June 24, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
Submitted electronically to: http://www.regulations.gov

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Proposed Policy Changes and Fiscal Year 2020 Rates.

Dear Administrator Verma:

On behalf of the Premier healthcare alliance serving approximately 4,000 leading hospitals and health systems, hundreds of thousands of clinicians and 165,000 other providers and organizations, we appreciate the opportunity to submit comments regarding the regulation proposed by the Centers for Medicare & Medicaid Services (CMS) for the Inpatient Prospective Payment System (PPS). Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, 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. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the Inpatient PPS. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

DISPROPORTIONATE SHARE HOSPITAL

Beginning in fiscal year (FY) 2018, CMS began a three-year phase-in of incorporating hospitals' Worksheet S-10 data into the methodology for determining uncompensated care payments. Premier requested an additional year delay before the Worksheet S-10 was incorporated due to concerns over the accuracy and consistency of data. However, we supported its use so long as CMS continued to incorporate stakeholder feedback to continue to refine the Worksheet S-10 instructions and allow for resubmission of data when necessary. CMS has incorporated stakeholder feedback in making changes to the cost report instructions effective for cost reporting periods beginning on or after October 1, 2016 and by undertaking an audit process beginning with FY 2015 hospital cost reports. Further, CMS allowed hospitals to resubmit FY 2014 and FY 2015 cost reports to make corrections to data submissions when it was apparent those data would be used in the uncompensated care distribution. We commend the agency for its furtherance of its uncompensated care payment policy consistent with guidance received in the public comment process. **Accordingly, we urge the agency to take the following actions.**

Factor 3

CMS incorporated the use of Worksheet S-10 data to calculate uncompensated care payments beginning in FY 2018 utilizing an average of data derived from three cost reporting periods with two of those years using low-income patient days and one year using Worksheet S-10 (FY 2014). For FY 2019, CMS

continued that transition using 1-year of low-income patient days and 2-years of Worksheet S-10 data from FY 2015 and FY 2016. However, none of the Worksheet S-10 data used for FY 2018 and FY 2019 reflected any audits. CMS proposes to move exclusively to Worksheet S-10 data in FY 2020 using one year of data from FY 2015 that has been audited for about one-quarter of the hospitals eligible to receive uncompensated care payments. These hospitals, however, account for approximately 50 percent of total uncompensated care payments.

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.

Premier healthcare alliance prefers the Worksheet S-10 data as the source for calculating uncompensated care payments and commends CMS for auditing the cost report data that will be used in the distribution. In the past, Premier was concerned about the use of low-income patient days as a proxy for uncompensated care as it is not a reliable measure and not a true representation of uncompensated care provided by hospitals.

The Premier healthcare alliance previously commented on the need for significant modification and clarification related to the Worksheet S-10 cost report instructions. We applaud CMS for issuing several iterations of updated instructions and urge the agency to continue to seek feedback from stakeholders for future modifications.

As CMS does more comprehensive audits, we believe additional issues will arise that CMS will need to address through more precise audit instructions as well as continuing audits. For instance, earlier this year CMS instructed Medicare Administrative Contractors (MAC) on the treatment of charge discounts for patients eligible for the hospital's charity care or financial assistance policy. CMS originally instructed the MACs to substitute total patient liability after the uninsured discount on line 22 of Worksheet S-10 instead of the actual amount received from the patient. This instruction could have resulted in zero or negative charity care for hospitals despite discounting charges by millions of dollars. The issue arose because the amount on line 20 is reported at full charges, not the charges written off to charity care. Further, the amount on line 21 is adjusted by the hospital's cost-to-charge ratio (CCR), while the amount on line 22 is not and does not reflect an amount due that may or may not be received.

CMS was legitimately concerned about the potential for duplicate payment of charity care and bad debt but provided an instruction that would have significantly disadvantaged audited hospitals reporting charity care discounts. However, CMS reversed its instruction based on input from the hospital community and the issue resolved. The problem is eliminated with the instructions for cost reports beginning on or after October 1, 2016 because the amount on line 20 is not full charges but the charges that are written off to charity care and the amount on line 22 is the amount actually received.

As CMS proceeds with audits, it will encounter other issues that will need to be resolved over time. One issue that auditors should be aware of is excessive charity care deductibles and coinsurance. On Worksheet S-10, line 20, column 2, hospitals are allowed to report unpaid deductibles and coinsurance written off to charity care. Prior to Transmittals 10 and 11 issued in 2016 and 2017 respectively, CMS' instructions required CCRs to be applied to deductibles and coinsurance. It is possible that many hospitals inflated the amounts on those lines to reflect the actual amounts reported after the CCR was applied. Now that the CCR is not being applied, it appears that deductibles and coinsurance may be excessive for some hospitals.

