THELEAPFROGGROUP

June 24, 2019

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

RE: RIN 0938-AT73 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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

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 collects and publicly reports safety and quality data at the 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, 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 2020 Inpatient Prospective Payment System (IPPS) rule.

We appreciate the leadership you and Secretary Azar have demonstrated in advancing price transparency throughout the health care system, which has value not only to Medicare beneficiaries but also to employers and other purchasers in the private sector and the public at large. However, price transparency is inadequate without robust and meaningful transparency on quality and safety. A treatment or procedure at a good price is not a good value if the outcome is poor.

While we appreciate the intentions of the "Meaningful Measures" initiative, we are concerned it will result in a shortage of publicly available measures to assess quality and safety. In particular, purchasers and consumers consider the Inpatient Quality Reporting program (IQR), launched in the early 2000's, one of the most significant achievements in American health care, and a critical platform for using transparency to build a more cost-effective, higher quality health care system. The IQR publicly reports information on hospitals that employers, purchasers, health plans and individual consumers cannot get otherwise. The important data in the IQR has driven significant innovation in the public and private sectors to pursue value in health care. This has demonstrated meaningful impact, including over 40,000 fewer avoidable deaths this year than 2016. We are disappointed in CMS' operationalization of its "Meaningful Measures" policy to date, which has focused on removing measures without adding needed high value measures. For instance, in the IPPS FY19 rule CMS

specified a timetable to retire 39 IQR measures of which nearly half (49%) are high-value outcome measures that purchasers and payors cannot readily obtain from any other source. Many of these outcome measures are significant to patient safety, such as removing all of the CDC healthcare-associated infection (HAI) measures. Despite the erosion of important publicly available measures people need and deserve to know about the performance of American hospitals, the FY20 proposed rule only proposes to add two measures to the IQR and solicits comments on just three others. There are a number of additional measures worthy of consideration to add to IQR. We urge CMS to take advantage of the IPPS process to solicit comments on a much fuller set of measures. Given hospitals are about one-third of the U.S. health care spend[1], inpatient care is an area CMS needs to focus on for the agency to be a good steward of the Medicare and Medicaid programs and a good partner with the private sector in advancing transparency.

Additionally, we have 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 how Hospital Compare presents information collected through the IQR, Leapfrog believes strongly that in order for the data to be valuable for health care consumers, 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 this is not the case and the difference can mean life and death for patients.

   That said, 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 Hospital Compare as meaningful to consumers.

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 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 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 a MPN. When safety, quality and resource use 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 more easily discern the performance at their own facility and determine where improvements are needed.

3. **Restore DRA – 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 reporting programs. We recommend reinstating the hospital-acquired condition measures

removed from the IQR 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. The measures provide key information to the research community as well, which is why Leapfrog's Hospital Safety Grade Expert Panel selected four of the measures to be part of the Safety Grade composite.

4. **Stop exempting hospitals from public reporting.** Patients who receive care in critical access hospitals, pediatric hospitals, military hospitals, hospitals in Maryland and 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.

Below are detailed comments pertaining to the following programs addressed in the proposed rule:

- Inpatient Quality Reporting Program
- Hospital Acquired Condition Reporting Program
- Value Based Purchasing Program
- Hospital Readmissions Reduction Program

The enclosed appendix includes detailed comments on each of the individual programs noted above along with additional recommendations for consideration.

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 2020 IPPS proposed rule.

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 2020 proposed rule:

airPHX Health; McLean, Virginia
Colorado Business Group on Health
Connecticut Center for Patient Safety
Consumer's Checkbook; Washington, DC
Dallas Fort Worth Business Group on Health
Economic Alliance for Michigan

Florida Alliance for Healthcare Value
Greater Philadelphia Business Coalition on Health
G. Richard Wagoner; Leapfrog Board Member; Birmingham, MI
Health Action Council; Cleveland, Ohio
HealthCare 21 Business Coalition; Knoxville, Tennessee
Health Policy Corporation of Iowa
Healthcare Purchaser Alliance of Maine
Houston Business Coalition on Health
Lehigh Valley Business Coalition on Healthcare
Louisiana Business Group on Health
Mary Brennan-Taylor; Patient Safety Advocate; Niagara, New York
Maureen Ryan; Leapfrog Board Member; Washington, DC
Memphis Business Group on Health
Midwest Business Group on Health
Mothers Against Medical Error; Columbia, South Carolina
New Jersey Health Care Quality Institute
New Jersey Department of Health
Pacific Business Group on Health
Pittsburgh Business Group on Health
SchoolCare Health Benefit Plans; Manchester, New Hampshire
Sharon M. Castillo; Leapfrog Fellow; Philadelphia, Pennsylvania
South Carolina Business Coalition on Health
St. Louis Area Business Health Coalition
Texas Business Group on Health
University System of New Hampshire
University of Michigan Benefits Administration Office
Washington Advocates for Patient Safety
Wyoming Business Coalition on Health

