



June 28, 2021

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

RE: RIN 0938–AU44 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

Dear 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 2022 Inpatient Prospective Payment System (IPPS) rule.

In the appendix to this letter, we detail our comments on items in this proposed rule. However, there is one item that raises the strongest opposition among our constituents. Leapfrog strongly opposes the removal of "Death Among Surgical Inpatients with Serious Treatable Complications" (PSI-4) from the Inpatient Quality Reporting (IQR) Program. This measure is of critical importance to the public and to purchasers for the following key reasons:

- **PSI-4 is a powerful and important patient safety measure, and patient safety is one of the most significant death risks Medicare beneficiaries and the public will ever encounter.** According to a landmark article in The BMJ that summarized earlier research, safety problems in U.S. hospitals are estimated to kill over 250,000 people every year. Despite this, there are relatively few patient safety measures reported in the IQR or used in payment programs, especially considering the evidence of the risk faced by Medicare beneficiaries and the public at large. CMS should be adding more patient safety measures, not removing any.
- **PSI-4 is one of the highest priority measures for purchasers and consumers.** The Leapfrog Group uses PSI-4 in its Leapfrog Hospital Safety Grade, which assigns letter grades to hospitals based on their record of patient safety, and thus provides important safety information to thousands of consumers and purchasers. Without a doubt, PSI-4 is the measure in the Safety Grade that resonates most with purchasers and consumers.

- **Deaths counted in PSI-4 can be prevented by hospitals; deaths from all causes are not always the fault of the hospital.** The Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure is not a replacement for PSI-4 as the proposed rule suggests, because many hospital deaths are not related to preventable safety problems. While the all-cause mortality measures are useful, they are not a substitute for reporting hospital mortality from preventable safety problems that occur after surgery. Medicare beneficiaries deserve to know which hospitals perform best at protecting patients from surgical harm.
- **PSI-4 is a Surgical Measure.** When consumers are researching hospitals, they are often searching for a place to have a surgical procedure. There are very few measures that are focused on surgical safety or surgical outcomes in general. CMS should be adding more surgical outcome measures, not removing the one most important to consumers and purchasers.
- **Improvements to PSI-4 can occur while the current measure continues to be included in the IQR and is publicly reported.** Medicare beneficiaries and the public deserve the best available information to protect their lives and health, and PSI-4 provides that. We are aware that the measure developer has suggested refining the types of surgical patients and complications included in the measure. However, these improvements will only strengthen an already robust measure and can be made while the current measures continue to be used in the IQR and in public reporting.

Additionally, we have recommendations on transparency that are important principles for IPPS but continue to be overlooked in 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. In order 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. **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
- Hospital Readmissions Reduction Program

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 2022 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 2022 proposed rule:

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2022 IPPS PROPOSED RULE

INPATIENT QUALITY REPORTING PROGRAM

- **Proposed Addition of Five IQR Measures**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1263 – June 28, 2021

While The Leapfrog Group supports the proposal to add the listed five measures to the Hospital Inpatient Quality Reporting (IQR) Program, we urge CMS to expand the number of new measures.

One area that is ripe for improvement is maternity care. Childbirth is the number one reason for hospitalization in the U.S. Many expecting parents are researching birthing hospitals and deserve to have more publicly available information about the safety and quality of maternity care.

The current maternity care measures used in the IQR Program (and the one proposed additional measure) provide consumers with very a limited view of maternity care quality. We recommend that CMS evaluate the following outcome measures for inclusion in the IQR in FY2022 or beyond:

- Unexpected Complications in Term Newborns (PC-06) *Measure steward: The Joint Commission*
- Cesarean Birth (PC-02) *Measure steward: The Joint Commission*
- Obstetric Trauma Rate – Vaginal Delivery with Instrument (PSI-18) *Measure steward: The Agency for Healthcare Research and Quality*
- Obstetric Trauma Rate – Vaginal Delivery without Instrument (PSI-19) *Measure steward: The Agency for Healthcare Research and Quality*

- **Proposed Removal of Five IQR Program Measures**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1317 – June 28, 2021

We support the removal of four of the five listed measures, but we strongly oppose removing Death Among Surgical Inpatients with Serious Treatable Complications (PSI-4). As described in the body of this letter, this measure provides both unique and valuable information on a critical aspect of patient safety.