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. CMS should implement fatal edit to ensure the S-10 is complete and internally consistent and instruct the MAC to audit negative, missing or suspicious values.

Using 3 Years or One Year of Data and FY 2015 or FY 2017

CMS has been using an average of three years of data to allocate uncompensated care payments in recent years but proposes to move to one year of data for FY 2020. Prior use of three years of data to allocate uncompensated care payments allowed CMS to transition from use of low-income patient days a proxy for uncompensated care to use of Worksheet S-10. CMS' ostensible reason for using only one year of data rather than three years of data is that it is concerned about mixing audited and unaudited data to distribute uncompensated care payments and it only has one year of audited data.

Premier believes the preferred policy approach would be to use three years of audited Worksheet S-10 in the uncompensated care distribution and CMS should work towards that goal over time. Given that the preferred policy approach is not a possibility for FY 2020, CMS is left with the dilemma of whether to use one year of audited data or three years of data with the possibility of only one of these years being audited.

This decision is further compounded by whether to use FY 2015 data which is audited or FY 2017 data which reflects improved cost report instructions. CMS has proposed use of one year of audited FY 2015 data for the distribution but requested comments on whether to use FY 2017 data in the final rule which has not been audited. CMS provided impact information for both options.

Premier believes stability in the allocation should have preference over concerns about mixing of audited and unaudited data in the uncompensated care distribution. For this reason, we would recommend that CMS continue to use an averaging of three years of data irrespective of whether it uses FY 2015 or FY 2017 data for distributing FY 2020 uncompensated care payments. For FY 2021, Premier would recommend undertaking audits of FY 2017 data and incorporating that data into the allocation methodology dropping the oldest year from the allocation that was used for FY 2020. A similar process would be used for FY 2022. By FY 2023, CMS would be able to use fully audited data from FY 2017 through FY 2019 to allocate uncompensated care payments. At that point, CMS could roll forward by dropping the oldest year of audited data and incorporating the newest year. Further, once the distribution of uncompensated care payments stabilizes from year-to-year as a result of improved cost reporting instructions and multiple years of audits, CMS could consider whether to drop from three years of data to two or one year of data like it does for the hospital wage index.

Transition Period

Medicare has a longstanding history of transitioning in policies with significant impacts on providers. For example, the capital PPS used a 10-year transition, while the inclusion of MS-DRGs and the decennial census data used a three-year transition period. While our recommendation to continue using three years of data in the uncompensated care distribution will smooth out the variation in uncompensated care values, it may not be sufficient. If after auditing the data, applying trim points and using a three-year rolling average of data there is still a significant negative impact at the hospital level, CMS should consider additional transition policies. For example, at the inception of the outpatient PPS, CMS created a series of transition policies to account for concerns with the hospital billing data, including its effects on device-dependent APCs. CMS used several policies in setting the payment rates for 2003 and 2004 to address these concerns including using only those claims that contained the C codes for devices, making limited use of external data and applying a "dampening" policy to moderate payment reductions. **CMS**

should consider a series of transition polices such that no hospital experiences more than a 5 percent change in overall uncompensated care payment in any given year.

Definition of Uncompensated Care

For purposes of calculating Factor 3 and uncompensated care costs beginning in FY 2018, 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. In using Worksheet S-10, Premier continues to believe that CMS should capture the fact that many of the states do not fully cover the costs associated with the newly insured Medicaid recipients. Just because the patients are now covered, does not mean that there are no remaining uncompensated costs associated with these patients. 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 Medicare 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 Affordable Care Act, has more permissive Medicaid eligibility criteria, or simply has a high proportion of its citizens that qualify for Medicaid. **The Premier healthcare alliance again urges CMS to include Medicaid shortfalls in the definition of uncompensated care.**

Trimming and Audits

CMS acknowledges concerns expressed by Premier and others that uncompensated care costs reported on Worksheet S-10 should be audited due to extremely high values consistently reported by some hospitals. The accuracy of all payments is in question when certain hospitals misreport information due to the relativity of the calculation. CMS believes that it would be appropriate to apply statistical trims to the CCRs on line 1 of Worksheet S-10 that are considered anomalies, just as CMS applies trims to hospitals' CCRs used to calculate high-cost outlier payments. Utilizing a four-step process outlined in the proposed rule, CMS would assign a statewide average CCR (rural or urban) for all hospitals with a CCR greater than 3 standard deviations above the corresponding national geometric mean.

