THE LEAPFROG GROUP
Giant Leaps for Patient Safety

September 13, 2022

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

RE: RIN 0938–AU82 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Ms. Brooks-LaSure,

The Leapfrog Group, our Board of Directors, members and interested parties 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 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs rule.

For over 20 years, Leapfrog has been collecting quality and safety information about hospital inpatient care. In 2019, Leapfrog expanded to also collect information from ambulatory surgery centers (ASCs) and hospital outpatient departments (HOPDs). Leapfrog began publicly reporting these data in September 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 (e.g., 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. We know the COVID-19 pandemic has placed an incredible strain on the U.S. health care system. However, there is no more important time than the present for consumers and purchasers to have access to quality and safety data about the facilities they are sending their families and employees to for their care.

Therefore, we strongly urge CMS to require all accredited ASCs to submit comprehensive safety and quality data to a nonprofit organization with extensive experience in collecting and reporting hospital and ASC quality data on a public website, such as The Leapfrog Group. In order to ensure the data is trusted and useful for purchasers and consumers, the reporting should utilize consensus-based nationally endorsed standards. The annual Leapfrog ASC Survey, as well as the Leapfrog Hospital Survey, are predicated on the latest science and are

selected with guidance from scientific advisors at the Armstrong Institute for Patient Safety at Johns Hopkins Medicine as well as Leapfrog's volunteer Expert Panels. More and more complex surgeries are moving to an outpatient setting, yet patients and purchasers do not have access to enough information to be able to make an informed decision on where to go for care. It is critical for CMS to make this requirement to ensure Medicare beneficiaries have access to the safest, highest quality surgical care possible.

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

1.) Report by individual bricks-and-mortar facility

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 and shared NPI.

There are instances where up to nine hospitals several miles apart and offering very different services share a single Medicare identifier. When safety, quality and resource use metrics are reported in this way, it obscures the individual performance of a given facility delivering the care, which is misleading and unhelpful to patients. Patients do not seek care from a system; they seek care from individual facilities and clinicians. Providers and administrators can also benefit from being able to readily discern the performance at their own facility and determine where improvements are needed.

2.) Improved comparison between hospital outpatient departments and ASCs

Consumers 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 agnostic to setting. At present, this is infeasible.

Given that CMS is a primary funding source for measure development, the agency can substantially reshape the measurement landscape to promote measures equally applicable in multiple care settings. In fact, the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) prioritized cross-setting comparisons in the post-acute and long-term care domain. Likewise, we recommend that CMS implement requirements in future measure development and maintenance contracts to rectify this serious deficit in measure's utility to consumers. 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 assess 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 settings.

In the appendix below are detailed comments pertaining to the HOQR and ASCQR programs as addressed in the FY 2023 Proposed Rule.

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 interested parties, we appreciate the opportunity to provide comments on the proposed changes to the FY 2023 proposed rule.

Sincerely,

Leah Binder, M.A., M.G.A

President & Chief Executive Officer
The Leapfrog Group

Additional Individuals and Organizations Supporting Leapfrog's comments on the CMS OPPS FY 2023 proposed rule:

William Bonk, Techtronic Industries North America, Inc.
Raquel Bono, RCB Consulting LLC
Capital HealthCare Group, LLC
CSS/Consumers' Checkbook
DFW Business Group on Health
The Economic Alliance for Michigan
The ERISA Industry Committee
Florida Alliance for Healthcare Value
Maureen Ryan Fogarty, Odgers Berndtson
Irene Fraser, Leapfrog Group Board Member
Greater Philadelphia Business Coalition on Health
Health Action Council
HealthCare 21
Health Policy Corporation of Iowa
Karen Jupiter, Consumer
Kentuckiana Health Collaborative
Lehigh Valley Business Coalition on Healthcare
Louisiana Business Group on Health
Ashley Tait-Dinger, Consumer
Health Transformation Alliance
Purchaser Business Group on Health
Kara Sasse, Consumer
WellOK - The Oklahoma Business Coalition on Health

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2023 OPPS AND ASC PROPOSED RULE

