February 1, 2023

Patients for Patient Safety US (PFPS US) submitted the following:
Public Comment on January 26, 2023.

Request for Information on Creating a National Healthcare System Action Alliance To Advance Patient Safety (FR Doc. 2022-26897)

We appreciate the opportunity to contribute observations, ideas and actionable recommendations for solutions from the point of view of users of healthcare services and products.

We believe the U.S. Department of Health and Human Services (DHHS) and the newly formed National Healthcare System Action Alliance should consider the following challenges and recommendations from PFPS US to reduce avoidable harm from unsafe care and ensure health equity. This is inclusive of preventable medical errors and diagnostic errors across all healthcare settings and for all persons, from mothers and babies to seniors, regardless of race, ethnicity, sexual preference, gender identity, income, education, socioeconomic status, insurance status, physical and mental ability, or other characteristics of more vulnerable populations.

1. No-one is in Charge at the Federal Level

There is fractured oversight of patient safety among multiple Federal agencies, State agencies, quasi-governmental entities such as The Joint Commission and private sector organizations, with no person or place accountable to measurably reduce avoidable harm to patients from unsafe care. In the absence of committed and coordinated leadership patient safety has drifted as a national priority, become marginalized and has been positioned, alarmingly, as competitive with other priorities, such as worker safety or health equity.

Recommendations:

DHHS should establish greater national oversight and coordination of patient safety, and engage the Action Alliance to re-invigorate systems approaches for identifying threats and preventing avoidable harm.

- Secretary Becerra should prominently re-inforce patient safety as a priority in the DHHS national healthcare strategy and establish a related Federal Advisory Committee to coordinate efforts across DHHS and in communication with other Federal agencies that deliver or oversee delivery of healthcare services and products.
- DHHS should establish an independent agency similar to the National Transportation Safety Board that will analyze data, conduct investigations and make improvement recommendations to all stakeholders, including federal and state agencies, accreditors, healthcare providers, and other public or private stakeholders. The independent agency should also provide mechanisms for patients and the public to report harms and threats to patient safety. PFPS US is active in the National Patient Safety Board coalition (www.npsb.org), with many other stakeholders who support this approach because it has proven so successful in ensuring system-wide safety in the aviation field.
- DHHS should reallocate resources to effectively invest in patient safety and embed accountability for delivering safe care, building on lessons learned from the Partnership for Patients and other 'all teach - all learn' collaboratives.
- DHHS agencies should use their leverage as regulators and payors to establish effective incentives for delivering safer care and consistently applied and meaningful penalties for failing to report harm events to regulators or accreditors.
    - The Centers for Medicare and Medicaid Services (CMS) and other DHHS agencies should develop and implement structural metrics where hospitals with board oversight ties compensation of physicians and executives to outcomes.
    - CMS and other DHHS agencies should develop and implement structural, process and outcomes measures for the safety of clinical practices including measures for diagnostic errors, infection control and maternal/newborn safety.

2. Lack of Data Reliability and Transparency

After more than 20 years of research and policymaking in the field of patient safety, we still do not know the magnitude of harm. Estimates of harm are piecemeal, based on narrow subsets of adverse events and sample studies in

siloed delivery settings rather than systemic surveillance and reporting that can reliably inform improvement work across the continuum of care. There is a disturbing tolerance among oversight agencies when provider organizations fail to report harm from unsafe care when required by law or regulation to do so. There is valuable data that is not shared because it is kept behind privileged and protective walls such as in Patient Safety Organizations (PSOs), the vast majority of which do not contribute to the National Patient Safety Database. All of these barriers to transparency impede continuous, system-wide learning.

