September 9, 2024

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

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Ms. Brooks-LaSure,

The Leapfrog Group is a 501c3 national nonprofit organization governed by employers and other purchasers committed to improving patient safety and health care quality in the United States. 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. On behalf of our Board of Directors, members and interested parties, including hundreds of purchasers and employer organizations across the country, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services on the proposed changes to the CY 2025 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. Recognizing that most surgeries are performed in outpatient or ambulatory settings, employers and other purchasers, as well as consumer advocates, appreciate that these settings offer the opportunity for improved patient experience, greater cost-efficiency, and the prevention of unintended patient harm that can result 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.

The attached appendix contains our detailed comments on the following proposals:

- Hospital Outpatient Quality Reporting (OQR) Program
- Ambulatory Surgical Center Quality Reporting (ASCQR) Program
- Rural Emergency Hospital Quality Reporting (REHQR) Program
- Overall hospital quality star rating
- Obstetrical Conditions of Participation
- Hospital Inpatient Quality Reporting (IQR) Program

The Leapfrog Group, including our Board, members, and interested parties, appreciates the opportunity to share our comments on the proposed changes to the CY 2025 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 CY 2025 proposed rule:

APPENDIX: THE LEAPFROG GROUP'S DETAILED COMMENTS REGARDING CY 2025 OPPS AND ASC PROPOSED RULE

HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

- **Proposal to adopt three measures to the Hospital OQR Program**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 614 – September 9, 2024

While three measures are proposed to be added to the Hospital OQR Program, The Leapfrog Group offers support for two of the measures, which are:

- Hospital Commitment to Health Equity (HCHE) measure
- Screening for Social Drivers of Health (SDOH) measure

These measures represent a significant enhancement to the current Hospital OQR Program, which has previously been limited in scope. Notably, until now, there have been no measures addressing these critical topics within the Hospital OQR Program.

We have two suggestions aimed at improving these measures. First, to ensure the self-reported measure results accurately reflect what is occurring in the facility, we suggest CMS develop a stronger audit function. Without an adequate auditing function, the measure remains highly susceptible to gaming.

Secondly, we recommend greater transparency in the public reporting of performance in the measures beyond reporting the facility attained zero to five points in the HCHE measure. More specifically, consumers should be able to see performance at the domain level as to whether the hospital earned a point for that domain or not. Such granularity of reporting would be kindred to the level of transparency of HCAHPS. Results are reported not only by way of an overall summary question/measure, but at the sub-measure/domain level as well. HCAHPs should be seen as a guide here and CMS should strive for consistency in how such measures that are comprised of individually scored domains are publicly reported.

Our call for enhanced transparency is similar for the SDOH measure. In this measure what is publicly reported is the rate at which a facility screens for all five domains. Consumers should be able to identify the screening rate a facility attains for each domain. The reporting of more granular level results for each measure will contribute to driving improvement where the largest deficits are identified. The adage of "what gets measured gets improved" applies to not only to public reporting at the aggregate measure level, but also such reporting of results at the domain level.

- **Proposal to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance measure (Information Transfer PRO-PM)**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 646 – September 9, 2024

We support the Information Transfer PRO-PM as it addresses an important component of the outpatient care delivery process that we need to get right to ensure success after discharge. Evidence demonstrates that poor discharge information results in poor outcomes, such as mortality and readmissions[1,2].

We offer several suggestions aimed at improving upon the measure. First, while we support implementation of the measure in the timeframe per the OPPS proposed rule, we recommend beginning to plan for integrating the measure into the OAS CAHPS instrument. With the recent introduction of OAS CAHPS and the forthcoming addition of the Information Transfer PRO-PM, individuals will soon be required to complete at least two surveys regarding their recent procedure. While it appears that administering the Information Transfer PRO-PM two to seven days post-procedure will help with the completion rate, we are all very aware that CAHPS instruments generally are experiencing declining response rates overtime. A recent study across eight CAHPS tools revealed an 18% drop in survey response rates in a seven-year period[3]. We need to address and mitigate the impact that the addition of the Information Transfer PRO-PM will have on the rate of patients completing both surveys. We urge CMS to consider consolidating these two instruments to potentially enhance the response rates for both the Information Transfer PRO-PM and OAS CAHPS surveys.

