden on providers and confusion among consumers and purchasers and operational difficulties and administrative expense for both payers and providers. Health information technology offers the potential to streamline the burden and cost related to reporting and collecting data needed to support measurement, while allowing measurement of novel concepts that could not previously be assessed due to data limitations.

We agree with CMS that dQMs must operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange. First and foremost, we believe that the data exchange and tools must protect patient privacy and the security of the 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 result in sensitive information being shared with entities that are not covered by the Health Insurance Portability and Accountability Act (HIPAA) or a similar, equally protective, regulatory paradigm. Digital quality measures requiring potentially sensitive patient data sent over an API and being held by unregulated entities could be at risk of 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.

Digital quality measures 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 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 the digital quality measures 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. Quality improvement depends not only on the measures used but also how they are collected, calculated, reported, applied and displayed. To achieve improvements care, measurement must be associated with the right incentives and lead to the ability to analyze and utilize results effectively.

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

Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?

Digital quality 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 of quality measurement such as the surveys used to generate patient-reported outcome measures. Digital quality measures as outlined in the proposed rule could allow for automated extraction and reporting that could reduce the time and staff resources required. As the most used type of dQM, overcoming the challenges that have plagued eCQMs is an important step in transitioning to digital measurement. Converting current eCQMs to the FHIR-standard could streamline reporting and reduce burden.

However, while we agree that FHIR-based quality reporting has the potential to reduce burden, such 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 we agree that 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.

As discussed above, increased used of eCQMs, the full 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. 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. Assuring universal EHR adoption and utilization will be critical to the success of digital quality 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 Health Information Exchanges (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. Thus, transitioning to digital quality measurement by 2025 may not be feasible. 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.

Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach?

AHIP supports aligning with the requirements of the Interoperability and Patient Access final rule. This approach could support measure alignment across payers, allow comparisons across provider types and settings, prevent competing or duplicative requirements, and allow the incorporation of new types of data into performance measures. Improvements happen when data is available and easily accessed and tracked or reported. Sharing of the digital quality measurement within workflows in an accessible and near real-time fashion can enable the information to be acted upon more rapidly and accurately. However, CMS should consider ways to improve and strengthen the interoperability requirements to ensure they support a successful transition to a digital measurement infrastructure.

First, there are challenges to aligning digital measurement with interoperability requirements. 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. Thus, it is key that the HHS quickly issue the Trusted Exchange Framework and Common Agreement (TEFCA) proposed rule. 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.

Are there specific FHIR Implementation Guides suggested for consideration?

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. The use of common open HL7 FHIR standards would ensure dQM data is consistent and allow the exchange of the data with CMS and other quality programs.

How important is a data standardization approach that also supports inclusion of person-generated health data (PGHD) and other currently non-standardized data?

Standardizing data that is not currently standardized could allow for measurement of novel concepts that we are currently unable to evaluate. This could facilitate quality improvement efforts in areas that have previously been unassessed. Working with EHR vendors to standardize additional clinical data such as physician notes and other free text fields could allow for better understanding of clinical decision making and new opportunities for quality 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 PGHD has the potential to provide a wide-ranging picture of a person's health and healthcare outcomes, we are concerned that the level of standardization necessary to support quality measurement may not be possible at this time. Instead, 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.

What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable (for example, standardized EHR data available via FHIR-based APIs)?

AHIP supports the vision for the future of digital quality measurement outlined by CMS in the proposed rule. We agree that digital measures should perform the functions outlined in Section (4)(b), specifically, that digital quality measurement should obtain data via automated queries

from a broad set of digital data sources, calculate the measure score according to measure logic, and generate a measure score report. AHIP recognizes potential of APIs and digital measures to reduce burden and promote innovative measurement. We agree with the agency 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.

However, from our perspective, this will be a journey over time as only hospitals are subject to this requirement and only a subset of data will be available at first. 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. Moreover, additional work must be done to further flesh out the FHIR-based standards for the exchange of quality information between providers and payers.

We agree that digital measures should be compatible with any source data systems that implement standard interoperability requirements. If separate data systems require separate digital measures, that will only reinforce the current fragmented and siloed approaches to medical data and performance measurement. We agree that digital measures should exist separately from digital data sources and be tested and maintained independently from the data source systems. The adoption of digital measures should not require that healthcare providers or public or private payers adopt specific electronic health record systems or join certain registries or health information exchanges to calculate digital measures.

We also agree that digital quality measures should have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications. 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.

AHIP and its members support exploring opportunities to further align measures across public and private payers. We appreciate the agency's recognition of the work of the Core Quality Measures Collaborative (CQMC) to support this goal. We agree leveraging the work of the CQMC could provide a framework for greater public/private alignment of measurement. For example, 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. We look forward to continuing the partnership with CMS to improve care for all Americans through these efforts.

Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

AHIP agrees with CMS that aggregation of data from multiple sources could alleviate the burden of measurement while providing better information to assess quality of care. We also agree 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. 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.

