



June 13, 2017

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services

***RE: RIN 0938-AS98 Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals; Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices***

Dear Ms. Verma,

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 report safety and quality data on a national level, thereby bringing a unique perspective to 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, thereby increasing their meaning and 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 2018 Inpatient Prospective Payment System (IPPS) rules.

As an organization representing purchasers of health care, we are working to ensure that patient safety remains a top priority and that value-based purchasing efforts are effective in transforming both the cost and quality of care for patients and families. With that in mind, we urge CMS to aggressively pursue opportunities to work more closely with private purchasers. To achieve the improvements in safety, quality and resource use that the U.S. health care system desperately needs, it is imperative that all purchasers work together to send a strong signal to the market. This starts with communicating aligned priorities through measurement, payment and public reporting programs, which will ultimately enable providers to focus on improvement rather than on fulfilling disparate measurement requests.

**The Fundamental Principle for Public-Private Alignment: Transparency**

Along with CMS, employers and purchasers have a vested interest in ensuring Americans have the tools to compare hospitals before selecting one to care for themselves and their loved ones. With that in mind, we strongly advise CMS to put the priority on transparency throughout all of its programs. From a business

perspective, there is no force for change greater than the demands of alert consumers, and transparency is the necessary first step to galvanize a market. From a public policy perspective, there is broad bipartisan consensus that people who use the health care system deserve to know how it is doing.

**In light of the importance of transparency, we first and foremost commend CMS for the recommendation to publicly report accreditation survey reports.** Such accreditation reports determine whether organizations are eligible to accept public funds, and so they should be available to the public. In addition, we have some recommendations on transparency that are not addressed in the proposed rule, but should be included in the final rule:

1. **We implore CMS to meaningfully differentiate the very real variation in hospital performance on the safety and quality measures published on the Hospital Compare website.** Though this proposed rule does not solicit comments on the issue of public reporting of the data collected through these various programs, Leapfrog believes strongly that in order for the data to be valuable for health care consumers, one of the largest market forces today, the data has to differentiate between hospitals on safety, quality and cost. 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 indeed this is not the case.
2. **Report results from all federal hospital programs by bricks-and-mortar facility, not Medicare Provider Number.** We strongly recommend that CMS align with Leapfrog in 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 Medicare Provider Number (MPN) or CMS Certification Number (CCN). There are instances where up to nine hospitals several miles apart and offering very different services share an MPN. When safety, quality and resource use metrics are reported out in this way it obscures the individual performance of the hospital delivering the care and is misleading to patients everywhere. Patients do not seek care from a system; they seek care from individual hospitals and clinicians. Providers too can benefit from being able to more easily discern the performance at their own facility and determine where improvement is needed.
3. **Restore Healthcare Acquired Conditions (HACs) and Never Events Reporting on Hospital Compare.** We suggest that CMS take a timely approach to implementing existing measures that address current gap areas. This requires revisiting measures that have been removed from federal hospital inpatient programs. We recommend reinstating the hospital-acquired condition measures removed from the Inpatient Quality Reporting Program in 2013. We have found through our experience with the Leapfrog Hospital Safety Grade that these measures tell an important story about patient safety that consumers and purchasers understand and find valuable. While imperfect, the measures provide key information to the research community as well, which is why Leapfrog’s Blue Ribbon Panel of experts selected four of the measures to be part of the Safety Grade composite. We also recommend including Never Events in the Inpatient Quality Reporting Program, which The Leapfrog Group has focused on since 2007. Adverse events in health care are one of the leading causes of death and injury in the U.S. today. Requiring hospitals to report Never Events not only saves lives, but also saves purchasers countless wasted dollars.

The average employer pays nearly \$9,000 for every hospital admission for medical errors and many errors are never reported. Without these measures, we compound the scarcity of nationally reported information on hospital safety.

4. **Stop Exempting Hospitals from Public Reporting.** Patients who receive care in critical access hospitals, pediatric hospitals, military hospitals, hospitals in Maryland, Guam, and Puerto Rico, and beyond, 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 and those in communities served by hospitals exempted from the federal reporting programs are highly disadvantaged.

