THELEAPFROGGROUP
Giant Leaps for Patient Safety

June 9, 2023

Ms. Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD

RE: RIN 0938-AV08 Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership

Dear Ms. Brooks-LaSure,

The Leapfrog Group, our Board of Directors, and members collectively comprise hundreds of the leading purchaser and employer organizations across the country. We are committed to improving the safety, quality, and affordability of health care with meaningful metrics that inform consumer choice, payment, and quality improvement. We are one of the few organizations that both collects and publicly reports safety and quality data at the national level, thereby bringing a unique perspective on measures that can be effectively collected by hospitals and reported to health care consumers. In addition, we use CMS measures in the Leapfrog Hospital Safety Grade, amplifying the measures' usefulness to consumers and strengthening the alignment between private and public purchasers. We appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services on the proposed changes to the FY 2024 Inpatient Prospective Payment System (IPPS) rule.

In the appendix to this letter, we detail our comments on items in this proposed rule. There is one area of particular importance we'd like to draw your attention to.

The Leapfrog Group is opposed to the removal of the elective delivery measure based on CMS' perception that the measure is "topped out," which is measure removal factor #1. The data still suggests that tens of thousands of mothers and newborns are at high risk of this unnecessary and dangerous intervention. Moreover, per CMS' analysis of the measure in the proposed rule, the rate of elective procedures is increasing (43% in the past two years). This alarming increase is despite the fact the measure steward has increased the ICD-10 code exclusions in the measure by 26% over the last several years, suggesting the rate should be decreasing, not increasing. We suggest it is not the time to remove the measure from public scrutiny when the rates are substantially increasing year over year and when so many lives are still at risk from known poor performance on this measure. CMS should not be moving the focus away from the measure, but further shining a light on this important clinical area that is going in the wrong direction. This is also an issue of health equity, with a large and growing body of literature suggesting maternity care disparities are an urgent issue in the United States.

Additionally, we have recommendations on transparency that are important principles for IPPS but continue to be overlooked in rulemaking.

1. **We implore CMS to meaningfully differentiate the very real variation in hospital performance on the safety and quality measures published on the Care Compare website.** We applaud CMS for revealing variation among hospital performance in its excellent Star Ratings program, and we encourage you to extend that leadership to make Care Compare more meaningful to consumers. For the data to be valuable for health care consumers, the data has to differentiate between hospitals on safety and quality. Publicly reporting over 90% of hospitals as "no different than the national average" sends a dangerous message to consumers: all hospitals are the same. We all know that this is not the case, and the difference can mean life or death for patients.

2. **In alignment with recommendations from the Office of the National Coordinator, we implore CMS to report results from all federal hospital programs by bricks-and-mortar facility, not CMS Certification Number (CCN).** We strongly recommend that CMS align with Leapfrog and its purchaser constituency by publicly reporting data in a way that puts the needs of consumers first and foremost. Fundamental to meeting that goal is to collect and report data for individual, bricks and mortar facilities (i.e., campuses and locations), not CCN as currently constructed. There are instances where up to nine hospitals several miles apart and offering very different services share a CCN. When safety and quality metrics are reported in this way, it obscures the individual performance of the hospital delivering the care and is misleading and unhelpful to patients. Patients do not seek care from a system; they seek care from individual hospitals and clinicians. Providers and administrators too can benefit from being able to discern the performance more easily at their own facility and determine where improvements are needed.

3. **Stop exempting hospitals from public reporting.** Patients who receive care in critical access hospitals, pediatric hospitals, hospitals in U.S. territories and other exempt facilities deserve the same safety, quality, and resource use information that patients of general, acute care facilities have access to. Rates of infections, hospital-acquired conditions and mortality and readmission rates are all important factors in selecting a hospital. Those in communities served by hospitals exempted from the federal reporting programs are highly disadvantaged.

In the appendix to this letter, we offer comments on the following:

- Hospital Inpatient Quality Reporting Program
- Hospital Acquired Conditions Reporting Program
- Hospital Value Based Purchasing Program
- Additional RFI

On behalf of The Leapfrog Group, our Board, our members, and the others who have signed in support of our letter, we appreciate the opportunity to provide comments on the proposed changes to the FY 2024 IPPS proposed rule.

