THELEAPFROGGROUP

September 27, 2019

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

RE: RIN 0938-AT74 Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-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 from health care facilities at the national level, thereby bringing a unique perspective to measurement. We appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services on the proposed changes to the FY 2019 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs rule.

Along with CMS, employers and purchasers have a vested interest in ensuring Americans have the tools to compare health care facilities, including hospitals and ambulatory surgery centers, before selecting the place where they, and their loved ones, will receive care. With that in mind, we strongly advise CMS to put a priority on transparency throughout all of its programs. From a business perspective, there is no force for change greater than the demands of well-informed 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 and of patient safety and other risks associated with receiving care in various health care settings.

For the past 19 years, Leapfrog has been collecting quality and safety information about hospital inpatient care. Beginning this year, Leapfrog expanded to also collect information from ambulatory surgery centers (ASCs) and hospital outpatient departments (HOPDs). Leapfrog will begin publicly reporting this data in 2020. Today, the majority of surgeries are performed in outpatient or ambulatory settings. That trend is growing rapidly because these settings offer the opportunity for improved patient experience, greater cost-efficiency, and the prevention of unintended patient harm that can results from hospital stays (i.e. healthcare associated infections). Unfortunately, the availability of independent, publicly reported information about patient safety and quality for

outpatient and ambulatory surgery is currently inadequate, so purchasers and consumers do not have the information they need to select the best place for their care.

Additionally, we have three key recommendations related to the proposed rule we feel are critical enough to warrant more detail in our letter:

1.) More and better information

The vast majority of surgeries in the United States are now performed either as outpatient procedures at hospitals or at ASCs. This is a phenomenon that emerged rapidly over the past decade, and one that many welcome, since it suggests opportunities for patients to receive less-invasive surgical care, and for costs to be reduced. However, the opportunity is wasted when consumers and payors lack basic information to compare the safety and quality of surgical care offered at these settings. Yet beneficiaries and the public at large have almost no information about quality and safety to use in selecting a site for their surgery, unless they seek inpatient care. That is because the Hospital Outpatient Quality Reporting Program (HOQR) and Ambulatory Surgical Center Quality Reporting Program (ASCQR) are much less evolved compared to inpatient hospital-level measurement and transparency.

Despite the urgent need to offer consumers and payors information to compare among surgical procedures not performed on an inpatient basis, this proposed rule does not propose enough new measures.

We are disappointed in the early stages of CMS's Meaningful Measures initiative. CMS has used the initiative as a tool to reduce versus further transparency of value to consumers and payors. To be impactful in the Meaningful Measures areas, CMS should quickly add instead of remove performance measures in these facility types that are meaningful to consumers, payors and purchasers for use in selecting facilities for their care, for their networks and for alignment of payment with performance.

2.) Improved comparison between hospital outpatient surgery centers and ASCs

Beneficiaries and consumers at large care about the quality and safety of the procedure they seek, not whether the setting it is performed in is a hospital or an ASC. Measures of surgical procedures should produce ratings that allow for comparisons of the same procedure when performed in both settings. Presently this is not occurring.

Given that CMS is a primary funding source for measurement, the agency can substantially reshape the landscape as to the units of analysis addressed by measures. We recommend that CMS implement requirements in future measure development and maintenance contracts to address this issue of units of analysis. In terms of measure maintenance contracts, where there are existing measures of specific surgical procedures for ASCs only or outpatient hospitals only, CMS should direct its contractors to re-specify the measure to also work for the unit of analysis not yet measured. For measure development contracts, CMS should require that any measures of surgical procedures that occur in the ASC and outpatient hospital setting be specified for both units of analysis.

3) Cost data must be paired with quality data in order to provide consumers with valuable information

The Leapfrog Group supports President Trump's and CMS' commitment to improving transparency for consumers. However, reporting of cost needs to occur concurrently with quality. Reporting price alone will not result in any substantial change. A service offered at a low price is not a bargain when quality is poor.

