THELEAPFROGGROUP

September 17, 2021

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

RE: RIN 0938-AU43 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

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 2022 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 and not by CCN

We strongly recommend that CMS align with Leapfrog and its purchaser constituency by publicly reporting data in a way that puts the needs of consumers first and foremost. Fundamental to meeting that goal is to collect and report data for individual bricks-and-mortar facilities (i.e. campuses and locations), not by CCN.

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 surgery centers 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 2022 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 2022 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 2022 proposed rule:

Carolyn Skinner, Dembo Jones
Dallas Fort Worth Business Group on Health
Florida Alliance for Healthcare Value
Greater Philadelphia Business Coalition on Health
G. Rumay Alexander, Nurse and Advocate
HealthCare21
Healthcare Purchaser Alliance of Maine
Horizon Blue Cross Blue Shield of New Jersey
Houston Business Coalition on Health
Lehigh Valley Business Coalition on Healthcare (LVBCH)
Louisiana Business Group on Health
Maureen Ryan, Odgers
Memphis Business Group on Health
Midwest Business Group on Health
New Jersey Health Care Quality Institute
North Carolina Business Group on Health
Purchaser Business Group on Health
Richard Reguzzoni, Consumer Advocate
Sally Welborn, Welborn Advisory Services, LLC
St. Louis Area Business Health Coalition
The ERISA Industry Committee
William Sheffel, Capital HealthCare Group, LLC

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING FY 2022 OPPS AND ASC PROPOSED RULE

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

- **Proposal to remove two measures from the OQR**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 523 – September 17, 2021

The Leapfrog Group supports the removal of the two proposed measures from the OQR Program, which are:

- Fibrinolytic Therapy Received Within 30 Minutes of [ED] Arrival (OP-2)
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)

Our support is based on the proposal in this rule to adopt ST-Segment Elevation Myocardial Infarction (STEMI) eCQM. CMS' stated rationale for removing the measures listed above is that the STEMI eCQM is more applicable. However, our support is absolutely conditional on implementation of STEMI eCQM. It is also critical that there should be no gap in reporting between the removal of these measures and reporting on the new measures. Therefore, CMS should wait to remove the measures until they have data to report on the new eCQM measures.

- **Proposal to adopt five new measures to the OQR program**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – pp. 525, 552– September 17, 2021

We are very encouraged to see CMS beginning to add important dimensions of care by proposing to add a total of five measures across two proposals noted in the pages numbers above. We greatly commend CMS's leadership in proposing these new measures which are of deep interest and importance to consumers and purchasers. Thus, we strongly support the addition of all of the proposed measures, which are:

- COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure
- Breast Screening Recall Rates measure
- ST-Segment Elevation Myocardial Infarction (STEMI) eCQM.
- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP–37a–e)
- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31)

- **Request for comment: Potential future measures and topics for the OQR Program**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 561– September 17, 2021

The following are recommendations with regard to specific measure additions as well as topics and concepts for future use in the OQR Program:

Specific measures:

- Volume of select procedures measures
    - We suggest CMS re-introduce these measures. It is very important to patients and families when selecting a site for surgery that they learn whether and how often facilities perform the procedure. Without CMS collecting this data there are few, if any, resources to monitor this fundamental data about critical ASC operations.

- Ambulatory Breast Procedure Surgical Site Infection (SSI) outcome measure (NQF# 3025)
    - While the measure is currently specified for the ASC setting, we recommend CMS report an aligned measure for use in the HOPD setting as well.

- Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (OP-30) (NQF #0659)
    - CMS recently removed this measure from OQR. We recommend this measure be reinstated for reporting. A number of studies have evidenced that screening colonoscopy can have adverse effects, including complications, hospitalizations and death[1,2,3]. We are not talking about a few people being screened unnecessarily, there is also evidence of a high rate of complications which should be reported by CMS. A recent study of Medicare beneficiaries who had a colonoscopy found that nearly a quarter (23.5 percent) of the sample had a follow up colonoscopy within a time window where there was no clear indication for the early re-examination[4]. This suggests the need for this measure to ensure avoidance of inappropriate use. With regard to ASCs, we recommend adding ASC-10, which is essentially the same measure as OP-30.
- We strongly recommend that CMS require facility-acquired infection reporting through NHSN.

Topics / concepts:

- **Improve the alignment of measurement and reporting between hospital outpatient surgery centers and ambulatory surgery centers.** 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 beneficiaries and the public to compare quality for the same procedure agnostic to setting. At present, this is infeasible.