While a trimming approach is necessary, we do not believe it is sufficient. Blunt outlier trim points will both overlook inaccurate values that are closer to the average and disallow values that may be correct. By solely defaulting to the statewide average, CMS will introduce its own bias into the system that could be just as inaccurate as the initial values. The proposed four step methodology for trimming CCRs should be used as an outlier identification process to alert auditors, not a policy in and of itself. **As CMS continues to work on the Worksheet S-10 audit process, we would expect that the need for outlier trims as CMS has proposed would become an audit tool rather than a mechanism to trim what appears to be aberrant data.**

HOSPITAL READMISSIONS REDUCTION PROGRAM

Removal of HRRP Measures

The Premier healthcare alliance supports the adoption for the HRRP of the eight measure removal factors that have been put in use as guidelines for measure removal in other quality programs. We

feel that this allows for consistency in measure evaluation methodology across programs. As we have noted with respect to the use of these factors in other programs, CMS should be transparent in how these factors are applied when a measure is considered for removal.

Definition of Dual Eligible Beneficiary

CMS proposes to modify the definition of dual eligible beneficiary to include the dual eligible status of individuals who die in the month of the readmission. **Premier supports this change** which will allow CMS to properly account for all dual eligible beneficiaries in determining the peer groupings used in calculating the HRRP adjustment. Our support is based on an understanding that this policy change involves a small number of beneficiaries and would not have a substantive impact.

Subregulatory Process for Changes to Payment Adjustment Factor Components

Premier appreciates that CMS should not have to use notice and comment rulemaking to make timely, minor changes to elements of the HRRP, such as updating naming or locations of data files. However, we are concerned that under the proposal some subregulatory changes may result in significant changes for hospitals, such as programming measure changes in their own internal monitoring systems. **Premier requests that prior to implementing a subregulatory change to payment adjustment factor components, CMS should establish a process for obtaining stakeholder input to ensure the change is not substantive and to identify any burdens that might result from the change that should be considered.**

Confidential Reporting of Stratified Readmissions Data

Premier supports the forthcoming inclusion in the confidential hospital-specific reports data on the six readmission measures stratified by patient dual eligible status. We agree that within-hospital and across-hospital comparisons of a hospital's readmissions of dual eligible beneficiaries compared with other beneficiaries will be helpful to hospitals as they continue to work toward reducing preventable readmissions.

HOSPITAL VALUE-BASED PURCHASING PROGRAM

National Healthcare Safety Network (NHSN) Measure Data

Premier supports the proposal to use the same data collection to calculate the NHSN hospital-associated infection measures that is used for the Hospital-Acquired Condition (HAC) Reduction Program. This change would be effective with calendar year 2020 reporting for the FY 2022 VBP performance score and is needed because at that time these measures will have been removed from the Inpatient Quality Reporting Program, which has been the source of data collection for these measures in the VBP Program. In the final rule CMS should clarify that this proposal to rely on the same data collection does not affect the previously adopted and differing measurement periods used for calculating performance under the VBP and HAC Reduction programs. The measurement period for the NHSN measures is two calendar years for the HAC reduction program (e.g., applicable period is CYs 2019 and 2020 for FY 2022 payment) and one calendar year for the VBP Program (e.g., performance period is CY 2020 for the FY 2022 VBP program adjustment).

HOSPITAL-ACQUIRED CONDITION REDUCTION PROGRAM

Removal of HAC Reduction Program Measures

Consistent with our position with respect to the HRRP, t**he Premier healthcare alliance supports the adoption of the eight measure removal factors for CMS' use in considering whether to retain or remove HAC Reduction Program measures.** This would provide for consistency in measure removal considerations across the hospital quality programs. As noted earlier, CMS should be transparent in how these factors are applied when a measure is considered for removal.

Data Validation

The current policy for validation of chart-abstracted measures involves annual random selection of 400 hospitals and targeted selection of another 200 hospitals. **Premier supports the proposals to make the targeted selection up to 200 hospitals and to filter the cases selected for validation of the Central Line Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures** to exclude cases where the positive cultures were collected on the first or second day following admission. Limiting the CLABSI and CAUTI cases will better identify infections that were acquired in the hospital and not in the community.

INPATIENT QUALITY REPORTING PROGRAM

Proposed New Opioid-Related eCQMs

Premier supports the addition of the proposed new eCQM Safe Use of Opioids-Concurrent Prescribing, which has been endorsed by the National Quality Forum. However, we believe that CMS should delay making this measure mandatory until the FY 2023 reporting/2025 payment period to allow hospitals an opportunity to implement the measure and receive one year of confidential data prior to public reporting.

However, Premier does not support addition of the Hospital Harm—Opioid Related Adverse Events eCQM. This measure has not been endorsed by the NQF. Moreover, as the Measure Applications Partnership (MAP) pointed out in its comments on this measure, the use of naloxone alone is not an indicator of quality care. CMS acknowledges that use of naloxone during an inpatient admission is a rare event. As a result, testing results did not show much variability in hospital performance, in which case the implementation of this measure would not provide useful information to providers or consumers.

