



June 17, 2022

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

RE: RIN 0938-AU84 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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation

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 collect 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 FY 2023 Inpatient Prospective Payment System (IPPS) Proposed 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. **We want to express our strong opposition to CMS' proposal to suppress calculation and publication of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) for FY 2023.** Suppressing CMS PSI 90 would be a giant leap backward in patient safety and transparency, literally life-threatening, and an outrageous violation of the trust Americans place in the Medicare program.

In its rule, CMS proposes to suppress the PSI 90 measure *"due to the fact that the reference period (calendar year 2019) ... does not include data affected by the COVID-19 Public Health Emergency and the applicable period (calendar year 2020) does include such data, this would result in risk adjustment parameters that do not account for the impact of COVID-19 on affected patients."*

While we recognize that the COVID-19 pandemic has put an unprecedented strain on the entire health care system, we firmly reject the implication that this is an adequate reason to simply stop reporting on lifesaving patient safety information. Indeed, in the middle of a global pandemic, it is more important than ever that the public have access to information that could save their lives.

We oppose the proposal to suppress PSI 90 for the following reasons:

- **25,000 Deaths A Year Should Never Be Ignored or Hidden**

The 10 dangerous complications that make up PSI 90 are largely preventable, yet kill 25,000 people per year and harm 94,000⁵. There is no other publicly available source for data on the complications included in PSI 90. If CMS suppresses it, the American public will be in the dark on which hospitals put them most at risk. Suppressing PSI 90 would be a giant leap backward in patient safety and transparency, literally life-threatening, and an outrageous violation of the trust Americans place in the Medicare program. Medicare beneficiaries and the American public have the right to access this lifesaving data.

- **Dangerous Spikes in Infections and Medical Errors Are Relevant**

Suppressing information on hospital dangers covers up an alarming spike in those dangers that federal officials themselves have warned us about. Just two months ago, leaders at CMS and CDC reported that since 2020, federal data shows a significant increase in the number of common hospital infections and patient safety mistakes¹. These federal officials have the data, but now want to suppress much of it from the American public.

It is particularly concerning that most of the patient safety measures included in PSI 90 reveal significant health care disparities. While health inequities are often caused by sociodemographic factors outside the health care system, the data included in PSI 90 allows policymakers and researchers to see inequities resulting from factors within the health care system: avoidable patient safety lapses. For example, Black patients are 27 percent more likely to experience sepsis after an operation than white patients and are 15 percent most likely to experience a kidney injury requiring dialysis². By proposing to suppress information on PSI 90, CMS is effectively seeking to hide invaluable data regarding inequities in health care delivery.

- **Suppression Directly Contradicts the May 2022 Recommendation of the Office Inspector General, Which Advised CMS to Add More Safety Measures – Not Take Critical Ones Away**

In early May, the HHS Office of the Inspector General (OIG), an independent governmental oversight agency, reported that one in four Medicare beneficiaries admitted to a hospital were harmed by an error or accident during the stay⁶. The OIG advised that CMS' current reporting on safety problems is inadequate to capture all the dangers they discovered were harming or killing Medicare beneficiaries, and recommended CMS expand their reporting to include more measures. In the OIG report, CMS formally agreed with that recommendation. But now CMS is heading in the opposite direction: instead of expanding measures, they want to suppress ten of those they currently report and they threaten to suppress more.

- **Suppression Will Cost the Medicare Trust Fund \$350 Million Without Helping Beneficiaries**

In the proposed rule, CMS also proposes to suspend the HAC Reduction Program, which reduces Medicare payments to hospitals that do poorly on the ten patient safety hazards in PSI-90 as well as hospital-acquired infections. This will cost the Medicare Trust Fund over \$350 million, as estimated by CMS and noted in the proposed rule. We believe some payment penalty should be imposed on hospitals that are catastrophically dangerous to patients, especially in a public health emergency.

- **CMS is Operating Outside of Its Own Policy**

In the FY 2022 IPPS Final Rule CMS stated a policy to suppress measures if one or more Measure Suppression Factors (MSFs) are met. But in this FY 23 Proposed Rule CMS proposes suppression of PSI 90 without referring to any MSFs. This is a blatant disregard for the agency's own rulemaking policy.

Recommendations Related to the PSI 90 Proposal

Given our profound opposition to the suppression of PSI 90 data, we offer the following recommendations to CMS:

1. **Withdraw the Proposal to Suppress New PSI 90 Data in 2023:** CMS should fully withdraw its proposal to suppress the calculation and publication of PSI 90 data and should publish its data on its regular schedule, or preferably in a more timely fashion.
2. **Continue to Maintain Publication of Previous PSI 90 Data:** It is important that historians, public health experts, and policymakers have access to all previous PSI 90 data from Calendar Year 2019 and years previous.
3. **Do Not Suppress Future Measures Without Proper Rulemaking:** The American public deserves to have access to lifesaving data about hospital quality and safety. If CMS continues to propose to suppress these types measures, it is imperative that they allow the public to comment before a decision is made so others can see the rationale and share feedback.
4. **Maintain HAC Reduction Program:** During the COVID-19 pandemic, federal taxpayers have provided tens of billions of dollars in aid to hospitals to ensure they remained able to provide high quality care to all patients. CMS should maintain the HAC Reduction Program, which provides a financial incentive for hospitals avoid patient harm.