  In CMS' measure maintenance, where there are existing measures of specific surgical procedures for ASCs only or HOPDs only, CMS should direct contractors to re-specify the measure to also work for the unit of analysis not yet measured. In Task Orders to develop new measures, 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.

- **Report by individual bricks-and-mortar facility and not by CCN.** We strongly recommend that CMS align with Leapfrog and its purchaser constituency by publicly reporting data in a way that puts the needs of consumers first and foremost. Fundamental to meeting that goal is to collect and report data for individual bricks-and-mortar facilities (i.e. campuses and locations), not by CCN.
  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.

- **A topic that should be addressed in the OQR is medication safety.** Medication errors are the most common errors made in hospitals, and likely in outpatient settings as well. As CMS moves toward eCQM measures, medication safety should be a priority for reporting. In the short term, there medication safety measures in other settings could be adapted. One example is the measure titled "Safe Use of Opioids – Concurrent Prescribing" (eCQM) (NQF #3316e). While the measure is specified at the hospital level, CMS can gain efficiencies in adapting such a measure vs. developing a HOPD measure from scratch. Another example is the measure titled "Normothermia Outcome" (ASC 13, OP13) which is specified for both ASCs and HOPDs.

- **We recommend CMS take advantage of patient reported outcome performance measure (PRO-PM**) in systematically measuring various outcomes across a number of procedures. More specifically:

  - Regarding types of outcomes to measure, while measurement type will ultimately be determined by the type of surgery, the following are outcomes we recommend for measurement and reporting where possible:
    - Rate of improvement: pre and post procedure
    - Pain management: pre and post procedure
    - Quality of life: pre and post procedure
    - Observed errors: peri-operative attributable to facility
  - Regarding surgical areas to measure, The Leapfrog Group has deemed a short list of high priority outpatient surgical areas to measure for transparency applications[6]. Thus, we recommend measuring quality in the following areas from our list for these are presently not represented in OQR nor are there plans to add measures to OQR through CY26:
    - Orthopedics
    - Otolaryngology
    - Urology
    - Dermatology
    - Neurology
    - Plastic and reconstructive surgery
    - Pediatrics

- **Request for comment: Potential future adoption of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 562– September 17, 2021

Leapfrog applauds CMS for considering use of a PRO-PM measure to measure a dimension of quality that consumers say is important to them: Improvement in functional status before and after surgery. We encourage that on parallel tracks CMS adapt the THA/TKA PRO-PM measure for application in all salient settings, such as inpatient, HOPDs and ASCs.

A specific area that CMS requests comments on regarding this measure is essentially how to address the challenges unique to the HOPD setting regarding this measure. We anticipate one particular issue will be achieving an adequate denominator, which directly impacts:

- Acceptable reliability, and
- A sufficient number of facilities meeting a minimum threshold to be rated in the measure.

We encourage CMS to explore and consider methods to address these denominator issues. We offer the following methods to bolster the denominator:

- Use a three-year measurement period.
  - Given this will be a new measure with a new data source, CMS may need to incrementally build up to a three-year measurement period over time.

- Use of an all-payer population.
  - CMS tends to base their measures on Medicare FFS beneficiaries. There is no methodological reason to limit the denominator to this narrow population. The inclusion of other populations (such as commercial), addresses a repeated aim of CMS to partner with the private sector on matters of transparency and value based purchasing[7].

- Base the denominator on all ages or age 18 and over.
  - CMS tends to base their measures on age 65 and over. As noted immediately above, there is no methodological reason to limit the denominator to such a narrow age band of the population. Given the state of risk adjustment, we can expand the measure to younger age groups to test and identify risk factors associated with this broader population.

- **Request for comment: Potential future efforts to address health equity in the OQR Program**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 565– September 17, 2021

This section asks for comment in two areas. The first is regarding expanding the stratified reporting of measure results by dual eligibility to several OQR Program measures. We fully support extending such reporting to all nine of the measures noted in this section.

Second, this section requests input on short- and long-term stratification measure results by social risk factors for measures in the OQR Program. Leapfrog supports the short-term stratification of race and ethnicity based on indirect rate estimation methods.