What are initial priority areas for the digital quality measurement portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)? We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

To provide better information for consumers and reduce the burden of measurement on providers, AHIP and CMS convened the CQMC to align performance measures 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. CMS and its measure developers could look to the work of the CQMC to identify priority areas where digital measurement could reduce clinician burden and address variations in cost and quality.

We recommend that CMS continue to consider the role of currently NQF-endorsed process measures and process measures prioritized by the CQMC as the agency develops digital measures. While outcome measures are the gold standard, process measures can serve a valuable purpose in demonstrating adherence to evidence-based care particularly, when measure concepts are new and outcomes measures are not yet developed. Process measures could also serve an important role in promoting health equity. These measures provide important protections against stinting of care, especially for patients who may experience discrimination or access challenges.

However, despite the importance of the process measures described above, digital measurement should focus on outcomes measures, including reducing the burden associated with existing measures based on the legacy chart-based system. The new opportunity presented by movement towards digital measures greater ability to collect high-value but hard to collect data such as patient experience and patient-reported outcome measures. There is often a disconnect between the patient and the provider, and so the patient perspective would be a valuable new source of information. Consumers need this information to support their choices about where to seek care and health insurance providers could use this data to build high-quality networks of patient-centered health care providers.

We also recommend that CMS ensure digital measures are based in sound scientific evidence, are reliable and valid, and feasible to implement. To ensure digital measures meet these requirements, CMS should submit such measures for a multi-stakeholder review through a consensus-based entity and coordinate with the private sector through the Core Quality Measure collaborative.

IX.B. Closing the Health Equity Gap in CMS Hospital Quality Programs – Request For Information

CMS seeks feedback on "closing the gap in health equity" through looking more closely at race and ethnicity for condition and procedure specific readmissions, potentially developing a health equity score measure for hospitals modeled off the Health Equity Summary Score designed for Medicare Advantage contracts and plans, and the concept of hospitals collecting a minimum set of demographic data at the time of beneficiaries' admissions. CMS intends to release a subsequent RFI that is more comprehensive than the requests included in this proposed rule.

CMS first provides background on their efforts to date. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN-QIOs); Federal, State, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity. The CMS Quality Strategy and Meaningful Measures Framework also include elimination of racial and ethnic disparities as central principles. Efforts aimed at closing the health equity gap to date have included providing transparency of health disparities, supporting providers and health officials with evidence-informed solutions to address social determinants of health and achieve health equity, and reporting to providers on gaps in quality as follows:

- The CMS Mapping Medicare Disparities Tool, which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.
- The Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report, which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.

Response:

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 this request for information and consider health equity a priority of our own. 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 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 CMS considers options to address equity through its quality programs, we recommend continued consideration of the challenges to 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. 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.

AHIP believes it is important to understand the impact that structural and socioeconomic factors have on outcomes and disparities. Patient outcomes are not the solely a product of healthcare and there is a need to balance improving results with the risk of unfairly penalizing health care or health insurance providers in public reporting or value-based purchasing programs. We also believe in the importance to addressing the structural and socioeconomic barriers to health. This speaks to the value of incorporating social risk factors into the risk adjustment models of performance measures used for payment purposes or to account for differences in populations in scoring algorithms so that hospitals, health plans, and other organizations who serve more socioeconomically complex populations receive the appropriate resources and support to properly care for these populations while also not being unfairly penalized for doing so. Measures must be accurate and reflect the quality of care provided, especially when used for accountability purposes such as public reporting or value-based purchasing. We are pleased to provide the following information to support CMS's work to reduce gaps in health equity.

The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for hospital--level disparity reporting, until more accurate forms of self-identified demographic information are available.

AHIP supports adding stratification by race and ethnicity 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. We also agree with CMS that self-reported data is the gold standard, and we are supportive of efforts to enhance data collection. We appreciate CMS acknowledging the challenges of collecting self-reported 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 request CMS adopt policies across its programs to improve the collection of self-reported data on race and ethnicity and social risk. CMS should work with the states so 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. We appreciate the need to urgently address issues of health equity and as such, recognize NCQA's leadership in this area through potential 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.

Health insurance providers are working to improve our data and to advance the collection of self-reported data to support efforts to promote health equity by developing demographic data standards for standardization and interoperability, developing scripts to explain why this information is being collected and how it will be used to inform care and services, updating privacy policies to ensure sociodemographic data is appropriately protected, and developing data governance policies to ensure consumer ownership of the data.

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. However, while such indirect data is more feasible to obtain, it is also less accurate, especially as America becomes more diverse with people identifying as more than one race or ethnicity. Moreover, this data may lack face validity with consumers and other stakeholders who distrust this data and fear it could mask disparities. As such, we would support the use of imputed data for the purposes of identifying disparities for quality improvement only and not public reporting. We also recommend that CMS work with regulators and private payers to coalesce around a standardized imputed method be used across the industry given the variability and lack of alignment in imputed methods—which could lead to comparisons that are not apples to apples misleading improvement efforts.