Sincerely,

Leah Binder, M.A., M.G.A
President & Chief Executive Officer
The Leapfrog Group

Cosigning Individuals and Organizations Supporting these comments on the CMS FY 2024 proposed rule:

DFW Business Group on Health

Florida Alliance for Healthcare Value

Georgia Watch

Greater Philadelphia Business Coalition on Health

Health Action Council

Health Policy Corporation of Iowa

Healthcare Purchaser Alliance of Maine

HealthCareTN

Irene Fraser, Leapfrog Board Member

John Zern, Ryan Specialty Benefits

Kansas Business Group on Health

Lehigh Valley Business Coalition on Healthcare

Montana Association of Health Care Purchasers

Nancy Johnson, Consumer

New Jersey Health Care Quality Institute

North Carolina Business Coalition on Health

Pittsburgh Business Group on Health

Sally Welborn, Welborn Advisory Services, LLC

St Louis Area Business Health Coalition

Texas Business Group on Health

The Asthma and Allergy Foundation of America

The Economic Alliance for Michigan

Washington Health Alliance

Well OK, The Oklahoma Business Coalition on Health

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2024 IPPS PROPOSED RULE

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

- **Addition of Measures to the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 925 – June 9, 2023

The Leapfrog Group commends CMS for a much-needed expansion of measures included in the Hospital IQR Program. We support the addition of all three proposed measures to the program as follows:

- Hospital Harm – Pressure Injury eCQM
- Hospital Harm – Acute Kidney Injury eCQM
- Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) eCQM

- **Refinement of Three Existing IQR Program Measures**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 941 – June 9, 2023

We support the proposed refinements to the following three measures and believe the changes will result in improvements:

- Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure
- Hybrid Hospital-Wide All-Cause Readmission (HWR) measure
- COVID-19 Vaccination Among Healthcare Personnel (HCP) measure

We strongly support expanding the population of the hospital-wide mortality (HWM) and readmission (HWR) measures to include Medicare Advantage, and we urge CMS to extend this to other Hospital IQR measures as well.

In 2022, Medicare Advantage grew to nearly half (48%) of Medicare beneficiaries. The rate of growth in Medicare Advantage participation has more than doubled from 2007 to 2022 (19% to 48%)[1]. Measurement and accountability should not be a privilege extended only a minority of beneficiaries. This issue will grow even more dramatically given ASPE's projection that Medicare Advantage will grow from approximately 30M in 2022 to 41M in 2030[2]. We are encouraged that CMS is taking an initial step with the HWM and HWR measures, but we need to quickly take similar steps with other Hospital IQR measures to not only preserve but improve the measures' reliability.

- **Removal of Three Measures from the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 954 – June 9, 2023

Of the three measures proposed for removal from the IQR program, we support removal of the following two measures *if they continue to be publicly reported on the Care Compare website*:

- Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty measure
- Medicare Spending Per Beneficiary (MSPB)—Hospital measure

There is a precedent when a measure removed from the IQR Program is used in a value-based purchasing program. In the IPPS FY2019 final rule, CMS removed the NHSN Healthcare-Associated Infection measures (HAIs) from IQR while they were retained in the HVBP Program. In that final rule, CMS noted it planned to continue to publicly report performance in these measures[3] and has done so.

We do not support removal of the third of the three measures proposed for removal:

- Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01) measure from the Hospital IQR.

The Leapfrog Group is opposed to the removal of the elective delivery measure based on CMS' perception that the measure is "topped out," which is measure removal factor #1. We do not agree this measure has reached maximum potential when hundreds of hospitals continue to perform this procedure, endangering thousands of mothers and newborns each year. Americans deserve to know which hospitals are failing to meet the standard. Moreover, without public reporting hospitals that currently meet the standard could shift their focus and begin increasing these dangerous deliveries. Slippage backwards would not be detectable by CMS or the public.

That slippage is not mere speculation. Per CMS' analysis of the measure in the proposed rule, the rate of elective procedures has increased 43% from FY2020 (mean rate of 1.73) to FY2023 (mean rate of 2.47). This alarming increase is despite the fact the measure steward has increased the ICD-10 code exclusions in the measure by 26% over the last several years (i.e., v2018A to v2023B)[5,6]. Such incremental exclusions tend to be higher risk cases. Thus, with all things being equal, we would expect the rate of elective procedures over time to decrease; not increase. We suggest it is not the time to remove the measure from public scrutiny when the rates are substantially increasing year over year. CMS should not be moving the focus away from the measure, but further shining a light on this important clinical area where quality appears to be eroding.