Confidential Reporting of Stratified Data for Hospital Quality Measures

As noted earlier, Premier supports CMS' plan to continue to provide hospitals with confidential hospital-specific reports on the pneumonia readmission measure stratified by dual eligible status and to expand this effort to include five additional readmission measures. We agree that within-hospital and across-hospital comparisons of a hospital's readmissions of dual eligible beneficiaries compared with other beneficiaries will be helpful to hospitals as they continue to work toward reducing preventable readmissions. Any consideration of public reporting of the stratified data in the future should be proposed as part of notice and comment rulemaking.

Hybrid Hospital-Wide Readmission Measure

The Premier health alliance has supported CMS efforts to develop a hybrid readmissions measure and test it through voluntary reporting mechanisms. Testing a measure through voluntary collection can help elucidate any data collection issues; however, hospitals need time to redesign their EHRs to collect and validate these data. CMS proposes two 12-month voluntary reporting periods for this measure, beginning on July 1, 2021 and July 1, 2022, followed by mandatory reporting beginning on July 1, 2023 for the FY 2026 payment determination.

Premier supports signaling a gradual movement to mandatory reporting, but urges CMS to actively solicit feedback from hospitals during the voluntary period to determine if the required data elements can feasibly be obtained from EHRs. The results of this solicitation should be shared with the field. Prior eCQMs have been difficult to collect and costly to hospitals. Recent interoperability rules may ease collection over time but the timing of benefits for this measure is unclear. For this reason, **we also recommend that CMS maintain flexibility in the reporting requirements for several years, with the amount of data submitted gradually increasing over time** rather than the proposal to submit data on 90 percent of Medicare beneficiaries in both voluntary periods. Further, we believe that **voluntary reporting on this measure should be counted as one of the four eCQMs** required under the IQR Program. **Finally, as experience with this approach evolves, Premier requests that CMS explore using the hybrid approach for developing modified condition-specific readmission measures used in the Hospital Readmission Reduction Program.**

Possible Future eCQMs

CMS identifies three potential future IQR Program measures, all of which are eCQMs. **Premier supports future consideration of the two Hospital Harm measures relating to Hypoglycemia and Pressure Ulcer if the Measures Applications Partnership recommendations are incorporated into the measure specifications and the National Quality Forum endorses the measures.**

We do not support potential addition of the eCQM on Cesarean Birth. This measure previously lost NQF endorsement, and the eCQM version does not appear to address past concerns with the measure.

PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM

CMS proposes to remove the three pain management questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) from the PCHQRP and also to remove the measure External Beam Radiotherapy for Bone Metastases. **Premier supports these removals.** The pain management questions have already been removed from the IQR Program out of concern that the questions could unintentionally encourage over-prescribing of opioids during the hospital stay. The External Beam Radiotherapy measure lost its NQF endorsement and is no longer being maintained by the measure steward.

LONG-TERM CARE HOSPITAL QUALITY REPORTING PROGRAM

New Measures for FY 2022

CMS proposes the addition of two new process measures for the LTCH QRP beginning with FY 2022 for a new quality measure domain entitled “Transfer of Health Information”: Transfer of Health Information to

the Provider – Post-Acute Care (PAC) Measure and Transfer of Health Information to the Patient— PAC Measure. These measures would assess whether a current reconciled medication list is given to the subsequent provider or patient (including family or caregiver) respectively, when a patient is discharged or transferred. CMS notes that both proposed measures support their Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability.

Premier supports CMS' proposals to ensure the transfer of health information to other providers and to the patient; however, CMS can help make this process more efficient and accurate by focusing on additional efforts to advance interoperability across the care continuum via electronic data exchange. Ensuring interoperability across EHR systems and settings of care can unlock barriers to data sharing and care coordination between health systems, physician group practices, independent physicians, and PAC settings. CMS' pilot testing of the proposed measures confirms that the most common mode of information transmission to the patient and to the provider was paper based.[1] LTCHs and other PAC providers were not provided financial incentives under the HITECH Act, and there has been no other comparable mandate to adopt certified EHR systems. As a result, many PAC providers are not using EHRs or are using EHRs that are not designed for interoperability. [2]

We urge CMS to enhance its efforts to develop standards and measures for data exchange and sharing across all care settings, including post-acute care. The transfer of information between LTCHs and other providers most often occurs via cumbersome and resource-intensive manual processes. CMS needs to consider ways to incentivize SNF and other PAC providers to more readily adopt health IT in support of wider efforts to standardize patient data, improve care quality, and reduce costs. Standardized data elements and common data reporting processes alone will not achieve interoperability across the care continuum.