Regarding the population that is the focus of each measure: While CMS PSI-4 looks at surgical cases at high risk of death (16.4%)¹, the HWM measure examines a more general set of cases, which are not limited to surgical cases and in turn are at a lower mortality risk (7.6%)². Given the risk of death in CMS PSI-4 is more than double, there is arguably a much greater opportunity for improvement with this population.

Furthermore, PSI-4 is a measure of “failure to rescue.” Silber contended that high quality hospitals are more likely to prevent death in surgical cases³. In comparison, CMS makes no mention of failure to rescue regarding the HWM measure. CMS’ stated rationale for the HWM measure is to identify hospital performance regarding mortality via a crosscutting measure that is as inclusive as possible⁴.

This measure is of critical importance to the public and to purchasers for the following key reasons:

- **PSI-4 is a powerful and important patient safety measure, and patient safety is one of the most significant death risks Medicare beneficiaries and the public will ever encounter.** According to a landmark article in The BMJ that summarized earlier research, safety problems in U.S. hospitals are estimated to kill over 250,000 people every year. Despite this, there are relatively few patient safety measures reported in the IQR or used in payment programs, especially considering the evidence of the risk faced by Medicare beneficiaries and the public at large. CMS should be adding more patient safety measures, not removing any.
- **PSI-4 is one of the highest priority measures for purchasers and consumers.** The Leapfrog Group uses PSI-4 in its Leapfrog Hospital Safety Grade, which assigns letter grades to hospitals based on their record of patient safety, and thus provides important safety information to thousands of consumers and purchasers. Without a doubt, PSI-4 is the measure in the Safety Grade that resonates most with purchasers and consumers.
- **Deaths counted in PSI-4 can be prevented by hospitals; deaths from all causes are not always the fault of the hospital.** The Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure is not a replacement for PSI-4 as the proposed rule suggests, because many hospital deaths are not related to preventable safety problems. While the all-cause mortality measures are useful, they are not a substitute for reporting hospital mortality from preventable safety problems that occur after surgery. Medicare beneficiaries deserve to know which hospitals perform best at protecting patients from surgical harm.
- **PSI-4 is a Surgical Measure.** When consumers are researching hospitals, they are often searching for a place to have a surgical procedure. There are very few measures that are focused on surgical safety or surgical outcomes in general. CMS should be adding more surgical outcome measures, not removing the one most important to consumers and purchasers.
- **Improvements to PSI-4 can occur while the current measure continues to be included in the IQR and is publicly reported.** Medicare beneficiaries and the public deserve the best available information to protect their lives and health, and PSI-4 provides that. We are aware that the measure developer has suggested refining the types of surgical patients and complications included in the measure. However, these improvements will only strengthen an already robust measure and can be made while the current measures continue to be used in the IQR and in public reporting.

- **Potential Future IQR Measures and Topics**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1331 – June 28, 2021

We appreciate that CMS is asking the public for input on a number of potential future measures and measurement topics. We offer the following comments on several areas in this section:

[Potential Future Inclusion of a Hospital-Level, Risk Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty](#)

The Leapfrog Group strongly supports mandatory provider organization reporting of the Risk Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty. We

applaud CMS' leadership proposing to adapt the hospital level version of the measure for use in Hospital Outpatient Departments (HOPDs) and Ambulatory Surgery Centers (ASCs).

It is a consumer centered approach to rate provider performance in this measure across the settings noted in the proposed rule: hospital inpatient, HOPD and ASC. The concept of deploying a given measure across various units of analysis (e.g. hospital, HOPD, ASC) gained support of the Measure Application Partnership (MAP) as a means to mitigate the proliferation of measures that are unique to each setting⁵.

Further, it is particularly timely to specify and deploy this measure across the settings mentioned above given the recent CMS rule that will phase in the payment for hip and knee replacement in these settings. We applaud CMS for such forward thinking to sync up recent payment policy with plans for transparency of provider quality in this important measurement area.