The extent of variability and lack of alignment in imputed methods should preclude its use for public reporting or payment purposes. The use of imputed data for such purposes risks inaccurately penalizing hospitals. We request that CMS develop appropriate guardrails to ensure accuracy of indirect data.

We are also concerned about the potential for small denominators of different racial or ethnic groups at some hospitals given regional variation in population demographics. We request that CMS establish minimum denominators that are statistically significant for fair comparisons on reducing disparities. Indirect data methods, in particular, may struggle to appropriately segment populations with statistical significance as the volume for certain populations (such as American Indian, Alaska Native, Asian American, Native Hawaiian, Pacific Islander) is too low. Imputed data should serve as a bridge to self-reported data. The use of imputed data should add burden to consumers or providers and should not distract from efforts to transition to self-reported data.

We agree with CMS's concerns about the potential for harmful bias in imputed algorithms. However, we first need better definitions and approaches to measure bias. As an interim step, greater transparency of how imputed algorithms are calculated could allow for monitoring of potential harmful biases. We caution that efforts to enhance race and ethnicity data must be done carefully to ensure consumer trust and confidence is maintained. 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.

Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data is properly identified if/when it is shared with providers.

AHIP agrees that privacy is an essential component of increased use of data on race and ethnicity. We concur that examining performance data to understand the care that different populations receive is essential to finding and eliminating healthcare disparities. However, the use of data on race and ethnicity or other sociodemographic factors introduces a risk that must be mitigated as such data could leave consumers open to a greater threat of discrimination.

First, we recommend that CMS ensure there are an adequate number of patients included in reports so that no individual could be inadvertently identified. 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).

Second, as CMS transitions from imputed data to self-reported data, we recommend that safeguards to protect patient privacy be implemented across the entire process of data collection, reporting, and data sharing. We recommend that CMS include guidance for best practices on how data is gathered and identified as well to ensure that individuals retain agency in providing sensitive demographic information or declining to provide this information. This holistic view of data handling would strengthen consumer ownership and agency while ensuring sensitive data are accurate and protected. CMS should consider opportunities for consumer education and notification on the importance of self-reported data and the use of indirect methods in the interim.

Finally, CMS should consider ways to develop demographic data standards that are evidence-based and stakeholder-driven. CMS could work with stakeholders to improve data collection for race, ethnicity, and language data such as improving the granularity of the Office of Management and Budget (OMB) standards to allow consumers to report how they truly identify. AHIP has a Health Equity Workgroup composed of member health plans who have developed recommended, voluntary evidence-based and stakeholder-driven demographic data standards for these demographic elements with the intention of standardizing these data elements across the insurance industry. We would be happy to share these standards for CMS's consideration use in data standardization across the health care industry. We reviewed the following sources to inform our data standards: The Agency for Healthcare Research and Quality (AHRQ) for collecting information on English Proficiency & Language Preference in health care specific settings; the Affordable Care Act's (ACA) Sec. 4302 National Health Information Survey (NHIS) survey questions, and the International Classification of Functionalities, Disabilities, and Impairments (ICF) model for disability; and the Fenway Institute's National LGBTQIA+ Education Center & the Health Resources and Services Administration (HRSA) Uniform Data System (UDS) for sexual orientation and gender identity; and the PRAPARE Social Determinants of Health Assessment tool for homelessness and housing instability as well as educational attainment.

Ways to address the challenges of defining and collecting, accurate and standardized, self-identified demographic information, including information on race and ethnicity, disability, and language preference for the purposes of reporting, measure stratification, and other data collection efforts relating to quality.

Health insurance providers have been working to collect self-identified demographic data on their members but have faced barriers. While payers and hospitals may have different options for collecting the data from a patient, trust and understanding of the purpose for which the data will be used is essential. Surveys that include questions on demographic data are often met with negative reaction and response. There may be a perception of potential discrimination for benefit or service eligibility, distrust, and lack of understanding of the purpose. 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 demographic 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.

Improving the patient experience is a key tenet of value-based care. Public and private payers have implemented efforts to ensure hospitals are incentivized to provide patient-centered care, communicate clearly, and treat all patients with respect. Efforts to collect data should not jeopardize efforts to build trust between patients and providers and improve the patient experience. 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. This could alleviate the need for hospital staff to ask for demographic data at such a delicate time. We would also encourage CMS to work with hospitals to consider utilizing non-clinical staff (e.g., social worker or community health workers) who may be better trained to build trust in short periods of time.

We would encourage CMS to work with hospitals 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 to improve demographic data collection to develop frameworks, workflows, guidance, and best practices to collect race/ethnicity 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.

We ask that stakeholders be prepared to address the sanctity of personal data to avoid the risk of discrimination. For example, 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.

We also caution there may be challenges with data fidelity and validation with self-reported data. Consumers may not feel comfortable disclosing data in all situations, leading to potential discrepancies and underreporting. We 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 data collection. For example, consumers should be provided multiple opportunities to share their demographic information privately.

CMS should 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. Well-intentioned but hastily implemented efforts to collect personal data risks jeopardizing these efforts.