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. 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 by 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 Acquired Conditions Reporting Program
- Hospital Value Based Purchasing Program
- Hospital Inpatient Quality Reporting Program
- Hospital Readmissions Reduction Program
- Additional RFIs

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 2023 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 2023 proposed rule:

Organizations

A Leading Light LLC
Arizona Benefit Consultants LLC
Bukaty Companies
California Health Care Coalition
Catherine M Baase, MD Consulting LLC
Center for the Study of Services/Consumers' Checkbook
Chicago Hispanic Health Coalition
Citrus Pulmonary and Sleep Disorders
Connecticut Center for Patient Safety (CTCPS)
DFW Business Group on Health
Economic Alliance for Michigan
Florida Alliance for Healthcare Value
Fringe Benefit Analysts, LLC
Gillroy & Associates Inc
Greater Philadelphia Business Coalition on Health
Health Action Council
Healthcare Purchaser Alliance of Maine

Heartland Health Research Institute
Houston Business Coalition on Health
HR Policy Association
ICI
Louisiana Business Group on Health
Louisiana Health Care Quality Forum
Lucerno Dynamics
MGH Stoeckle Center for Primary Care Innovation
Mothers Against Medical Error
Moxtek
New England Patient Voices
New Jersey Health Care Quality Institute
Nile's Project MRSA
North Carolina Business Group on Health
OAI Consult, Dba
Patient Advocate Certification Board
Patient Safety Action Network
Patient Safety Advocacy
Patient Safety America
Patients for Patient Safety US
PFPS US
PHC4
Purchaser Business Group on Health
Rhode Island Business Group on Health
Robert Slayton & Associates, Inc.
Sepsis Alliance
Silicon Valley Employers Forum
St. Louis Area Business Health Coalition
SwipeSense
The Burrows of Hollywood, Inc.
The ERISA Industry Committee
The Texas Patient Safety Initiative
WellOK - The Oklahoma Business Coalition on Health
WOConsultation, LLC
Zaggo, Inc.

Individuals

Juli Anderson-Bjerke
Mary Arnold-Long, President, WOConsultation, LLC
Catherine, Baase, Owner of Catherine M Baase MD Consulting LLC
Wendy Bailey, VP of Health Plan Pharmacy Strategy, Centene Corporation
Linda Baldino
Marlene Bandfield, Physical Therapist
Rosie Bartel, Leapfrog Patient Advisory Board
Hale Becker, Director, Analytics and Information Services, St. Louis Area Business Health Coalition
Joan Benincasa
Louis Bernardi, Founder, BritePath
Bruce E. Bradley, Founder, The Leapfrog Group

Steve Burrows, Writer/Director, The Burrows of Hollywood, Inc.
Linda Burton, DRW and Associates, Inc.
Roberta Carson, President, Zaggo, Inc.
Deborah Castagnola
David Cavalleri
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Susan Conn, RN, Medical City Denton
Caroline Corum, RN, Patient Advocate
Will Craghead, Ark Family Health
Vicki Dailey
Kathy Day, RN, Patient Safety Advocate/Activist
Helene DeLuca, Patient
Scott Deru, President, Fringe Benefit Analysts, LLC
Susan Edgman-Levitan, Executive Director, MGH Stoeckle Center for Primary Care Innovation
K. Douglas Fillmore, VP, Human Resources & Administration, Moxtek
Crissy Flake, Quality Improvement Director, WelbeHealth
Edward Ford, RN, Regulatory Project Manager, Tideland Health
Ted Fox, Founder and Leader, The Texas Patient Safety Initiative
Kathleen Fox
Harold Freehling Jr
Philip Fulchino
Susan Gallant
Sharon Giarrizzo-Wilson, Assistant Professor, University of Colorado College of Nursing
Donna Gillroy, Gillroy & Associates Inc
Carole Guinane, RN, MBA, FNAHQ, CPHQ, BBS, Healthcare Leader
Martin Hatlie, President & CEO, Project Patient Care
Peter Hayes, President & CEO, Healthcare Purchaser Alliance of Maine
Carole Hemmelgarn, Patient Activist
Steve Hetey, Associate Chief Pharmacy Officer (retired)
Marian Hollingsworth, Patient Safety Advocate, Patient Safety Action Network
Bill Hughes, President, Benafix
Krista Hughes, BCPA, Founder and CEO, Passion 4 Patients
Vanessa Ivey, Health and Wellness Director
John James, CEO, Patient Safety America
Nancy J. Johnson
Tina Jones, Analytics Leader, Baptist Health
Soojin Jun, Patients for Patient Safety US
Carol Keeling
Sally Kerr
Anne Klar, Student Nurse
David Knowlton, CEO, NJ Health Care Quality Institute - Retired
Ronald Lattanze, CEO, Lucerno Dynamics
Joel Lee, Professor Emeritus
Sandra Less

