June 28, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD, 21244
Attention: CMS–1752–P
Submitted electronically to: http://www.regulations.gov

Re: CMS–1752–P Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

Dear Administrator Brooks-LaSure:

On behalf of the Premier healthcare alliance serving more than 4,100 U.S. hospitals and health systems, hundreds of thousands of clinicians and approximately 200,000 other providers and organizations, we appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) FY 2022 proposed rule for the Medicare Inpatient Prospective Payment System (IPPS). Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Premier healthcare alliance, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

MEDICARE SHARED SAVINGS PROGRAM

In response to the COVID-19 public health emergency (PHE), CMS is proposing that Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs) that are in the BASIC track can opt to maintain their existing level of risk and forgo automatic advancement for PY2022. This builds on a policy finalized last year which allowed ACOs in the BASIC track to maintain their PY2020 risk-level for PY2021. Nearly three-quarters of eligible ACOs opted to “freeze” their risk track for PY2021. Under both policies, ACOs will automatically move to the level they would have otherwise advanced to in PY2023 if they had not chosen to freeze their risk level. For example, an ACO that was in Level B (one-sided risk) in PY2020 and opted to freeze its risk level for PY2021 and PY2022 would automatically advance to Level E (two-sided risk) – the highest level of risk under the BASIC track – in PY2023.

Under Pathways to Success, CMS designed the BASIC track to provide ACOs with a glide path to risk. ACOs can initially participate with no downside risk (Levels A and B) for two years, but incrementally assume greater downside risk over time, under Levels C through E. While ACOs automatically advance through each level on an annual basis, they can opt to advance more quickly if the ACO chooses.

While Premier appreciates that CMS is providing ACOs with additional flexibility in PY2022, we are concerned that automatically advancing ACOs in PY2023 removes the intended glide path for the BASIC track. Taking on additional risk under value-based models takes time and resources, as organizations adapt their organizational structure and systems to succeed under value-based models, such as MSSP. Over the past year, health systems and providers have had to refocus a significant amount of resources and time to fighting the ongoing COVID-19 pandemic. While participation in an APM allowed health systems to more quickly respond to the pandemic, the expanded population health focus has not allowed health systems to continue planning for increased risk. Many ACOs would benefit from the proposed policy, as it would allow them to continue to focus on their COVID-19 response. However, many are not considering freezing their risk track for PY2022 because they are deeply concerned about their organizations' ability to move from one-sided risk to the highest level of risk under the BASIC Track without a transition period.

Premier strongly urges CMS to modify its policy to reinstate the glide path available to ACOs. Specifically, CMS should allow ACOs the option to incrementally increase their level of risk. For example, ACOs that choose to freeze at Level B in PY2022 should automatically increase to Level C in PY2023 (not Level E) unless they opt to move to a higher risk level.

In addition to allowing ACOs to freeze their risk track, we encourage CMS to consider additional COVID-19 mitigation policies. For the duration of the PHE, CMS is adjusting program calculations to exclude payments for COVID-19 episodes of care. These episodes are triggered by and start with an inpatient admission and extend one month following a patient's discharge from an inpatient hospital. As the medical community has learned more about COVID-19 and treatments have evolved, more patients are being treated in outpatient settings for severe COVID-19. As a result, the current episode definition may not fully help mitigate the financial impact of high-cost COVID-19 patients, which are not accounted for in an ACO's benchmark. **We recommend that CMS exclude outpatient COVID-19 therapies from MSSP program calculation.** Additionally, the medical community is still learning about the longer-term health impacts of COVID-19 on certain patients. For example, many patients may continue to experience higher medical costs beyond the currently defined episode of care. **We encourage CMS to lengthen the episode of care or explore additional ways to mitigate the financial impact of higher cost COVD-19 patients on MSSP expenditures**, such as implementing an outlier policy, excluding payments for COVID-19 therapies, or shifting how a prior COVID-19 diagnosis is incorporated into the clinical risk adjustment.

Additionally, with many ACOs renewing their MSSP participation in 2022, additional guidance is needed on how CMS will address COVID-19 impacts when rebasing benchmarks. When setting the MSSP benchmarks, CMS typically uses the three most recent years prior to the start of the agreement period, which, for 2022, would include CY2020. Without additional guidance at this time, many ACOs are concerned that their rebased benchmarks will be artificially low because of the lower than average utilization seen during the pandemic, particularly in 2020. **We encourage CMS to release additional guidance as soon as possible on how it will address impacts of 2020 in setting benchmarks, particularly for renewing ACOs.**

Finally, Premier continues to recommend that CMS implement a transition period to the new MSSP quality performance standard, which takes effect in 2022. Adoption of these changes will require substantial time and resources to implement and will place significant burden on providers, during a time in which they are still actively responding to the ongoing COVID-19 pandemic. As a result, **we recommend that CMS create a smoother transition to these requirements by limiting ACO reporting to aligned populations and starting with a lower data completeness rate.** Additionally,

CMS should set benchmarks specific to MSSP (rather than adopting those set for the APM Performance Pathway under MIPS) and establish benchmarks in advance to help inform ACO quality improvement activities.

QUALITY REPORTING PROGRAMS

Cross Program Measure Suppression Policy

To address the effects of the COVID-19 pandemic on quality measurement, CMS proposes to adopt a measure suppression policy across its value-based programs, including the Hospital Readmissions Reduction Program (HRRP), Hospital Value-Based Purchasing (HVBP) program, and Hospital Acquired Condition (HAC) Reduction program. Under this policy, CMS would still calculate rates for measures but would suppress the use of the measure rates when calculating performance under the value-based program. CMS proposes to adopt four broad factors (called Measure Suppression Factors) for determining if a measure should be suppressed:

1. Significant deviation in national performance on the measure during the public health emergency (PHE) for COVID-19 as compared to preceding program year
2. Clinical proximity of measure to relevant disease, pathogen, or health impacts of the COVID-19 PHE
3. Rapid or unprecedented change in clinical guidelines, care delivery/practice, treatments, etc. or generally accepted scientifical understanding of the disease or pathogen
4. Significant national shortages or rapid of unprecedented changes in healthcare personnel, medical supplies, equipment, or diagnostic tools/material, or patient volumes or facility-level case mix.

Premier applauds CMS for taking a proactive and thoughtful approach to addressing the impacts of the COVID-19 pandemic on quality measurement under the value-based programs. The ongoing pandemic has impacted quality measurement in a multitude of ways that are beyond the control of facilities.

In general, we have seen a decrease on measure performance across the board – even after accounting for COVID-19 patients. There are a variety of reasons for why the data may show a decrease in quality, even for patients without COVID-19. For example, hospitals saw lower than average admissions in 2020, which resulted from a combination of hospitals curtailing elective procedures and patients forgoing care. Not only did this result in a smaller overall population against which to measure performance, but patients who were admitted were generally higher acuity. Additionally, some measures may have also been impacted by changes in care practices in response to the pandemic. For example, the pandemic created significant disruptions in care, with providers having to rapidly shift their processes to support virtual care and care furnished in new settings. These types of rapid disruptions could have had unintended consequences on quality performance. The risk adjustment models applied to these measures should generally account for increased severity of patients. However, the models will not address the additional strain that facilities may have faced in the wake of COVID-19 as they shifted care and processes and faced limited resources.