Finally, CMS should work with health insurance providers and other stakeholders to identify ways to improve demographic data collection across the healthcare industry. For example, improvements could be made to the application and enrollment processes for health insurance to collect this data more directly, as well as to standardize and include more data than what is typically collected at the state level, i.e. age and gender. There is also a need for additional standardized categories that could provide health care and health insurance providers with more information about the relative disadvantages a person may be experiencing, or information that would provide for more predictive analysis for a patient. An important component of this could be to align race and ethnicity assessments and categories across states and with the standards maintained by the Office of Management and Budget (OMB). Currently, it is a challenge to align with OMB categories when state files do not align. CMS could also work with state Medicaid agencies to improve the consistency of data collection at the time of Medicaid enrollment. We also support the adoption of the United States Core Data for Interoperability (USCDI) task force recommendations to include SDOH in USCDI v2. Including SDOH in the USCDI would allow for broader sharing of this data and improved interoperability across systems.

Recommendations for other types of feasibly collected data elements for measuring disadvantage and discrimination, for the purposes of quality reporting and measure stratification, in addition to, or in combination with, race and ethnicity.

CMS should consider advancing data collection on other sociodemographic data elements that are associated with healthcare disparities and can influence health over time. We recommend the following data elements:

- English proficiency and language preference
- Disability status
- Sexual orientation
- Gender Identity
- Veteran status
- Homelessness and Housing Instability
- Highest level of educational attainment

Several potential sources could be leveraged to standardize collection of these data elements. AHIP has a Health Equity Workgroup composed of member health plans who have developed recommended evidence-based and stakeholder-driven demographic data standards for these demographic elements with the intention of voluntary standardization of these data elements across the insurance industry. We would be happy to share these standards for CMS's consideration for data standardization across the health care industry to promote interoperability and greater apples to apples comparisons across systems. As noted above, we reviewed numerous sources to identify potential data standards.

We also recommend developing more granular standards for race and ethnicity and working with electronic health record (EHR) vendors to allow consumers to report more than one race and ethnicity. Most EHRs do not currently have this function. Stakeholders could explore ways to allow organizations to choose which nationalities to include when asking more granular race/ethnicity questions based on the most common nationalities in their areas in order to reduce data collection burden while supporting consumers' identities.

Finally, CMS could consider use of the Area Deprivation Index (ADI) to support quality measurement efforts and stratification to incorporate a composite view of social risk factors and geographical disparities. Should CMS decide to use the ADI, the NQF is developing guidance on the appropriate use of ADI and other social risk factors for quality measures in their forthcoming report on when and how to adjust quality measures using social risk factors that could prove useful.

Future potential stratification of quality measure results by race and ethnicity

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, the Medicare Spending Per Beneficiary measure and the risk-standardized payment measures, and HCAHPS and other patient experience measures. Mortality is an essentially important outcome and unfortunately disparities exist in this area. We note that 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.

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.

CMS could also explore stratifying process measures that address conditions with known disparities (e.g., maternal health measures, cancer measures, cardiology measures, CKD measures). Ostensibly, process measures are more in the control of providers, thus the concern about inadequate risk adjustment is minimized.

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 aligning stratification of conceptually similar measures across programs and with other stakeholders such as NCQA who are also exploring ways to use measurement to identify and address disparities by stratifying HEDIS measures by race and ethnicity.

CMS could help facilitate health plans' and hence health care organizations' abilities to address health-related social needs by including medically related social services into Medicaid managed care contracts and capitation rates (with eligibility for federal match) as well as covered Medicare Advantage benefits. Because medically related social services improve outcomes and reduce costs, they should be considered quality improvement activities and should be counted towards the numerator of the Medical Loss Ratio (MLR) requirement applied to health plans.

Examples of approaches, methods, research, and/or considerations for use of data driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in algorithms or be encoded in datasets.

Artificial intelligence (AI) is a fairly new and emerging field that can enhance efficiencies, improve outcomes, and yield benefits by leveraging automated processes. AI, however, must be deployed prudently to try to ensure that the goal of the technology is achieved without causing any unintended, adverse outcomes. For example, concerns have been raised regarding the potential incorporation of unintended bias. At this time, there are no standardized ways to assess whether algorithms may result in an unintended, biased result. At this time, it may be premature to measure and identify bias, and more discussion and collaboration can be done in this area. Transparency in how algorithms are calculated and what data sets are used is a good first step in this process. AHIP is working with the Consumer Technology Association in the areas of standards development and trust and we expect to continue this engagement as there is not yet industry consensus on these important concepts.

The possible collection of a minimum set of demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, tribal membership, and disability status),by hospitals at the time of admission, using electronic data definitions which permit nationwide, interoperable health information exchange, for the purposes of incorporating into measure specifications and other data collection efforts relating to quality.

AHIP supports the exploration of a possible minimum data set of demographic data elements. We agree such a set should include race, ethnicity, sex, sexual orientation and gender identity, primary language, tribal membership, and disability status. We would also recommend including veteran status, housing status, and highest level of educational attainment.