Second, the testing of the Transfer PRO-PM instrument needs to quickly expand beyond being offered in only English and Spanish. Given that the HCAHPS survey is available in nine languages, CMS has established a standard that all other survey tools should also meet. We need one standard for the languages in which surveys required by CMS will be available. We strongly recommend facilities be required to offer the survey in the language preferred by the person when it is one of these nine languages. It is aligned with the ethics and inclusivity efforts that are stated priorities of the Administration. Further, such a requirement (vs. allowing it to be voluntary) mitigates gaming the measure when the facility perceives it may receive a poor rating from a particular person or population.

Lastly, as measuring and reporting performance in the Information Transfer PRO-PM is important in the hospital outpatient department, it is just as significant in the ambulatory surgery center (ASC) setting. We recommend adding this measure to the ASCQR Program. Medicare beneficiaries and others seek to compare the safety and outcomes of care in various settings in selecting a facility based on quality. This is particularly true and important in the case of ASCs and HOPDs as many procedures are performed in both types of facilities. However, without aligning measures where appropriate, consumers are unable to make fully informed decisions.

- **Proposal to remove the MRI Lumbar Spine for Low Back Pain measure**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 654 – September 9, 2024

We recommend retaining this measure in the Hospital OQR Program. One of the primary reasons CMS cites to retire the measure is *"studies have shown … the measure … has not correlated with improved outcomes."* Of the studies cited in the OPPS to support this assertion, none studied the relationship between the measure and outcomes. In fact, one of the studies provides a rationale to retain the measure as it illuminates disparities in care. The article by Lind and Flug found that those less likely to receive conservative therapy before MRI were Black, Hispanic, Latino and people with low incomes[5]. Meanwhile, there are studies that evidence a correlation between early inappropriate MRIs and poor outcomes. Jacobs et al. found such inappropriate MRI use was associated with excessive surgeries, higher costs for other care and worse outcomes, which includes risk of harm from prescription opioids[6].

The other rationale CMS cites for measure removal is the volume of cases that qualify for the measure is declining over time as more cases are being documented as meeting exclusion criteria. The public is not able to

verify this claim nor the degree to which it is occurring as CMS suppresses the denominator figure from the CMS Provider Data Catalog (PDC) for this measure. As the inclusion of the denominator figure is present for some measure results in the CMS PDC and not others, we encourage CMS to consistently be transparent with the denominator across measure results in the CMS PDC.

In addition to our rationale for maintaining the measure beyond a correlation with outcomes, the rate of inappropriate use of MRIs in this measure is unacceptably high. The Partnership for Quality Measurement (PQM) recently released its 2024 Preliminary Assessments on CMS' measure portfolio. For this specific measure, PQM reports over 96,000 cases qualify to be measured. Given the measure only represents Medicare Fee-For-Service Providers, this means there's about 500,000 cases annually. With a recent rate of occurrence in OP-8 of 38%, that means there's about 190,000 instances each year of inappropriate use of MRIs for back pain.[7]

- **Proposal to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 656 – September 9, 2024

We recommend retaining this measure in the Hospital OQR Program, as we find the use of measure removal factor #2 (Performance or improvement does not result in better outcomes) is inapplicable here. Such inappropriate testing increases unnecessary radiation[8], risk of adverse reaction to contrast materials and repercussions after the diagnostics, such as delay in diagnosis (false negatives) or inappropriate diagnosis (false positives)[9].

Furthermore, we respectfully disagree with the rationale provided for removing the measure, which characterizes the improvement from 2020 to 2024 as 'slight'—from 4.7% to 3.6%. This actually represents a 23.4% improvement. We believe that such a significant reduction in unnecessary testing over a short period should be considered a 'substantial' rather than a 'slight' achievement.

- **Proposal to require EHR technology to be certified to all eCQMs available to report**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 662 – September 9, 2024

The Leapfrog Group is very supportive of this proposal. Enacting this proposal would force the vendor community to take responsibility for all eCQMs as opposed to being certified in a subset of eCQMs. The solution to improving the accuracy of reporting these measures needs to involve the vendors, which is the focus of this proposal.

- **Proposal to modify the immediate measure removal policy**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 642 – September 9, 2024

While the proposal is an improvement to the current policy of measure removal, we oppose granting CMS sole ability, and without public scrutiny, to suspend measures. The agency should be required to go through rulemaking as was required in the past (prior to the measure removal policy) where a proposal is made in a draft rule that is available for public comment. Additionally, considering that over 140 million procedures are performed annually in HOPDs and ASCs, the Hospital OQR Program currently lacks sufficient quality measures[11]. Our efforts need to be centered on improving the current measures and developing new measures in this setting as opposed to removing measures.