David Levine
David Lind, President, Heartland Health Research Institute
Diana Little, Payroll and Benefit Manager
Elizabeth Londo, Vice President, Client Services, qrcAnalytics
Ariana Longley, Patient Safety Consultant
Ann MacDonald
Kathryn MacDonald
Megan Malone-Franklin, Riverbend Birth
Michelle Martin, Paramount
Karl Maurer, Patient Safety Advocacy
Enrique R. Mazas, CPA, MBA
Monica McDade, MLM Creative Consulting
Lisa McGuire
Janet McNichol, CHRO, American Speech-Language-Hearing Association
Christine Meyer, RN, PhD
Michael Millenson, Author
Kim Miller, President, Baptist Health Western Region
Roxann Montgomery
Patricia Morfeld, Clinical Nurse IV, Outpatient Oncology Services UNC Healthcare
Mary Morris, President, Jessica's Enterprises, Ltd.
Carole Moss, Founder, Nile's Project MRSA
Mike Muldoon, Healthcare Consultant, Bukaty Companies
Cindy Munn, CEO, Louisiana Health Care Quality Forum
Armando Nahum, Founding Member, PFPS US
Heather Nairn, Deputy Executive Director, PHC4
Lori Nerbonne, President & Co Founder New England Patient Voices
Robert Oshel
Mary Overall, CEO, OAI Consult, Dba
Roy Owens, Vice President, Employee Benefits, ICI
Emily Paterson, Patient Advocate Admin
Daphne Polynice, Jamaica Hospital
Carol Raymond, Henry Ford Patient Advisor
Lizette Rivera
David Rivera, AdventHealth
Yvonne Rocco
David Romito, VP Commercial, SwipeSense
Maureen Rorke, Nurse Executive (Retired)
Dr. James Rybacki, President and Author, The Medicine Information Institute
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Esther Sciammarella, Executive Director of Chicago Hispanic Health Coalition
Manojkumar Shukla, Retired Pulmonary/Critical Care
Karen Simonton, Simonton Ventures LLC
Karen Simonton, Strategic Alliance Director, The OrthoForum
Rose Skarbek
Carolyn Skinner, Dembo Jones PC

Robert Slayton, President, Robert Slayton & Associates, Inc.
Deborah Strock, Mental Health Counselor
Ashley Tait-Dinger
Evelyn Taylor, Branch Manager, Freedom Medical Inc
Gloria Torres
Jane Trahanovsky, Lavonne's Florals
Carol Trinchitella, Patient
William Trinchitella, Patient
Thomas Trinchitella, Patient
Brian Tschetter, Benefits Consultant, Arizona Benefit Consultants LLC
Cindy Umberger
Karen van Caulil
Alicia Vann, TelAffects
Carol Vierima
Diane Walter
Douglas White
Coleen Widell
Billy Williams, L Properties
Patricia Wilson
S. Wraight

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2023 IPPS PROPOSED RULE

HOSPITAL ACQUIRED CONDITIONS REPORTING PROGRAM

- **Suppression from HACRP: CDC NHSN HAIs**

The Leapfrog Group and cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 906 – June 17, 2022

The Leapfrog Group disagrees with the proposal to suppress the CDC NHSN HAIs from the HACRP based on the cited Measure Suppression Factors (MSFs). Our multi-part rationale follows:

First, a transparent and quality-focused financial incentive system must recognize the reality that there are always changes in the national environment, and expect that hospitals adapt to those changes and thus demonstrate resilience. CMS senior leaders discussed weaknesses in the resilience of the health system in a statement in the *New England Journal of Medicine (NEJM)* in February 2022¹. Yet the MSFs justify suppression for a wide variety of environmental shifts, including changes in national performance, guidelines, and case mix. Suppressing payment incentive programs when the environment shifts does nothing to strengthen resilience, and likely accomplishes the opposite. With the implementation of the MSFs, we are concerned that CMS is not building a resilient system, but a system that shuts programs down when the winds shift.

Secondly, we expressed an issue with the lack of definition, and thus transparency of, the terms used in the MSFs in our IPPS FY 2022 Proposed Rule comments. To illuminate our point: In MSF 1 and 4, CMS does not define “significant” when referencing “significant deviation in national performance.” Regarding MSF 3 and 4, we do not know what CMS operationally means by such terms as “rapid” when referencing “rapid change in guidelines.” These opaque terms are now used in this proposed rule to suppress critically important data on hospital acquired infection measures that consumers and employers deserve access to.

Third, there are issues with CMS adhering to, interpreting, and operationalizing the MSFs. An example of such flaws:

Regarding *Clostridium difficile* Infection (CDI), CMS' rationale to suppress the measure based on MSF 3 follows:

- *“Improvements to ... practices such as hand hygiene, PPE practices and environmental cleaning*
- *A decline in outpatient antibiotic prescribing*
- *Use of inpatient antibiotic stewardship programs”*

Such observations of the ever-changing landscape can be tied to most measures. Further, the creation and/or uptake of best practices does not necessarily mean the measure has no value in making comparisons between hospitals based on their performance, or should not be used in a financial incentive program.