Appendix: Detailed Comments

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2020 IPPS PROPOSED RULE

INPATIENT QUALITY REPORTING PROGRAM

- **Proposed addition of two opioid eCQMs to IQR**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule –pp. 1114; 1116; 1126 – June 24, 2019

The Leapfrog Group supports the addition of the two proposed opioid related measures with some recommended modifications.

Regarding the "Safe Use of Opioids" measure, we recommend measuring the degree to which orders for opioids involve the use of a Computerized Physician Order Entry (CPOE) system. The effective use of CPOE results in safer prescriptions given the checks and balances of such systems[2]. While opioids are understandably at the forefront of national headlines, there is also a need for a broader measure of medication errors. Knowing that 1.5 million medication errors occur each year in the U.S.[3], it is a glaring omission that Hospital Compare has historically not measured this area.

Regarding the "Hospital Harm" measure, given the narrow type of adverse events captured in the numerator, along with a very broad denominator, the result is a very small number of cases experiencing such harm and thus a very low rate of opioid adverse events[4]. We encourage CMS as the measure steward to more fully capture the harm occurring in the hospital and post-hospitalization that are the result of poor management of opioids.

Overall, however, we are deeply disappointed that these are the only two measures proposed. We do not support CMS' apparent priority of removing measures and not adding high value measures. In the IPPS FY19 rule, CMS specified a timetable to retire 39 IQR measures where nearly half (49%) are outcome measures. Many of these outcome measures are significant to patient safety, the third leading cause of death in America, such as removing all of the CDC healthcare-associated infection (HAI) measures. However, in the FY20 proposed rule we see CMS is only proposing to add two measures to IQR and is soliciting comments on just three others.

We urge CMS to take steps to truly get to "Meaningful Measures" as opposed to creating more gaps in what we know about hospital quality. A glaring example of a gap is occurring in the IQR program, which is phasing out all of the CDC HAI measures. Though thankfully CMS did commit to continued public reporting of infections, we strongly recommend CMS restore these measures to IQR, which is best designed for sustained and meaningful public reporting. Given hospitals are about one-third of the U.S. health care spend[1], inpatient care is an area where CMS needs to focus on for the agency to be a good steward of the Medicare and Medicaid programs and a good partner with the private sector in advancing transparency.

- **Proposed adoption of Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data to IQR**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule –p. 1135 – June 24, 2019

We support the proposed planned transition from a claims-only based hospital-wide readmission measure to a hybrid measure. Our support is based on evidence that the hybrid measure is an improvement to the existing measure. More specifically, the testing of the risk model demonstrated better discrimination of the risk model in the hybrid measure[5]. We applaud CMS for their effort to improve upon this important measure of inpatient quality.

- **Solicitation of public comments on select measures for potential future IQR use**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p.1161 – June 24, 2019

The Leapfrog Group supports the three noted measures for future inclusion in the IQR. We want to especially stress the importance of the Cesarean Birth (PC-02) measure, which begins to address a gap in the measurement and reporting of maternity care. Childbirth is an important area to address for both public and private payors as childbirth is the number one reason for hospitalization in the United States[6]. Moreover, given approximately half of all births are paid for Medicaid[7], maternity should be a high priority area for CMS to measure performance. While a number of states report C-section rates to some extent using varied measures and methodologies, implementing this standardized measure in Hospital Compare would give us national benchmarks as the basis for ascertaining hospital performance.

Having expressed support for these measures, we reiterate our disappointment that CMS is only soliciting comments on three measures for potential use in IQR, despite a clear need for more and better information available to the public, as well as private and public sector purchasers.

There are a number of additional measures worthy of consideration to add to IQR. We urge CMS to take advantage of the IPPS process to solicit comments on a much fuller set measures. One example is the recently developed Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure. There is both a claims only version (NQF #3504) and a hybrid version (NQF #3502) of the measure. This measure, as with many other measures absent from CMS' solicitation, shows promise and the NQF Scientific Methods Panel recently approved both versions of the measure. Additionally, in the March 2019 MedPAC report to Congress, MedPAC recommended including this measure in their proposed overhaul of the CMS hospital value-based purchasing program[8].