We further urge CMS to work with ONC to ensure that the US Core Data for Interoperability (USCDI) includes data classes and elements relevant to LTCHs and other PAC providers. CMS should also work with ONC to leverage ongoing efforts to adopt data standards and implementation guides for certified EHRs (such as the USCDI) and to build on efforts to base measures and calculations (numerators/denominators) on data within certified EHRs. **Additionally, while the dichotomous yes/no approach to assessing medication reconciliation is an important step, Premier encourages CMS to continue to refine the measures to ensure a quality medication reconciliation is performed.** Consideration for future measures could capture quality metrics, such as the accuracy of the medication reconciliation and the extent to which the reconciliation influenced the care when the patient moves to a new setting.

Reporting for High Risk Drug Classes

CMS proposes a series of Standardized Patient Assessment Data Elements (SPADEs) for reporting by LTCHs and other PACs, including a new data element would ask at admission and discharge whether the resident is taking any medications in six specific drug classes, and if so, whether there is an indication noted for all the medications in the drug class.

Premier strongly supports CMS efforts to ensure LTCH patients are protected from unintended consequences that may occur with the use of high-risk medications. We support the inclusion of the

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[1] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-2018-Pilot-Test-Summary-Report_Final.pdf

[2] https://www.newswire.com/news/post-acute-care-the-next-frontier-for-health-systems-under-risk-black-20056199

six drug classes identified by CMS in the proposed rule: antipsychotics, anticoagulants, antibiotics, opioids, antiplatelets, and hypoglycemics (including insulin). However, **CMS should consider the addition of the classes of high-risk medications captured in measures currently used in the Medicare Advantage program and the Merit-based Incentive Payment System, which are also based on the Beers criteria**. Aligning the classes of high-risk medications across settings and programs that impact Medicare beneficiaries will ensure care processes and interventions are aligned. Premier agrees that an indication for use should be documented for medications prescribed to LTCH patients. As proposed, the data elements that capture these high-risk drugs that include a documented indication for use may be helpful in assessing quality of care.

MEDICARE AND MEDICAID PROMOTING INTEROPERABILITY PROGRAMS

Reporting Period

Premier supports continuation of the minimum reporting period of any continuous 90-day period for calendar year 2021. Furthermore, we believe that CMS should consider establishing a continuous 90 day reporting period for 2022 and later years. Given the broad scope of changes recently proposed by the Office of the National Coordinator regarding the 2015 Edition, APIs, information blocking, and other elements of electronic health data exchange, along with the impending roll out of the Trusted Exchange Framework and Common Agreement (TEFCA), hospitals will need to continue to adapt to updated EHRs and modify workflows. Expanding the reporting period should not be considered until the underlying technology and methods for data exchange have further evolved and stabilized.

Changes to Measures

Query of PDMP

CMS proposes to continue the Query of PDMP measure as a voluntary measure instead of moving forward with mandatory reporting in 2020 as previously finalized. In addition, the measure would be respecified as a yes/no measure instead of a numerator/denominator percentage calculation. ("Yes" would indicate that CEHRT was used to query a PDMP for at least one Schedule II opioid prescribed during the reporting period.) The existing exclusion would be removed, and a hospital voluntarily reporting this measure would receive a bonus equal to 5 points. **Premier supports all the proposed changes to the Query of PDMP measure.** 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.

Verify Opioid Treatment

Premier strongly supports the proposed removal of the Verify Opioid Treatment measure. As CMS has acknowledged, there are many problems with this measure, including the lack of defined data elements (including the definition of an opioid agreement), structure, standards and criteria for the

electronic reporting exchange of opioid agreements, and calculating the 30-day lookback period. The resulting measure is burdensome, vague and subject to misinterpretations, and removal of the measure is the best course. We are pleased to see CMS take this action.

Elimination of Attestation

CMS proposes to eliminate the attestation option completely beginning with the 2023 reporting period. At that time all eligible hospitals and CAHs would have to submit eCQM data electronically. **While Premier agrees that most hospitals and CAHs have the capacity or will have the capacity for electronic reporting of eCQMs, CMS should retain a hardship exceptions process for all the situations where a hospital can meet all of the Promoting Interoperability Program (PI) requirements but is unable to submit/report eCQMs electronically.** For example, there needs to be a hardship exception process for small rural hospitals and CAHs that have met other requirements of the PI program but for whom electronic reporting of eCQMs is not feasible.

Actions Must Occur During Reporting Period

Premier supports the proposal that beginning with 2020 reporting periods, measure numerators and denominators could only include actions that occurred during the hospital's chosen reporting period. That is, the policy of allowing actions occurring during the calendar year that the reporting period falls within but outside the hospital's chosen reporting period for measures in the public health and clinical data change objective would no longer apply. It is appropriate that there be an exception for the Security Risk Analysis measure, as proposed, because actions included in the measure may occur anytime during the calendar year.