For example, a procedure even at the most competitive price is a waste of money if it was not needed in the first place. Also, if the person suffers an infection or error that needs to be later fixed, it can result in the provider actually being the highest price when looking at the total cost for the episode of care. Price transparency alone does not bring down costs. Quality is a critical part of transparency because there is wide differentiation in quality between facilities, as seen in the data reported in our annual Leapfrog Hospital Survey. If you want to focus on cost control, you must drive a market for quality. We strongly urge CMS to take this into consideration.

In the appendix below are detailed comments pertaining to the following areas addressed in the proposed rule:

- **ASCQR Program**
  - Proposed addition of Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
  - Solicitation of comments on updating the submission methods for four measures
- **HOQR Program**
  - Proposed removal of External Beam Radiotherapy for Bone Metastases
  - Solicitation of comments on adopting four patient safety measures in the future
  - Solicitation of comments on measures to add to, and remove from, the OQR program in the future
- **Other**
  - Solicitation of comments on improvements to hospital price transparency
  - Proposal to add select knee procedures and coronary intervention procedures to the list of ASC covered procedures
  - Solicitation of comments on the potential to add coronary intervention procedures to the list of ASC covered procedures
  - Quality and price transparency to improve beneficiary access to information

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, and our members, we appreciate the opportunity to provide comments on the proposed changes to the FY 2020 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 OPPS FY 2020 proposed rule:

Colorado Business Group on Health
Consumers' Checkbook
Dallas Fort Worth Business Group on Health
The Economic Alliance for Michigan
Florida Alliance for Healthcare Value
Greater Philadelphia Business Coalition on Health
Health Action Council
HealthCare 21
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
Memphis Business Group on Health
Midwest Business Group on Health
New Jersey Health Care Quality Institute
Pacific Business Group on Health
Pittsburgh Business Group on Health
South Carolina Business Coalition on Health
St. Louis Area Business Health Coalition
WellOK, The Northeastern Oklahoma Business Coalition on Health
Wyoming Business Coalition on Health

Appendix: Detailed Comments

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2020 OPPS AND ASC PROPOSED RULE

AMBULATORY SURGICAL CENTER QUALITY REPORTING PROGRAM

- **Proposed addition of Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (ASC-19) (NQF #3357)**

The Leapfrog Group comments to CMS on the FY 2020 ASC Proposed Rule – p. 534 – September 27, 2019

The Leapfrog Group strongly supports the addition of the proposed measure titled "Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers".

As with all measures, there is room for improvement. The proposed rule notes some questionable exclusions to the measure, which are:

a) Gastrointestinal endoscopy, endocrine, or vascular procedures, other than varicose vein procedures;
b) High risk profile cases; and
c) Cases outside the scope of general surgery practice

Reducing cases captured in the denominator results in the measure being less and less representative of consumers' situations when shopping for facilities based on quality. Additionally, in the NQF endorsement process, it is desirable for measures to minimize exclusions. Thus, NQF requires that exclusions need to be justified. Note that the proposed rule states no rationale for the "b" and "c" exclusions.

The reason provided in the OPPS proposed rule for excluding "a" (i.e. events are typically due to comorbidities vs. quality) is arguable. There are methodologies to address such cases, which would preserve these cases in the measure. We urge CMS to reconsider these exclusions, especially "a," as people undergoing such procedures represent a significant share of cases for an ASC.

However, we strongly support this measure regardless of the modifications, because employers need and cannot collect this data without CMS. This measure fosters public-private alignment in pursuing quality improvement.