Childbirth is one of the most common reasons for hospitalization and one hospital service where the public has a strong interest in researching options before seeking care. To ensure they have the information they need to make the best decision about where to have their baby, mothers need and deserve information on as many relevant measures as possible. Moreover, the U.S. rate of maternal mortality, particularly for women of color, suggests quality is an urgent issue. Yet publicly reported maternity measures are sparse. The removal of this important measure would eliminate any outcomes-based maternity care quality information available on the CMS Care Compare website. We urge CMS to retain this measure and enable mothers to make informed decisions in maternity care.

- **Codifying Measure Retention and Removal Policies for the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 964 – June 9, 2023

First and foremost, the measure removal policy should center on the best interests of Medicare beneficiaries. Secondly, the policy should consider the best interests of the public at large. The best interests of hospital administration should not eclipse the interest of beneficiaries or the public, yet surprisingly there is no criterion proposed on whether the measure is important to them. We recommend the addition of that criterion as the new "Factor 1" to stress that the measure removal policy is indeed consumer-centered.

Regarding the current "Factor 1" (i.e., "topped out" measures), we suggest removing this criterion. CMS' methodology to identify "topped out" performance in a measure is problematic for several reasons. First, some of the measures included in the IQR Program quantify "never events" which, while rare, are catastrophic to patients when they do happen. Secondly, CMS primarily determines "topped out" by comparing performance at the 75th and 90th percentile where a higher percentile means better performance. This too is problematic.

Consumers and purchasers are often interested in avoiding the worst performers, those hospitals that are in lower percentiles. CMS' method does not consider the variation between hospitals performing at the highest versus the lowest percentiles. Additionally, our analysis of the application of this criteria to measures in the FY2023 Proposed Rule highlighted the high degree of variation between hospitals, which could represent thousands of preventable complications and harms to patients. Finally, many of the IQR measures only include patients covered by Medicare's fee-for-service plans, which ignore the almost 50% of Medicare beneficiaries covered by Medicare Advantage plans. In this proposed rule, CMS announced taking an initial step to include Medicare Advantage claims when calculating the HWM and HWR measures, but we need to quickly take similar steps with other Hospital IQR measures before we can consider them "topped out."

Regarding the current "Factor 8" (i.e., a cost – benefit of the measure), Leapfrog opposes this criterion unless "costs" and "benefits" are defined as "costs to Medicare beneficiaries and the public" and "benefits to Medicare beneficiaries and the public." When this criterion was introduced in the IPPS FY2019 proposed rule, CMS appeared to define "costs" and "benefits" as "cost to hospitals" and "benefits to hospitals," which is not an appropriate criterion for CMS' stewardship of public funds.

We recommend full transparency in the defining of each criterion including how a given calculation applies to beneficiaries. To achieve this, CMS needs to develop and publicly share how the terminology in each criterion is operationalized (see "cost" and "benefit" example discussed above). Specifically, it should be made transparent how such terms are tested and what results will empirically determine whether the criterion is met or not. In most cases, the terminology used across these eight criteria are not defined, specified nor defended.

- **Public comment: Potential future addition of two geriatric care measures to the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 975 – June 9, 2023

We support the introduction of the two specified geriatric measures: Geriatric Hospital and Geriatric Surgical.

While the geriatric program starts with only two measures, we look forward to CMS expanding the measure set and adding outcome measures in the future.

We have suggestions for the development of geriatric measures in the following areas:

<u>Measure clinical areas important to a geriatric population.</u>
We suggest convening a clinical panel to identify areas that both: a) frequently occurring in the geriatric population, and b) are significant to getting right to ensure a successful inpatient admission. Examples of areas a panel may identify include mental health, arthritis, frailty, and cognition. With such areas articulated, the panel should then be charged with identifying important aspects of quality in these areas. For example, in identifying mental health as a key area, the panel may recommend developing a process measure of the rate of administering a specific screen at admission/prior to surgery. In other words, we need a systematic and empirical approach to the development of geriatric measures.