We appreciate CMS taking steps to ensure that hospitals are not unfairly penalized because of these impacts. **We support the adoption of the measure suppression factors,** which are broad and capture the main impacts from the pandemic. **We would encourage CMS to broaden the language to make the suppression factors applicable for future public health emergencies.** This would provide greater

transparency and assurance around how CMS would address impacts during an emergency. When applying these factors during future public health emergencies, CMS should continue to seek public comment on application of their suppression policies, similar to this year's rulemaking.

In addition to suppressing measures based on deviations in national performance, **CMS should consider suppressing measures for individual hospitals in instances where their performance may have significantly deviated from past performance.** The impacts of COVID-19 vary depending on region and facility, as the pandemic peaked in different regions at different times. The medical community's response to the pandemic also evolved over time, as medical professionals gained more knowledge of the virus and potential treatments and available resources stabilized. As a result, depending on where a facility was located, the impacts may have varied. Below we have provided additional feedback on the application of these factors on each value-based program.

Hospital Readmissions Reduction Program

As part of its August interim final rule, CMS finalized adoption of a nationwide extreme circumstances exception (ECE) policy to exclude all Q1 and Q2 claims data from quality reporting and calculation. As a result, the calculation of HRRP performance for PY2022 already excludes all data from the COVID-19 PHE and will be calculated based on data from July 1, 2017 through December 1, 2019.

CMS proposes polices to address COVID-19 impacts to the HRRP for PY2023, which includes data from July 1, 2018 through June 30, 2021. First, CMS proposes to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) measure based on its clinical proximity to COVID-19. Second, CMS proposes to update measure specifications for the remaining 30-day readmissions measures to exclude patients with a COVID-19 secondary diagnosis.

Premier agrees with CMS assessment that the pneumonia measure should be excluded based on its clinical proximity to COVID-19. In its analysis, CMS found that a substantial portion of pneumonia-related readmissions included admissions with a COVID-19 diagnosis. However, we are concerned that the proposal to only exclude COVID-19 patients from the remaining readmissions measures may not properly adjust for the impacts of COVID-19. As noted above, there are a variety of reasons for why the data may show a decrease in quality, even for patients without COVID-19, including hospitals seeing a smaller and more acute population, general disruptions in care practices during the pandemic, and challenges with available resources.

As CMS continues to evaluate 2020 performance for the PY2023 payment year, **we would encourage CMS to consider additional suppression policies to address the impacts of COVID-19 on the other readmissions measures, beyond just excluding patients who have been diagnosed with COVID-19**.

As noted above, the impacts of COVID-19 will vary depending on region and facility, as the pandemic peaked in different regions at different time. We would recommend that CMS when considering whether to suppress measures also consider significant deviations in individual facility performance, in addition to national performance.

Hospital Value-Based Purchasing Program

COVID-19 measure suppression and changes to scoring for PY2022.

In response to the COVID-19 PHE, CMS proposes several changes to measures and scoring under the Hospital Value-Based Purchasing Program (HVBP) for PY2022. First, CMS proposes to suppress all measures in three of the four program domains. Specifically, CMS proposes to suppress the HCAHPS measure in the Person and Community Engagement Domain and the hospital-acquired infection (HAI) measures in the Patient Safety Domain because of significant deviation in national performance. Additionally, CMS proposes to suppress the Medicare Spending per Beneficiary measure in the Efficiency and Cost Reduction Domain because of an unprecedented change in patient case mix as a result of the PHE. Since CMS adopted a nationwide ECE policy to exclude all claims data from the first half of 2020, CMS is not proposing any changes to measures in the Clinical Outcomes Domain. As a result, those measures will have a shortened performance period that runs through the end of CY2019.

In addition to the measure suppression policies, CMS is proposing to not calculate total performance scores (TPSs) for hospitals since they would be based on only measures in one domain. CMS is statutorily required to reduce operating DRG payments by 2 percent under the HVBP program. As a result, CMS proposes to still reduce payments, but each hospital will receive a value-based incentive payment that matches the 2 percent reduction, resulting in a neutral payment adjustment for FY2022. CMS still plans to provide hospitals with confidential feedback and to publicly display the Q3 and Q4 2020 hospital data.

Premier supports CMS' decision to suppress the measures included in the Person and Community Engagement, Patient Safety, and Efficiency and Cost domains and to not calculate a total performance score. This policy will help ensure hospitals are not penalized for impacts outside of their control.

However, we do not support CMS' proposal to publicly display rates. CMS has determined that rates were significantly impacted by the pandemic. As a result, displaying this information will have limited value and is likely to cause confusion or misinterpretation of quality. Even with a note acknowledging the impacts from COVID-19, consumers will have no reference to understand how much of an impact COVID-19 had on quality measurement for the facility. Some consumers may continue to use the information and compare data across facilities. As noted above, the impacts of COVID-19 will vary depending on region and facility, as the pandemic peaked in different regions at different time. Additionally, the medical community's response to the pandemic evolved overtime, as knowledge of the virus increased and new treatments became available. As a result, depending on where a facility was located, the impacts may have varied for reasons completely out of the facility's control. **We recommend that CMS not publicly display the HVBP rates**. At a minimum, CMS should provide hospitals with the option to opt-in to public reporting as part of their confidential feedback review.

COVID-19 measure suppression for PY2023.

For PY2023, CMS is proposing to suppress the Pneumonia (PN) 30-Day Mortality Rate (MORT-30-PN) measure due to its clinical proximity to COVID-19. For the remaining measures in the Clinical domain (other mortality measures and complications from hips and knees measure), CMS is proposing to exclude patients with a principal or secondary COVID-19 diagnoses. CMS does not propose any mitigation policies for the remaining three domains: Person and Community Engagement Domain, Efficiency and Cost Reduction Domain, and Patient Safety. Measures in these domains will be calculated based on CY2021 data.

Premier agrees with CMS assessment that the pneumonia measure should be excluded based on its clinical proximity to COVID-19. We encourage CMS to consider additional suppression policies to address the impacts of COVID-19 on other measures in the Clinical Outcomes Domain for PY2023, beyond just excluding patients who have been diagnosed with COVID-19. As noted above, there are a variety of reasons for why the data may show a decrease in quality, even for patients without COVID-19, including hospitals seeing a smaller and more acute population, general disruptions in care practices during the pandemic, and challenges with available resources.

We would also encourage CMS to continue to monitor the impacts of COVID-19 on 2021 performance for the other three domains and take appropriate action as warranted. While many of the issues hospitals experienced in 2020 have subsided in 2021 and COVID-19 cases have continued to trend downward as more Americans are vaccinated, hospitals may continue to see lower performance on HAC measure as a result of COVID-19 patients. At a minimum, CMS should consider updating measure specifications to exclude patients with primary or secondary COVID-19 diagnoses from measures in these domains.

Additionally, CMS should consider not publicly reporting individual hospital data on measures that were impacted by COVID-19. As noted above, displaying this information will have limited value and is likely to cause confusion or misinterpretation of quality.

Finally, as noted above, the impacts of COVID-19 will vary depending on region and facility, as the pandemic peaked in different regions at different time. Treatment of COVID-19 evolved overtime as the medical community learned more about the virus and additional treatments became available. As a result, depending on where a facility was located, the impacts may have varied. We recommend that CMS when considering whether to suppress measures also consider significant deviations in individual facility performance, in addition to national performance.