AHIP has a Health Equity Workgroup composed of member health plans who have developed recommended, voluntary evidence-based and stakeholder-driven demographic data standards for these demographic elements with the intention of standardizing these data elements across the insurance industry. We would be happy to share these standards for CMS's consideration for data standardization across the health care industry to promote interoperability and greater apples to apples comparisons across systems. As noted above, we reviewed numerous sources to identify potential data standards.

As we note above, we recommend developing more granular standards for race and ethnicity and working with electronic health record (EHR) vendors to allow consumers to report more than one race and ethnicity as most EHRs do not currently have this function. Stakeholders could explore ways to allow organizations to choose which nationalities to include when asking more granular race/ethnicity questions based on most common nationalities in their areas in order to reduce data collection burden while supporting consumers' identities.

CMS could also consider how to include data on social determinants of health (SDOH), when possible, as well as strategies to improve these data elements. The Gravity Project is creating standards to represent data on social determinants in EHRs to promote interoperability of this data. The ICD-10 Z codes could facilitate this data collection but use of these codes continues to lag due to lack of education, limitations on staff able to input ICD-10 Z codes, and provider concerns Moreover, there may be a need to revise the language associated with these codes to ensure it is neutral and not judgmental to ensure consumers feel comfortable responding and clinicians feel comfortable asking the necessary questions. Many providers are not aware of Z codes and many EHRs do not have easy pathways to add a Z code to the problem or diagnostic list. Providers also have concerns over adding Z codes to the problem or diagnostic list because they then feel individually responsible for addressing these health-related social needs that occur outside of the doctor's office.

We would recommend CMS seek to align collection or sociodemographic and SDOH data around the Office of Management and Budget (OMB) standards to improve the consistency and thus interoperability of demographic data. CMS also should consider coordinating with the Office of the National Coordinator's (ONC's) efforts to update the USCDI to include SDOH to allow for better sharing of this data across providers. Finally, CMS should also collaborate with the Centers for Disease Control and Prevention to leverage their work to develop more granular race and ethnicity classifications that could be implemented voluntarily and then rolled up to the OMB codes.

A consumer-centric approach should be emphasized for how and when this data is collected. Hospitals and the employees tasked with supporting data collection efforts must build trust with consumers to ensure those consumers feel comfortable providing data and ensure data is collected at appropriate times in an appropriate manner. For example, collecting demographic data in the Emergency Department may not be the most appropriate time or location if the individual is experiencing an emergency or stressful, emotional, or traumatic experience.

While we agree with goal of electronic, interoperable information exchange, it may not be currently feasible. We would recommend CMS consider reasonable implementation timelines for the development and collection of a minimum data set of sociodemographic information as it can take time to create the data systems, collection points, coding systems, and technological infrastructure to support such efforts.

The possible creation and confidential reporting of a Hospital Equity Score to synthesize results across multiple social risk factors and disparity measures.

AHIP supports additional efforts to identify healthcare disparities and we agree that the creation and confidential reporting of a Hospital Equity Score could serve to provide important comparisons across social risk factors and among facilities while incentivizing hospitals to focus on reducing disparities and advancing health equity. We support alignment of the Hospital Equity Score with the Health Equity Summary Score (HESS) and would encourage CMS to consider expanding equity scores across healthcare settings to focus the entire industry on the need to address disparities.

To ensure transparency and promote stakeholder buy-in, we request that CMS publish the specifications, pursue specific input, and pilot test the HESS and the Hospital Equity Score, then seek public comment prior to implementation of these measures. We also request that CMS consider submitting these summary scores for stakeholder review through a consensus-based entity (e.g., NQF endorsement or review by the Measures Application Partnership). Appropriately benchmarking the between-hospital scores is essential to enable fair comparisons. We would recommend CMS identify and consider ways to address geographic variation and the potential influence of a hospital's location and patient population on its summary score and consider potential appropriate risk adjustment to ensure that hospitals that serve more complex populations are not unfairly penalized. The summary score should be designed to highlight true differences in performance, not underlying differences in a population served. CMS should consider how the hospital equity score or HESS 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.

CMS could also consider the types of measures that should be included in these summary scores. Measures that directly assess actions taken to address equity and address structural racism could be potential concepts to explore for inclusion in the Hospital Summary Score. AHIP has convened a Health Equity for Value-Based Care workgroup to identify the measurement domains that should be addressed to promote health equity. 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. We would be happy to share the results of this work with CMS.

Finally, we recommend CMS consider ways to balance the accuracy of the information conveyed by the Hospital Equity Score with the needs of stakeholders to understand performance related to

health equity. If equity information was made public, health insurance providers would be better able to better understand what health care providers in their networks were doing 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. We do not support the public reporting of data based on indirect or imputed methods to determine a consumer's demographics. However, CMS could consider reporting results of the Hospital Equity Score in the future if self-reported data is available and the tool is found to be evidence-based, valid, and reliable through a multistakeholder, consensus-based review. If results are publicly reported, CMS should make the Hospital Equity Score synergistic with the information currently reported on the *Care Compare* to avoid conflicting or misaligned information.