The solicitation of comments regarding long-term stratification addresses requiring facilities to capture a number of social risk factors. While we support facilities reporting such data, we observe the historical issues of reliability of newly reported data elements and sensitivity of the data requiring best practice implementation in protocols for collecting it. With that, we advise CMS to identify best practices in evaluating data reliability and collection protocols. In turn, we recommend CMS deploy such best practices for the purposes of examining data submissions of facilities and creating data quality standards of facilities. While we support reporting properly collected data on social risk factors, we do not support under any circumstance risk adjustment for social risk factors as part of the calculation of quality measures. Such risk adjustment distorts quality reporting in ways that

can create a moral hazard by suggesting that outcomes for one demographically defined population are expected to be inferior to outcomes for another similarly defined population.

- **Proposal to add data collection modes for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 584– September 17, 2021

The Leapfrog Group strongly supports adding the two proposed web-based modes for completing the OAS CAHPS. But we also support retaining the existing telephone means of survey administration. Further, we recommend clarification in the final rule how CMS defines smart phones in regard to whether it is considered a web-based survey response or a telephone based response.

With regard to the OAS CAHPS domain titled "Preparation for Discharge and Recovery" (OP-37c), we recommend publicly reporting the domain score with the inclusion of the current pain question. If this is not an option, we suggest omitting the pain question and publicly reporting the domain with the remaining questions.

- **Proposals related to administering eCQMs**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 577– September 17, 2021

We support the eCQM proposals with regard to administration of the measure to be introduced to the OQR Program: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM. The proposals for maintaining the eCQM technical specifications and data submission requirements are sound in that their mirror how CMS handles eCQMs in other programs. However, our support is absolutely conditional on implementation of STEMI eCQM. It is also critical that there should be no gap in reporting between the removal of these measures and reporting on the new measures. Therefore, CMS should wait to remove the measures until they have data to report on the new eCQM measures.

- **Proposals for phasing in eCQM data submission**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule – p. 582– September 17, 2021

Regarding the phased in data submission for the STEMI eCQM over four years, we recommend that, at a minimum, CMS require facilities to submit one year of data. The proposed phased in approach has facilities submitting one quarter of data in the first year and incrementally submitting three quarters of data in the third year.

While this is progress, it remains inadequate in terms of reliability and rate of providers qualifying to report results. Regarding reliability, typically one to three years of data are used to drive up the denominator so as to obtain a reasonable level of reliability. One of the key drivers that impact reliability is the size of your sample[11]. In terms of providers meeting a minimum threshold to report, given the narrow population measured we are likely to see a very small number of providers with an adequate denominator to report with one, two or three quarters of data. The result is denying consumers to identify provider performance until at least the fourth year of the implementation of the measure.

Further, we recommend the time period of data submission should be identified by CMS; not facilities as proposed for the first three years. Such self-selection of data by facilities threatens transparency by hindering comparability, encourages the selection of unrepresentative quarters, and permits the use of outdated data when newer data are available.

AMBULATORY SURGICAL CENTER QUALITY REPORTING PROGRAM

- **Proposal to add seven new measures to ASCQR Program**

The Leapfrog Group comments to CMS on the FY 2022 ASC Proposed Rule – pp. 612,625 – September 17, 2021

We are encouraged to see CMS beginning to add important dimensions of care by proposing to add a total of seven measures across the two proposals noted in the page numbers referenced above. Thus, we strongly support the addition of all of the proposed measures, which are:

- COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)
- Patient Burn (ASC-1)
- Patient Fall (ASC-2)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC-3)
- All-Cause Hospital Transfer/Admission (ASC-4)
- Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11)
- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP–37a–e)

Additionally, Leapfrog urges CMS to mandate reporting of ASC-1, ASC-2, ASC-3, and ASC-4 through NSHN OPC so that the surveillance and reporting can encompass all patients, not just Medicare Fee-for-Service patients.

- **Proposal to add data collection modes for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems**

The Leapfrog Group comments to CMS on the FY 2021 ASC Proposed Rule – p.655 – September 17, 2021

The Leapfrog Group supports adding the two proposed web-based modes for completing the OAS CAHPS. We also urge retaining the existing telephone means of survey administration. Further, we recommend to clarify in the final rule how CMS defines smart phones in regard to whether it is considered a web-based survey response or a telephone based response.

- **Request for comment: Potential future measures and topics for the ASCQR Program**

The Leapfrog Group comments to CMS on the FY 2022 ASC Proposed Rule – p.636 – September 17, 2021

The following are recommendations with regard to specific measure additions as well as topics and concepts for future use in the ASCQR Program:

<u>Specific measures:</u>

- Volume of select procedures measures

  - We suggest CMS re-introduce these measures. It is very important to patients and families when selecting a site for surgery that they learn whether and how often facilities perform the procedure. Without CMS collecting this data there are few, if any, resources to monitor this fundamental data about critical ASC operations.