- **Solicitation of comments on updating the submission methods for four measures**

The Leapfrog Group comments to CMS on the FY 2020 ASC Proposed Rule –p. 552 – September 27, 2019

In general, we support the CMS proposal to update the data submission for ASC-1 through ASC-4 measures. But we feel it is critical that these measures should apply to all adult patients, not just Medicare fee-for-service. The

reporting of these measures could occur through QualityNet as other chart abstracted measures have been reported there for both ASCs and HOPDs.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

- **Proposed removal of External Beam Radiotherapy for Bone Metastases (OP-33) (NQF #1833)**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule – p. 506 – Sept. 27, 2019

The measure is valuable in that it gauges overuse of health care services. Given that waste in our health care system is approximately 30% of health care spend[1], which purchasers and ultimately consumers end up bearing, The Leapfrog Group recommends maintaining this measure. Further, this is a measure where overuse means exposing people unnecessarily to radiation. Such exposure puts the person at risk of harm. In the current measurement period reported on CMS Hospital Compare, the average rate of occurrence in this measure is 85% for facilities qualifying to report[2]. This very high rate of incidence indicates there is much harm that can be avoided and waste that can be curbed.

Two of the primary reasons stated for removing the measure from the OQR program is that health care providers complain about accurately documenting the information necessary to calculate the measure. CMS needs to adopt a measurement framework that prioritizes consumer needs, not industry preference. We have little empathy for such complaints from the health care industry when it is concurrently exposing people to harmful radiation and taxing patients' pocketbooks. In fact, 20% of consumers go without needed medical care due to high health care costs[3].

The third rationale provided for retiring the measure is that the measure steward is no longer maintaining the measure. Without an entity in the role of measure steward, the measure will eventually be invalid and unreliable. We note here that the measure steward is presently CMS4. Thus, it is readily within the control of CMS to decide to continue supporting the measure. We urge CMS to continue the maintenance of the measure or identify an entity to act as the measure steward, which would allow the measure to stay in the OQR program.

- **Solicitation of comments on adopting four patient safety measures in the future**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule – p. 512 – Sept. 27, 2019

Leapfrog fully supports aligning measures employed in the ASCQR and OQR programs wherever possible. This is a prime example of the opportunity to make progress in such alignment. We applaud that CMS is considering re-specifying the ASC-1 through ASC-4 measures (which are currently specified for the ASCQR program) for the OQR program. In many instances, a consumer has the option to have a given service rendered in an ASC or hospital outpatient department. In these circumstances, a person should have the ability to ascertain quality in both ASCs and outpatient facilities in their area. Reporting these important outcome measures in both types of settings furthers consumers' ability to factor in quality while shopping for services. However, one important note is that these measures should apply to all adult patients, not just Medicare fee-for-service.

- **Solicitation of comments on measures to add to, and remove from, the OQR program in the future**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule – p. 518 – Sept. 27, 2019

In regard to soliciting process measures for removal, if any the OAS CAHPS measures are considered processes, we recommend maintaining these measures in the OQR program. These are important measures of quality for a variety of reasons. CAHPS instruments have a long standing track record of meeting high reliability and validity standards. Additionally, a number of the CAHPS domains have been evidenced to be correlated with outcomes of care[5].

HOSPITAL PRICE TRANSPARENCY

- **Solicitation of comments on improvements to hospital price transparency**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule– p.578 – Sept. 27, 2019

We applaud the Administration's leadership improving price and quality transparency as stated in President Trump's June 24th Executive Order. This specific section of the OPPS proposed rule focuses on soliciting comments regarding cost reporting. The Leapfrog Group recommends that reporting of cost needs to occur concurrently with quality. Reporting price alone will not result in any substantial change. A service offered at a low price is not a bargain when quality is poor. For example, a procedure even at the most competitive price is a waste of money if it was not needed in the first place. Also, if the person suffers an infection or error that needs to be later fixed, it can result in the provider actually being the highest price when looking at the total cost for the episode of care. Price transparency alone does not bring down costs. Quality is a critical part of transparency because there is wide differentiation in quality between facilities, as seen in the data reported in our annual Leapfrog Hospital Survey. If you want to focus on cost control, you must drive a market for quality. We strongly urge CMS to take this into consideration.

The section below titled "RFI: Quality and price transparency to improve beneficiary access to information" invites comments regarding the reporting of quality and costs. Thus, we provide additional recommendations in this section below.