When developing the HESS and the Hospital Equity Score, CMS should consider:

- How to incentivize and reward both attainment and improvement. We recognize the inherent challenges of serving the socially vulnerable; however, we must ensure quality is improving for all.
- Criteria for selecting measures included in the score. CMS should develop specific criteria for inclusion and vet them with stakeholder prior to implementation.
- How to address the potential small number problems.
- A confidential reporting period to allow plans and hospitals time to understand their scores.

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

The Hospital IQR Program is a pay-for-reporting program that reduces payment for hospitals that fail to meet program requirements. In the FY 2022 IPPS/LTCH PPS proposed rule, CMS proposes to adopt five new measures, remove five existing measures, and make changes to the existing EHR certification requirements along with other administrative updates.

Specifically, the rule proposes to adopt:

- A new structural measure—Maternal Morbidity Structural Measure—beginning with a shortened CY 2021 reporting period/FY 2023 payment determination;
- The COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination and for subsequent years;
- A Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure in a stepwise fashion, beginning with a voluntary reporting period that will run from July 1, 2022 through June 30, 2023, and followed by mandatory reporting beginning with the

reporting period which runs July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years; and

- Two medication-related adverse event electronic clinical quality measures (eCQMs) (Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e) and Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e)) beginning with the CY 2023 reporting period/FY 2025 payment determination.

The rule proposes to remove:

- The death Among Surgical Inpatients with Serious Treatable Complications measure (NQF #0351) beginning with the FY 2023 payment determination;
- The exclusive Breast Milk Feeding (NQF #0480) measure beginning with the FY 2026 payment determination;
- The admit Decision Time to Emergency Department (ED) Departure Time for Admitted Patients (NQF #0497) measure beginning with the CY 2024 reporting period/FY 2026 payment determination; and
- Two stroke-related eCQMs (Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436) and Discharged on Statin Medication eCQM (STK-06) (NQF #0439) beginning with the CY 2024 reporting period/FY 2026 payment determination.

Response:

AHIP supports the addition of the Maternal Morbidity Structural measure. Despite the United States' high maternal mortality rate, maternal health is an underassessed area in the IQR program. Improving maternal health will be essential to achieving health equity. This measure represents an important step toward improving quality in this area. However, we encourage CMS to transition this measure from a structural measure to an outcome measure over time.

We also support the addition of the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure. Vaccinations offer powerful protection against COVID-19 and consumers deserve to have information on rates of vaccination coverage among personnel at facilities where they may be served.

AHIP supports inclusion of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) with Claims and Electronic Health Record Data measure in the IQR program. We support CMS's promotion of innovative measures such as eCQMs. We support CMS's proposal to conduct a voluntary reporting period to allow hospitals that do not have experience reporting the measure to gain familiarity with the specifications. We recommend CMS closely monitor for unintended consequences during the voluntary reporting period and update this proposal accordingly.

AHIP supports the inclusion of the Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e) and Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e)) measures beginning with the CY 2023 reporting period/FY 2025 payment determination.

AHIP supports the removal of the Death Among Surgical Inpatients with Serious Treatable Complications (NQF #0351) pending finalization of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure. While we appreciate the need to keep measure sets as parsimonious as possible, we believe there may still be a role for the Exclusive Breast Milk Feeding (NQF #0480) measure even after finalization of the proposed Maternal Morbidity Structural Measure. This measure is in the CQMC Obstetrics and Gynecology Core Set. We recommend CMS coordinate with other stakeholders to determine if there may be value in retaining this measure.

We support the removal of Admit Decision Time to Emergency Department (ED) Departure Time for Admitted Patients (NQF #0497), Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436) and Discharged on Statin Medication eCQM (STK-06) (NQF #0439).

AHIP appreciates CMS's work to support the healthcare system throughout the COVID-19 pandemic. As noted in our response to other portions of this proposed rule, we agree with the need to adopt a measure suppression policy to mitigate the potential effects of the pandemic on the results of performance measures in CMS programs. We are concerned about publicly reporting skewed data that could mislead consumers and unfairly penalize providers. We recommend CMS perform analyses to determine if COVID-19 had a material impact on the results of measures that are publicly reported under the IQR program to determine if the results are accurate enough to post on *Care Compare*.

We would encourage CMS to consider the impact of COVID-19 on its entire portfolio of quality and value-based purchasing programs, including the Qualified Health Plan Quality Rating System and the Medicare Advantage Star Ratings to determine if other measures may require suppression or technical updates to account for the impacts of COVID-19. The factors that impact provider performance will in turn impact plan and issuer performance.

Recommendations:

- CMS should finalize the proposals to add the Maternal Morbidity Structural Measure, COVID-19 Vaccination Coverage Among Health Care Personnel (HCP), Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM), Hospital Harm-Severe Hypoglycemia (NQF #3503e) and Hospital Harm-Severe Hyperglycemia (NQF #3533e) to the IQR program measure set.
- CMS should finalize the proposal to remove Death Among Surgical Inpatients with Serious Treatable Complications (NQF #0351), Admit Decision Time to Emergency Department (ED) Departure Time for Admitted Patients (NQF #0497), Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436) and Discharged on Statin Medication eCQM (STK-06) (NQF #0439) from the IQR program measure set.