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

- **Proposal to change the cataract improvement in visual function measure (OP-31) from mandatory to voluntary**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 565 – September 13, 2022

The Leapfrog Group strongly recommends that CMS stay the course and keep to CMS' plan per the OPPS FY 2022 rule: Require reporting of the OP-31 measure for the FY 2025 reporting period. In the proposed rule, CMS provides a sound rationale for this plan, which is *"[H]ospitals have had the opportunity … to familiarize themselves with OP-31, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period."* Despite this reasonable approach, CMS is proposing in this rule to defer any plan to make this measure mandatory. There are four million cataract procedures performed every year in the U.S. and it is the most common procedure performed by ophthalmic surgeons.[12, 13] Outcomes from this procedure are not fully apparent until time has elapsed since the surgery. It should not be acceptable for a provider to consider this surgery complete without insight into the patient outcome.

Note that this plan to move from voluntary to mandatory reporting has already been delayed from CMS' initial plan to make the measure mandatory for the FY 2023 reporting period. CMS' stated reason for the two-year delay (from FY 2023 to FY 2025) was providers' perception of the reporting burden and that since the measure was voluntary, many facilities have failed to practice the reporting of it in the voluntary period. It is deeply concerning that only a handful of facilities are voluntarily collecting this data which is why it should be mandatory. While we recognize this involves some burden on the part of facilities, it is a burden that should be considered essential to the delivery of services, not just quality reporting. Just as facilities sanitize instruments and scrub prior to surgery, so should they monitor patient outcomes to be assured they are performing procedures that benefit their patients.

In this proposed rule, the reason CMS cites to cancel plans to make reporting of the measure mandatory is *"Interested parties have indicated that they are still recovering from the COVID-19 PHE and that the requirement to report OP-31 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes."* The party most interested in the outcome of cataract surgeries are patients, Medicare beneficiaries and others, who should be the priority for CMS rulemaking. While staffing shortages are a critical concern, that should not absolve facilities of the responsibility of determining outcomes of procedures that are performed. Indeed, patient reported outcomes should be part of the standard of care, especially in the outpatient and ambulatory setting where outcomes are often not observable as they are in the inpatient setting. Without information on patient outcomes, surgical teams could potentially repeat patterns of practice that are failing, or not take advantage of techniques that are exceptionally effective. The best way to know those outcomes is to ask the patient through a tested and reliable questionnaire. In addition

to giving surgical teams critical information to assure their safety, it gives patients needed data to make informed decisions about where to seek care.

- **Request for comment: Volume measurement**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 569 – September 13, 2022

We recommend the reintroduction of using the volume of procedures as a required quality measure. A plethora of studies have demonstrated a relationship between superior patient outcomes and routine procedures/care[1,2,3]. Given the scarcity of measures in the OQR Program, the measure would provide consumers with critical data on HOPD quality.

Beyond offering our support for the measure, we have several improvements to the use of volume as a measure of quality. First, we suggest expanding the dataset from Medicare Fee-for-Service (FFS), as was the data source when CMS last measured volume, to all payer data, which would then include pediatric cases as well as patients covered by commercial insurance, Medicaid, self-pay, and others. If CMS restricts the sample to Medicare FFS the volume calculations may not lead to evidence-based conclusions about outcomes, because Medicare FFS is a subset of the population.

The remaining recommendations center around the clinical areas that are proposed for inclusion in a volume measure. We recommend expanding the reporting of clinical areas beyond the eight stated in the proposed rule. If a volume measure has value for consumers to assist them in shopping in these eight areas, it is also important to consumers seeking care in other clinical areas as well. Lastly, it would be more useful and valuable to consumers if the reporting of volume was at a more granular level than the proposed clinical areas. For example, the proposed "musculoskeletal" area includes a very large number of procedures therein. Such a high-level grouping of procedures is of lower value to consumers as they wonder how well the measure result reflects the procedure they need. The proposed clinical groupings would be more helpful to consumers if each were broken out into several more specific areas (e.g., knee procedures, hip procedures, etc.).