Attached are detailed comments pertaining to the following sections of the proposed rule:

- Hospital Readmissions Reduction Program: Proposed Updates and Changes
- Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes
- Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program
- Hospital Inpatient Quality Reporting Program
- PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program
- Proposed Revisions to the Application and Re-Application Procedures for National Accrediting Organizations (AOs), Provider and Supplier Conditions, and Posting of Survey Reports and Acceptable Plans of Corrections (PoCs)

We provide additional recommendations below on opportunities to accelerate the aforementioned aspects of this proposed rule. The enclosed appendix includes detailed comments on each of the individual programs noted above.

On behalf of The Leapfrog Group, our Board, and our members, we appreciate the opportunity to provide comments on the proposed changes to the FY 2018 IPPS proposed rule. If you have any questions, please do not hesitate to contact me or Missy Danforth, Vice President for Hospital Ratings of The Leapfrog Group.

Sincerely,

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

**Additional Organizations Supporting Leapfrog's comments on the CMS FY 2018 proposed rule:**

Citizens for Patient Safety, Colorado  
Consumers' Checkbook/Center for the Study of Services, Washington, D.C.  
Dallas-Fort Worth Business Group on Health  
Economic Alliance for Michigan  
Florida Health Care Coalition  
Greater Philadelphia Business Coalition on Health  
Health Action Council, Ohio  
HealthCare 21 Business Coalition, Tennessee  
Health Policy Corporation of Iowa

Health Watch USA, Kentucky  
Institute for Health Policy & Practice, which convenes a New Hampshire-based purchasers group  
Lehigh Valley Business Coalition on Healthcare, Pennsylvania  
Maine Health Management Coalition  
Memphis Business Group on Health  
Midatlantic Business Group on Health, Maryland  
Mothers Against Medical Error  
National Accreta Foundation  
New Jersey Health Care Quality Institute  
Northeast Business Group on Health, New York  
Pacific Business Group on Health, California  
Society for Participatory Medicine, Massachusetts  
Texas Business Group on Health  
The Alliance, Wisconsin  
The Empowered Patient Coalition, San Francisco  
Washington Advocate for Patient Safety, Seattle  
WellOK, Oklahoma  
Wyoming Business Coalition on Health

***Appendix: Detailed Comments***

## APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2018 IPPS PROPOSED RULE

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### V. OTHER DECISIONS AND PROPOSED CHANGES TO THE IPPS FOR OPERATING SYSTEM

#### I. Hospital Readmissions Reduction Program: Proposed Updates and Changes

##### *8. Provisions for the Proposed Payment Adjustment Methodology for FY2019: Proposed Methodology for Assigning Hospitals to Peer Groups*

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, Leapfrog strongly opposes 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. Leapfrog continues to urge CMS against the use of social risk factors in measure specifications.

##### *11. Accounting for Social Risk Factors in the Hospital Readmissions Reduction Program*

The Leapfrog Group continues to urge CMS against the use of social risk factors to adjust quality measures. Given CMS' proposal to use peer groups for the purpose of adjusting payments through the Readmission Reduction Program, Leapfrog strongly urges CMS to take the time to evaluate and learn from this work before attempting to add any additional adjustment to either the program or the measures used in the program. Leapfrog has been a vocal opponent of any adjustments to quality measures that risk creating a two-tier system of care where those with few economic or social resources are diminished in the calculation of quality measures. At the same time, payment formulas can and should recognize special challenges faced by safety-net providers.

#### J. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

##### *2. Accounting for Social Risk Factors in the Hospital VBP Program*

The Leapfrog Group recommends that CMS first learn from its experience in assigning hospitals to peer groups for the purposes of determining payment penalties through the Readmissions Reduction Program before attempting to include social risk factors in any additional programs.

##### *3b. Retention and Removal of Quality Measures for the FY2019 Program Year: Proposed Removal of PSI 90*

As an organization representing purchasers who have worked to align their own purchasing practices with the federal government, we are disheartened that a critical patient safety composite which accounts for a significant number of surgical complications would be removed from CMS's signature value-based payment program.