- CMS should seek additional stakeholder feedback on continued use of the Exclusive Breast Milk Feeding (NQF #0480) as this measure may have value separate from the Material Morbidity Structural Measure.

Potential Future Development of Two Measures

The agency requests comment on the potential future development and inclusion of two measures: a mortality measure for patients admitted with COVID-19 and a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA).

Response:

AHIP agrees with the importance of gaining a better understanding of COVID-19 mortality rates and best practices for treatment. However, we do not support the potential future inclusion of a COVID-19 mortality measure in the IQR program at this time. While the PHE is ongoing, rates of COVID-19 are declining, and vaccination coverage continues to increase. It is too early to know the likely future rates of COVID-19 cases and how they will be distributed in different parts of the country and when they will occur. Additionally, treatment protocols for COVID-19 continue to evolve and performance benchmarks for COVID-19 mortality are unknown.

AHIP supports the potential future inclusion of a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA), including CMS's proposal for a phased implementation to allow hospitals time to develop data collection mechanisms and gain familiarity with the measure. We support 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.

Recommendations:

- AHIP does not support the potential future inclusion of a COVID-19 mortality measure in the IQR program at this time as it is too early to know the likely future rates of COVID-19 cases, treatment protocols for COVID-19 continue to evolve and performance benchmarks for COVID-19 mortality are unknown
- CMS should develop measures addressing priority measure concepts such patient-reported outcomes.

Modifying Promoting Interoperability Program Requirements

CMS proposes to modify the Promoting Interoperability program requirements for eligible hospitals and critical access hospitals to expand reporting within the Public Health and Clinical Data Exchange Objective. The proposal would require hospitals to report on all four of the

following measures: Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting.

Response:

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 program to require Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting. We believe this represents an important step to improving our nation's public health information infrastructure.

Potential Future Expansion of Hospital-Wide All-Cause Unplanned Readmission (HWR) Measure Data and Stratification

CMS is seeking comment on potentially expanding the agency's efforts to provide results of the Within- and Across-Hospital Disparity Methods to promote health equity and improve healthcare quality. Specifically, CMS is seeking comment on the idea of stratifying the performance results of the Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF# 1789) by dual eligibility and indirectly estimated race and ethnicity. CMS is also seeking comment on the idea of stratifying performance results by disability status and seeks suggestions for appropriate measures of disability status that could be derived from administrative data or self-reporting for this purpose.

Response:

AHIP would support confidentially reporting stratified results using indirectly estimated race and ethnicity, dual eligibility status and, potentially, disability status, for the Hospital-wide Readmission claims-only measure and showing results both within and across hospitals. We believe this would help to identify important disparities in care and allow hospitals to understand where improvement is possible. We would support the use of indirectly estimated or imputed data on race and ethnicity to stratify the measure in confidential reports.

Given our concerns about the variation and accuracy of indirect or imputed methods for collecting race and ethnicity data we would not support publicly reporting stratified results based on this type of data. In addition, we are not clear that the measure would remain accurate and valid after stratification given the smaller sample size. Tracking a single hospitals performance over time could provide actionable information for internal improvement efforts. However, using the stratified data to rank order across hospitals may not be supported. We fear it could unfairly penalize hospitals and mislead consumers. However, if CMS demonstrated the results are robust, we would support publicly reporting results stratified by dual eligibility, disability status, and self-reported data on race and ethnicity.

Recommendations:

- CMS should provide hospitals with confidential results of the Hospital-Wide Readmission Measure stratified by race and ethnicity, dual eligibility, and disability status. CMS should not publicly report results based on indirectly estimated or imputed data. If CMS chooses to publicly report results stratified by dual eligibly, disability status, and self-reported data on race and ethnicity the agency should demonstrate the statistical soundness of the results prior to posting the results on *Care Compare*.

Future Collection of Equity Structural Measure

CMS is seeking comment on the potential future collection of one or more attestation-based structural measure(s), to be developed, assessing priority domains related to organizational commitment to health equity.

Response:

AHIP supports CMS's proposal to develop a structural measure to assess a hospital's commitment to health equity. While we acknowledge the potential administrative burden of structural measures, we believe that such a 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 a measure 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 these structural measures should be reported on *Care Compare.* We also encourage CMS to develop process and outcome measures assessing health equity.