If CMS does finalize this rule to allow suspension, we recommend the suspension applies to the public reporting of the measure and not the data collection. While the measure is suspended, and prior to the measure removal, CMS should calculate measure results. This would address concerns about whether a lack of transparency leads to diminished performance in the area being measured. Should CMS see quality worsen during this period, it suggests retaining the measure for public reporting.

- **Proposal to report Median Time from ED Arrival to ED Departure for Discharged ED Patients measure stratified by psychiatric/mental health patients on Care Compare**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 667 – September 9, 2024

We strongly support this proposal to make care delivered in the ED setting for people with psychiatric/mental health issues more transparent to the public. Posting these stratified results on Care Compare would enhance accountability for the ED, as public reporting on Care Compare offers greater visibility compared to inclusion in the CMS Provider Data Catalog. We commend CMS for this proposal as it provides additional needed focus on this population as ED wait times for this group are longer[10].

AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

- **Proposal to adopt three measures to the ASCQR Program**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 614 – September 9, 2024

While three measures are proposed to be added to the ASCQR Program, The Leapfrog Group offers support for two of the measures, which are:

- Facility Commitment to Health Equity (FCHE) measure
- Screening for Social Drivers of Health (SDOH) measure

These measures represent a significant enhancement to the current ASCQR Program, which has previously been limited in scope. Notably, until now, there have been no measures addressing these critical topics within the ASCQR Program.

We have two suggestions aimed at improving these measures. First, to ensure the self-reported measure results accurately reflect what is occurring in the facility, we suggest CMS develop a stronger audit function. Without an adequate auditing function, the measure remains highly susceptible to gaming.

Secondly, we recommend greater transparency in the public reporting of performance in the measures beyond reporting the facility attained zero to five points in the FCHE measure. More specifically, consumers should be able to see performance at the domain level as to whether the hospital earned a point for that domain or not. Such granularity of reporting would be kindred to the level of transparency of HCAHPS. Results are reported not only by way of an overall summary question/measure, but at the sub-measure/domain level as well. HCAHPs should be seen as a guide here and CMS should strive for consistency in how such measures that are comprised of individually scored domains are publicly reported.

Our call for enhanced transparency is similar for the SDOH measure. In this measure what is publicly reported is the rate at which a facility screens for all five domains. Consumers should be able to identify the screening rate a facility attains for each domain. The reporting of more granular level results for each measure will contribute to driving improvement where the largest deficits are identified. The adage of “what gets measured gets

improved" applies to not only to public reporting at the aggregate measure level, but also such reporting of results at the domain level.

- **Proposal to modify the immediate measure removal policy**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 642 – September 9, 2024

While the proposal is an improvement to the current policy of measure removal, we oppose granting CMS sole ability, and without public scrutiny, to suspend measures. The agency should be required to go through rulemaking as was required in the past (prior to the measure removal policy) where a proposal is made in a draft rule that is available for public comment. Additionally, considering that over 140 million procedures are performed annually in HOPDs and ASCs, the ASCQR Program currently lacks sufficient quality measures[11]. Our efforts need to be centered on improving the current measures and developing new measures in this setting as opposed to removing measures.

If CMS does finalize this rule to allow suspension, we recommend the suspension applies to the public reporting of the measure and not the data collection. While the measure is suspended, and prior to the measure removal, CMS should calculate measure results. This would address concerns about whether a lack of transparency leads to diminished performance in the area being measured. Should CMS see quality worsen during this period, it suggests retaining the measure for public reporting.

- **Request for information: Specialty focused reporting and minimum case number for required reporting**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule – p. 691 – September 9, 2024

We recommend that ASCs continue to be required to report all mandatory measures for several reasons. In general, the set of ASCQR Program measures is presently thin. Reducing the number further does not serve consumers, Medicare beneficiaries nor ASCs themselves. Regarding consumers and Medicare beneficiaries, less measures means a less complete picture of quality to inform their decision when evaluating options among facilities. With much more robust quality reporting in IQR, this may have the unintended consequence of people migrating to the inpatient setting for procedures that could have been performed in an ASC. Regarding ASCs, removing the reporting of measures will hinder quality improvement as facilities' ability to compare their performance to their cohorts is curtailed.