- Ambulatory Breast Procedure Surgical Site Infection (SSI) outcome measure (NQF# 3025)
  - While the measure is currently specified for the ASC setting, we recommend CMS report an aligned measure for use in the HOPD setting as well.

- Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (OP-30) (NQF #0659)
  - CMS recently removed this measure from OQR. We recommend this measure be reinstated for reporting. A number of studies have evidenced that screening colonoscopy can have adverse effects, including complications, hospitalizations and death[1,2,3]. We are not talking about a few people being screened unnecessarily, there is also evidence of a high rate of complications which should be reported by CMS. A recent study of Medicare beneficiaries who had a colonoscopy found that nearly a quarter (23.5 percent) of the sample had a follow up colonoscopy within a time window where there was no clear indication for the early re-examination[4] . This suggests the need for this measure to ensure avoidance of inappropriate use. With regard to ASCs, we recommend adding ASC-10, which is essentially the same measure as OP-30.
- We strongly recommend that CMS require facility-acquired infection reporting through NHSN.

<u>Topics / concepts:</u>

- **Improve the alignment of measurement and reporting between hospital outpatient surgery centers and ambulatory surgery centers.** 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 beneficiaries and the public to compare quality for the same procedure agnostic to setting. At present, this is infeasible.

  In CMS' measure maintenance, where there are existing measures of specific surgical procedures for ASCs only or HOPDs only, CMS should direct contractors to re-specify the measure to also work for the unit of analysis not yet measured. In Task Orders to develop new measures, 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.

- **Report by individual bricks-and-mortar facility and not by CCN.** We strongly recommend that CMS align with Leapfrog and its purchaser constituency by publicly reporting data in a way that puts the needs of consumers first and foremost. Fundamental to meeting that goal is to collect and report data for individual bricks-and-mortar facilities (i.e. campuses and locations), not by CCN.
  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.

- **A topic that should be addressed in the OQR is medication safety.** Medication errors are the most common errors made in hospitals, and likely in outpatient settings as well. As CMS moves toward eCQM measures, medication safety should be a priority for reporting. In the short term, there medication safety measures in other settings could be adapted. One example is the measure titled "Safe Use of Opioids – Concurrent Prescribing" (eCQM) (NQF #3316e). While the measure is specified at the hospital level, CMS can gain efficiencies in adapting such a measure vs. developing a HOPD measure from scratch. Another example is the measure titled "Normothermia Outcome" (ASC 13, OP13) which is specified for both ASCs and HOPDs.

- **We recommend CMS take advantage of patient reported outcome performance measure (PRO-PM**) in systematically measuring various outcomes across a number of procedures. More specifically:

    - Regarding types of outcomes to measure, while measurement type will ultimately be determined by the type of surgery, the following are outcomes we recommend for measurement and reporting where possible:
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        - Pain management: pre and post procedure
        - Quality of life: pre and post procedure
        - Observed errors: peri-operative attributable to facility
    - Regarding surgical areas to measure, The Leapfrog Group has deemed a short list of high priority outpatient surgical areas to measure for transparency applications[6]. Thus, we recommend measuring quality in the following areas from our list for these are presently not represented in OQR nor are there plans to add measures to OQR through CY26:
        - Orthopedics
        - Otolaryngology
        - Urology
        - Dermatology
        - Neurology
        - Plastic and reconstructive surgery
        - Pediatrics

- **Request for comment: Potential future adoption of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)**

The Leapfrog Group comments to CMS on the FY 2022 ASC Proposed Rule – p.638 – September 17, 2021

[Leapfrog applauds CMS for considering use of a PRO-PM measure to measure a dimension of quality that consumers say is important to them: Improvement in functional status before and after surgery. We encourage that on parallel tracks CMS adapt the THA/TKA PRO-PM measure for application in all salient settings, such as inpatient, HOPDs and ASCs.

A specific area that CMS requests comments on regarding this measure is essentially how to address the challenges unique to the ASC setting regarding this measure. We anticipate one particular issue will be achieving an adequate denominator, which directly impacts:

- Acceptable reliability, and
- A sufficient number of facilities meeting a minimum threshold to be rated in the measure.