IX.F. Proposed Changes to the Medicare Promoting Interoperability Programs

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 is proposing several changes to the Medicare Promoting Interoperability Program. Specifically, CMS is proposing to:

- Continue the EHR reporting period of a minimum of any continuous 90-day period for new and returning eligible hospitals and CAHs for CY 2023 and to increase the EHR

reporting period to a minimum of any continuous 180-day period for new and returning eligible hospitals and CAHs for CY 2024;

- Maintain the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Programs (PDMP) measure as optional while increasing its available bonus from 5 points to 10 points;
- Modify technical specifications of the Provide Patients Electronic Access to Their Health Information measure to include establishing a data availability requirement;
- Add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation, beginning in CY 2022 to the HIE objective as an optional alternative to the two existing measures;
- Require reporting "yes" on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) or requesting applicable exclusion(s);
- Attest to having completed an annual assessment of all nine guides in the SAFER Guides measure, under the Protect Patient Health Information objective;
- Remove attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking attestation requirement;
- Increase the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) to be considered a meaningful EHR user; and
- Adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, in addition to removing four eCQMs from the measure set beginning with the reporting period in CY 2024 (in alignment with proposals for the Hospital IQR Program).

AHIP supports maintaining the Query of PDMP measure as optional. We are supportive of efforts to promote electronic exchange of information with PDMPs; however, we agree with CMS that the proportion of providers able to electronically access these systems remains low. CMS should work with states, providers, health plans, and other stakeholders to increase access and promote use of PDMP data, which can be a valuable resource for identifying high-risk patients.

We support aligning data availability requirements with the Interoperability and Patient Access final rule (lookback period through January 1, 2016). Aligning requirements across the healthcare sector would minimize confusion and burden.

We agree with the updated Reporting Requirements for the Public Health and Clinical Data Exchange Objective and support the measure incentivizing reporting existing Public Health and Clinical Data Exchange Objective measures. 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. These proposals would help to develop 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 to and removals from the Promoting Interoperability program pending finalization of changes to the IQR program.

Recommendations:

- CMS should finalize the proposal to maintain Query of PDMP measure as optional.
- CMS should align data availability requirements with the Interoperability and Patient Access final rule (lookback period through January 1, 2016).
- CMS should finalize its proposal to align the measures used in the Promoting Interoperability program with the IQR program.

X.A. Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost-Sharing for Services Furnished to Dually Eligible Beneficiaries—Proposed Policy Changes (§455.410) (86 Fed. Reg. 25654)

For the limited purpose of determining Medicare cost-sharing obligations for dual eligible beneficiaries, CMS proposes to require that state Medicaid programs accept enrollment of all Medicare-enrolled providers and suppliers that meet federal Medicaid enrollment requirements, even if the provider or supplier is not eligible to enroll in the state Medicaid program.

AHIP seeks further clarification regarding application of this proposal in certain situations. Specifically, we request additional information on how this policy would apply in the following instances: (1) when the allowed amount for the Medicaid service is less than what Medicare has already paid; (2) When the state does not offer any additional payment for the service; and (3) when Medicaid does not cover the service.

X.C. Medicare Shared Savings Program—Proposed Policy Changes (§425.600) (86 Fed. Reg. 25676)

CMS proposes to permit accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP)'s BASIC track to remain at their current risk level in performance year (PY) 2022, rather than automatically advance to an increased level of risk. An ACO that elects to delay advancement in the glide path in PY 2022 would be automatically advanced in PY 2023 to the risk track in which it would have participated in during PY 2023 had the freeze for PY 2022 not occurred.

This policy builds on previous efforts, finalized through an interim final rule published in the *Federal Register* on May 8, 2020, that permitted ACOs to remain in the same level of the BASIC track's glide path for PY 2021 rather than automatically advance. An ACO that elected to defer

advancement in PY 2021 will automatically advance to the level it would have participated in for PY 2022. Of eligible ACOs, 74% (148 of 201) elected the one-year freeze for PY 2021.[6]

AHIP appreciates CMS's efforts to make critical adjustments to the MSSP in light of the COVID-19 pandemic. However, we are concerned if ACOs elect to delay advancement in the BASIC track's glidepath for two years (e.g., PYs 2021 and 2022), requiring them to move to the risk track that would have applied for PY 2023 risks moving them into significant financial risk too quickly. This concern is particularly acute for ACOs in levels A or B, which do not require downside risk; ACOs in these tracks would automatically advance to level D in PY 2023 if they froze advancement in PYs 2021 and 2022. Therefore, if CMS finalizes a policy permitting ACOs to remain in their risk track for an additional year, we encourage the agency to consider allowing ACOs that maintained their risk track for two years the option to advance only one level. For example, if an ACO is in level A and freezes advancement for PY 2021 and PY 2022, it would advance only to level B in PY 2023.

While it is unknown how many ACOs would elect to maintain their risk level for two consecutive years, nearly two-thirds of ACOs took advantage of this policy in PY 2021 and may wish to continue to avail themselves to this flexibility again. While we support the move to value-based payment models that require downside financial risk, we are concerned that moving providers into high levels of financial risk too quickly risks pushing them out of the program. In turn, this could destabilize private payer arrangements as we believe those providers with larger portions of their book of business in these programs are more transformative and successful.

Recommendation:

- We encourage CMS to continue to evaluate the impact of the pandemic on ACOs and to consider stakeholder input to determine whether additional flexibilities are warranted beyond FY 2022, such as implementing a more gradual pathway toward adoption of financial risk.

[6] 88 Fed. Reg. at 25677 (May 10, 2021).