Request for Information (RFI) on Potential Future Opioid Quality Measures

CMS seeks comments on potential new eCQMs for opioid use disorder prevention and treatment that could be added to the Promoting Interoperability Program in future years. Premier is generally supportive of measures addressing opioid use in inpatient and ambulatory settings. Such measures should reflect appropriate use criteria for opioid prescribing and provide information that is meaningful in addressing the opioid epidemic, such as monitoring of patients with long-term opioid prescriptions and use of alternative pain management tools. However, development of quality metrics as eCQMs poses the added burden of ensuring that the information needed for calculating the measure can be drawn from the EHR and electronically reported using available technology. This includes ensuring that the information required for the eCQM can be captured without burdensome changes in clinical workflow, and that the technology provides for automatic application of exclusion criteria as well as calculation of numerator and denominator values.

Request for Information (RFI) on National Quality Forum and CDC Opioid Quality Measures

CMS seeks comment on the development of opioid-related measures for the Promoting Interoperability Program that are based on existing measures, including those endorsed by the NQF and the Centers for Disease Control and Prevention's (CDC's) Quality Improvement 16 opioid measures. Because the NQF-endorsed opioid measures were developed for pharmacy benefit managers and not hospitals, these measures would need to be reconfigured and explicitly tested for applicability to the hospital setting. The measures assess a population of inpatient and ambulatory patients across multiple providers, which would not be appropriate for use in assessing performance by individual hospitals or clinicians.

The CDC QI opioid measures are largely individual process measures, but some could be considered and tested as a composite. Several are visit-related measures which would not be appropriate for

hospitals (e.g., quarterly follow-up visit; quarterly pain and functional assessment) but these measures could be used to assess and ensure continuity of care with outpatient providers, particularly for beneficiaries managed by accountable care organizations (ACOs). Because other processes may be in place to ensure appropriate opioid related follow-up patient assessments, requiring a hospital to conduct follow-up for these patients may inadvertently lead to duplication and increased costs without improved patient outcomes.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

CMS requests comments on the potential for a metric to assess provider efficiency using EHRs**. Premier strongly believes that it is unreasonable and premature to develop measures to assess provider efficiency using EHRs.** We caution CMS against introducing any new provider requirements that will increase provider reporting burdens and costs. It is not feasible nor practical to expect providers to measure and assess efficiency of health IT nor their use of health IT. [3] [4] [5]

We strongly recommend that CMS work with ONC and NIST to focus greater effort and attention to improving the usability of certified EHRs and to identify best practices to ensure the incorporation of EHRs within the clinical workflow.[6] [7] We also urge CMS to accelerate efforts and work with ONC to continue to explore ways to increase provider and end user satisfaction with EHRs.[8] [9]

The 21st Century Cures Act (Cures) required the development of an *Electronic Health Record Reporting Program* (relating to vendor reporting about health information technology usability, interoperability, and security). Providers must have reliable, robust and transparent information about EHRs' usability, functions and interoperability, thus timely implementation of this provision is critical. Premier urges CMS and ONC to accelerate the implementation of this Cures' provision. At a minimum, EHR vendors should first be expected to report on their systems' capabilities and functions (such as usability, system efficiency and interoperability) as required by Cures.

Furthermore, should CMS decide to consider developing measures of provider efficiency, we urge CMS to ensure that the measures are field tested and piloted in advance of their incorporation into any CMS reporting program(s). Any measures of provider efficiency should be voluntary, optional and eligible for bonus points. Measures should be feasible in all applicable reporting methods. As we have previously stated in comment letters, CMS should work with ONC and first strengthen oversight of certified EHRs.

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[3] Optimizing Strategies for CLINICAL DECISION SUPPORT Summary of a Meeting Series https://www.healthit.gov/sites/default/files/page/2018-04/Optimizing_Strategies_508.pdf

[4] Lise Poissant, Jennifer Pereira, Robyn Tamblyn, Yuko Kawasumi, The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review, Journal of the American Medical Informatics Association, Volume 12, Issue 5, September 2005, Pages 505–516, https://doi.org/10.1197/jamia.M1700

[5] Commonwealth Fund. Using Electronic Health Records to Improve Quality and Efficiency: The Experiences of Leading Hospitals July 2012 https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2012_jul_1608_silowcarroll_using_ehrs_improve_quality.pdf

[6] Po-Yin Yen, Suzanne Bakken, Review of health information technology usability study methodologies, Journal of the American Medical Informatics Association, Volume 19, Issue 3, May 2012, Pages 413–422, https://doi.org/10.1136/amiajnl-2010-000020

[7] Johnson CM, Johnston D, Crowley PK, et al. EHR Usability Toolkit: A Background Report on Usability and Electronic Health Records (Prepared by Westat under Contract No. HHSA 290- 2009-00023I). AHRQ Publication No. 11-0084-EF. Rockville, MD: Agency for Healthcare Research and Quality. August 2011. https://healthit.ahrq.gov/sites/default/files/docs/citation/EHR_Usability_Toolkit_Background_Report.pdf

[8] Williams DC, Warren RW, Ebeling M, Andrews AL, Teufel Ii RJ. Physician Use of Electronic Health Records: Survey Study Assessing Factors Associated With Provider Reported Satisfaction and Perceived Patient Impact. JMIR Med Inform. 2019 Apr 4;7(2):e10949. doi: 10.2196/10949. PubMed PMID: 30946023; PubMed Central PMCID: PMC6470463.