Leapfrog, through the use of several of the individual PSI components included in PSI 90 in the Leapfrog Hospital Safety Grade, has worked diligently to encourage payers and purchasers to incorporate these critical patient safety measures, which are not only harmful, but costly, in their own value-based payment programs. Leapfrog fully understands the limitations of the VBP statute which requires that measures included in the VBP Program be publicly reported on Hospital Compare for a minimum of one year and that baseline performance on each measure be established at least 60 days prior to the performance period. However, it is unacceptable to allow a three-year lapse in public reporting of this critical safety measure, during which time tens of thousands of Americans will die or suffer harm from the complications included in the measure. We urge CMS to look more broadly for opportunities to accelerate the inclusion of the updated PSI 90 Patient Safety and Adverse Events Composite into the VBP Program, or perhaps include older PSI 90 rather than waiting for the new measures to become available to ensure that surgical complications remain a key component of the VBP Program.

*4b. Proposed New Measures for the FY 2022 Program year, FY 2023 Program Year, and Subsequent Years: Proposed New Measure for the FY 2023 Program Year and Subsequent Years: Patient Safety and Adverse Events (Composite) (NQF #0531)*

Leapfrog strongly supports the inclusion of the Patient Safety and Adverse Events composite measure in the VBP Program in 2023 and beyond, and would urge CMS to look for opportunities to advance the use of this measure in the VBP Program prior to 2023.

## **K. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program**

### *4. Request for Comments on Additional Measures for Potential Future Adoption*

Leapfrog encourages CMS to consider the addition of a Medication Safety Domain (Domain 3) within the HAC Reduction Program. As described by [AHRQ](#), an adverse drug event (ADE) is defined as harm experienced by a patient as a result of exposure to a medication, and ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year. ADEs affect nearly 5% of hospitalized patients, making them one of the most common types of inpatient errors. To construct this domain, Leapfrog is suggesting two measures which address well-documented sources of medication errors and related adverse events: medication ordering and medication reconciliation (including medication history errors):

- Medication Reconciliation: Unintentional Medication Discrepancies (NQF #2456):** This measure results in a rate of unintentional medication discrepancies per patient and is currently in use by Leapfrog on its annual hospital survey and in the MARQUIS Multi-Center Medication Reconciliation Quality Improvement Study funded by AHRQ. The measure calls for hospitals to sample 25 adult inpatients per quarter and have a licensed pharmacist create a ‘gold standard’ preadmission medication list (PAML), which is then compared to the medication list from admission and to the medication list on discharge. Hospitals report on the number of unintentional medication discrepancies identified between the PAML and the admission and discharge orders, resulting in a rate of unintentional medication discrepancies per patient. This measure goes beyond the current proforma measures required by CMS or The Joint Commission and truly measures the outcomes of a hospital’s medication reconciliation process. The measure also provides meaningful and actionable results to patients, payors and providers alike.

- Computerized Prescriber Order Entry (CPOE) Evaluation Tool:** Funded by AHRQ and recently updated by the original tool developers at Brigham and Women’s Hospital and the University of Utah, the CPOE Evaluation Tool was designed to test the ability of inpatient CPOE systems to alert prescribers to common, serious medication errors. In addition, the Tool was designed to help hospitals improve on their use of clinical decision support to reduce adverse drug events and improve medication safety. The Tool was first included on the Leapfrog Hospital Survey in 2008 and has been evaluated in peer reviewed [articles](#). The timed simulation tool provides users with a set of test patients, along with a corresponding set of test medication orders that users enter into their hospital’s CPOE and related clinical systems. Those conducting the test record the alerts they received, if any, from their hospital’s CPOE system onto an observation sheet, and then record and complete an online answer sheet. Users receive immediate scoring and feedback summarizing the results of the test. The Tool includes several order checking categories including drug:drug interaction, drug:allergy interactions, therapeutic duplications, single and daily dose limits and others.

In addition to adding a medication safety domain, Leapfrog recommends the addition of several of the DRA HAC measures previously removed from the IQR in 2013, including foreign object retained after surgery, air embolism and falls with injury. These measures capture harms not currently included in the PSI 90 Patient Safety and Adverse Events Composite.