<u>Convert the measure domains to process measures where possible.</u>
Attesting to a given domain does not provide the granularity of the degree to which the hospital adheres to a protocol they have in place. Most domains ask the facility to attest to whether it does things like assessing psychosocial risk factors. For facilities that attest in the affirmative, it is highly likely that there is great variability in how they collect this information. As the attestation is currently proposed, it both masks the variation that exists and provides the public with a false assurance about the quality of care they will receive.

- **Public comment: Potential designation of quality and safety of patient-centered geriatric care to the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 986 – June 9, 2023

Leapfrog does not support the designation as currently proposed, because it will be misleading to consumers without a more robust set of measures and procedures to support such recognition. That said, we strongly support CMS use of the two geriatric care measures within the IQR and encourage further growth toward a designation program. Future steps would be inclusion of a wider set of measures including outcome measures, and a process for auditing and verifying the accuracy of attestations from hospitals about these two measures and other measures.

- **Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Updates for the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 987 – June 9, 2023

The Leapfrog Group strongly supports the administrative revisions to HCAHPS per the proposed rule, especially the addition of the proposed three survey implementation modes (i.e., web-mail, web-phone, web-mail-phone). The recent analysis cited in the proposed rule demonstrates that adding these modes increases the response rate[7], which is needed considering the declining rates we have seen over time and changing modes of communication in the evolving digital age.

We also recommend expansion of the proposed use of the HCAHPS Spanish translation for Spanish language-preferring patients, and given the survey is also available in seven other languages, we strongly recommend that hospitals should be required to offer the survey in the language preferred by the person when it is one of these languages. First and foremost, it is aligned with ethics and inclusivity that are stated priorities of the administration. Secondly, such a requirement (vs. allowing it to be voluntary as it is presently) mitigates gaming the measure when the hospital perceives it may receive poor rating from a particular person or population.

- **RFI: Patients with primary psychiatric diagnosis participation in HCAHPS for the IQR Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 1004 – June 9, 2023

We support administering the HCAHPS survey to patients with a primary psychiatric diagnosis, but CMS should raise the minimal sample size to ensure the psychiatric patient population is adequately represented in reporting. To accomplish this, we suggest basing the sample size on an analysis of the proportion of admissions with a primary psychiatric diagnosis. This would result in avoiding reducing the number of other cases in the sample while also including this new population proportionate to a given hospital's proportion of patients with a primary psychiatric diagnosis.

HOSPITAL ACQUIRED CONDITIONS REDUCTION PROGRAM (HACRP)

- **Public Comment: Advancing Patient Safety in the HACRP**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 833 – June 9, 2023

Comment Regarding the Addition of Six eCQMs to the HACRP

The Leapfrog Group strongly supports the addition of five of the six proposed measures for use in the HACRP noted in this call for public comments as follows:

- Hospital Harm - Opioid-Related Adverse Events eCQM
- Hospital Harm - Severe Hypoglycemia eCQM
- Hospital Harm - Severe Hyperglycemia eCQM
- Hospital Harm - Acute Kidney Injury eCQM
- Hospital Harm - Pressure Injury eCQM

Regarding the sixth proposed measure for use in the HACRP, Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults, we would urge CMS to add the measure to both the IQR Program and the VBPP, but not the HACRP, as the measure does not meet the criteria for measures included in the HACRP. The IPPS FY2014 rule, which launched the HACRP, defined hospital acquired conditions (HACs) that will be considered for this program as a "condition as described in section 1886(d)(4)(D)(iv) of the [ACA] … that an individual acquires during a stay in an applicable hospital"[8]. Further, the Affordable Care Act (ACA) defines a HAC as "a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code"[9]. Given the measure's focus on excess radiation and image quality, it would be an important addition to both the IQR and VBPP.

Comment Regarding the HACRP's Role in Furthering Patient Safety

Response to public comment question #1: What measures should be introduced in the [HACRP] to address emerging high priority patient harm events and healthcare-associated infections?

A primary role the HACRP can play in patient safety is by establishing and deploying a more robust set of hospital acquired conditions (HACs). The recent OIG report found that of the types of preventable harm they identified, CMS only includes 5% of these in the HACRP[11]. Given this finding, their recommendation to CMS is to expand the set of measures used in the HACRP. The OIG suggests developing measures in these areas where patient harm is most frequently occurring. The categories identified by the OIG, which we recommend exploring for measure development include:

Medication Safety Related Adverse Events

Example of such adverse events include (but not limited to):

- Rates and severity of medication errors
- Acute kidney injury due to a medication ordering or administration error

Procedure or Surgery Related Adverse Events

Example of such adverse events include (but not limited to):

- Patient-reported adverse outcomes
- Excessive bleeding
- Cerebrovascular accident

Healthcare-Associated Infections

Example of such adverse events include (but not limited to):

- Fungal infections
- Respiratory infection
- Surgical site infection (SSI)

Note: SSI measures reported by CMS are limited to colon and hysterectomy surgery. The OIG encourages CMS to add additional procedures.