- **Request for comment: Principles for measuring healthcare quality disparities across CMS quality**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 574 – September 13, 2022

Leapfrog supports CMS' overarching theme that runs through this request for comment: Consistency among salient CMS programs regarding the measurement of quality disparities. CMS' message touches more lives when the same message is sent regardless of the program. Further, such consistency provides a stronger, more articulate message to the provider community when that direction is unwavering. With this, we are surprised to see this request for comments appears in the OQR Program section, but it is absent from the ASCQR Program section. In fact, the proposed rule states "…considerations that we might take into account across all CMS quality programs, including the Hospital OQR Program". Note again the silence regarding the ASCQR Program. We perceive the finalized principles that are arrived on should apply to not only the OQR Program, but the ASCQR Program as well.

Lastly, we would like to restate our comments on the same request for comment that appeared in the IPPS FY 2023 proposed rule. These comments follow:

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 our country is facing. A model for such investigation is recent Urban Institute research on the differences between Black and white patients in their experience of adverse safety events in an inpatient setting[11].

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.

AMBULATORY SURGICAL CENTER QUALITY REPORTING PROGRAM

- **Proposal to change the cataract improvement in visual function measure (ASC-12) from mandatory to voluntary**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 597 – September 13, 2022

The Leapfrog Group strongly recommends that CMS stay the course and keep to CMS' plan per the OPPS FY 2022 rule: Require reporting of the ASC-12 measure for the FY 2025 reporting period. In the proposed rule, CMS provides a sound rationale for this plan, which is "[Surgery Centers] have had the opportunity … to familiarize themselves with [ASC-12], prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period." Despite this reasonable approach, CMS is proposing in this rule to defer any plan to make this measure mandatory. There are four million cataract procedures performed every year in the U.S. and it is the most common procedure performed by ophthalmic surgeons.[12, 13] Outcomes from this procedure are not fully apparent until time has elapsed since the surgery. It should not be acceptable for a provider to consider this surgery complete without insight into the patient outcome.

Note that this plan to move from voluntary to mandatory reporting has already been delayed from CMS' initial plan to make the measure mandatory for the FY 2023 reporting period. CMS' stated reason for the two-year delay (from FY 2023 to FY 2025) was providers' perception of the reporting burden and that since the measure was voluntary, many facilities have failed to practice the reporting of it in the voluntary period. It is deeply concerning that only a handful of facilities are voluntarily collecting this data which is why it should be mandatory. While we recognize this involves some burden on the part of facilities, it is a burden that should be considered essential to the delivery of services, not just quality reporting. Just as facilities sanitize instruments and scrub prior to surgery, so should they monitor patient outcomes to be assured they are performing procedures that benefit their patients.

In this proposed rule, the reason CMS cites to cancel plans to make reporting of the measure mandatory is "Interested parties have indicated that they are still recovering from the COVID-19 PHE and that the requirement to report ASC-12 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes." The party most interested in the outcome of cataract surgeries are patients, Medicare beneficiaries and others, who should be the priority for CMS rulemaking. While staffing shortages are a critical concern, that should not absolve facilities of the responsibility of determining outcomes of procedures that are performed. Indeed, patient reported outcomes should be part of the standard of care, especially in the outpatient and ambulatory setting where outcomes are often not

observable as they are in the inpatient setting. Without information on patient outcomes, surgical teams could potentially repeat patterns of practice that are failing, or not take advantage of techniques that are exceptionally effective. The best way to know those outcomes is to ask the patient through a tested and reliable questionnaire. In addition to giving surgical teams critical information to assure their safety, it gives patients needed data to make informed decisions about where to seek care.

- **Request for comment: Specialty centered approach for the ASCQR Program**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 601 – September 13, 2022

Given the fact that nearly two-thirds of ASCs are single specialty facilities[4], Leapfrog supports the reporting of specialty specific measures where appropriate. Our support for such specialty specific measurement is contingent on three key considerations.

First, where an ASC elects to report a specialty measure, the facility should be required to report all measures in the specialty measure set. Such uniformity of measures provides consumers a comparable evaluation of quality when reviewing facilities for a given specialty care area. It also removes the gaming of measures where each facility selects the measures that they perform well in.