Specific to the "Specialty Select framework" (where CMS specifies the number of measures to report) the result will be inconsistent ASC reporting on any particular measure. One ASC will report optional measures such as those related to aspects like patient satisfaction and surgical outcomes, while another ASC will report on aspects like infection rates and recovery times. This variability in reporting will make it challenging for consumers to compare facilities. A second issue with this framework is it introduces the opportunity for ASCs to cherry pick the measures they will elect to report. Some facilities may prioritize reporting on measures where they have greater potential for improvement over those where they already perform well. To ensure the integrity of any public reporting program, it is essential to avoid allowing such selective reporting practices.

Regarding the "Specialty Threshold framework" (where the requirement to report a measure is based on a volume threshold), a key issue here is that volume is itself a quality measure as outcomes and volume are correlated[12,13,14]. Thus, omitting measures where facilities have lower volumes of specialty care means we are, in general, suppressing reporting in clinical areas where performance is worse and electing to report on areas where quality is better. This will only bolster the public misconception that quality is uniform and high.

RURAL EMERGENCY HOSPITAL QUALITY REPORTING (REHQR) PROGRAM

- **Proposal to adopt three measures to the REHQR Program**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule– p. 614—September 9. 2024

While three measures are proposed to be added to the REHQR Program, The Leapfrog Group offers support for two of the measures, which are:

- Hospital Commitment to Health Equity (HCHE) measure
- Screening for Social Drivers of Health (SDOH) measure

These measures represent a significant enhancement to the current REHQR Program, which has previously been limited in scope. Notably, until now, there have been no measures addressing these critical topics within the REHQR Program.

We have two suggestions aimed at improving these measures. First, to ensure the self-reported measure results accurately reflect what is occurring in the facility, we suggest CMS develop a stronger audit function. Without an adequate auditing function, the measure remains highly susceptible to gaming.

Secondly, we recommend greater transparency in the public reporting of performance in the measures beyond reporting the facility attained zero to five points in the HCHE measure. More specifically, consumers should be able to see performance at the domain level as to whether the hospital earned a point for that domain or not. Such granularity of reporting would be kindred to the level of transparency of HCAHPS. Results are reported not only by way of an overall summary question/measure, but at the sub-measure/domain level as well. HCAHPs should be seen as a guide here and CMS should strive for consistency in how such measures that are comprised of individually scored domains are publicly reported.

Our call for enhanced transparency is similar for the SDOH measure. In this measure what is publicly reported is the rate at which a facility screens for all five domains. Consumers should be able to identify the screening rate a facility attains for each domain. The reporting of more granular level results for each measure will contribute to driving improvement where the largest deficits are identified. The adage of "what gets measured gets improved" applies to not only to public reporting at the aggregate measure level, but also such reporting of results at the domain level.

- **Proposal to modify the reporting period for the Risk-Standardized Hospital Visit Within 7 Days After Hospital Outpatient Surgery measure**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule– p. 676—September 9. 2024

We are in favor of the proposal to increase the measurement period as it will have the result of more REHs to qualify to have their results publicly reported. Extending the reporting period from one year to two will not only provide consumers with ratings for a greater number of facilities but will also enhance the reliability of the measure results due to the larger sample size.

OVERALL HOSPITAL QUALITY STAR RATING

- **Request for information: Potential options to emphasize patient safety in the Overall Hospital Quality Star Rating**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule– p. 824—September 9. 2024

The maximum rating should be two stars where there is poor performance in the Safety of Care measure group. Here "poor performance" is based on the example provided in the OPPS proposed rule where a hospital is in the lowest (i.e. worst) quartile. If a hospital's patients are not safe, CMS should not label a facility as "average" (i.e. three stars) or higher regardless of performance in the other measure groups. We agree conceptually with CMS' discussion in the RFI regarding safety of care measures exerting more influence on the overall rating. Where we differ from what the three options CMS presents is our premise that subpar performance in safety should commensurately and inherently be reflected in a subpar overall star rating.

OBSTETRICAL CONDITIONS OF PARTICIPATION

- **Request for information: Potential options to emphasize patient safety in the Overall Hospital Quality Star Rating**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule– p. 746—September 9. 2024

Purchasers and consumers involved with The Leapfrog Group strongly support developing COPs for obstetrical care and urge CMS to move as rapidly as possible in this direction. Over our history of more than two decades, Leapfrog has witnessed time and again the remarkable impact of transparency in galvanizing change. We believe that advancing public reporting of maternity care data will advance critically needed improvement that will save lives and improve the outcomes for mothers and newborns.