Recommendations:

- DHHS should redesign reporting and surveillance of patient harm to be standardized at the Federal level and coordinate state integration of safety data.
- The Agency for Healthcare Research and Quality (AHRQ) and CMS should coordinate the redesign of the current national patient experience surveys (e.g. HCAHPS and CAHPS) used in CMS payment models to capture patient reported experiences relating to safety, both in real time and post discharge, as other developed countries now do.
- DHHS should develop mechanisms and platforms to capture patient, healthcare worker and public event reports and related data.
- CMS should expand the list of reportable serious harms (and align with state health departments) to capture patient safety events or threats, including diagnostic errors, from EMRs and administrative data.
- CMS should require mandatory reporting of harms to the Centers for Disease Prevention and Control (CDC), Food and Drug Administration (FDA), CMS itself, State agencies with reporting programs or quasi-governmental bodies like The Joint Commission, as part of the Conditions of Participation (CoPs) in the Medicare Program with appropriate penalties if not reported.
- The Office of Inspector General (OIG) should expand its trigger tool mechanisms to capture a wider variety of harms and expand their surveillance beyond just the Medicare population.
- CDC should count how many people die from medical error by including the option of “medical error” as a cause of death on death certificates to be captured in the National Death Index.

- DHHS should issue a call to action to States encouraging them roll up their all claims data bases.
- DHHS should lead the effort to require PSOs to contribute to the National Patient Safety Database, or find some other pathway whereby government agencies or improvement organizations can access PSO data.
- DHHS should lead the effort to close the loopholes currently being used by provider organizations for reporting to the National Practitioner Data Bank (NPSD) that obscure accountability for harm events.
- Patients should be able to directly report harm events into the integrated databases.
- CMS should work through its Center for Medicare and Medicaid Intervention (CMMI) to evaluate new technologies such as AI that could facilitate the identification of harm and not solely rely on self-reported safety events.

3. **Lack of Truth Telling when Things Go Wrong**

Defensive practices after patient harm events, such as denying or obscuring the truth to patients and families about what happened, withholding patient data or insisting on gag clauses (aka confidentiality agreements) remain normalized, despite growing data that transparency is more cost effective than deny and defend reactions. These entrenched behaviors undermine trust and are anathema to systemwide, continuous learning. It is morally wrong to fight accountability to patients when healthcare systems know, or could know through effective cause analysis, that medical standards of care have not been met.

<u>Recommendations:</u>

- CMS should require implementation of Communication and Resolution Programs such AHRQ's Communication and Optimal Resolution (CANDOR) approach as a CoP with meaningful financial penalties when there is no disclosure.
- CMS should ensure that timely reporting and disclosure of patient safety events are required in accreditation standards. Accreditors should include audits of claims reporting timeliness and disclosure as part of their surveys of healthcare provider operations to achieve "deemed status."

- DHHS should lead in using its regulatory, payment and education levers as well as judicial mechanisms, e.g. amicus briefs, to establish as public policy that timely communication and reconciliation after preventable harm events is part of the standard of medical care.
- The Office of the National Coordinator (ONC) and CMS should drive uptake and enforce compliance with the standards of the 21st Century CURES ACT to ensure patient access to medical records and notes, and impose meaningful penalties to deter information blocking.

4. Design and Oversight of Patient Safety is not Patient-Centered

Traditionally, patient safety solutions have been designed with scientific and technical expertise from policy makers, health system leaders, academics and other healthcare professionals using conventional methods. Engaging diverse patient, families and communities as co-creators of solutions provides a sense of urgency and a unique perspective otherwise unrecognized or not considered when developing patient safety solutions. Additionally, it is a low-cost, low-tech way to keep attention to patient safety prioritized as a fundamental in efforts to continuously improve quality, manage risk and deliver value.

<u>Recommendation:</u>

- All DHHS agencies, other government agencies that deliver or have oversight over healthcare, as well as quasi-governmental stakeholders such as accreditors and all National Healthcare System Action Alliance to Advance Patient Safety members, should establish structures, mechanisms, budgets, training and processes that ensure regular and formal input from patient, family, and community voices who are diverse with respect to race, ethnicity, age, sexual preference, gender identity, education, income or socioeconomic status, insurance status, and physical and mental ability. Any committees or working groups should have patient and family member representation.

Respectfully submitted,

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