Removal of the CMS PSI 90 Measure

CMS proposes to remove the Patient Safety and Adverse Events Composite (CMS PSI 90) (NQF #0531) measure from the HVBP measure set beginning with the FY2023 payment year, citing that the costs associated with the measure outweigh its benefits. The measure was originally adopted in FY2018 rulemaking for reporting beginning in FY2023. The HAC Reduction Program includes the same measure but does not include a baseline period. CMS believes that the removal of the measure will help streamline reporting and reduce burden on hospitals

Premier supports removal of the PSI-90 measure from the HVBP Program. Premier has long advocated for CMS to streamline its measure set to ensure hospitals do not face duplicative and unnecessary overlapping penalties across programs. As CMS notes, the measure will continue in the HAC Reduction Program and the HVBP Program will continue to include several other patient-safety focused measures. In general, Premier supports adoption of outcomes-based measures and continues to encourage CMS to find ways to reduce burden on providers while pursuing measures that better capture patient and care outcomes.

Hospital-Acquired Condition Reduction Program

In response to the COVID-19 pandemic, CMS is proposing to suppress data from the second half of 2020 in calculating Total HAC Scores for FYs 2022 and 2023. As noted above, CMS already adopted a nationwide ECE policy to exclude data from the first half of 2020 in measure calculations. As a result, if

this policy is finalized, CMS would exclude all data from CY2020 in calculating the Total HAC Score and measures would be calculated using a shortened performance period. CMS still plans to provide feedback reports to hospitals.

We support CMS' proposal to exclude the second half of 2020 data in its calculation of HAC Reduction program measures. With shorter performance periods, some hospitals may see more variability in their performance, as compared to prior years. CMS should monitor the impact of truncated performance periods and consider taking further action if hospitals experience significant fluctuation in performance from prior performance periods. As noted above, we recommend that CMS consider suppressing measures not only for significant deviation in national performance, but also if individual facilities performance significantly deviates from prior years.

Additionally, CMS should continue to monitor the impact of COVID-19 on 2021 performance. While many of the issues hospitals experienced in 2020 have subsided and COVID-19 cases have continued to trend downward as more Americans are vaccinated, hospitals may continue to see lower performance on HAC measure as a result of COVID-19 patients. At a minimum, CMS should consider updating measure specifications to exclude patients with a primary and secondary diagnosis of COVID-19 from the measure or adjust its risk adjustment models to account for prior COVID-19 diagnoses.

Hospital Inpatient Quality Reporting Program

Adopting New Maternal Morbidity Structural Measure.
CMS is proposing to adopt a new structural measure that would require hospitals to attest to participating in a state or national perinatal quality improvement collaboratives and to whether the hospital is implementing safety practices or bundles related to maternal morbidity to address complications. If finalized, the measure would begin with a shortened reporting period of October 1, 2021 through December 31, 2021 and would be used in making FY2023 payment determinations.

While Premier supports adoption of maternal health measures, we encourage CMS to continue to explore other measures that move beyond attestation and move towards measuring outcomes. The proposed measure aligns with national efforts to identify the causes of maternal mortality and morbidity, reduce disparities in maternal health outcomes, and advance best practices for improving care for mothers and infants. Because reliable data has long been incomplete or unavailable, the U.S. lacks a clear understanding of the number of women who die or sustain lifelong harm as a result of pregnancy and childbirth. Maternal care improvement must start with reliable data that identifies the root causes. Using data to understand the root causes of mortality and severe maternal morbidity is critical to attacking this problem. With that information we will be able to better assess interventions that can be scaled to solve this problem for our country.

However, there are several potential challenges with adoption of the maternal morbidity structural measure as proposed. For example, not all states have maternal infant and/or perinatal collaboratives. There is also significant variation from state-to-state on area of focus, approaches, and level of support. National perinatal quality collaboratives are needed and HHS should consider expanding these efforts, such as through the Hospital Improvement Innovation Networks (HIINs). At a minimum, CMS should clarify how it is defining state or national Perinatal quality improvement collaboratives. In defining eligible collaboratives, CMS should include HHS' Office of Women's Health Perinatal Collaborative and the National Network of Perinatal Quality Collaboratives (NNPQC), which is coordinated by the National Institute for Children's Health Quality (NICHQ) and funded by the CDC.

States also lack standardized data collection to validate that processes are in place and to evaluate outcomes. As noted above, current data on maternal outcomes is limited. Premier has partnered with HHS' Office of Women's Health to leverage Premier's data and proven performance improvement methodology to scale advancements in care for mothers and infants across the nation. Premier is also uniting a cohort of more than 200 hospitals across the country – particularly those that serve vulnerable populations – to reduce health disparities; scale standardized, evidence-based practices; and reliably measure associated outcomes. These efforts are generating positive outcomes and needed to be scaled nationwide**. While a structural measure, as proposed, is a step in the right direction, we must also shift the focus to assessing specific outcomes to better understand and recommend what structure measures need to be in place**. Additionally, we urge CMS to seek National Quality Forum (NQF) endorsement for the proposed measure before including in the IQR program.

Finally, there are several factors that occur outside of the hospital during pre- and postpartum care that could be influencing overall maternal mortality and morbidity trends. The U.S. healthcare system continues to be fragmented in the way it cares for pregnant women, new mothers and infants. A more integrative approach to the care expectant and new mothers receive before, during and after delivery is needed in order to improve overall maternal and infant health in the U.S.

Adopting new COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure.

CMS proposes to adopt a new process measure across its Medicare quality reporting programs, including the Hospital IQR program, which would track the percentage of HCP who have received a complete COVID-19 vaccination course. CMS proposes an initial data reporting period of October 1, 2021 through December 31, 2021 for use in the FY2023 payment year. Hospitals would be required to collect data from one self-selected week each month and submit the data quarterly through the CDC National health Safety Network (NHSN) web-based survey. CMS plans to publicly report each quarterly vaccination coverage rate.

We understand the importance of assessing vaccination coverage across health care professionals. **However, we believe that adoption of this measure into the Hospital IQR and other Medicare quality reporting programs is premature and could place significant burden on hospital facilities.** As a result, we do not recommend that CMS adopt the COVID-19 Vaccination Coverage Among HCP measure at this time.

CMS notes that it and the CDC aligned the measure as closely as possible with the specifications for the Influenza HCP vaccination measure, which has received NQF endorsement. However, the COVID-19 vaccine differs significantly from the flu vaccine in several key ways. First, it is still unknown if individuals will need to receive annual COVID-19 vaccines or booster shots. As a result, the measure specifications for a COVID-19 vaccination measure are likely to change as the definition of a completed COVID-19 vaccination course changes overtime. Secondly, while facilities have often set-up flu clinics to vaccinate their staff, the rollout of the COVID-19 vaccine has differed across facilities. Some hospitals did set-up clinics to vaccinate their staff as doses became available. Still some personnel may have received the vaccine outside the facility at mass vaccination sites or other health care settings. Collecting this data across all personnel could prove burdensome for facilities.

Additionally, rates of vaccination will be largely dependent on factors outside the facility's control, such as where the facility is located and personal preference of the facility's staff. Vaccine hesitancy has varied significantly across states, with the percentage of states' populations who are fully vaccinated ranging

from 29 percent to 63 percent, as of mid-June.[1] Additionally, state, local, and even individual health system policies governing COVID-19 vaccinations also vary. Some facilities are requiring that all staff receive the vaccine, while some facilities are located in states or localities where political pressure prevents them from setting a mandatory vaccine policy. Finally, some personnel have indicated a preference to wait until the vaccine receives full FDA approval before receiving it.