PROCEDURES PAID FOR ON AN OUTPATIENT BASIS

- **Proposal to add select knee procedures and coronary intervention procedures to the list of ASC covered procedures**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule– p.462 – Sept. 27, 2019

The Leapfrog Group recommends that CMS develop and implement quality measures for any procedures under consideration for adding to the list of ASC covered procedures. Further, these measures, at a minimum, should be comprised of patient safety measures. Such measurement would ensure Medicare beneficiaries will not be exposed to unnecessary risk of harm in electing to have a procedure performed in an ASC setting.

An efficient measure development process would identify and adapt measures already in place in the inpatient setting. For example, CMS presently has a measure titled "Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and total knee arthroplasty" (NQF #1550), which is used in Hospital Compare. Additionally, many AHRQ Patient Safety Indicators (PSIs) are based on surgical cases. A number of surgical PSI are in a composite appearing on Hospital Compare (i.e. "PSI 90"). The PSIs are important given the types and extent of harm measured. CMS could benefit from AHRQ's work in these measures by modifying the denominator to work for procedures being considered for an ASC setting. Elsewhere in this proposed rule, CMS notes it is considering re-specifying ASC measures to the outpatient hospital setting. Thus, it would be consistent for CMS to explore repurposing such inpatient measures for the ASC and/or outpatient hospital setting.

- **Solicitation of comments on the potential to add coronary intervention procedures to the list of ASC covered procedures**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule– p.469 – Sept. 27, 2019

The Leapfrog Group recommends that CMS develop and implement quality measures for any procedures under consideration for adding to the list of ASC covered procedures. Further, these measures, at a minimum, should be comprised of patient safety measures. Such measurement would ensure Medicare beneficiaries will not be exposed to unnecessary risk of harm in electing to have a procedure performed in an ASC setting.

An efficient measure development process would identify and adapt measures already in place in the inpatient setting. For example, many AHRQ Patient Safety Indicators (PSIs) are based on surgical cases. A number of surgical PSI are in a composite appearing on Hospital Compare (i.e. "PSI 90"). The PSIs are important given the types and extent of harm measured. CMS could benefit from AHRQ's work in these measures by modifying the denominator to work for procedures being considered for an ASC setting. Elsewhere in this proposed rule, CMS notes it is considering re-specifying ASC measures to the outpatient hospital setting. Thus, it would be consistent for CMS to explore repurposing such inpatient measures for the ASC and/or outpatient hospital setting.

REQUESTS FOR INFORMATION

- **RFI: Quality and price transparency to improve beneficiary access to information**

The Leapfrog Group comments to CMS on the FY 2020 HOQR Proposed Rule– p.654 – Sept. 27, 2019

The Leapfrog Group recommends that reporting of cost needs to occur concurrently with quality. Reporting price alone will not result in any substantial change. A service offered at a low price is not a bargain when quality is poor. For example, a procedure even at the most competitive price is a waste of money if it was not needed in the first place. Also, if the person suffers an infection or error that needs to be later fixed, it can result in the provider actually being the highest price when looking at the total cost for the episode of care.

Secondly, consumers tend to associate cost with quality. For example, people often perceive that low cost providers provide lower quality care[6,7,8]. To address this misunderstanding, methods have been developed and tested that report quality alongside cost. Providing a fuller "value" picture consisting of quality plus cost, using consumer friendly techniques, leads to people more appropriately identifying higher value health care providers. With the right information and reporting methods people can see that low cost providers often

provide high quality care[6,8]. In regard to the methods and attributes of effectively reporting quality and cost, we recommend to also consider criteria developed by AHRQ to use in designing CMS' transparency tools. AHRQ's "PRICE" criteria consist of: 1) price transparency, 2) real comparisons, 3) information on value, 4) connect to care, and 5) ease of use[9].