Fourth, regarding all five CDC NHSN HAIs: The proposed rule states:

“Because we cannot identify all potential elements that could be impacting the overall HAI ... during an unprecedented Public Health Event (PHE) as well as potential geographic disparities in the impact of the PHE that could cause uneven impact on facilities based on their location, like shortages of health care personnel, we believe all five CDC NHSN HAI measures should be suppressed.”

Any one of the five CDC NHSN HAIs alone can result in death or significant suffering for thousands of Medicare beneficiaries and other patients each year. Whether one HAI impacts the overall HAI rate is a question for statistical analysis, not for responsibly protecting the lives and health of Medicare beneficiaries and the public at large. Moreover, there are numerous factors with the potential to impact improvement in a given HAI or other outcome of interest³. If the fact we will never be able to isolate the degree to which each and every factor is impacting an outcome is grounds for suppressing all CDC NHSN HAIs, that logic can be used to suppress virtually all measures under virtually all circumstances.

This stated rationale is plainly not the intention of the original statute establishing payment programs and goes outside of CMS' authority as this reason for suppression is neither attributed to an MSF nor outlined in a prior IPPS rule that enables the agency to suppress measures. We suggest that CMS:

- Retract this stated rationale for the suppression of the NHSN CDC HAIs in the final IPPS rule
- Reinstate the NHSN CDC HAIs in the HACRP

Lastly, we are disturbed by CMS' inconsistency in the citation of MSFs across programs for the same measures. More specifically, in the HACRP the stated MSF for CAUTI, CLABSI and MRSA is MSF 1. However, in the HVBP Program, CMS applies not only MSF 1 to these three measures, but also adds MSF 4. As a result of this uneven application of the MSF policy, we are not convinced CMS used a consistent and reliable process in its decision-making nor can we be reassured of CMS' future use of their own MSF policy to evaluate measures against the current environment.

We challenge CMS to adhere to concepts in a recent article about resilience authored by CMS and CDC leaders¹. It cites recent dramatic increases in avoidable adverse events, then says "We therefore need to re-evaluate whether the health care system has sufficiently invested in ensuring a deeply embedded safety culture and maintaining an unflagging commitment to safety." This "unflagging commitment" needs to include finding ways to adapt so CMS can continue to use these critical safety measures discussed in transparency and value-based purchasing.

- **Suppression from Care Compare: CMS PSI 90**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 906 – June 17, 2022

The Leapfrog Group strongly opposes CMS' proposal to suppress calculation and publication of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) for FY 2023. Suppressing CMS PSI 90 would be a giant leap *backward* in patient safety and transparency, literally life-threatening, and an outrageous violation of the trust Americans place in the Medicare program.

In its rule, CMS proposes to suppress the PSI 90 measure "*due to the fact that the reference period (calendar year 2019) ... does not include data affected by the COVID-19 Public Health Emergency and the applicable period (calendar year 2020) does include such data, this would result in risk adjustment parameters that do not account for the impact of COVID-19 on affected patients.*" While we recognize that the COVID-19 pandemic has put an unprecedented strain on the entire health care system, we firmly reject the implication that this is an adequate reason to simply stop reporting lifesaving patient safety information. Indeed, in the middle of a global pandemic, it is more important than ever the public have access to information that could save their lives.

We oppose the proposal to suppress PSI 90 for the following reasons:

- **25,000 Deaths A Year Should Never Be Ignored or Hidden**

The 10 dangerous complications that make up PSI 90 are largely preventable yet kill 25,000 people per year and harm 94,000⁵. There is no other publicly available source for data on the complications

included in PSI 90. If CMS suppresses it, the American public will be in the dark on which hospitals put them most at risk. Suppressing PSI 90 would be a giant leap backward in patient safety and transparency, literally life-threatening, and an outrageous violation of the trust Americans place in the Medicare program. Medicare beneficiaries and the American public have the right to access this lifesaving data.

- **Dangerous Spikes in Infections and Medical Errors Are Relevant**

Suppressing information on hospital dangers covers up an alarming spike in those dangers that federal officials themselves have warned us about. Just two months ago, leaders at CMS and CDC reported that since 2020, federal data shows a significant increase in the number of common hospital infections and patient safety mistakes¹. These federal officials have the data, but now want to suppress much of it from the American public.

It is particularly concerning that most of the patient safety measures included in PSI 90 reveal significant health care disparities. While health inequities are often caused by sociodemographic factors outside the health care system, the data included in PSI 90 allows policymakers and researchers to see the differential impact on people of color by hospital patient safety lapses. For example, black patients are 27 percent more likely to experience sepsis after an operation than white patients and are 15 percent most likely to experience a kidney injury requiring dialysis². By proposing to suppress information on PSI 90, CMS is effectively seeking to hide invaluable data regarding real inequities in health care delivery.