Patient Care Related Adverse Events
Example of such adverse events include (but not limited to):

- Severe sepsis
- Fluid and electrolyte disorders
- Acute myocardial infarction – delayed diagnosis
- Opioid-related adverse events, including Safe Use of Opioids – Concurrent Prescribing (eCQM)
- Falls with injury

An additional category for measure development that we would add is diagnostic errors. In ARHQ's response to the OIG report, the agency specifically calls out diagnostic safety. Specifically, AHRQ memo states "Diagnostic safety improvement is a critical patient safety issue that is relevant to preventing patient harm in all settings." AHRQ subsequently released Common Formats for Event Reporting – Diagnostic Safety Version 1.0[12]. It would behoove CMS to take advantage of this existing resource to expediate the development of measures for hospital transparency, and eventually HACRP, purposes.

Response to public comment question #2: What measures should be introduced in the [HACRP] to address equity gaps in the rate and severity of patient harm events and healthcare-associated infections?

To further improvements in health equity as it relates to patient safety, we recommend that CMS require that hospitals stratify results by patient-reported race, ethnicity, language, sexual orientation, and gender identity. CMS has established a similar precedent in the HRRP. Since there is a template and a process has been established, CMS will realize efficiencies in extending this model to similar reporting of measures that comprise the HACRP.

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM

- **Codifying Measure Retention and Removal Policies for the Hospital VBP Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 774 – June 9, 2023

First and foremost, the measure removal policy should center on the best interests of Medicare beneficiaries. Secondly, the policy should consider the best interests of the public at large. The best interests of hospital administration should not eclipse the interest of beneficiaries or the public, yet surprisingly there is no criterion proposed on whether the measure is important to them. We recommend the addition of that criterion as the new "Factor 1" to stress that the measure removal policy is indeed consumer-centered.

Regarding the current "Factor 1" (i.e., "topped out" measures), we suggest removing this criterion. CMS' methodology to identify "topped out" performance in a measure is problematic for several reasons. First, some of the measures included in the IQR Program quantify "never events" which, while rare, are catastrophic to patients when they do happen. Secondly, CMS primarily determines "topped out" by comparing performance at the 75th and 90th percentile where a higher percentile means better performance. This too is problematic. Consumers and purchasers are often interested in avoiding the worst performers, those hospitals that are in lower percentiles. CMS' method does not consider the variation between hospitals performing at the highest versus the lowest percentiles. Additionally, our analysis of the application of this criteria to measures in the FY2023 Proposed Rule highlighted the high degree of variation between hospitals, which could represent

thousands of preventable complications and harms to patients. Finally, many of the IQR measures only include patients covered by Medicare's fee-for-service plans, which ignore the almost 50% of Medicare beneficiaries covered by Medicare Advantage plans. In this proposed rule, CMS announced taking an initial step to include Medicare Advantage claims when calculating the HWM and HWR measures, but we need to quickly take similar steps with other Hospital IQR measures before we can consider them "topped out."

Regarding the current "Factor 8" (i.e., a cost – benefit of the measure), Leapfrog opposes this criterion unless "costs" and "benefits" are defined as "costs to Medicare beneficiaries and the public" and "benefits to Medicare beneficiaries and the public." When this criterion was introduced in the IPPS FY2019 proposed rule, CMS appeared to define "costs" and "benefits" as "cost to hospitals" and "benefits to hospitals," which is not an appropriate criterion for CMS' stewardship of public funds.

We recommend full transparency in the defining of each criterion including how a given calculation applies to beneficiaries. To achieve this, CMS needs to develop and publicly share how the terminology in each criterion is operationalized (see "cost" and "benefit" example discussed above). Specifically, it should be made transparent how such terms are tested and what results will empirically determine whether the criterion is met or not. In most cases, the terminology used across these eight criteria are not defined, specified nor defended.