Secondly, reporting on a given specialty measure set must always include multiple patient safety measures, and those measures must be mandatory. Patient safety is a direct hazard to patients that can cut across all specialties, so it should be considered alongside reporting on outcomes and processes specific to the specialty.

Finally, measures employed in the ASCQR Program should be consistent with the OQR Program as well to assure reliable comparisons among facilities. For many procedures a consumer has the option to have it performed in an ASC or HOPD. To increase the comparability across programs for consumers, CMS should strive to measure these two types of facilities with the same measures where possible.

- **Request for comment: Volume measurement**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 611 – September 13, 2022

We recommend the reintroduction of using the volume of procedures as a required quality measure. Recent studies have demonstrated a relationship between superior patient outcomes and routine procedures/care[1,2,3]. Given the scarcity of measures in the ASCQR Program, the measure would provide a critical data about ASC quality to consumers and purchasers.

Beyond offering our support for the measure, we have several improvements to the use of volume as a measure of quality. First, we suggest expanding the dataset from Medicare Fee-for-Service (FFS), as was the data source when CMS last measured volume, to all payer data, which would then include pediatric cases. If CMS restricts the sample to Medicare FFS the premise is this sample fairly represents the volume across the total population served by the facility. However, this assumption is not always the case. Thus, for facilities where Medicare FFS is a small portion of their business, a volume measure solely based on this population would provide an incorrect measure rating that would be stated or interpreted as “low” / “poor.”

The remaining recommendations center around the clinical areas that are proposed for inclusion in a volume measure. We recommend expanding the reporting of clinical areas beyond the six stated in the proposed rule. If a volume measure has value for consumers to assist them in shopping in these six areas, it is also important to

consumers seeking care in other clinical areas as well. Lastly, it would be more useful and valuable to consumers if the reporting of volume was at a more granular level than the proposed clinical areas. For example, the proposed "musculoskeletal" area includes a very large number of procedures therein. Such a high-level grouping of procedures is of lower value to consumers as they wonder how well the measure result reflects the procedure they need. The proposed clinical groupings would be more helpful to consumers if each were broken out into several more specific areas (e.g., knee procedures, hip procedures etc).

- **Request for comment: ASC migration to eCQMs**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule – p. 612 – September 13, 2022

The Leapfrog Group fully supports opportunities to institute improvements to how we measure quality in health care settings. Thus, we strongly support CMS' consideration to transitioning to eCQMs in the measurement of ASC performance with several specific recommendations related to the request for comment in the OPPS proposed rule.

First, in this migration to eCQMs, we recommend that CMS align measures for a given concept (e.g., patient safety) across the ASC, HOPD, and inpatient hospital settings. An NQF report, which was based on deliberations of the Measure Application Partnership, recommended such an approach in creating / identifying "families" of measures[5]. Medicare beneficiaries and others seek to compare the safety and outcomes of care in various settings, and without aligned data they are unable to do so.

A second recommendation is regarding the use of "meaningful measures" when moving to eCQMs. Per the CMS "Meaningful Measures 2.0" framework, one of the primary aims of the framework is to "prioritize outcome and patient-reported measures"[6]. However, in the list of measures that appear in the proposed rule that CMS is requesting feedback on, the measures are solely structure and process measures. We would like to see CMS more fully operationalize their aim for their Meaningful Measures initiative: increase the use of outcome measures.

Lastly, and related to our meaningful measures recommendation above, we suggest that CMS act on the research and recommendations in a recent Office of Inspector General (OIG) report that CMS agreed with[7] and expand the number of measures reported. The May 2022 OIG report observed that over a quarter of Medicare patients were victim to a harmful event in the inpatient hospital setting, but only 5-10% of events were accounted for in currently deployed measures. The Inspector General recommended a significant expansion of measures and CMS agreed in the report. More specifically, the most frequently occurring type of harmful event cited in this recent report was medication related. Thus, we urge CMS to use the OIG report as a guide in the identification and development of eCQMs.