Potential Future Efforts to Address Health Equity in the Hospital IQR Program:

- Potential Future Confidential Stratified Reporting for the Hospital-Wide All-Cause Unplanned Readmission Measure Using Both Dual Eligibility and Race/Ethnicity

We support the health equity plans and methods discussed in this section regarding the Hospital Wide All Cause Unplanned Readmissions measure. The proposed private reports to hospitals that stratify results by dual eligibility and race / ethnicity is a good first step in that it gives facilities information that supports quality improvement efforts.

Such confidential reporting should be followed by full public reporting of the same stratified findings when valid. Given the broad base of stakeholders that would view these publicly reported results, we recommend that CMS provide the findings in a highly evaluable manner and furnish surrounding user-friendly context to aid in the appropriate interpretation of results.

- Potential Future Reporting of a Structural Measure to Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

The Leapfrog Group is supportive of a future CMS proposal to gauge health equity reporting as it relates to hospital leadership. While this section states reporting to leadership and the board of directors in several health equity areas, we note the absence of reporting regarding LGBTQ status. There are longstanding and significant issues in all professional sectors regarding fair and equal treatment of the LGBTQ population⁶. Thus, we strongly recommend expanding health equity to include LGBTQ as it relates to this structural measure. If the health care sector is to improve in this important area, hospital leadership and the board need to be routinely informed of the status and engaged in crafting solutions.

HOSPITAL ACQUIRED CONDITIONS REDUCTION PROGRAM

- **Policy to Enable CMS to Suppress Measures from the Total HACRP Score in FY2022 and FY2023**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1052 – June 28, 2021

We have two recommendations with regard to the suppression factors proposed. First, we recommend CMS more tightly define these measure suppression factors to be transparent with the terms of the factor, and consistently operationalize them in the future.

The proposed Measure Suppression Factors attempt to guide CMS as to scenarios where it may be appropriate to remove measures from the HACRP financial penalty. While the concept of creating such factors is practical, we do not support the proposed Measure Suppression Factors as written. One issue is several factors are stated in broad and general terms with a lack of definition of each. For example, factor #1 allows for measure suppression where there is “significant” deviation in national performance on the measure during the PHE. The term “significant” is not defined. Further, such deviation in and of itself does not inherently result in a bias in the ratings that the measure will yield. Another measure (#8) refers to costs outweighing benefits but does not specify to whom the costs or benefits apply, and should specifically state that they apply first and foremost to Medicare beneficiaries and then to the public at large. The cost and benefits to health care providers should not be a factor in suppression if the benefits outweigh costs to beneficiaries and the public.

Second, as a general principle, all suppression factors should put the priority on impact to Medicare beneficiaries. Some of the factors (or aspects of the factors) are related to the provider organization’s interests and not the interests of beneficiaries. For example, factor #4 is in regard to shortages or changes in “healthcare personnel” or “medical supplies and equipment”. Whether, or the degree to which, a hospital has challenges in these areas is not inherently, nor 100%, due to external environmental factors outside the control of the hospital. Indeed, often such shortages in personnel and equipment are the result of decisions made by hospital leadership over time, impacting such variables as the hospital’s ability to attract and retain talent, and plan for, order and stock materials. It can also be the result of the hospital’s decision to furlough staff and maintain cash reserves. A basic principle in quality measurement is to avoid excluding from consideration variables that directly impact quality. This doesn’t make logical sense and doesn’t serve the interest of beneficiaries. In CMS’ creation of such suppression factors, such a principle should be applied as well.

- **Potential Future Measure Suppression Policy for Public Health Emergencies (PHE) Beyond FY2023**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1055 – June 28, 2021

We have three primary recommendations concerning the proposed policy in this area.

First, CMS should clearly articulate the criteria and factors that must be met before CMS suppresses measures affected by the criteria. As discussed elsewhere in our comments regarding CMS’ proposed Measure Suppression Factors, these criteria need to be clearly specified to eliminate ambiguity as to whether the criteria has been met and to reassure beneficiaries that their interests were paramount.