- **Refinement of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (CBE #1550) measure for use in the Hospital VBP Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 777 – June 9, 2023

We strongly support the proposed respecification of the hip and knee complication measure. In particular, we commend CMS for their due diligence in identifying additional complication ICD-10 codes that are potentially preventable adverse events. Expanding the numerator events for this measure provides a more comprehensive picture of hospital performance for hip and knee arthroplasty procedures.

We do not support the proposed delay in implementing the updated measure until the FY2030 program year. Delay makes this important information unavailable for millions of patients, and delays the galvanizing impact of public reporting for six years. The measure is well known to providers and of high priority to the public. The respecified measure appeared in the Measures Under Consideration list in December 2021, and the updated measure was employed in the IQR Program in the IPPS FY2023 rule. There is no evidence that further delay in implementing in the VBP program would positively impact beneficiaries or the public. We strongly support CMS deploying this measure in the VBP program in FY2024.

- **Addition of a Measure to the Hospital VBP Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 780 – June 9, 2023

Leapfrog supports the addition of the sepsis management bundle measure (SEP-1) to the Hospital VBP Program. Addressing sepsis is a much-needed area in that sepsis is the most frequent non-maternity related inpatient diagnosis[13] and the highest cause of mortality in acute care settings[14]. As many as 80% of septic shock patients can be saved with the kind of rapid diagnosis and treatment that SEP-1 guides clinicians toward.[22] Further, this is a process measure with an evidence-based correlation to outcomes. More specifically, a recent study involving over 3,000 hospitals showed that compliance with SEP-1 was associated with a lower 30-day mortality, leading the study's authors to conclude that SEP-1 compliant care "reduce[s] the incidence of avoidable deaths."[15]

Related, we observe that this proposed IPPS rule notes that CMS is developing an eCQM for a sepsis outcome measure. Given it is mentioned in the Hospital VBP Program section, it appears CMS is targeting the new sepsis measure for this program. As it is preferable to measure outcomes where possible, we support the development of this measure and look forward to the opportunity to review and comment on it when it becomes available.

Additionally, we urge CMS to add the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults eCQM measure to both the IQR Program and the VBPP, but not the HACRP, as the measure does not meet the criteria for measures included in the HACRP. The IPPS FY2014 rule, which launched the HACRP, defined hospital acquired conditions (HACs) that will be considered for this program as a "condition as described in section 1886(d)(4)(D)(iv) of the [ACA] … that an individual acquires during a stay in an applicable hospital"[8]. Further, the Affordable Care Act (ACA) defines a HAC as "a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code"[9]. Given the measure's focus on excess radiation and image quality, it would be an important addition to both the IQR and VBPP.

- **HCAHPS Updates for the Hospital VBP Program**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 790 – June 9, 2023

The Leapfrog Group strongly supports the administrative revisions to HCAHPS per the proposed rule, especially the addition of the proposed three survey implementation modes (i.e., web-mail, web-phone, web-mail-phone). The recent analysis cited in the proposed rule demonstrates that adding these modes increases the response rate[7], which is needed in light of the declining rates we have seen over time and changing modes of communication in the evolving digital age.

We also recommend expansion of the proposed use of the HCAHPS Spanish translation for Spanish language-preferring patients, and given the survey is also available in seven other languages, we strongly recommend that hospitals should be required to offer the survey in the language preferred by the person when it is one of these languages. First and foremost, it is aligned with ethics and inclusivity that are stated priorities of the administration. Secondly, such a requirement (vs. allowing it to be voluntary as it is presently) mitigates gaming the measure when the hospital perceives it may receive poor rating from a particular person or population.

- **Changes to the Hospital VBP Program Scoring Methodology**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 801 – June 9, 2023

Leapfrog continues to strongly oppose risk adjustment of measures for patient characteristics other than clinical characteristics. This includes adjustment for sociodemographic, racial, or ethnic characteristics of patients. Such risk adjustment results in the unintended consequence of devaluing negative outcomes that occur in certain defined populations.

That said, Leapfrog supports this proposed scoring revision to the Hospital VBP Program because it continues to maintain the measurement of quality performance, while changing the payment formula to account for additional challenges hospitals overcome to achieve high standards for all their patients. This proposed rule rewards "hospitals that are able to overcome the challenges of caring for high proportions of patients with [dual eligibility status]" while not obscuring the actual quality performance of such facilities with regard to each patient.