- **Solicitation of public comments on expanded confidential reporting of social risk factors**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 1184 – June 24, 2019

Leapfrog strongly opposes the private sharing of social risk factor reports. Hospital Compare is a program funded with taxpayer dollars and the program should inform the public on how hospitals differentiate in quality and safety, and should not be used as a conduit for hidden data. Therefore, all IQR related reporting should be fully transparent to the public.

Leapfrog does not support any actions by CMS, publicly reported or not, to alter measure technical specifications to include social risk factors. It appears CMS is contemplating this; an example of such text from the FY20 proposed rule follows:

> "The two disparity methods and the stratified methodology used by the Hospital Readmissions Reduction Program are all part of CMS' broader efforts to account for social risk factors in quality measurement…."

Quality measurement should gauge how well the facility performs while adjusting for clinical variables of its population. Measurement should not control for social risk factors which has the result of hiding the quality of care a hospital delivers to people given their race, income or other such characteristics unrelated to diagnosed health status. While CMS appears to note that baking social risk factors into the measures may occur later, we want to state that The Leapfrog Group is strongly against revising measures—and hiding the experience of patients with these characteristics— by way of including such variables. We support CMS pursuing instead strategies to revise payment rules to reflect the population factors that create unusual challenges for safety-net hospitals, but revising the public reporting of quality and safety data is not good public policy and a moral hazard.

- **Proposed reporting and submission requirements for eCQMs for the CY21 – 22**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 1195 – June 24, 2019

We recommend that CMS set the mandate for hospitals regarding which measures are to be reported as well as the time period for reporting the measures. Permitting self-selection of measures by hospitals hinders transparency, as consumers do not have a standardized set of measures in their evaluation of hospitals. It also promotes allows hospitals to cherry pick the measures they look the best in. The information is too critical to consumers' life and health to permit such gaming.

Regarding the self-selection of the measurement time period, this is problematic in that older data would then be permitted to be used. One of the primary concerns levied in health care performance measurement is the lack of timeliness of the data. If CMS allows for hospitals to draw on older data, this timeliness issue is exacerbated. It also allows for further gaming. When a hospital can pick which time period to use, they are likely to select the quarter they appear the best in from the available quarters.

Lastly, regarding the measurement period, the CMS proposal discussed the selection of a quarter of data. In most circumstances, a quarter of data is woefully insufficient to both appropriately measure a given dimension of quality and identify issues with the data. An example of the former: Small and rural hospitals often have a challenge meeting a minimum reporting threshold (such as 25 cases) when the measurement period is a year, two or even three. We recommend that CMS should not only require the time period to employ, but that time period needs to be a year or greater.

HOSPITAL ACQUIRED CONDITION REDUCTION PROGRAM

- **Proposed adoption of measure removal policy for the HACRP**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 987 – June 24, 2019

First and foremost, the measure removal policy should center on the best interests of Medicare beneficiaries and Medicaid recipients. Secondarily, the policy should consider the best interests of the public at large. The proposed measure removal policy does not put a priority on either of these constituencies. Surprisingly there is no criterion proposed on whether the measure is important to beneficiaries or the public at large. We recommend addition of that criteria as the new "Factor 1" to stress that the measure removal policy is indeed consumer-centered.

Regarding the current "Factor 1" (i.e. "topped out" measures), we suggest removing this criterion. CMS' methodology to identify "topped out" performance in a measure is problematic for two reasons. First, a

number of measures employed in health care performance measurement are "never events" which, while acknowledged as rare, are catastrophic when they do happen. What looks like a low prevalence might in fact be unacceptably high when events are both highly preventable and catastrophic to the patient. Secondly, CMS primarily determines "topped out" by comparing performance at the 75th and 90th percentile where higher percentile means better performance. This is problematic in several ways. Often consumers and purchasers are interested in avoiding poor performers who are in lower percentiles. CMS' method does not take into account the extent of variation of performers in the lower percentiles. Additionally, last year we looked at several measures that were removed citing "Factor 1" (i.e. topped out) as the rationale. However, across all facilities with ratings (not just examining this narrow band of 75th to 90th percentile) we observed a high degree of variation from bottom to top performers.