We encourage CMS to explore and consider methods to address these denominator issues. We offer the following methods to bolster the denominator:

- Use a three-year measurement period.
  - Given this will be a new measure with a new data source, CMS may need to incrementally build up to a three-year measurement period over time.

- Use of an all-payer population.
  - CMS tends to base their measures on Medicare FFS beneficiaries. There is no methodological reason to limit the denominator to this narrow population. The inclusion of other populations (such as commercial), addresses a repeated aim of CMS to partner with the private sector on matters of transparency and value based purchasing[7].

- Base the denominator on all ages or age 18 and over.
  - CMS tends to base their measures on age 65 and over. As noted immediately above, there is no methodological reason to limit the denominator to such a narrow age band of the population. Given the state of risk adjustment, we can expand the measure to younger age groups to test and identify risk factors associated with this broader population.

- **Request for comment: Potential future efforts to address health equity in the ASCQR Program**

The Leapfrog Group comments to CMS on the FY 2022 ASC Proposed Rule – p.641 – September 17, 2021

We offer the following comment on health equity issues that are directly or indirectly related to the ASCQR Program:

There are numerous individual studies[12,13] and synthesis of the literature[14,15] that demonstrate clear health inequities across facilities and across the U.S. on the aggregate. While such research suggests inequities within facilities as well, a recent study by the Urban Institute[16] evidences clear inequities within the inpatient setting. Given the outcomes examined in this study, we believe these findings suggest the need to examine similar issues in ASCs and HOPDs.

While CMS is beginning to make strides in reporting socioeconomic disparities, we have yet to see the agency deploy a user-friendly means of publicly reporting within facility health equity performance. Given issues with small sample size (especially given the denominator would further be broken out of such groupings as race), we suggest reporting within facility health equity performance at the composite level, meaning aggregating the ASCQR measures for each facility. The result would be less about performance in a specific measure, while the focus would be the ASC's ability to treat its clientele equitably regardless of race, ethnicity and other factors.

- **Request for comment: Future development of a pain management measure**

The Leapfrog Group comments to CMS on the FY 2022 ASC Proposed Rule – p.646 – September 17, 2021

We have two primary recommendations regarding developing a measure of pain management.

1) Use of patient reported outcome performance measure (PRO-PM)
Meaningful measures to consumers in the area of pain management include the outcome of service delivery. More specifically, to accomplish the measurement of a number of outcomes we recommend measuring the person's status prior to health service intervention and status 30, 60 days post intervention. The best measurement type to gauge this outcome is a PRO-PM. Several types of outcomes can be measured with such an instrument. Outcomes we recommend to explore include:

- Change in level of pain
- Change in activities of daily living
- Change in quality of life

2) Tracking health equity
However CMS elects to measure the quality of pain management services rendered, we recommend gauging health equity in regard to the area being measured within, and across, facilities. There is a body of evidence that demonstrates that there are health equity issues in pain management diagnosis and treatment[8,9,10]. Our takeaway from such studies is that any foray into quality measurement in pain management needs to include the monitoring of health equity to inform where and how to intervene.

OTHER PROPOSALS/REQUESTS FOR COMMENTS

- **Proposed changes to the Inpatient Only (IPO) list**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– p.347—September 17, 2021

We have comments on the following criterion that CMS proposes to use in considering whether to remove a procedure from the IPO list: "A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC list."

First, we recommend that CMS should be transparent in how the agency is making that "determination". The specific guidelines for a determination is lacking in the proposed rule. Thus, CMS needs to be much clearer as to their decision-making process.

Secondly, we perceive that to truly make such an informed decision as to the safety of performing a given procedure in the ASC setting, we need measures. CMS is the logical agency to invest in such measure development. We suggest CMS employ a base set of complications that indicate adverse outcomes in the domain of safety to define the numerator (e.g. various infections, respiratory failure). The measure would need to be constructed in such a way to change out the denominator to reflect a given procedure that CMS is examining on the IPO list.

In all cases, CMS should specify a policy that when a procedure is removed from the IPO list, CMS always specify the set of measures that will be used to report outcomes and complications for the procedure when performed at any of the authorized settings.

- **Request for Comment: Inpatient Only (IPO) list**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– p.378—September 17, 2021

The Leapfrog Group appreciates CMS soliciting input from the public on the IPO list. The first set of questions posed in this regard follow:

"Should CMS maintain the longer-term objective of eliminating the IPO list? … What method do stakeholders suggest CMS use to approach removing codes from the list?"