- **Potential Hospital VBP Program Changes to Address Health Equity**

The Leapfrog Group comments to CMS on the FY 2024 IPPS Proposed Rule –p. 825 – June 9, 2023

We offer the following suggestions on changes to the Hospital VBP Program to positively impact health equity.

Stratify results. First, we suggest CMS prioritize examining disparities in the treatment rendered and outcomes attained in our health care system for each measure used in payment and reporting programs. Such understanding is foundational to informing where and how to invest in rectifying substantial health disparities our country is facing.

Maternity care measures. Presently the VBP Program Safety Domain is arguably one dimensional as it is solely comprised of five infection measures. An immediate glaring omission is measuring the safety of maternity care. Maternity care is the most common reason for admission to a hospital, and evidence suggests significant disparities in outcomes based on race and ethnicity. Examples of maternity measures CMS should consider using, stratified by race, ethnicity, and language, follow:

- Unexpected Newborn Complications in Term Infants (CBE #0716)
  -The steward is the California Maternal Quality Care Collaborative. The measure has been endorsed by the CBE since 2011.

- Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01) (CBE #0469)
  -While this is a process measure, it is a proxy for patient safety. Early elective deliveries result in higher rates of adverse respiratory outcomes, mechanical ventilation, sepsis and hypoglycemia for the newborns[17].

- Cesarean Birth (ePC-02) (CBE #0471e)
  -This eCQM measure received endorsement by the CBE December 12, 2022.

More measures to fill gaps identified by the OIG Report: The 2022 OIG report found that of the types of preventable harm they identified, CMS only includes 5% of these in the HACRP[11]. Regarding the Hospital VBP Program, the figure would be even less as safety measure set is thinner in the Safety Domain. Given this finding, the OIG's recommendation to CMS is to expand the set of measures. The OIG suggests to develop measures in these areas where patient harm is most frequently occurring. The categories identified by the OIG, which we recommend to explore for measure development, include:

<u>Medication Safety Related Adverse Events</u>
Example of such adverse events include (but not limited to):
- Rates and severity of medication errors
- Acute kidney injury due to a medication ordering or administration error

<u>Procedure or Surgery Related Adverse Events</u>
Example of such adverse events include (but not limited to):
- Patient-reported adverse outcomes
- Excessive bleeding
- Cerebrovascular accident

Healthcare-Associated Infections
Example of such adverse events include (but not limited to):

- Fungal infections
- Respiratory infection
- Surgical site infection (SSI)

Note: SSI measures reported by CMS are limited to colon and hysterectomy surgery. The OIG encourages CMS to add additional procedures.

Patient Care Related Adverse Events
Example of such adverse events include (but not limited to):

- Severe sepsis
- Fluid and electrolyte disorders
- Acute myocardial infarction – delayed diagnosis
- Opioid-related adverse events, including Safe Use of Opioids – Concurrent Prescribing (eCQM)
- Falls with injury

Medication safety: We offer a specific recommendation regarding the above medication safety category as it is by far the area that the OIG found to have the most frequent number of harmful events per OIG's study. By way of a preface to our recommendation, the ONC SAFER Guides include an attestation that a hospital has reviewed their EMR against the SAFER Guides. Neither the SAFER Guides nor the attestation holds the facility to testing their CPOE nor set minimum standards for their CPOE[18].

Given ONC's guides are presently recommendations vs. requirements, we recommend requiring hospitals to regularly test their CPOE. As stated in the ONC SAFER Guide on CPOE and example of such a CPOE evaluation tool is the Leapfrog Group's CPOE "flight simulator" for hospitals. The tool evaluates the safety and effectiveness of CPOE and clinical decision support functionality[19,20,21].

Diagnostic safety: An additional category for measure development that we would add is diagnostic errors. In ARHQ's response to the OIG report, the agency specifically calls out diagnostic safety. Specifically, AHRQ memo states "Diagnostic safety improvement is a critical patient safety issue that is relevant to preventing patient harm in all settings". AHRQ subsequently released Common Formats for Event Reporting – Diagnostic Safety Version 1.0[12]. It would behoove CMS to take advantage of this existing resource to expediate the development of measures for hospital transparency, and eventually Hospital VBP Program, purposes.

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