CMS notes its preference to collect vaccination data on a more frequent basis. By the time that the vaccination rate is reported by CMS it will likely be out-of-date and no longer reflective of the vaccination rates within a given facility.

We recognize the critical importance of vaccinating frontline workers and that this measure would provide valuable information to the government as part of its ongoing response to the pandemic. HHS is currently collecting COVID-19 related data from hospitals. One of the optional fields that hospitals can submit on a weekly basis is related to the vaccination of their personnel. Despite the voluntary nature of this measure, nearly 64 percent of hospitals are reporting data on personnel vaccination rates.[2]

We do support collecting this information in a format that is less burdensome to hospitals and would support collection of this data through CDC's National Healthcare Safety Network (NHSN). **However, CMS should not include this measure in IQR that would require publicly reporting data on individual hospital performance.** Rather, CMS could collect the measure through NHSN, provide confidential feedback reports to hospitals and support hospitals with increasing adoption by healthcare professionals. At a minimum, we urge CMS to seek NQF endorsement prior to proposing adoption of this measure in the IQR program. The NQF endorsement process will provide an opportunity for technical experts to consider and work through the various challenges noted above.

***Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure*.**

CMS is proposing to adopt the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data (Hybrid HWM Measure; NQF #3502) into the Hospital IQR program beginning with FY2026 payment year. Under the proposal, an initial voluntary reporting period would run from July 1, 2022 through June 30, 2023. Mandatory reporting would begin July 1, 2023 for use in FY2026 payment determinations.

While Premier supports adoption of the Hybrid HWM measure, we encourage CMS to lengthen the voluntary reporting period. This approach can help elucidate any data collection issues and allow hospitals time to redesign their electronic health records (EHRs) to collect and validate these data. As part of this, CMS should explore whether additional risk adjustment is needed for the measure. Additionally, CMS should offer several options for how the data would be publicly reported and seek stakeholder feedback.

The aim of the hybrid measure is to improve the clinical risk adjustment of the all-cause mortality measure. We understand why CMS started with the all-cause mortality measure, even though it has been removed from the Hospital IQR program. However, **rather than making this measure a permanent measure within IQR, CMS should quickly adapt the condition-specific mortality measures to be hybrid.** The condition-specific mortality measures are more actionable for health systems and are currently included in HVBP.

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[1] CDC, "COVID-19 Vaccinations in the United States," https://covid.cdc.gov/covid-data-tracker/#vaccinations
[2] HHS, COVID-19 Hospital Data Cvoerage Report, https://healthdata.gov/Hospital/COVID-19-Hospital-Data-Coverage-Report/v4wn-auj8

Consideration for Future Measures.

CMS is seeking comment on potential future adoption of the following measures. CMS is considering developing a 30-day all-cause mortality measures for patients admitted to a hospital with COVID-19. CMS would calculate the model using claims and would use a methodology similar to other condition-specific mortality measures. **We do not support adoption of this measure into the IQR program.** As noted above, the COVID-19 pandemic has had differential impacts on regions and hospitals. Certain regions of our country were harder hit earlier in the pandemic when less was known about the virus and fewer treatments were available. Additionally, the medical community is still learning about the COVID-19 virus and the factors that place certain patients at higher risk of infection and mortality. As a result, it is unlikely that CMS would be able to adopt a sufficient risk adjustment methodology that would account for the various underlying factors that may have caused certain patients to be at higher risk. Certain hospitals may appear to have higher mortality rates in the data, which is not truly reflective of the care they furnished as compared to other hospitals. We recognize the value that this information could have in evaluating the impacts of the pandemic. **We encourage CMS to provide this information in confidential reports to hospitals outside of the IQR program and to publish national aggregate benchmarks that hospitals can use to consider quality improvements.**

CMS is also considering inclusion of the Patient Reported Outcomes (PRO) Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) performance measure as part of the IQR. Hospitals participating in the Comprehensive Care for Joint Replacement (CJR) payment model have had the option of reporting this measure since the model began in 2016. Under the model, participants can increase their composite quality score by two points if they successfully reported on the measure. Many model participants have found that the burden of data collection outweighed the potential for bonus points. As a result, completion rates for the measure have been low. Introducing the measure to all hospitals may result in even more burden. **CMS should also evaluate and release feedback on the voluntary reported measure under CJR before considering adoption of this measure into the IQR program.**

<u>Closing the Health Equity Gap in CMS Hospital Quality Programs</u>

Reducing disparities in care and achieving health equity across communities requires a holistic approach to care, shifting the incentives in our health system from sickness-based to wellness-based**. When providers are responsible for total cost of care for their patients and have flexibility to address social determinants of health, providers will be proactive in addressing inequity and disparities.** Addressing the underlying social and economic inequities as well as systemic barriers and biases that drive disparities in care requires (1) data collection and monitoring of key outcomes and health equity measures and (2) shifting the payment system to account for a more comprehensive set of services that address disparities. We appreciate CMS' commitment to closing health equity gaps in the CMS quality programs and look forward to partnering with CMS in this area.

Stratification of Measure Results by Race and Ethnicity

CMS seeks comment on approaches to stratify measures by race and ethnicity. Stratifying measures by race, ethnicity, gender and disability will give providers needed insight into potential disparities. As noted above, Premier has partnered with HHS' Office of Women's Health to leverage Premier's data and proven performance improvement methodology to scale advancements in care for mothers and infants across the nation. This effort includes stratifying measures by race and ethnicity with the aim of reducing health

disparities and scaling standardized, evidence-based practices. We believe stratification of outcomes is one of several useful tools to improve health disparities.

CMS proposes using algorithms to indirectly estimate the race and ethnicity of Medicare beneficiaries to overcome the current challenges with demographic information collection and enable timelier reporting of equity results until other ways to improve demographic data accuracy materialize. The agency notes that indirect estimation techniques do not impose additional data collection burden on hospitals, since these are derived using administrative and census-linked data. **We do not support the use of indirect estimation techniques due to data inaccuracy.** Health systems are currently collecting self-reported sociodemographic data from their populations through a variety of methods. Inaccurate measure stratification can disrupt ongoing efforts to improve disparities in care. **Instead, we urge CMS to rapidly and meaningfully pursue efforts to improve access to directly collected race and ethnicity data from self-reported sources.**

Additionally, **we recommend that all efforts to stratify measures by race and ethnicity begin with confidential reporting and appropriate risk adjustment to account for factors associated with outcomes that cannot be addressed by providers**. We must avoid a perverse cycle, wherein we deny resources in the form of both payment penalties and income by discouraging beneficiaries from using providers that care for patients in marginalized communities, subsequently leading to unequal care for those patients due to lack of equal resources to treat them. It is critical that information publicly shared on disparities in care is accurate and can be understood by consumers. Moreover, while stratification and comparing providers with similar populations helps identify opportunities for improvement, it does not provide hospitals with all the tools necessary to address any underlying factors contributing to health inequities. **These efforts must be combined with a broader set of supports to enable providers to respond to disparities in care**, such as learning networks and data on available community support services.

Finally, we request that CMS also focus on stratifying measures using a broader set of sociodemographic factors, such as income and other social determinants of health.

Improving Demographic Data Collection

CMS seeks input on improving data collection practices to improve capture of demographic elements. We strongly encourage CMS to focus its efforts on driving toward standardization of data capture and measurement, leveraging resources currently available and accessible to providers, and streamlining administrative burden across programs.