[9] Singh RP, Bedi R, Li A, Kulkarni S, Rodstrom T, Altus G, Martin DF. The Practice Impact of Electronic Health Record System Implementation Within a Large Multispecialty Ophthalmic Practice. JAMA Ophthalmol. 2015 Jun;133(6):668-74. doi: 10.1001/jamaophthalmol.2015.0457. PubMed PMID: 25880083.

The CEHRT requirements should ensure that standardized data elements are implemented and supported to populate measures for all the federal reporting programs; ideally we believe it is essential for the certified EHRs to be able to calculate the measures; at a minimum they should be able to seamlessly and reliably produce the required data elements.

Request for Information (RFI) on the Provider to Patient Exchange Objective

CMS seeks comment on whether eligible hospitals and CAHs should make patient health information available immediately through the open, standards-based API, no later than one business day after it is available to the eligible hospital or CAH in their CEHRT. **Premier is opposed to CMS requiring providers to make patient health information available immediately through the open, standards-based API, no later than one business day after it is available**. We are supportive of CMS considering awarding bonus points under the Promoting Interoperability Programs for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs.

CMS needs to clarify what it means by "available". CMS and ONC should ensure that providers have sufficient time beyond receiving their "new" EHR from the vendor (for example, an additional 12-24 months from the date they receive the "new EHR" from their vendors) to test and implement the new system along with adequate time to train dozens if not hundreds of staff and clinicians. Similarly, additional time is needed for providers to work with their EHR vendors, patients and third party-applications developers to launch appropriate policies, procedures and processes.

Providers will need to implement similar operational steps associated with enabling patients' access to their health information as they currently do in order to comply with appropriate federal, state and or local laws, regulations and guidance (regardless of whether the data are electronic or not).

CMS also seeks comment on an alternative measure under the Provider to Patient Exchange objective that would require healthcare providers to use technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR. We believe that it is premature to comment on CMS' specific questions about the EHI export function until the ONC rule is finalized. We are supportive of CMS exploring alternatives and options for providers to meet the Provider to Patient Exchange objective, including awarding bonus points for measures (such as for providers attesting to providing patients with the USCDI).

CMS asks about criteria that CMS should employ to identify high priority health IT activities for the future of the program. Premier supports CMS' effort to encourage the use of health IT and suggest that at a minimum, CMS provide bonus points and/or recognize as alternatives to the traditional program measures, activities that require health IT use, rather than only recognize the use of CEHRT. We believe this approach will encourage more innovative approaches for using health IT to improve quality of care and ultimately to achieve interoperability. We urge CMS to incentivize healthcare providers for adoption and use of various health information technology that contribute to efficient, safe and effective care delivery, such as electronic prior authorization (ePA); clinical surveillance and patient safety software, analytics and technologies; and clinical decision support. We also believe that CMS should incentivize providers' current participation in health information exchanges and/or national networks. We urge CMS to incentive and recognize providers' participation in the (future) Trusted Exchange and Common Agreement (TEFCA).

We also recommend that CMS incentivize providers to pilot test emerging data and interoperability standards. We note that ONC would need to require EHR vendors to implement/allow/use emerging standards before expecting providers to pilot them. We urge CMS and

other agencies to accelerate and support development, implementation and adoption of appropriate transmission, syntactical and sematic standards.

CMS must consider the availability and adoption of data and interoperability (transmission, syntax, semantic) standards along with the readiness and feasibility of adopting available standards and the willingness and ability of vendors to support those standards. Our enthusiasm is tempered by the need for technical, syntactical and sematic interoperability and the requirement for more efforts to accelerate current standards development, testing, adoption, implementation and vendor support in order for interoperability to be fully realized. Such standards efforts are essential pre-requisites to achieving interoperability across the care continuum and healthcare settings.