- **Suppression Directly Contradicts The May 2022 Recommendation of the Office Inspector General, Which Found Alarming Problem with Patient Safety and Advised CMS to Add More Safety Measures – Not Take Critical Ones Away**

In early May, the HHS Office of the Inspector General (OIG), an independent governmental watchdog, reported that one in four Medicare beneficiaries admitted to a hospital were harmed by an error or accident during the stay⁶. The OIG advised that CMS' current reporting on safety problems is inadequate to capture all the dangers they discovered, and recommended CMS expand their reporting to include more measures. In the report, CMS agreed. But now CMS is heading in the opposite direction: instead of expanding measures, they want to suppress ten of those they currently report and threaten to suppress more.

- **CMS is Operating Outside of Its Own Policy**

In the FY 2022 IPPS Final Rule CMS stated a policy to suppress measures if one or more Measure Suppression Factors (MSFs) are met. But in this FY 23 Proposed Rule CMS proposes suppression of PSI 90 without referring to any MSFs. At best, this is a blatant disregard for the agency's own rulemaking policy.

Recommendations Related to the PSI 90 Proposal

Given our profound opposition to the suppression of PSI 90 data, we offer the following recommendations to CMS:

1. **Withdraw the Proposal to Suppress New PSI 90 Data in 2023:** CMS should fully withdraw its proposal to suppress the calculation and publication of PSI 90 data and should publish its data on its regular schedule, or preferably in a more timely fashion.
2. **Continue to Maintain Publication of Previous PSI 90 Data:** It is important that historians, public health experts, and policymakers have access to all previous PSI 90 data from Calendar Year 2019 and years previous.
3. **Retract the current MSFs and restate through rulemaking consistent and reliable criteria for the extremely rare need to suppress measures:** The foremost responsibility of CMS is to protect the interests of Medicare beneficiaries and the public at large, and that cannot be accomplished by suppressing measures that would alert them to hazards in the health care system.

- 4. Maintain the HAC Reduction Program:** During the COVID-19 pandemic, federal taxpayers have provided tens of billions of dollars in aid to hospitals to ensure they remained able to provide high quality care to all patients. CMS should maintain the HAC Reduction Program, which provides a financial incentive for hospitals avoid patient harm. It is particularly offensive that the public must also pay \$350 million to cover the cost of this proposal, which does nothing to serve the interests of Medicare beneficiaries.

As stated above, The Leapfrog Group strongly disagrees with the proposal to suppress CMS PSI 90 for FY 2023. We are disappointed that CMS states as its rationale the challenge of comparing pre- and post-pandemic populations. The rationale provided by CMS to suppress the composite is the “reference period for this measure does not include data affected by the COVID-19 PHE and the applicable [measurement] period does include such data...”.

We offer the following additional recommendation specifically aimed at the FY 2023 reporting CMS PSI 90: The AHRQ QI software version 12 should be used for calculating ratings for FY 2023. Regarding the measurement period, we recommend using 7/1/2019 through 12/31/19 and 1/1/21 through 9/30/21. While CMS previously proposed to use nine months of data, this expanded data set to 15 months will result in increasing the number of hospitals with a rating and improve reliability in general.

Given the AHRQ QI software version 12 is based on a reference population that is pre-COVID-19, we suggest CMS examine excluding cases with a COVID-19 diagnosis code that was present on admission in the primary or secondary position. We do not normally suggest to exclude such COVID-19 cases from the input data set used with the AHRQ QI software, but if this is the only option to preserve the CMS PSI 90 in FY 2023 it should be considered. Such a measure refinement has precedent given CMS has decided to employ the same COVID-19 exclusion from the Pneumonia 30 day mortality measure. We perceive these revisions can be performed so as to publicly report the CMS PSI 90 measure ratings in the CMS Care Compare October 2022 update.

If CMS is unwilling to undertake the above recommendation for calculating CMS PSI 90, there are two other options which would adjust for COVID-19 cases. We do NOT recommend these options because the avoidable complications in CMS PSI 90 are as tragic and important for COVID-19 patients as they are for any other patients. However, we would prefer these options over the dangerous and irresponsible proposal of full suppression of CMS PSI 90. These options include:

- Excluding cases with a COVID-19 diagnosis 12 months prior to admission and/or
- Including a COVID-19 diagnosis at admission as a variable in the risk adjustment

The changes noted above could be made in a timely fashion to avoid any disruption in reporting in FY 2023. This proposed rule provides several examples of such technical measure refinements CMS decided (vs. proposed) to make, which result in avoiding suppressing ratings for a year. Examples (not exhaustive) include use of COVID-19 as a risk factor for six 30-day mortality measures and six 30-day readmission measures.

- **Reporting on Care Compare: CDC NHSN HAIs**

The Leapfrog Group and Cosigners’ comments to CMS on the FY 2023 IPPS Proposed Rule –p. 913 – June 17, 2022

We support CMS’ proposal to base FY 2024 reporting of the CDC NHSN HAIs on CY 2022 data. We understand that in FY 2025 the plan is to base results for these measures on two years of data: CY 2022 and CY 2023.