#### *5. Accounting for Social Risk Factors in the HAC Reduction Program*

Leapfrog does not support any adjustment for social factors to patient safety measures or payment programs focused on reducing patient harm, such as the HAC Reduction Program. This position has been taken by the National Quality Forum, and patient safety measures were not eligible to be included in the two-year trial period. Safe care must be an expectation of all patients.

#### *6. Request for Comments on Inclusion of Disability and Medical Complexity for CDC NHSN Measures*

As the CDC NHSN Measures used by CMS were developed by the CDC, Leapfrog feels strongly that any adjustments to the measures should come directly from CDC based on their experience, testing and feasibility of accurately obtaining the additional data.

## **IX. QUALITY DATA REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS AND SUPPLIERS**

### **A. Hospital Inpatient Quality Reporting Program**

#### *1d. Accounting for Social Risk Factors in the Hospital IQR Program*

The Leapfrog Group continues to urge CMS against the use of social risk factors to adjust quality measures. Leapfrog has been a vocal opponent of any adjustments to quality measures that risk creating a two-tier system of care where those with few economic or social resources are diminished in the calculation of quality measures. At the same time, payment formulas can and should recognize special challenges faced by safety-net providers such as CMS is proposing in the Hospital Readmissions Reduction Program.

*6a. Refining Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166) for the FY2020 Payment Determination and Subsequent Years*

We support the proposed rule to refine the Communication About Pain HCHAPS measure to dissuade the over prescription of opioids. We agree it is important to remove ambiguities in the wording or intent of the questions and appreciate that CMS has taken the steps to appropriately test the measure for reliability and validity.

We are encouraged that CMS would begin using the updated measure as soon as January 2018, but in light of the seriousness of the opioid epidemic, we would encourage CMS to not delay public reporting of this measure on Hospital Compare until October 2019. Rather, we encourage CMS to consider publicly reporting less than four quarters of data in the interim period in which less than four quarters of data are available so that this important measure can be brought to the public sooner.

In addition, as disparities in pain manage are well [documented](#), we would encourage CMS to develop other means to allow patients to assess the degree to which hospital personnel listened to them and responded to their pain, including offering non-opioid options.

*9a-d. Possible New Quality Measures and Measure Topics for Future Years: Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures Measure; Four End-of-Life (EOL) Measures for Cancer Patients; Two Nurse Staffing Measures; and Additional Electronic Clinical Quality Measures in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs*

We strongly support the addition of the Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures Measure and applaud CMS' move to elevate the critical issue of patient consent in the IQR Program and support the recommendation to deploy the Quality of Informed Consent Documents measure immediately.

We would also urge CMS to work rapidly to strengthen the informed consent measure to ensure that patients' needs and well-being are at the center. Informed consent is a critical component of shared decision-making and shared care planning, and they must be evaluated more thoroughly from the patient's assessment of the interaction and communication with the surgeon. We agree with recommendations from other purchaser and consumer groups that this measure does not go far enough and would benefit from the following additions:

- A mechanism to ensure patient satisfaction with the process for gathering signatures on the consent form;
- Information on the risks and benefits of the procedure as performed by that provider in that setting;
- A longer interval of time between signature and elective procedure. The current measure gives credit for 24 hours; for the gold standard in shared decision-making the standard should be longer and that is where credit should be awarded;
- A tight, defined process for CMS data validation;
- A higher bar for meeting the standards of the measure instead of scaling expectations higher over time. While the measure is new to hospitals, carefully scrutinized and validated consent procedures are not. Consent is a critical part of hospital operations, well understood in literature and heavily evaluated by



hospital leaders and clinicians. A temporary lesser standard, which could misinform and/or harm patients, is unnecessary since all hospitals are capable of meeting acceptable standards.

We support the addition of the four EOL Measures for Cancer Patients. The primary reason for implementing these measures is to treasure the humanity and dignity of patients and their loved ones at life's most difficult moments.