Request for Information (RFI) on Integration of Patient-Generated Health Data into EHRs Using CEHRT

Although in the FY 2019 IPPS/LTCH final rule CMS removed a previously finalized Promoting Interoperability Program measure related to patient-generated health data (PGHD), CMS notes that their decision was due to flaws in the measure and not the concept of capturing PGHD into EHRs. CMS seeks comments on ways that the Promoting Interoperability Program could adopt new elements related to PGHD. CMS believes that the bi-directional availability of data is critical, including patients being able to import their health data into their medical record and have it be available to health care providers. Premier agrees that patient generated health data are important**. Premier is supportive of CMS exploring ways to include bonus points for healthcare providers engaging in activities that pilot approaches for capturing PGHD** and incorporating it into CEHRT using standards-based approaches. We urge **CMS to work with ONC to identify and prioritize (PGHD) data classes and elements for inclusion in the USCDI**.

Premier recommends that CMS and ONC convene and engage with public and private sector stakeholders, including other federal agencies (i.e., CDC, FDA and CMS), providers (hospitals and health systems), payors, EHR vendors, third party application developers, professional and trade associations, disease and patient advocacy organizations, public health entities and medical specialty societies). It is important to identify the common priority issues, current challenges and potential solutions including specific use cases to capture PGHD as part of treatment and care coordination. **Premier recommends that CMS work with ONC to ensure that standards for bi-directional data exchange are developed and adopted by ONC for use within CEHRT** prior to any further consideration of integrating PGHD into EHRs.[10] [11] [12]

Request for Information (RFI) on Engaging in Activities that Promote the Safety of the EHR

CMS seeks comments on ways that the Promoting Interoperability Program may reward hospitals for engaging in activities that can help to reduce errors associated with EHR implementation. We support CMS consideration to reward activities that promote reduction of safety risks associated with EHR use and implementation. CMS is interested especially in comments on whether to award points under the program for hospitals that attest to performance of an assessment based on one of the ONC SAFER Guides. **Premier supports CMS awarding bonus points towards the Promoting Interoperability Program score for hospitals that attest to conducting an assessment based on the High Priority**

[10] ONC Issue Brief: Patient-Generated Health Data and Health IT http://wanghaisheng.github.io/images/pghd_brief_final122013.pdf
[11] https://www.healthit.gov/topic/scientific-initiatives/patient-generated-health-data
[12] Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024 https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf

Practices and/or the Organizational Responsibilities SAFER Guides and/or for review of all nine of the SAFER Guides. We urge CMS to work with ONC to develop and implement information dissemination, training and/or technical assistance for providers about the SAFER Guides in advance of including any measures relating to their use. Additionally, as we noted above, **CMS needs to work with ONC and NIST to focus additional attention on improved usability of EHRs**.[13] [14] [15]

Request for Information on Including Promoting Interoperability Program Data on the Hospital Compare Website.

Premier supports public reporting of hospital performance on quality measures, as is routinely done with respect to IQR Program measures. Medicare beneficiaries and the public at large can benefit from reviewing and comparing hospital performance on measures of patient safety, outcome, and patient experience of care. However, in considering whether to begin similar public reporting of any of the Promoting Interoperability Program measures, CMS should consider 1) whether hospitals have had sufficient experience in collecting the data and calculating and reporting the measures to ensure meaningful comparisons and 2) whether the information provided would be of interest and useful to patients or the broader public.

Premier believes that it is premature to consider public reporting of hospital performance on many of the PI measures. Major changes to the Promoting Interoperability Program measures and scoring were finalized in 2018 for implementation in the 2019 and 2020 reporting years, and prior to that program requirements were changed annually. Hospitals are just now becoming familiar with the revised measures. Before proposing public reporting of a measure CMS should review performance data to assess whether performance on the measure is stable and whether the results indicate meaningful differences among hospitals. CMS should also make the information about measure performance available to hospitals, allowing sufficient time to review and analyze results. **Premier believes at least two-years of reporting is required prior to making a measure publicly available.** CMS could make measure data available via the downloadable database prior to including the measure on the Hospital Compare profile pages.

Further, CMS should only consider public reporting via the Hospital Compare profile pages of interoperability measures that will have meaning to and can be easily understood by patients, in consultation with patient groups and other stakeholders. Accordingly, we request that CMS test consumer/patient response to Promoting Interoperability Program Data in order to understand how consumers will use and interpret this information and to verify that the proposed Promoting Interoperability Program Data is understood.

[13] Howe JL, Adams KT, Hettinger AZ, Ratwani RM. Electronic Health Record Usability Issues and Potential Contribution to Patient Harm. JAMA. 2018;319 (12):1276–1278. doi:10.1001/jama.2018.1171
[14] NIST Health IT Usability. https://www.nist.gov/programs-projects/health-it-usability
[15] NIST Safety-Related Usability Framework https://www.nist.gov/programs-projects/safety-related-usability-framework

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the Inpatient Prospective Payment System proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, senior director, payment and quality policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

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Premier healthcare alliance