- **Revise the Minimum Threshold for PSI 90**

The Leapfrog Group and Cosigners’ comments to CMS on the FY 2023 IPPS Proposed Rule –p. 921 – June 17, 2022

While we support the proposed increase to the minimum threshold, we have concerns that the unintended consequence is omitting many hospitals from being rated in CMS PSI 90. The proposed rule estimates the increased threshold will result in approximately 5% less facilities rated in this composite. Further, half of these facilities (2.5% of all hospitals) will not receive a Total HAC Score. This could result in hospitals entrusted by hundreds of thousands of people being excluded from accountability.

Given this concern, we suggest that CMS obtain all-payer claims to drive up the denominator (and likely the reliability) as well as reduce the number of hospitals that do not qualify for a rating. CMS has previously stated they have statutory authority to collect all-payer claims. We urge CMS to act on this authority which will serve as a valuable asset in all CMS claims-based measures. Beyond the benefits noted above, use of an all-payer claims data set will allow for inclusion of additional risk factors, provide CMS the ability to respecify measures to a more encompassing population, and increase the relevancy of the measures to providers and a broader base of consumers.

- **RFI: Digital CDC NHSN HAI Measures**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 924 – June 17, 2022

The Leapfrog Group appreciates the solicitation of comments on the potential to add two digital CDC NHSN HAI measures to several CMS programs, such as the Hospital IQR Program and the HACRP. We are in support of the addition of these two important measures and in strong support of the use of digital measures to upgrade the quality reporting enterprise.

However, we strongly recommend maintaining the CDC NHSN MRSA and CLABSI HAIs in their current programs. While the Hospital-Onset Bacteremia & Fungemia Outcome Measure captures a larger set of HAIs, such broader based measures can be more confusing to consumers and less useful to hospitals for quality improvement. In comparison, the more specific / discreet HAIs (such as MRSA and CLABSI) are more readily understood by consumers.

HOSPITAL VALUE-BASED PURCHASING PROGRAM

- **Suppression from VBP: HCAHPS and CDC NHSN HAIs and Calculation of VBP Program Score**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –pp. 858; 872 – June 17, 2022

The Leapfrog Group disagrees with the proposal to suppress the CDC NHSN HAIs from the HACRP based on the cited Measure Suppression Factors (MSFs). Our multi-part rationale follows:

First, a transparent and quality-focused financial incentive system must recognize the reality that there are always changes in the national environment, and expect that hospitals adapt to those changes and thus demonstrate resilience. CMS senior leaders discussed weaknesses the resilience of the health system in a statement in New England Journal of Medicine (NEJM) in February 2022¹. Yet the MSFs justify suppression for a wide variety of environmental shifts, including changes in national performance, guidelines, and case mix. Suppressing payment incentive programs when the environment shifts does nothing to strengthen resilience, and likely accomplishes the opposite. With the implementation of the MSFs, we are concerned that CMS is not building a resilient system, but a system that shuts programs down when the winds shift.

Secondly, we expressed an issue with the lack of definition, and thus transparency of, the terms used in the MSFs in our IPPS FY 2022 Proposed Rule comments. To illuminate our point: In MSF 1 and 4, CMS does not define “significant” when referencing “significant deviation in national performance.” Regarding MSF 3 and 4, we do not know what CMS operationally means by such terms as “rapid” when referencing “rapid change in guidelines.” These opaque terms are now used in this proposed rule to suppress critically important data on hospital acquired infection measures that consumers and employers deserve access to.

Third, there are issues with CMS adhering to, interpreting, and operationalizing the MSFs. An example of such flaws:

Regarding Clostridium difficile Infection (CDI), CMS’ rationale to suppress the measure based on MSF 3 follows:

- *“Improvements to ... practices such as hand hygiene, PPE practices and environmental cleaning*
- *A decline in outpatient antibiotic prescribing*
- *Use of inpatient antibiotic stewardship programs”*

Such observations of the ever-changing landscape can be tied to most measures. Further, the creation and/or uptake of best practices does not necessarily mean the measure has no value in making comparisons between hospitals based on their performance, or should not be used in a financial incentive program.

Fourth, regarding all five CDC NHSN HAIs: The proposed rule states:

“Because we cannot identify all potential elements that could be impacting the overall HAI ... during an unprecedented Public Health Event (PHE) as well as potential geographic disparities in the impact of the PHE that could cause uneven impact on facilities based on their location, like shortages of health care personnel, we believe all five CDC NHSN HAI measures should be suppressed.”

Any one of the five CDC NHSN HAIs alone can result in death or significant suffering for thousands of Medicare beneficiaries and other patients each year. Whether one HAI impacts the overall HAI rate is a question for statistical analysis, not for responsibly protecting the lives and health of Medicare beneficiaries and the public at large. Moreover, there are numerous factors with the potential to impact improvement in a given HAI or other outcome of interest³. If the fact we will never be able to isolate the degree to which each and every factor is impacting an outcome is grounds for suppressing all CDC NHSN HAIs, that logic can be used to suppress virtually all measures under virtually all circumstances.