Secondly, we support the ability to suppress a measure when the data that are used in performance measurement are impossible to collect. An example is inpatient claims that could not be due to a catastrophic systems breakdown.

Lastly, we recommend avoiding the development of criteria that may be reflective of the quality of the provider organization as opposed to the public health emergency per se. A basic principle in quality measurement is to avoid including variables in the measure that may be due to the hospital's quality. In CMS' creation of such suppression factors, such a principle should be applied as well.

- **Suppression of Third and Fourth Quarter 2020 Data in Calculating the Total HACRP Score**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1056 – June 28, 2021

The Leapfrog Group supports the proposal that results in maintaining PSI-90 and the CDC NHSN healthcare-associated infection measures in the HACRP for FY22 and FY23 and further supports CMS' plan to publicly report the above measures. However, we urge CMS to consider using the same reporting period, which will include third and fourth quarter 2020 data, for both public reporting and for calculating the Total HACRP Score. Rather than suppressing third and fourth quarter 2020 data, we recommend that CMS risk-adjust for COVID-19 as a patient-level risk factor. This approach will help avoid confusion between having a 12-month version of PSI 90 (used in the HACRP) and an overlapping 18-month version (used in Care Compare) available at the same time.

HOSPITAL VALUE BASED PURCHASING PROGRAM

- **Proposed Measure Suppression Policy for the Duration of the PHE**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 992 – June 28, 2021

We have three primary recommendations concerning the proposed policy in this area.

First, CMS should clearly articulate the criteria and factors that must be met before CMS suppresses measures affected by the criteria. As discussed elsewhere in our comments regarding CMS' proposed Measure Suppression Factors, these criteria need to be clearly specified to eliminate ambiguity as to whether the criteria has been met and to reassure beneficiaries that their interests were paramount.

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Lastly, we recommend avoiding the development of criteria that may be reflective of the quality of the provider organization as opposed to the public health emergency per se. A basic principle in quality measurement is to avoid including variables in the measure that may be due to the hospital's quality. In CMS' creation of such suppression factors, such a principle should be applied as well.

- **Proposed Removal of CMS PSI-90 from the HVBP Program**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1016 – June 28, 2021

We strongly oppose the removal of the CMS Patient Safety and Adverse Events Composite (PSI-90) from the HVBP Program in FY2023. The HVBP program has solely relied on CDC NHSN healthcare-associated infection

measures to populate the Safety Domain, and those measures represent one among several important threats to patient safety in hospitals. The PSI-90 composite provides CMS with a more representative picture of hospital safety by measuring providers in a wider array of safety events that harm or kill hundreds of thousands of patients every year.

We strongly disagree with the rationale CMS uses to propose removal of PSI-90, which is that: “Costs associated with the measure outweigh the benefit of its use in the program”. The additive costs of continuing to include the measure in HACRP are miniscule for CMS and hospitals, since it is already calculated for the HACRP. The benefit of its use is highly significant to beneficiaries. The serious errors and harms accounted for in PSI-90 cause preventable death and enormous suffering to hundreds of thousands of Medicare beneficiaries, and result in enormous financial costs to CMS and to the beneficiaries and their families.

- **Updates to Technical Specifications of Five Measures**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 1019 – June 28, 2021

It would be unwise of CMS to completely exclude COVID-19 patients from hospital mortality measures. Thus, we do not support the proposed revision to the technical specifications of the five 30-day mortality measures unless one critical improvement is made: excluding only cases where the COVID-19 diagnosis was present on admission (POA). The proposed revision excludes all cases from the denominator with a COVID-19 ICD-10 diagnosis code in the principal or secondary field, but hospitals should be accountable for deaths of patients who were infected while in the hospital.

The hospital should be accountable for the transmission of COVID-19. Given that CMS is measuring quality, the spread of COVID-19 within the facility is a quality of care issue and should remain in the denominator. We recognize the many challenges hospitals have endured and respect the courage of health care workers in treating COVID-19 patients. But hospitals’ ability to prevent the spread of SARS-Cov-19 infection within their walls is of enormous importance to the public and to health care workers as well, and CMS should ensure full accountability.