Health systems are currently capturing sociodemographic data, but this information is not easily translatable for CMS purposes. For example, despite an available framework for mapping the more than 900 race ethnicity codes provided by the CDC to the OMB, race and ethnicity codes captured in the EHR cannot be consistently mapped. This is a result of lack of use of standard taxonomies—in part by the EHRs and in part by the providers to allow the category selections to align with how their populations would like to report information. Similarly, there are an abundance of tools to screen for social determinants of health with underlying definitions for certain social risk factors (e.g. food insecurity) significantly varying even when the same tool is used by different providers.

Standardization is vital to providers' success in driving towards health equity, as it will foster the development and sharing of best practices within and among clinical settings, health systems, and delivery system designs. The Agency for Healthcare Research and Quality (AHRQ) has found that one of the biggest barriers most health systems face in improving quality and reducing disparities within their

own walls is systematically identifying the populations they serve, addressing the needs of these populations, and monitoring improvements over time. AHRQ further found that the principal challenges in obtaining race, ethnicity, and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected.

We ask that CMS make a concerted effort to advance standards for the collection of socio-demographic information, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and Fast Healthcare Interoperability Resources (FHIR) standards.

Creation of a Hospital Equity Score

CMS seeks comment on creation of a Hospital Equity Score to synthesize results across multiple risk factors. The score would quantify how hospitals are performing at reducing disparities of care for patients who traditionally have experienced inequitable access to care and subsequent poor outcomes in contrast to their peers. While we conceptually support endeavors to reward providers for reducing disparities in care, we believe this effort is premature. As noted above, we encourage CMS to focus on standardizing the collection of sociodemographic data and include factors beyond race and ethnicity. With more robust sociodemographic data we must consider the most appropriate uses (i.e. stratification or risk adjustment) and how that information is publicly reported.

We appreciate that CMS has begun stakeholder engagement through this request for information and encourage CMS to engage with stakeholders throughout the entire process of advancing health equity in measurement.

Advancing to Digital Quality Measurement

CMS articulates its goal of moving to fully digital measurement by 2025. As part of this goal CMS aims to streamline the approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning. Premier appreciates CMS' commitment to advancing digital measurement. We have long been committed to advancing providers' capability to analyze data from multiple sources and to manage the health of their populations. We offer the following comments on advancing digital quality based on experience with supporting providers in advanced data analytics and quality reporting:

- ***Definitions***. CMS defines digital quality measurement as software that processes digital data to produce measures scores. While we support this definition, we caution CMS from creating separate standards or requirements for digital quality measurement software. Many systems such as EHRs, health information exchanges (HIEs), and registries currently meet this definition and are regulated by CMS and ONC. Any requirements of these tools should be incorporated into existing regulation in order to reduce inconsistencies in requirements and timelines and alleviate any additional provider reporting burden.

- ***Data Access***. CMS notes that data sources for digital quality measurement may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information HIEs, or registries, and other sources. We appreciate that CMS is broadly considering numerous types and sources of data; however, we note that providers currently have limited real-time

access to robust claims and EHR data. Federal efforts are needed to accelerate adoption and consistent implementation of data and interoperability standards, enhance certification of EHRs, require seamless and unfettered provider data access at the point of care and within the workflow, and make claims-data more readily available to providers. As access to existing digital data sources is limited, we ask that CMS speed access to those sources and consider provider access to novel digital data sources (e.g. wearable device) prior to implementing measures that require use of novel data.

- ***Timing.*** We appreciate the commitment to rapidly move to digital quality measurement by 2025. We ask that in setting timelines for the transition CMS consider how digital quality measures timelines align with other implementation timelines, such as ONC's promoting interoperability and CEHRT.

- ***Data Standards.*** CMS notes that its potential action steps are to leverage and advance standards for digital quality and to redesign measures to be self-contained tools. Specifically, CMS discusses using FHIR for electronic clinical quality measures (eCQMs) and designing software solutions for digital quality measures to be compatible with any data sources that implement standard interoperability requirements. A holistic approach is needed for data standards whereby standards are developed and adopted for use across care settings. There are at present a limited number of common data elements across inpatient, outpatient, and post acute care; however, these elements could serve as a starting point for cross-continuum patient assessment. While FHIR will likely make development and maintenance of measures easier over time, measure developers are just beginning to test measures using FHIR. We will need sufficient testing and consideration by multi-stakeholder groups such as HITAC and NQF prior to wide-spread adoption. A critical component to using FHIR for eCQMs is the adoption of bulk FHIR transactions to simplify and speed transmission. In the absences of bulk FHIR transactions, providers will be unable to support FHIR implementation. CMS needs to work with ONC to advance the adoption and consistent implementation of data and interoperability standards so that provider data collection and reporting requirements are enabled by health information technology

  Meanwhile, we ask that CMS and ONC continue to address some of the underlying data issues. For example, the annual iteration of QRDA-I file standards creates a burden on EHRs to frequently adopt and roll-out the new standards to their customers and this results in many health systems/practices not being able to produce a current-year file through much of the reporting year. The costs of these annual updates are often factored into the pricing of these reporting modules, which can be cost-prohibitive to smaller health systems/practices. Where possible, Premier encourages CMS to promote backward compatibility in both reporting modules and measure development/updates

- ***Data Aggregation.*** CMS discusses actions to better support data aggregation. In addition to EHR oversight, claims data access and promotion of standards. Premier urges HHS to continue efforts to address the need for a national strategy and approaches to improve patient identification and matching to support patient care and facilitate more accurate data aggregation. In the absence of this it is difficult to track patients across a single encounter, rending it impossible to assess outcomes using numerous types of data.

- ***Measure Alignment.*** CMS notes its continued focus on aligning measurement across reporting programs. Alignment would focus on measure concepts, specifications and individual data

elements used to calculate measures. We appreciate the continued focus on measure alignment across CMS programs and the private sector. In aligning measures, we urge CMS continue to continue to address the need for more timely access to robust data.

MARKET-BASED MS-DRGS

As part of last year's rulemaking, CMS adopted a policy to require hospitals to report median Medicare Advantage (MA) payer-specific negotiated charges by MS-DRG on their Medicare cost report, beginning with cost reporting periods ending on or after January 1, 2021. CMS also finalized a policy to use the MA payer-specific negotiated charges in setting MS-DRG relative weights beginning with FY2024.

Premier, along with several other stakeholders, raised significant concerns with this policy. While we are supportive of improving the efficiency of care and ensuring payments are set appropriately, using negotiated rates for the MS-DRG relative weights has several significant flaws. Most notably, the policy would not result in market-based rates. As MA plans often use the MS-DRG relative weights as the basis for their negotiated rates, the policy would be circular as the MA rates would be based on the fee-for-service rates that are themselves based on MA rates. Effectively, such a policy would leave CMS without a mechanism to annually update the MS-DRG relative weights. Additionally, reporting median negotiated rates places significant burden on hospitals, which was grossly underestimated in last year's rulemaking. **Premier strongly supports CMS proposal to repeal these reporting requirements and changes to the MS-DRG relative weight methodology.** Additionally, we encourage CMS to avoid policies like this that hinder the movement to value. This policy would have created distortions for members in risk-based arrangements with payers that cannot be easily mapped to MS-DRGs. Additionally, where possible, CMS should look to reduce burden and duplicative payment cuts to ensure those who have moved to value-based care are rewarded.