This stated rationale is plainly not the intention of the original statute establishing payment programs and goes outside of CMS’ authority as this reason for suppression is neither attributed to an MSF nor outlined in a prior IPPS rule that enables the agency to suppress measures. We suggest that CMS:

- Retract this stated rationale for the suppression of the NHSN CDC HAIs in the final IPPS rule
- Reinstate the NHSN CDC HAIs in the HACRP

Lastly, we are disturbed by CMS’ inconsistency in the citation of MSFs across programs for the same measures. More specifically, in the HACRP the stated MSF for CAUTI, CLABSI and MRSA is MSF 1. However, in the HVBP Program CMS applies not only MSF 1 to these three measures, but also adds MSF 4. As a result of this uneven application of the MSF policy, we are not convinced CMS used a consistent and reliable process in its decision-making nor can we be reassured of CMS’ future use of their own MSF policy to evaluate measures against the current environment.

We challenge CMS to adhere to concepts in a recent article about resilience authored by CMS and CDC leaders¹. It cites recent dramatic increases in avoidable adverse events, then says “We therefore need to re-evaluate

whether the health care system has sufficiently invested in ensuring a deeply embedded safety culture and maintaining an unflagging commitment to safety.” This “unflagging commitment” needs to include finding ways to adapt so CMS can continue to use these critical safety measures discussed in transparency and value-based purchasing.

- **Pneumonia Mortality Measure: Reintroduction and Respecification**

The Leapfrog Group and Cosigners’ comments to CMS on the FY 2023 IPPS Proposed Rule –p. 883 – June 28, 2021

The Leapfrog Group supports CMS’ plan to respecify the 30-day pneumonia mortality measure and reintroduce it to public reporting in FY 2023. While the measure was suppressed for FY 2023 per the most recent final IPPS rule, it is commendable to see that CMS now plans to publicly report the measure in January 2023.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM

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

The Leapfrog Group and Cosigners’ comments to CMS on the FY 2023 IPPS Proposed Rule –p. 1065 – June 17, 2022

The Leapfrog Group commends CMS for a much-needed expansion of measures to the Hospital IQR Program. We support the addition of the ten proposed measures to the program.

In particular, we welcome the introduction of the two measures regarding screening for social drivers of health. One modification to these two measures that we recommend is requiring facilities to use a uniform instrument for use in these measures. Unstandardized data collection tools threaten the reliability of the measure and open the measure up to gaming. The Proposed Rule discusses the AHC instrument, which includes a ten item AHC Health-Related Social Needs Screening Tool. This instrument appears to be the best candidate to require in the measure technical specifications.

- **Refinement of the Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) Measure**

The Leapfrog Group and Cosigners’ comments to CMS on the FY 2023 IPPS Proposed Rule –p. 1198 – June 17, 2022

We support the proposed re-specification of the measure to increase the minimum threshold. Increasing the minimum denominator from 25 to 50 improves the reliability of the measure. The downside of increasing the denominator is that less hospitals will qualify. We suggest CMS identify methods to address this issue. Given this concern, we suggest that CMS obtain all-payer claims data to drive up the denominator, and likely the reliability, as well as reduce the number of hospitals that do not qualify. CMS has previously stated they have statutory authority to collect all-payer claims. We urge CMS to act on this authority which will serve as a valuable asset in all CMS claims-based measures. Beyond the benefits noted above, use of an all-payer claims data set will allow for inclusion of additional risk factors, provide CMS the ability to respecify measures to a more encompassing population, and increase the relevancy of the measures to providers and a broader base of consumers.

- **Establishment of a Publicly Reported Hospital Designation to Capture the Quality and Safety of Maternity Care**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 1210 – June 17, 2022

While we conceptually agree with creating a maternity care designation that is consumer friendly, we do not concur with the measure proposed to serve as the basis for the designation. The primary challenge is the lack of evidence that the proposed structural measure correlates with superior results for maternity cases. Thus, the “quality and safety” designation is misleading to the public as it does not tell consumers anything about the facility’s attainment of a minimum level of quality or safety.

A secondary challenge is that the proposed structural measure is solely comprised of two questions where the response options are limited to “yes,” “no,” and “NA”. Given the questions and the limited response categories, this will be a low bar measure. Adherence to such low bar measures does not indicate “high quality” or “high safety,” but merely compliance with a minimum standard of practice. Consumers have a right to expect facilities already meet minimum standards, and quality reporting should allow them to compare to find excellence.

We encourage CMS to revisit creating this designation when this structural measure can be replaced by or combined with a number of maternity outcome measures that are meaningful to consumers and better recognize excellence.

- **Digital CDC NSHN Measures**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 1219 – June 17, 2022

The Leapfrog Group appreciates the solicitation of comments on the potential to add two digital CDC NSHN HAI measures to several CMS programs, such as the Hospital IQR Program and the HACRP. We support the addition of these two important measures. However, we strongly recommend maintaining the CDC NSHN MRSA and CLABSI HAIs in their current programs. While the Hospital-Onset Bacteremia and Fungemia Outcome Measure captures a larger set of HAIs, such broader based measures can be more confusing to consumers. In comparison, the more specific and discreet HAIs (such as MRSA and CLABSI) are more readily understood by consumers.