OTHER PROPOSALS/REQUESTS FOR COMMENTS

- **Clarification (vs. a change of intent): Overall Hospital Quality Star Rating: Frequency of publication**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule– p. 785—September 13, 2022

We appreciate CMS clarifying the intent of the OPPS FY 2021 final rule regarding the refresh rate of the Overall Hospital Quality Star Rating. While the clarification is to essentially state that the star rating will be refreshed once a year, we recommend updating the rating twice a year. Consumers and purchasers deserve to have the most up to date data possible to use when evaluating facilities for care.

- **Request for comment: Additional release of information regarding mergers, acquisitions, consolidations and changes in ownership**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule– p. 768—September 13, 2022

It is commendable that CMS is asking for input about additional data to release on mergers, acquisitions, consolidations, and changes in ownership that would be of value to the public. We strongly support full transparency and insight into such ownership transitions which clearly have impact on the delivery of care, and likely on quality outcomes if such information were more readily available. Consumers and purchasers are deeply concerned about the impact of mergers and this information would help inform the market.

However, to ensure data on ownership can be correlated with quality, CMS must take an additional step. As Leapfrog has advocated in a number of OPPS and IPPS comments, we recommend reporting by CMS on quality measures at the bricks and mortar locations as opposed to a rolled-up result of a number of facilities under one CCN. Patients do not seek care from a system; they seek care from individual facilities and clinicians. Providers and administrators can also benefit from being able to readily discern the performance at their own facility and determine where improvements are needed.

In order to discern whether changes in ownership structure have benefited patients, it is critical to have facility-level data on quality to track over time. As CMS states in the proposed rule: *"[W]hile provider mergers increased prices, their effects on quality were mixed. The MedPAC report noted 'Because the literature is mixed, we cannot make a definitive conclusion about the effect of mergers on the quality of care …."*

When quality metrics are reported at a corporate (vs. individual facility) level, it not only renders consumers unable to discern the performance of a given facility, but also limits the ability to study the impact on quality in light of corporate changes such as mergers. For example, if a once individually owned facility had their quality performance reported, but that facility has since been acquired by a corporation, we are typically unable to identify if / how that previously independent facility's performance changed after the acquisition.

In closing, there is evidence that hospitals being acquired has negative impacts on quality[8,9]. This evidence suggests that if CMS consistently reports quality at the facility level, we can better study the implications of mergers, acquisitions, consolidations and changes in ownership on quality of care of the individual facility.

- **Request for comment: Requirements for the Rural Emergency Hospital Quality Reporting**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule– p. 625—September 13, 2022

We support the introduction of required reporting of a specified set of measures in the upcoming REHQR Program. In addition to the draft set of measures for the REHQR Program listed in the OPPS proposed rule, we recommend including measures of access to obstetrical / midwife care in the emergency department settings. The present draft measure set omit any measures of maternity care. Given that labor and delivery is the most prevalent type of hospital admission[10], it appears most hospitals that qualify for the REHQR Program would have

a sufficient denominator to report on such measures. Thus, maternity measures are responsive to the concern stated in the OPPS proposed rule regarding identifying measures for the REHQR Program that notes "it is vital that measure information be of sufficient volume to meet case thresholds for facility level public reporting."

- **Clarification (vs. a change of intent): Overall Hospital Quality Star Rating suppression**

The Leapfrog Group comments to CMS on the FY 2023 OPPS Proposed Rule– p. 786—September 13, 2022

Leapfrog strongly opposes CMS suppressing the Overall Hospital Star Rating, which is contrary to the intent of the enabling statute and not in the best interests of Medicare beneficiaries or the public at large. Given the types of measures that comprise the Overall Hospital Quality Star Rating, we know such decisions may mean whether the person survives their admission or experiences a preventable adverse event that can have lifelong implications. We encourage CMS to continue to evolve the rating methodology to be sufficiently robust and resilient to adapt to various measurement challenges, such as public health emergencies. But those changes over time should be made in the public eye. The public deserves to know what CMS knows about the quality and safety of facilities.

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