PAYMENTS FOR INDIRECT AND DIRECT GRADUATE MEDICAL EDUCATION

CMS is proposing to implement several provisions from the *Consolidated Appropriations Act (CAA), 2021* related to graduate medical education (GME), including establishing a process for distributing newly funded GME slots. Under the legislation, Congress authorized CMS to distribute 1,000 additional Medicare-funded GME positions over five years, or 200 new residency FTE slots each year. As part of this, CMS is proposing to limit hospitals to only one FTE slot each year in the interest of distributing additional residency positions to as many hospitals as possible. This approach is narrower than what Congress had specified in statute. Specifically, Congress allowed hospitals to receive up to 25 additional positions over the course of 5 years.

While we understand CMS' interest in distributing slots to as many hospitals as possible, **we recommend that CMS maintain flexibility in its process to allow them to distribute slots to those hospitals with the highest need and in a way that makes sense for hospitals operationally.** For example, some hospitals may prefer to receive all of their slots up front in the first year, allowing them to begin their cap-building window. At a minimum, CMS should provide more clarity on the number of slots awarded over time to reduce the need for annual applications and to allow hospitals to better plan for their graduate medical programs.

Finally, we support adoption of the Alternative 2 methodology for FY2023, as it aligns with the categories specified in the CAA. Additionally, we appreciate that under Alternative 2 CMS would engage with stakeholders to develop a more refined approach for future years.

DISPROPORTIONATE SHARE HOSPITAL (DSH) AND UNCOMPENSATED CARE

CMS estimates that approximately $7.628 billion will be available in uncompensated care payments for qualifying IPPS hospitals in FY 2022, which is an 8.0 percent decrease from FY 2021. Since FY 2014, CMS has calculated uncompensated care payments as the product of three factors:

- *Factor 1:* 75 percent of the aggregate DSH payments that would be made in the absence of the Affordable Care Act (ACA)
- Factor 2: Percentage change in uninsured since implementation of ACA; and
- Factor 3: A hospital's uncompensated care costs for a given time period relative to uncompensated care costs for that same time period for all hospitals that receive Medicare DSH payments.

Factor 1

CMS Office of the Actuary estimates Factor 1 based on the most recent available data and adjusts this estimate to account for inflation and changes in utilization and case-mix. Since the FY 2021 IPPS Final Rule, CMS has updated several of its assumptions, which have led to a nearly $805 million decrease (or -7.1%) in Factor 1 in FY 2022 as compared to FY 2021.

The primary drivers of this decrease are changes in CMS assumptions around discharges and the "Other Factor," which includes various adjustments to payment rates not accounted for by the update, case-mix, or discharge factors. The Other Factor also includes a factor for Medicaid expansion due to the ACA. To-date, CMS has provided minimal transparency of how the Other Factor is calculated. **We continue to encourage CMS to provide additional information on the calculation of Factor 1**, including the parameters around any assumptions CMS made in this calculation. Additionally, we request that CMS provide more information on how it accounted for the impacts of COVID-19 in its assumptions for Factor 1.

Auditing Worksheet S-10

CMS proposes to continue its policy of using one-year of audited Worksheet S-10 data for use in Factor 3 in determining the distribution of uncompensated care. If finalized, CMS would use data from the FY 2018 cost report for determining uncompensated care distributions in FY 2022.

As a fixed pool of uncompensated care payments is available to distribute to eligible hospitals, Premier healthcare alliance believes it is essential that CMS audit all hospitals receiving these payments so that a consistent set of rules and protocols applies uniformly nationwide. Nevertheless, if CMS' audit resources are limited, we commend CMS for focusing its limited audit resources on those hospitals that receive that highest amount of uncompensated care payments.

We appreciate the effort CMS has put forth to ensure Worksheet S-10 instructions are clear. CMS should continue to revise the instructions associated with the Worksheet S-10 to ensure additional clarity. For example, some stakeholders have expressed concern with the lack of consistency that the Medicare

Administrative Contractors (MAC) apply to audits – both across MAC jurisdiction and across auditors within the same MAC. This has resulted in auditors requesting hospitals to resubmit information in completely different formats than what is required by their usual MAC or hospitals having to submit different information depending on the individual auditing them. **We urge CMS to work with their MACs to establish consistent auditing practices and to provide greater transparency on auditing protocols, such as making audit instructions publicly available.** Additionally, CMS should consider implementing a fatal edit to ensure the S-10 is complete and internally consistent and instruct the MACs to audit negative, missing or suspicious values.

Definition of Uncompensated Care

For purposes of calculating Factor 3 and uncompensated care costs, CMS defines "uncompensated care" as the amount on line 30 of Worksheet S-10, which is the cost of charity care and the cost of non-Medicare bad debt. CMS continues to exclude Medicaid shortfalls reported on Worksheet S-10 from the definition of uncompensated care for purposes of calculating Factor 3. As we have previously commented, the Premier healthcare alliance believes that CMS should capture the fact that many of the states do not fully cover the costs associated with the newly insured Medicaid recipients.

Among other reasons, CMS notes that including Medicaid shortfalls in the calculation would represent a form of cross-subsidization from Medicare to cover Medicaid costs, a general policy that CMS and the Medicare Payment Advisory Commission have not supported. However, as the policy stands, Medicare will be significantly subsidizing those states with Medicaid payment rates that cover the cost of care relative to those with lower Medicaid payment rates that do not cover the cost of care. This problem is further compounded if a state has higher Medicaid enrollment if its payment rates do not cover the cost of care and the state has high Medicaid enrollment either because it has expanded under the ACA, has more permissive Medicaid eligibility criteria, or simply has a high proportion of its citizens that qualify for Medicaid. **The Premier continues to urge CMS to include Medicaid shortfalls in the definition of uncompensated care.**

Effects of the COVID-19 Public Health Emergency

The COVID-19 pandemic will likely result in significant anomalies in the FY 2020 and FY 2021 cost reports, which will impact future uncompensated care distributions. For example, many hospitals ended up having fewer discharges in 2020, as compared to prior years. We encourage CMS to explore mechanisms to minimize any negative effect that these anomalies may have on future distributions. As part of this process, CMS should seek stakeholder input.

PROMOTING INTEROPERABILITY PROGRAM

Premier appreciates proposals made by CMS intended to improve the electronic exchange of healthcare data. Premier shares that vision and supports the following goals:

- encourage value-based healthcare delivery that emphasizes integrated and coordinated care for patients;
- ensure provider access to accurate health information at the point of care to inform healthcare decisions and achieve best patient outcomes;
- increase the efficiency of the administrative aspects of healthcare delivery, including data collection and reporting and information exchange for treatment, payment, and operations; and

- recognize meaningful privacy and security rights for the protected health information (PHI) of patients.

Harmonizing rules

Complying with the many new data access, exchange, interoperability, and reporting requirements is already a daunting task for healthcare providers at a time when resources are stretched thin due to the ongoing public health emergency. This must be accomplished in a manner that minimizes regulatory and administrative data collection, documentation, and reporting burdens, as well as related costs. It is critical for HHS to align terminology, compliance dates, and data and interoperability standards across agencies. Harmonizing rules will help improve compliance and reduce the operational and reporting burdens on entities subject to a myriad of new rules, each with its own scope, definitions, and requirements.