We urge CMS to align measures it uses to identify whether a facility meets the minimum COPs standards with Hospital IQR measures. If an area is important enough to create a given COP and specify a minimum performance standard, it is also significant enough to create a related measure to be used to inform consumers of obstetrical quality per the Hospital IQR Program.

Despite the fact that childbirth is the most common reason for hospital admissions, the Hospital IQR maternity measures are very thin and made even more so with CMS' very unfortunate finalized rule to retire the Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks measure. We strongly encourage CMS to use this measure in its future obstetrical care COPs and reinstate the measure in the Hospital IQR Program. As stated in our IPPS FY24 comments opposing removal of the measure from the IQR, it is not a time to remove a measure when rates are increasing, and thousands of births occur outside of the recommended guidelines. Specifically, rates of early elective delivery have increased 43% in the past two years per CMS' figures. At a minimum, there needs to be a Hospital IQR measure and a COP that a hospital must have an evidence-based policy in place to eliminate such early elective deliveries.

Leapfrog supports the development of standards for managing pregnant, birthing, and postpartum patients with or at risk for obstetric hemorrhage and severe hypertension. Outcomes measures are always preferred, but process measures are a good starting point until outcomes measures can be developed.

The dire issue of maternal mortality is strongly related to these measures and cannot be ignored. More women die in the United States from maternal mortality than in any other developed nation, and Black pregnant patients are three times more likely to die than white patients[10].

To advance health equity, we urge CMS to report maternity measures by race, ethnicity, and other factors. Leapfrog began collecting stratified NTSV C-section rates this year and will release a national report on the findings this fall. This a good start, but we hope all maternity care data will soon be stratified to account better target health inequity.

There are resources in place at many hospitals that can help protect pregnant, birthing, and postpartum patients. This includes doulas, midwives, and lactation services. Last year Leapfrog began collecting and publicly reporting data on hospitals that make these services available for patients. We encourage CMS to report this information as well as affordable access to services where evidence demonstrates their effectiveness improving outcomes and reducing mortality. Another important area for CMS to consider is requiring hospitals to follow the nurse staffing standards published by AWHONN. This could improve outcomes, reduce complications and improve overall quality of care[11]. Leapfrog also strongly encourages CMS to pursue measures addressing maternal mental health.

Leapfrog is aware that smaller hospitals, particularly in rural areas, face unique challenges delivering maternal health care and may find quality reporting to be burdensome. Nonetheless, people in rural communities are just as deserving of high-quality maternity care as people in other regions of the country, and all hospitals should be held to high standards of accountability for that care. Nonetheless, with many rural hospitals closing their labor and delivery units or even closing down the entire hospital due to financial strain, it is important for CMS to plan special levels of support for rural hospitals to achieve the quality results their communities deserve. In addition, because so many rural and community hospitals are now part of larger hospital systems, CMS needs to develop COP policies that hold systems accountable for high quality, accessible hospital care and public reporting on quality for the rural communities they serve. In other words, CMS should not exempt rural and/or other challenged hospitals from quality standards and public hospitals.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

- **Proposed modification of mandatory reporting of the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures in the IQR Program**

The Leapfrog Group comments to CMS on the CY 2025 OPPS Proposed Rule– p. 788—September 9. 2024

The Leapfrog Group is opposed to delaying the mandatory reporting of the Hybrid HWR and Hybrid HWM measures for a year from the previously finalized FY26 payment determination. We appreciate CMS' analyses from recent voluntary reporting that 75% or more of hospitals are projected to not meet the reporting thresholds for key hybrid data elements. More specifically, the threshold reporting for linking variables is 95% of discharges, and reporting core clinical data elements (CCDEs) is 90% of discharges.

CMS should not allow hospitals to delay mandatory reporting in these important measures due to their own actions or inactions. As noted in the OPPS proposed rule, the result of not meeting the reporting threshold is a reduction of their annual payment update. This is a fair consequence given hospitals have had ample notification of CMS' plans for these measures. The Hybrid HWR measure was finalized in the IPPS FY18 rule, and the Hybrid HWM measure appeared in the IPPS FY22 rule. Allowing such delays sets a troubling precedent, as it implies that hospitals' actions or inactions during the voluntary reporting period can influence and potentially disrupt the established timeframes set by rulemaking.

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