Regarding the current "Factor 8" (i.e. a cost – benefit of the measure), Leapfrog opposes this criterion unless "costs" and "benefits" are defined as "costs to Medicare beneficiaries and the public" and "benefits to Medicare beneficiaries and the public." When this criterion was introduced in the IPPS FY19 proposed rule, CMS appeared to define "costs" and "benefits" as "cost to hospitals" and "benefits to hospitals," which is not an appropriate criterion for CMS' stewardship of public funds.

We recommend full transparency in the defining of each criterion including how a given calculation applies to beneficiaries. Furthermore, CMS needs to develop and publicly share how the terminology in each criterion is operationalized (see "cost" and "benefit" example discussed above). Specifically, it should be made transparent how such terms are tested and what results will empirically determine whether the criterion is met or not. In most cases, the terminology used across these eight criteria are not defined, specified or defended. That is unacceptable.

- **Proposed changes to validating the CDC HAI measures under the HACRP**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 992 – June 24, 2019

While we support improvements to data validation, what is proposed is woefully inadequate to making marked changes in data quality. All of the changes in the proposed rule are solely based on the selection process of hospitals for validation instead of being based on improvements to the methods for validation of the data elements. With recent attention given to data quality of the CDC HAIs, we are disappointed at CMS' tepid response. The Leapfrog Group supports efforts to better measure health care providers' performance, which is dependent on valid and reliable data.

There are a variety of recent high profile data validation recommendations that CMS should act on integrating as soon as possible. One such example comes from the OIG report that is cited in the proposed rule, which involves CMS and the CDC working collaboratively on sharing case level data for validation purposes[9]. Another example is a study by Calderwood[10], which was cited in MedPAC's March 2019 report to Congress[8], that contains viable data validation methods.

VALUE BASED PURCHASING PROGRAM

- **Proposed changes to validating the CDC HAI measures under the VBP Program**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 982 – June 24, 2019

While we support improvements to data validation, what is proposed is woefully inadequate to making marked changes in data quality. All of the changes in the proposed rule are solely based on the selection process of

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- **Proposed streamlining of processes regarding the CDC HAIs across VBP Program and IQR (as the measures are to be retired from IQR)**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 980 – June 24, 2019

In our review of the IPPS FY19 proposed rule, we were greatly concerned about CMS' commitment to publicly report the CDC HAIs in a consumer friendly way should these measures indeed be retired from IQR, as stated in the FY19 proposed rule. An excerpt from our comments regarding the FY19 proposed rule stated the following:

> "We strongly recommend CMS state the specifics of the way in which the CDC HAIs will be reported on Hospital Compare. While CMS makes some general statements about continuing to report on Hospital Compare, Leapfrog suggests to state precisely what will be reported (e.g. four quarters of data) and how (e.g. availability of results on the CMS Hospital Compare data download site at data.medicare.gov)…."

The FY19 final rule and the FY20 proposed rule unfortunately missed the opportunity for CMS to commit to specifics on the way in which the CDC HAIs will be reported on Hospital Compare after they are retired from IQR. Again, we urge CMS to provide much greater detail in the IPPS final FY20 rule on the future reporting of these important measures in regard to data refresh and reporting frequency, granularity of reporting hospital performance and display with supporting text that is highly evaluable and consumer friendly. **It is a major priority to our constituents and patient advocates that public reporting of infection measures will be at least as robust as it is today within the IQR.**

HOSPITAL READMISSIONS REDUCTION PROGRAM

- **Proposed adoption of measure removal policy for the HRRP**

The Leapfrog Group comments to CMS on the FY 2020 IPPS Proposed Rule – p. 938 – June 24, 2019

First and foremost, the measure removal policy should center on the best interests of Medicare beneficiaries and Medicaid recipients. Secondarily, the policy should consider the best interests of the public at large. The proposed measure removal policy does not put a priority on either of these constituencies. Surprisingly there is no criterion proposed on whether the measure is important to beneficiaries or the public at large. We recommend addition of that criteria as the new "Factor 1" to stress that the measure removal policy is indeed consumer-centered.

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We recommend full transparency in the defining of each criterion including how a given calculation applies to beneficiaries. Furthermore, CMS needs to develop and publicly share how the terminology in each criterion is operationalized (see "cost" and "benefit" example discussed above). Specifically, it should be made transparent how such terms are tested and what results will empirically determine whether the criterion is met or not. In most cases, the terminology used across these eight criteria are not defined, specified or defended. That is unacceptable.

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