- **eCQM Reporting Requirements**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 1235 – June 17, 2022

We commend the CMS policy direction toward expansion of eCQMs. We conditionally support the proposed requirement to expand the reporting of eCQMs from four to six measures. The condition for our support is that CMS mandate reporting requirements and remove self-selection of eCQMs by facilities. The present requirement is that three of the four eCQMs are self-selected by the facility. The proposed requirement maintains the self-selection of three eCQMs (and adds two specified eCQMs). We recommend that CMS mandate which eCQM measures must be reported. Self-selection by facilities significantly reduces or even eliminates the value of transparency by hindering comparability among facilities and encouraging the selection of measures that are unrepresentative.

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

- **RFI: Inclusion of Health Equity Performance in the HRRP**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 849 – June 17, 2022

The Leapfrog Group supports CMS' efforts to develop peer groups among participating hospitals for the purposes of payment. However, for purposes of calculating readmission rates and for public reporting, we strongly oppose risk adjustment based on income or other demographic, racial, ethnic, or other human characteristics unrelated to diagnosed health status. Leapfrog supports transparency in calculating measures and stratification for purposes of payment as a way to ensure both high quality for all patients and fair payments to those safety net hospitals in communities truly lacking the appropriate supports for patients.

We continue to urge CMS against the use of social risk factors in measure specifications. Leapfrog has been a vocal opponent of any adjustments to quality measures that can diminish the value of an individual patient based on that patient's socio-demographic characteristics. This is a moral hazard. At the same time, payment formulas can and should recognize special challenges faced by safety-net providers while still reporting the quality data comprehensively.

ADDITIONAL RFIs

- **RFI: Principles for Measuring Health Care Quality Disparities across CMS quality**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 1022 – June 17, 2022

The Leapfrog Group suggests CMS prioritize examining disparities in the treatment rendered and outcomes attained in our health care system. Such understanding is foundational to informing where and how to invest in rectifying substantial health disparities evident across the significant body of research in health equity. A model for such investigation is the recent Urban Institute research on the differences between Black and white patients with adverse safety events in an inpatient setting². Disparities were found between patients with the same payor, in the same hospitals, with similar conditions. Once hospitals can detect this kind of evidence of bias in treatment, it is possible to correct behaviors that lead to these different outcomes and thus improve equity, long before it will be feasible to address all social determinants of health.

Another area of focus for CMS is to study where the agency can have the biggest impact on substantial disparities that are rooted in quality of care. It appears the best fit for this conversation is the RFI heading that states "Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs". With such a focus, CMS' short-term goal should be to identify and implement strategies to address where the delivery of care is most adversely impacting disparities.

- **RFI: Social determinants of Health (SDOH) Diagnosis Codes**

The Leapfrog Group and Cosigners' comments to CMS on the FY 2023 IPPS Proposed Rule –p. 175 – June 17, 2022

While this RFI focuses on the reporting of SDOH ICD-10 Z codes, we recommend articulating the specific uses of the codes. This subsection states these codes "may improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources". This stated aim, and other similar statements, are unclear as to their specific application. For example, will CMS use such data points for internal research? Is CMS

considering using these codes in measure technical specifications for such purposes as risk adjustment to publicly report performance? We would support the former and strongly object to the latter purpose.

The capture of such SDOH data includes sensitive information. When such data appear in publicly available claims data sets, it creates the potential for it to be misused by others. Thus, we suggest that any discussion of collecting SDOH data include a conversation about a process to screen and approve such data set requests.

CITATIONS

1. Fleisher, L.A., Schreiver, M., Cardo, D., Srinivasan, A. (2022). Health care safety during the pandemic and beyond: Building a system that ensures resilience. *NEJM*, 386;7, p. 609 – 611.
2. Gangopadhyaya, A. (2021). Do black and white patients experience similar rates of adverse safety events at the same hospitals? The Urban Institute. Report accessed 5/2/22 at <https://www.urban.org/research/publication/do-black-and-white-patients-experience-similar-rates-adverse-safety-events-same-hospital>
3. Mosadeghrad, A.M. (2012). A conceptual framework for quality of care. *Mat Soc Med*. 24(4): 251–261.
4. Laiteerapong, N., Huang, E.S. (2015). The pace of change in medical practice and health policy: Collision or coexistence? *J Gen Intern Med*, 30(6), p. 848-852.
5. Armstrong Institute for Patient Safety and Quality, *Lives Lost, Lives Saved: An Updated Comparative Analysis of Avoidable Deaths at Hospitals Graded by The Leapfrog Group*, May 2019: <https://www.hospitalsafetygrade.org/media/file/Lives-Saved-White-Paper-FINAL.pdf>.
6. Department of Health and Human Services, Office of the Inspector General, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*, May 9, 2022. <https://oig.hhs.govAd/oei/reports/OEI-06-18-00400.asp>