HOSPITAL REDADMISSIONS REDUCTION PROGRAM (HRRP)

- **Proposed Flexibility for Changes Affecting Measures During a Performance Period in the HRRP**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 961 – June 28, 2021

The proposed Measure Suppression Factors attempt to guide CMS as to scenarios where it may be appropriate to remove measures from the HACRP financial penalty. While the concept of creating such factors is practical, we do not support the proposed Measure Suppression Factors as written. One issue is several factors are stated in broad and general terms with a lack of definition of each. For example, factor #1 allows for measure suppression where there is “significant” deviation in national performance on the measure during the PHE. The term “significant” is not defined. Further, such deviation in and of itself does not inherently result in a bias in the ratings that the measure will yield. Another measure (#8) refers to costs outweighing benefits, but does not specify to whom the costs or benefits apply, and should specifically state that they apply first and foremost to Medicare beneficiaries and then to the public at large. The cost and

benefits to health care providers should not be a factor in suppression if the benefits outweigh costs to beneficiaries and the public.

Second, as a general principle, all suppression factors should put the priority on impact to Medicare beneficiaries. Some of the factors (or aspects of the factors) are related to the provider organization's interests and not the interests of beneficiaries. For example, factor #4 is in regard to shortages or changes in "healthcare personnel" or "medical supplies and equipment". Whether, or the degree to which, a hospital has challenges in these areas is not inherently, nor 100%, due to external environmental factors outside the control of the hospital. Indeed, often such shortages in personnel and equipment are the result of decisions made by hospital leadership over time, impacting such variables as the hospital's ability to attract and retain talent, and plan for, order and stock materials. It can also be the result of the hospital's decision to furlough staff and maintain cash reserves. A basic principle in quality measurement is to avoid excluding from consideration variables that directly impact quality. This doesn't make logical sense and doesn't serve the interest of beneficiaries. In CMS' creation of such suppression factors, such a principle should be applied as well.

- **Updates to Technical Specifications of Five Measures**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –pp. 967, 972 – June 28, 2021

It would be unwise of CMS to completely exclude COVID-19 patients from hospital mortality measures. Thus we do not support the proposed revision to the technical specifications of the five 30-day mortality measures unless one critical improvement is made: excluding only cases where the COVID-19 diagnosis was present on admission (POA). The proposed revision excludes all cases from the denominator with a COVID-19 ICD-10 diagnosis code in the principal or secondary field, but hospitals should be accountable for deaths of patients who were infected while in the hospital.

The hospital should be accountable for the transmission of COVID-19. Given that CMS is measuring quality, the spread of COVID-19 within the facility is a quality of care issue and should remain in the denominator. We recognize the many challenges hospitals have endured and respect the courage of health care workers in treating COVID-19 patients. But hospitals' ability to prevent the spread of SARS-Cov-19 infection within their walls is of enormous importance to the public and to health care workers as well, and CMS should ensure full accountability.

- **Possible Future Stratifications of Results**

The Leapfrog Group comments to CMS on the FY 2022 IPPS Proposed Rule –p. 987 – June 28, 2021

We support the future means to stratify results that CMS is soliciting comment on. The proposed private reports to stratify results by dual eligibility, race and ethnicity, language preference and disability status is a good first step in that gives facilities information that supports quality improvement.

Such confidential reporting should be followed by full public reporting of the same stratified findings. Given the broad base of stakeholders that would view these publicly reported results, we recommend that CMS provide the findings in a highly evaluable manner and furnish surrounding user-friendly text to aid in the appropriate interpretation of results.

While the stratification areas mentioned above are important, we note the absence of reporting on LGBTQ. There are long standing and significant issues in all professional sectors regarding fair and equal treatment of the LGBTQ population⁶. Thus, we strongly recommend expanding the areas for stratification to include

LGBTQ. If the health care sector is to improve in this important area, the hospital and the public need to be informed of performance with this population.

CITATIONS

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