We are not opposed to the eventual removal of the IPO list given the appropriate steps have been accomplished. A key early step is developing methods to evaluate the safety and quality of outcomes of care for a given procedure. It is only when such a systematic measurement is in place can we truly understand whether there are adverse ramifications of such procedures being performed in outpatient settings.

- **Proposal to revise criteria to add to the ASC covered procedures list (ASC CPL)**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– p.455—September 17, 2021

In general, we support CMS in its efforts to revise the criteria needed to add a service to the ASC CPL. However, we feel CMS is missing the bigger picture. Medicare beneficiaries, purchasers, and other consumers generally do not have access to enough safety and quality data about ASCs. This is life-saving information that they deserve, and critical for ongoing evaluation of the safety of expanded ASC offerings.

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 a significant strain on the U.S. health care system. However, that strain only heightens the urgency 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 publicly 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. It is critical for CMS to make this requirement to ensure Medicare beneficiaries have access to the safest, highest quality surgical care possible and that information on safety and quality is made freely available to the public in a format accessible to them.

- **Request for Comment: Remote mental health services**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– p.406—September 17, 2021

An issue with the provision of remote mental health services is the fact these cases are currently excluded from quality and safety measures. In the event CMS authorizes an extension of such services remotely, we recommend revising the salient measure technical specifications to include such cases in the denominator. The public has a right to know the quality of providers' mental health care for all their cases; not just a subset of cases based on the mode of service delivery.

- **Request for Information: Digital quality measurement and fast health care interoperability resources (FHIR) in outpatient quality programs**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– pp.504, 513-517—September 17, 2021

The Leapfrog Group supports the move to fully utilize dQMs and FHIR. This is a move in line with the ONC's data blocking standards and will move the industry to adopt full interoperability in multiple care settings.

We support leveraging and advancing standards for digital data and obtaining all EHR data captured for quality measure via provider FHIR-based APIs. Interoperability is an important patient safety goal. Islands of data in multiple EHRs that are unable to be shared gives providers an incomplete picture of the patients record. Moving the quality measures to FHIR-Based APIs will help bring the industry to full interoperability.

We support redesigning quality measures to be self-contained tools for the same reasons, but only if there is no disruption in the continuous public reporting on topics of quality and safety currently reported. In other words, our strong support for CMS' leadership toward digital quality measurement does not mean we ever support dropping public reporting of valuable patient safety measures. It is not in the best interests of beneficiaries or the public at large if standardization and digitalization disrupt transparency for patient safety.

We support building a pathway to data aggregation in support of quality measurement.

We also support potential future alignment of measures across reporting programs, federal and state agencies, and the private sector. The full transparency of quality measurement will not be achieved unless the same standards reported bear on Medicaid patients and the private sector. While having transparent data on Medicare patients is valuable it is only a portion of the full picture. A push that endorses dQMs across all payers will also help standardize data interoperability on all fronts.

- **Request for Information: Safe Use of Opioids Measures in the IQR Program**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– p.761—September 17, 2021

Leapfrog supports the continued inclusion of the Safe Use of Opioids - Concurrent Prescribing eCQM in the Hospital Inpatient Quality Reporting (IQR) Program. While facilities can self-select three eCQMs to report on the OQR Program, the Safe Use of Opioids eCQM is the one required eCQM to report. We want to echo our past recommendation that CMS should identify the four eCQMs for required reporting, and discontinue allowing facilities to self-select measures.

- **Request for Information: Rural Emergency Hospitals (REHs)**

The Leapfrog Group comments to CMS on the FY 2022 HOQR Proposed Rule– p.665—September 17, 2021

While there appear to be benefits of REHs, our initial concern is the potential for reducing access to maternity care in some rural areas. Example: The Consolidated Appropriations Act (CAA), allows Critical Access Hospitals (CAHs) to change their status to REHs. In turn, we may see what once was a CAH that provided maternity care convert to an REH. Given REHs are currently limited to providing emergency department services and observation services (unless otherwise specified by the Secretary), the result of such a CAH converting to a REH is the disappearance of obstetric services. In some rural areas, the CAH may be the only option for a delivery within a reasonable geographic radius.

We recommend CMS take action to anticipate, and avoid, the unintended consequence of restricting access to maternity care in rural areas. One mechanism to avoid such restricted access is to factor into the REH approval process an analysis of maternity coverage in the area if an eligible entity were to change status to a REH.

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