We support the inclusion of the two Nurse Staffing Measures: Nursing Skill Mix Measure (NQF #0204) (MUCEO204) and Nursing Hours per Patient Day Measure (NQF #0205) (MUCEO205), but encourage CMS to review the [evidence](#) on nursing workforce and patient safety and consider measures that assess not only skill mix and hours per patient day, but importantly education and work environment.

We strongly support the addition of The Safe Use of Opioids—Concurrent Prescribing (MUC16–167) to the IQR Program. We agree that adopting a measure that calculates the proportion of patients prescribed two or more different opioids or opioids and benzodiazepines concurrently has the potential to reduce preventable mortality and reduce the costs associated with adverse events. Though we recognize this behavior change for providers will be challenging, we feel it is critical to encourage providers to identify patients with concurrent prescriptions of opioids or opioids and benzodiazepines and discourage providers from prescribing two or more different opioids or opioids and benzodiazepines concurrently.

Given the problem, we would encourage CMS to publicly report the non-adjusted results of this measure by hospital. The measure should not be risk-adjusted for social risk factors as there is no valid reason why certain populations should be prescribed or concurrently prescribed opioids or opioids and benzodiazepines with greater frequency. Patients should be aware if the facility they choose for care prescribes opioids at a higher-than-optimal rate, particularly if they have a history of addiction or substance abuse and therefore require a heightened awareness of medication prescribed for pain relief.

In addition, Leapfrog strongly urges CMS to consider the addition of PC-02: All-Payer Cesarean Births to the IQR Program. Following a recommendation by ACOG during the 2016-17 MAP cycle, we recommended that CMS add a measure of low-risk cesarean section rate to the IQR Program. Measuring and tracking unnecessary cesarean sections is an important step toward improving perinatal care. The Joint Commission's Cesarean Birth (PC-02) all-payer measure is ready to be implemented and would nicely complement the all-payer Elective Delivery measure now in use in IQR (PC-01). PC-02 is NQF-endorsed and is a component of The Joint Commission's Perinatal Care Core Set used for facility accreditation.

## **B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program**

### *4b. Proposed New Quality Measures Beginning with FY 2020 Programs*

We support CMS's proposal to add the following measures: Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210); Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213); Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); and Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216) as we believe they will help to achieve the National Quality Forum's goal of

improving end-of-life care. We are satisfied with the strong evidence behind these measures. In addition, we respect the critical importance of ensuring a more humane approach to patients as they near the potential end of life, as well as the necessity of full patient and family engagement in decision-making about all aspects of care.

We wholeheartedly agree that risk adjustment or risk stratification are not appropriate for these measures as the goal is to assess the quality of care provided to all cancer patients at the end of life.

In addition, we recommend that these measures be included in the IQR in the future as many patients receiving cancer treatment do so in general acute care hospitals.

## XI. PROPOSED CHANGES RELATING TO SURVEY AND CERTIFICATION REQUIREMENTS

### **A. Proposed Revisions to the Application and Re-Application Procedures for National Accrediting Organizations (AOs), Provider and Supplier Conditions, and Posting of Survey Reports and Acceptable Plans of Corrections (PoCs)**

**We support this proposed revision in the strongest possible terms.** CMS's efforts to increase transparency by requiring private, national accrediting organizations to make all survey reports and acceptable plans of correction publicly available on their websites is a critical next step in the path toward greater transparency in our health care system. We agree that making these reports publicly available will empower health care consumers and purchasers to make a more informed decision regarding where to receive health care, and in turn, encourage health care providers to improve the quality of care and services they provide.

Leapfrog was founded on the idea that transparency can improve health care quality and safety. Employers and other purchasers spend billions of dollars on health care every year but nearly one-third of health care spending is wasteful, including unnecessary procedures, administrative costs, medical errors and even fraud. For many years, purchasers have struggled to secure high-quality health care for their employees, simply because they can't easily discern which providers are safe or have the best patient outcomes. In no other industry do we encounter this lack of transparency and accountability.

Making private, national accrediting organization reports publicly available would be a significant step toward increased transparency in health care, and fully justified when accreditation reports are used to deem providers eligible to receive public funding. Leapfrog strongly believes that the best way to improve the quality, safety and affordability of health care in the United States is through transparency and public reporting, and consumers deserve to know how their providers perform.