Third, the reporting of quality and cost in health care is especially important in that there is a lack of evidence that health care quality and cost are strongly correlated[10]. Meanwhile, in other industries, price often provides us a reasonable proxy for quality. Given this is not true in health care, we must report quality and cost together. Further, the RFI solicits types of quality information to report with cost. Leapfrog recommends to measure and report outcomes where possible. Specifically, the RFI mentions reporting complications, which we whole-heartedly support. However, CMS' aspiration to report meaningful quality measures with cost is inconsistent with actions undertaken to date in its "Meaningful Measures" initiative. On one hand, CMS has used Meaningful Measures thus far as a tool to reduce versus further transparency of quality. On the other hand, in this proposed rule CMS is recommending to be transparent with the price of 300 shoppable services. For people to truly have meaningful and balanced information on these shoppable services means creating numerous quality measures to compliment the cost in these specific areas of care.

CMS notes that it defines "shoppable services" as "a service package that can be scheduled by a health care consumer in advance. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them." According to this definition, vaginal deliveries are not a shoppable service. However, virtually every time one reads about shoppable services, deliveries are cited as a prime example. Leapfrog recommends CMS amend its definition to include deliveries.

In summary, we applaud CMS' recommendation and direction to be transparent with cost. In light of this direction, CMS is now at a crossroads with Meaningful Measures. The Leapfrog Group recommends CMS needs to re-evaluate the goals of Meaningful Measures and how it will evaluate its progress. Simply put, we suggest that reporting cost without commensurate quality ratings will be an indication Meaningful Measures is failing. Reporting cost with quality in a highly evaluable manner that allows people to truly shop based on value indicates the initiative is succeeding.

Note: Page numbers correspond with rule issued in August 2019 at https://www.federalregister.gov/documents/2019/08/09/2019-16107/medicare-program-proposed-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical.

CITATIONS

1. Dzau, V. J., McClellan, M., McGinnis, J. M. and Finkelman, E. M., editors. 2017. "Vital directions for health and health care: An initiative of the National Academy of Medicine". Washington, DC: National Academy of Medicine.

2. Analysis performed with the CMS Hospital Compare download file accessed 9/9/10 at: https://data.medicare.gov/data/hospital-compare

3. Kaiser Family Foundation. "Key facts about the uninsured population". Published Dec. 2018. Accessed online 9/5/19 at https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/

4. Quality Reporting Center. "CMS measure inventory tool: External beam radiotherapy for bone metastases". Accessed online 9/5/19 at file:///C:/Users/thebo/Downloads/ExternalBeamRadiotherapyforBon%20(4).pdf

5. Price, R. A., Elliott, M. N., Zaslavasky, A. M., Hays, R. D., Lehrman, W. G., Rybowski, L., Edgman-Levitan, S., Cleary, P. D. "Examining the role of patient experience surveys in measuring health care quality". Medical Care Research and Review. July 2014; p. 1-33.

6. Hibbard, J. H., Greene, J., Sofaer, S., Firminger, K, Hirsh, J. "An experiment shows that a well-designed report on costs and quality can help consumers choose high-value health care". Health Affairs. 2012, p. 560 – 568.

7. Phillips, K. A., Schleifer, D., Hagelskamp, C. "Most Americans do not believe that there is an association between health care prices and quality of care". Health Affairs. 2016, p. 647 – 653.

8. Wu, S. J., Sylwestrza, G., Shah, C., DeVries, A. "Price transparency for MRIs increased use of less costly providers and triggered provider competition". Health Affairs. 2014, p. 1391 – 1398.

9. Bridges, J., F., P., Berger, Z., Austin, M., Nassery, N., Sharma, R., Chelladurai, Y., Karmarkar T., D., Segal, J., B. "Public reporting of cost measures in health: An environmental scan of current practices and assessment of consumer centeredness. Technical brief no. 19". (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No.290-2012-00007-I). AHRQ Publication No. 15-EHC009-EF. Rockville, MD: Agency for Healthcare Research and Quality. March 2015. Accessed online 9/9/19 at: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/public-reporting-cost-measures_technical-brief.pdf

10. Hussey PS, Wertheimer S, Mehrotra A. "The association between health care quality and cost: A systematic review". Annals of Internal Medicine. 2013 Jan. 1;158(1):27-34.