For example, ONC's interim final rules established information blocking timelines. Since healthcare providers depend on the practices of health information technology or EHR vendors to comply with CMS and ONC requirements, it is unreasonable to expect providers to meet CMS information requirements when certified EHR vendors are not required to comply with compatible ONC CEHRT requirements. Similarly, CDC (i.e., Reportable Condition Mapping Table (RCMT)) and NIST (i.e., NIST Electronic Laboratory Reporting (ELR) Test Tool) publish requirements and guidance related to public health data. **Premier urges CMS to harmonize its regulations with those of ONC and other federal partners including CDC, NIST, OCR, OIG, and ONC.**

Query of Prescription Drug Monitoring Program (PDMP) measure

Premier supports CMS' proposal to continue the Query of PDMP measure as a voluntary measure instead of moving forward with mandatory reporting. As we have previously commented, at this point the measure requires burdensome manual data collection activities, and mandatory reporting is not appropriate given the variation in state PDMPs. If CMS wants to promote routine electronic queries of PDMPs, it should work with ONC to support development of data and interoperability standards that would enable this type of electronic exchange. CMS should work with ONC to include data elements within the USCDI and functionality within CEHRT to enable better monitoring and reporting of opioid-related care, treatment, and outcomes. Additionally, given the ongoing criticality of addressing issues regarding opioid use, we once again urge CMS and ONC to identify and prioritize the need for revised or new CEHRT criteria as well as the potential need for development, adoption and support for additional data, interoperability, and transmission standards. CMS needs to address discrepancies and inconsistencies across state PDMPs, including regarding their functionality and use. Additionally, states' licensing requirements may present challenges and obstacles for clinicians accessing data.

Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

CMS proposes to modify the Provide Patients Electronic Access to their Health Information measure to better align with the recent Patient Access and Interoperability Final Rule. Under the modifications, eligible hospitals would be required to ensure patient health information remains available to the patient indefinitely and accessible through any application of the patient's choice. The policy would be applicable for all patient health information from encounters on or after January 1, 2016.

Premier **does not support the proposed requirement for "indefinite" data availability nor the proposed applicability for all patient health information from encounters on or after January 1,**

2016. CMS must ensure its policies are consistent with related and relevant federal and state laws and regulations. Additionally, CMS needs to ensure that any proposed data access specifications are aligned with ONC's requirements for CEHRT.

Health Information Exchange Objective: Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)

Premier supports CMS' ongoing focus on interoperability and access to data, as well as its intention to give providers flexibility while reducing administrative and reporting burdens. CMS proposes to adopt a new HIE Bi-Directional exchange measure to the Health Information Exchange objective, which would be worth 40 points. Hospitals would have the option of reporting the new measure in place of the two existing measures: Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information. CMS believes the proposed new measure would incentivize the eligible hospital or CAH to engage in health information exchange for care coordination that includes additional transitions and referrals as well as other potential scenarios such as where the recipient of the transition of care may be unknown, where the eligible hospital or CAH may not be the referring healthcare provider, or where the transition of care may happen outside the scope of the EHR reporting period.

CMS notes the proposed new measure is broader than the existing measures. The Support Electronic Referral Loops by Sending Health Information measure includes only new patients and known transitions or referrals received that occur during the EHR reporting period. The Support Electronic Referral Loops by Receiving and Reconciling Health Information measure includes only known transitions of care or referrals made that occur during the EHR reporting period. CMS should clarify if "HIE" includes exchange frameworks and networks as defined in ONC's information blocking regulations and/or if "HIE" includes other organizations focused on bi-directional health information exchange. Additionally, CMS needs to work with ONC to ensure that CEHRT requirements for EHRs are aligned with the proposed new measure. Bi-directional exchange implies transmission to and receipt of data; however, existing CEHRT criterion seems to focus only on transmission of data from providers. Bi-directional implies that EHRs can receive data from HIEs. The proposed measure also implies that HIEs will not only receive data from providers but also transmit data to providers.

Premier encourages CMS to continue to offer hospitals additional options and flexibility in meeting interoperability objectives. **However, we are concerned that the proposed bi-directional engagement measure would have to be enabled for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department and all unique patient records stored or maintained in the EHR for those departments during the EHR reporting period.** There would be no exclusions, exceptions or allowances made for partial credit.

Premier recommends that CMS work closely with ONC to ensure forward movement toward establishing the Trusted Exchange Framework and Common Agreement (TEFCA). Premier also recommends that the measure "Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)" remain optional. We further recommend that in addition to the measure's base 40 points, CMS consider bonus points for this measure.

Public Health and Clinical Data Exchange Objective

Proposed Modifications to the Public Health and Clinical Data Exchange Objective.

Beginning with the EHR reporting period in 2022, CMS proposes to require reporting on the following four measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. The remaining two measures (Public Health Registry Reporting and Clinical Data Registry Reporting) would be optional. and available for a total of five bonus points if a "yes" response is reported for either or both of the two optional measures.

Premier supports efforts to improve public health data collection and reporting. Current approaches to prevent, manage, mitigate, and track cases during the COVID-19 PHE relied on home-grown, siloed, and antiquated data collection systems that are grossly inadequate—data sets are incomplete, untimely, and collected in the wrong settings, rendering them virtually useless for identification and/or prediction of disease spread trends.

CMS is concerned by the uneven adoption of electronic case reporting and believes requiring this measure would accelerate the development of electronic case reporting capabilities in EHR systems. Public health reporting capabilities should be required as part of ONC's CEHRT requirements before expecting providers meet CMS measures. CMS should work with ONC to provide additional and harmonized regulatory clarity for EHR vendors. We urge CMS to work more closely with its federal partners, including CDC and ONC, to align requirements for public health data collection and reporting and the requisite health information technology capabilities. Additionally, we believe CMS' statement that their proposed public health reporting requirements would not pose a significant burden on hospitals as in 49 states already participate in the National Syndromic Surveillance Program (NSSP) is misplaced as state participation in NSSP is not an indicator of providers' burdens and does not reflect the degree to which EHRs are capable of meeting CMS' public health reporting measures. Given the federated approach to public health in the U.S., CMS needs to consider the disparate state-level public health data collection and reporting requirements.

Syndromic Surveillance Reporting.

CMS proposes modifications to the Syndromic Surveillance Reporting measure. Currently, under the measure, hospitals can attest to actively engaging with a public health agency to submit syndromic surveillance data from an urgent care or emergency setting. CMS notes that while data from urgent care settings are valuable, they are concerned that not all hospitals have the infrastructure in place to support reporting from this type of setting and that mandatory adoption of the measure into the Public Health and Clinical Data Exchange Objective could impose unnecessary burden on providers and public health agencies. As a result, CMS is proposing to modify the setting in which data is required from urgent care or emergency setting to emergency department (POS 23), beginning with the 2022 reporting period. Additionally, CMS proposes related technical changes to the first exclusion criteria to eliminate a reference to urgent care.

We are concerned about the proposal to eliminate syndromic reporting from urgent care given the importance of syndromic surveillance across settings. For example, many patients turned to alternative sites of care during the PHE out of concern for possible exposure to COVID-19 in emergency departments and other hospital settings. Public health surveillance was previously expected to improve due to increased use of EHRs and electronic exchange of health information; however, additional health information technology capabilities and applications are needed to further ensure syndromic surveillance data collection, reporting and exchange. The nation needs real-time data for syndromic surveillance,

providing an upstream alternative to identifying cases before tests can detect them or patients are hospitalized. This includes collecting data across multiple settings of care, such as urgent care, clinics, physicians' offices, and telehealth visits.

Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT

Under MACRA, CMS established attestation requirements for hospitals to implement and required that hospitals not knowingly and willfully take action, such as to disable functionality, to limit or restrict the compatibility or interoperability of certified EHR technology. As part of the Medicare Promoting Interoperability Program, eligible hospitals and CAHs must attest to three statements. In the ONC 21st Century Cures Act final rule (published on May 1, 2020), ONC finalized the following definition of information blocking for healthcare providers: Information blocking means a practice that, except as required by law or covered by an exception is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a healthcare provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. After review of the attestation statements and considering the information blocking regulations, CMS proposes to no longer require the second and third attestation statements.

Premier recommends that CMS not require any attestations related to the compatibility or interoperability of CEHRT. They are unnecessary given ONC's final information blocking rules. We encourage CMS to work closely with ONC and OIG to ensure that more complete and comprehensive clarification, education (including Frequently Asked Questions (FAQs)), and guidance about information blocking are widely disseminated to help ensure that stakeholders understand the regulations.

Changes to the Scoring Methodology for the EHR Reporting Period in 2022

CMS notes that performance results for 2019 showed that 3,776 of 3,828 participating eligible hospitals and CAHs met the minimum threshold score (or total score) of 50 points. For the EHR reporting period in 2022, CMS proposes to raise the minimum threshold score to 60 points. **Premier does not support raising the minimum threshold at this time.** Providers are still actively responding to the COVID-19 pandemic. Additionally, CMS is proposing several changes to the Promoting Interoperability objectives as part of this proposed rule. **We encourage CMS to continue to monitor and evaluate hospital performance across the Promoting Interoperability objectives prior to raising the threshold.**

Requests for Information

Additional Objectives or Measures Adopting FHIR-based API Standards.

CMS intends to further align Medicare Promoting Interoperability Program measures with approaches utilizing HL7® FHIR® standard Release 4-based Application Programming Interfaces (API) functionality (or the appropriately evolved standard), with the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. Premier supports the use of public, non-proprietary and open APIs to ensure health data exchange and sharing. EHR vendors need to open their data platforms to third party application developers through open APIs. This is critical to fostering an open health information technology and third-party application marketplace, allowing for easy-to-use applications for clinicians, and ensuring more efficient data reporting for public health and quality improvement. It is essential to address ongoing interoperability challenges so that providers can improve care delivery, patient safety and performance, and to drive operational efficiencies. Premier continues to advocate for, develop and implement innovative solutions to achieve open data access across health information

technology systems and technologies to support the industry's transition to value-based care across the care continuum. Interoperability will enable systems to move beyond simply recording data in EHRs toward integrating and combining data to streamline analytics for evidence-based decision-making

Designating High Performing Hospitals.

CMS seeks comment on the development of, or support and adoption of, designating high-performing hospitals in the context of EHR excellence. Premier believes that is premature for CMS to designate high-performing hospitals as proposed. Healthcare providers are highly dependent on CEHRT functionality and the timeliness and efficiency of its updates and implementation. Additional understanding about the status of health information technology functionality and the ability of providers to implement and use third-party applications of their choosing using open APIs by providers is critical to assessing provider performance in using health information technology. Furthermore, we urge CMS to consider increasing evidence about the unintended negative consequences of EHRs on workflow, patient safety and clinician burdens/burnout. [3] [4] [5] [6] We believe that PI measures are inadequate and inappropriate to identify excellence in use of health information technology **Premier is not supportive of including promoting interoperability measures in a hospital Star rating system**.

We reiterate our prior recommendations to introduce additional measures that encourage innovative uses of CEHRT and other health information technology. Premier urges CMS to identify health information technology activities as alternatives to the traditional program measures. Allowing hospitals to meet CMS' goals of coordinating care and achieving interoperability through providers' existing health information technology activities would allow hospitals greater flexibility in their approaches to improving care delivery and ensuring patients' access to their data. Additionally, we recommend that CMS' Promoting Interoperability program recognize hospitals', health systems', and other providers' use of health information technology beyond legacy EHRs, such as third-party applications to report public health data (including clinical and syndromic surveillance and innovative use(s) of machine learning, artificial intelligence and natural language processing to help facilitate data capture from unstructured text such as for clinical decision support and population health management). To the extent that CMS incentivizes and offers providers greater flexibility to use various health information technologies and activities, provider burdens can be reduced, duplicative reporting can be eliminated, and interoperability can be further advanced.

Clinical Notes.

The ONC 21st Century Cures Act final rule finalized eight types of clinical notes required under the USCDI version 1: (1) Discharge Summary Note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedure

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[3] Qi Yan, Zheng Jiang, Zachary Harbin, Preston H Tolbert, Mark G Davies, Exploring the relationship between electronic health records and provider burnout: A systematic review, Journal of the American Medical Informatics Association, Volume 28, Issue 5, May 2021, Pages 1009–1021, https://doi.org/10.1093/jamia/ocab009

[4] Sally L Baxter, Nate C Apathy, Dori A Cross, Christine Sinsky, Michelle R Hribar, Measures of electronic health record use in outpatient settings across vendors, Journal of the American Medical Informatics Association, Volume 28, Issue 5, May 2021, Pages 955–959, https://doi.org/10.1093/jamia/ocaa266

[5] Raj M Ratwani, Erica Savage, Amy Will, Ryan Arnold, Saif Khairat, Kristen Miller, Rollin J Fairbanks, Michael Hodgkins, A Zachary Hettinger, A usability and safety analysis of electronic health records: a multi-center study, Journal of the American Medical Informatics Association, Volume 25, Issue 9, September 2018, Pages 1197–1201, https://doi.org/10.1093/jamia/ocy088

[6] Dean F Sittig, Daniel R Murphy, Michael W Smith, Elise Russo, Adam Wright, Hardeep Singh, Graphical display of diagnostic test results in electronic health Records: a comparison of 8 systems, Journal of the American Medical Informatics Association, Volume 22, Issue 4, July 2015, Pages 900–904, https://doi.org/10.1093/jamia/ocv013

Note. In the 2021 physician fee schedule final rule, CMS aligned the CEHRT definition under the Medicare Promoting Interoperability Program with the updates to certification criteria finalized under the ONC 21st Century Cures Act final rule, including updates to several certification criteria to refer to the USDCI and the expanded support for clinical notes specified in USCDI version 1.

Regarding the Provide Patients Access to their Health Information measure, CMS seeks information about additional changes to this measure, or other program guidance, that could further facilitate the availability of clinical notes to patients. CMS also seeks feedback on the development of a mandatory and independently scored measure for the Medicare Promoting Interoperability Program to allocate points for the use of clinical notes types supported by certified health information technology. It also seeks comment on the types of clinical notes that are commonly sought by patients but not easily accessible to them.

Premier appreciates CMS' questions about changes that will better support the availability of clinical notes to patients. We urge CMS to work closely with ONC, and the Health Information Technology Advisory Committee (HITAC) and other federal partners to ensure that CMS algins the development of Medicare Promoting Interoperability Program measures with health information technology functions, capabilities, and CEHRT requirements. Since the ONC requirements related to clinical notes within the USCDI are new and stakeholders have little or no experience including clinical notes within the USCDI**, Premier believes that it is premature to develop and mandate any measures related to the use of clinical notes.**

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the IPPS proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, vice president, policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

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Premier healthcare alliance