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December 21, 2023

Re: Public Comment to CMS Proposed Patient Safety Structural Measure. Number: MUC2023-188.

On behalf of ECRI, an Agency for Healthcare Research and Quality (AHRQ) listed Patient Safety Organization (PSO) and Evidence-based Practice Center (EPC), I would like to applaud the Centers for Medicare and Medicaid Services (CMS) for proposing this critically important new patient safety measure. ECRI agrees with the recommendations from the recent President's Council of Advisors on Science and Technology (PCAST) report, *A Transformational Effort on Patient Safety,* calling for a nationwide transformational initiative on patient safety to support every hospital and practitioner with implementing safety solutions and sustaining them over time.

As a member of the National Steering Committee for Patient Safety, ECRI has led efforts to implement the National Action Plan to Advance Patient Safety in hospitals and other healthcare settings across the country. Through our partnerships with healthcare providers, ECRI has witnessed firsthand how a total systems approach to safety can have a profound impact on the reduction of preventable harm and build a strong and resilient healthcare workforce.

Through ECRI's review of the proposed measure we did see that several important elements of total systems safety were missing. ECRI recommends that CMS also include the following core elements of a total systems approach to safety:

- Develop an action-oriented **great catch reporting program** that uses recognition to encourage team members to report risks that could potentially cause harm. Great catches differ from traditional "good catches" by focusing on action responses to near miss events that are strong and reliable and have a system-wide impact.

- Implement a **peer support program** to create an environment that emphasizes peer support as part of its broader culture of patient safety and just culture, including fostering a culture in which all employees are resilient and mutually supportive before, during and after stressful events.
- Develop a structured process and establish clear channels for communication of risks and response plans to mitigate risks for **hazardous or recalled medical supplies, medications, and equipment.**
- Create an **equity plan** to increase inclusion, person-centeredness, and equitable health outcomes.
- Develop a process to assess, act on and learn from **diagnostic errors**.

ECRI agrees with the emphasis of the measure being placed on the five domains of:

- Domain 1: Leadership Commitment to Eliminating Preventable Harm
- Domain 2: Strategic Planning & Organizational Policy
- Domain 3: Culture of Safety & Learning Health System
- Domain 4: Accountability & Transparency
- Domain 5: Patient & Family Engagement

The domains and the individual elements within each will create a much-needed standardized framework that will guide hospitals to practice a systems-based approach to safety. Through our work as both a PSO and EPC, the proposed statements within the five domains resonated with us as essential to a total systems safety approach. Along with the additional statements aforementioned, we would like to highlight specific statements that we feel will have a major impact.

Domain 1: Leadership Commitment to Eliminating Preventable Harm

Statement: Our hospital leaders, including C-suite executives, place patient safety as a core institutional value. One or more C-suite leaders oversee a system-wide assessment on safety, and the execution of patient safety initiatives and operations, with specific improvement plans

and metrics. These plans and metrics are widely shared across the hospital and governing board.

ECRI supports the use of a system-wide assessment to create a baseline measure that improvement plans should be designed around. Associated action plans should include strong and high leverage actions that are aligned with organizational goals and metrics.

Domain 2: Strategic Planning & Organizational Policy

Statement: Our hospital has implemented written policies and protocols to cultivate a just culture that balances no-blame and appropriate accountability and reflects the distinction between human error, at-risk behavior, and reckless behavior.

ECRI supports the implementation of a just culture using consistent, fair, and systematic approaches to manage behavior to facilitate a balance between a nonpunitive learning environment and an equally important need to hold people accountable for their actions.

Domain 3: Culture of Safety & Learning Health System

Statement: Our hospital implements the following high reliability practices-The use of human factors engineering principles in the selection and design of devices, equipment, and processes.

As the largest independent device testing laboratory in North America, ECRI supports the use of human factors engineering in all aspects of a total systems approach to evaluate and improve safety. This includes assessing the complexity of devices, tools, technology, tasks, and the work systems in which team members conduct patient care.

Domain 4: Accountability & Transparency

Statement: Our hospital reports serious safety events, near misses and precursor events to a Patient Safety Organization (PSO) listed by the Agency for Healthcare Research and Quality (AHRQ) that participates in voluntary reporting to AHRQ's Network of Patient Safety Databases.

ECRI supports organizational accountability and transparency that allows team members from across the organization to identify safety events, near misses and unsafe conditions across healthcare settings, promoting transparent organizational learning and nurturing a culture that

promotes safety as a goal. Furthermore, we support healthcare organizations to report those events, near misses and unsafe conditions to a PSO to leverage the unique learning system provided under the federal Patient Safety and Quality Improvement Act.

While we support this statement, we urge CMS to remove the portion “that participates in voluntary reporting to AHRQ’s Network of Patient Safety Databases” as this is a voluntary reporting program, and it is not required for PSOs to report data under the Patient Safety and Quality Improvement Act.

Domain 5: Patient & Family Engagement

Statement: Our hospital incorporates patient and caregiver input about patient safety events or issues (such as patient submission of safety events, safety signals from patient complaints or other patient safety experience data, patient reports of discrimination).

ECRI supports partnering with patients, families, and caregivers in safety. This includes creating pathways for patients, families, and caregivers to report safety events with the expectation that their concerns will be reviewed and acted upon quickly with closed loop feedback on the resulting outcome and actions to improves safety.

While ECRI supports a standardized metric for safety, we also urge CMS along with other federal agencies to take actions to create a **powerful national learning ecosystem** where evidence-based best practices and safety lessons from other high- risk industries can be shared and modeled from to create innovative and sustainable change within healthcare systems. **Furthermore, as healthcare providers continue to struggle to overcome the impact of the pandemic, they will need support and practical tools to meet the elements outlined in the measure**. For example, the use of human factors engineering principles in the selection and design of devices, equipment and processes is demonstrated to be a powerful intervention, however in ECRI’s experience, most hospitals do not have access to human factors engineers and this creates inequities in how hospitals are able to address complex system safety issues. A national learning ecosystem should address how an equitable approach can be taken to implement the best practices outlined in the measure. A total systems approach to safety

should facilitate hospital teams to provide excellent care, not create additional disparate tasks and processes that complicate their work. Finally, CMS should consider how other reliable and valid forms of measurement can contribute to understanding the impact of each of the safety domains and statements. A structural measure alone will not provide the detail that is necessary to drive continuous performance improvement.

In conclusion, ECRI supports CMS's effort to transform patient safety through this proposed Patient Safety Structural Measure, but we recommend that they take a more comprehensive approach to ensure the successful and sustainable implementation of evidence-based practices for safety. Thank you for this opportunity to comment on this important advancement in patient safety.

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