Charles N. Kahn III
President and CEO

January 26, 2023

Dr. Robert Otto Valdez, PhD, MHSA
The Office of the Director
Agency for Healthcare Research and Quality
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Request for Information on Creating a National Healthcare System Action Alliance to Advance Patient Safety [AHRQ_FRDOC_0001-0956]

Dear Director Valdez:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. The FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to submit comments to the Agency for Healthcare Research and Quality (AHRQ) regarding its Request for Information on Creating a National Healthcare System Action Alliance To Advance Patient Safety published in the Federal Register (87 *Fed. Reg.* 76,046) on December 12, 2022.

We applaud the Department of Health and Human Services' (HHS) Secretary Xavier Becerra announcement for the creation of the National Healthcare System Action Alliance (the Alliance) to Advance Patient Safety. We believe the work of this future, multi-stakeholder collaboration will be vitally important to helping the health system return to pre-pandemic gains for hospital acquired infection rates and set an imperative for patient safety. The highest priority for hospitals and health systems is to make sure patients are safe. Our systems are working hard every day to define the root cause of problems and focus on targeted solutions that address today's patient safety challenges. We hope the Alliance will build on the 20+ year partnership on

quality and patient safety between health and hospital systems, patients and families, as well as federal partners, like HHS, the Centers for Medicare and Medicaid Services (CMS) and AHRQ.

COVID-19 exposed many of the strengths and vulnerabilities of the American health care system – especially when it comes to hospital services. While hospitals were instrumental in saving countless lives during the pandemic, past improvements in some underlying measures of patient safety were challenged as caregivers and hospitals dealt with providing care in an unprecedented and unpredictable pandemic. We continue to learn from this experience and hospitals are continuing the push to be better.

It is important to note the developments in patient safety prior to COVID-19. The health care landscape has been continually changing with health and hospital systems operating in increasingly complex and evolving environments. Despite steady improvements in patient safety pre-pandemic, COVID-19 showed us that our health care system and processes can be fragile. The pandemic had such an effect on health care delivery and safety outcomes that many hospitals witnessed some vulnerabilities, and our medical systems were less resilient to external factors than we thought. There was also variability in how states and locales responded to COVID-19, and the data reflect differences in which patients, those with and without COVID-19, experienced hospital harms.

More research is needed to better understand the impact of the pandemic on patients and the health care system. Those learnings can be applied to forging a new era in patient safety that detects and addresses patient harm at every point in the care-giving process. The highest priority for hospitals and health systems is to make sure patients are safe. Our systems are working hard every day to define the root cause of problems and focus on targeted solutions that address today's patient safety challenges. Below, we share the main challenges health care delivery systems and hospitals are facing in meeting their commitments to advancing patient safety, as well as the ways the Action Alliance can best support their patient safety efforts, including redesign of care delivery.

Identify and test new team-based models that address longstanding workforce issues.

Throughout the health care industry, the workforce challenge is the most impactful factor contributing to difficulties in maintaining safety systems. Highly reliable, safe systems of care depend on a stable, committed and synergistic workforce trained on the hospital's safety processes and systems.

The pandemic disrupted many aspects critical to the delivery of safe, high quality care including itinerate staffing, supply chain disruption and higher patient acuity- all having a disproportionate and negative effect on patient care and outcomes. Although it appears that the most severe impact of the pandemic may be behind us, many of the challenges that were seen during the pandemic live on – the most significant being the availability of caregivers and support staff to meet the health care demands of our communities. It appears that the health care workforce issues are now structural and will require support from both the public and private sectors to mitigate.

Existing patient safety models largely rely on the use of two RNs and a doctor for every patient. Nursing shortages are still prevalent and not going away. New approaches to patient safety that include a different team-based model should be considered and tested.

FAH members continue to prioritize securing and supporting a stable workforce. Any additional government, public or private partnerships to develop, grow and sustain the health care workforce are greatly needed. This would include enhancing academic preparedness for health care careers such as nursing. A survey (referenced in a September 2022 NY Times editorial) noted that the lack of academic preparedness was the top reason cited for delaying or forgoing nursing school.

Optimize the use of Patient Safety Organizations (PSO).

The Patient Safety and Quality Improvement Act (2005) authorized the creation of PSOs (Patient Safety Organizations) to improve quality and safety by reducing the incidence of events that adversely affect patients. To implement the Act, HHS and AHRQ published the Patient Safety and Quality Improvement Final Rule. A PSO works with health care providers to help them improve patient safety and encourage a culture of safety. PSOs also collect and analyze data voluntarily reported by health care providers that result in the sharing of evidence-based, best practices known to reduce harm and improve patient and workforce safety. Working with a PSO makes it possible for information from health care providers to receive certain legal protections and to be contributed to the Network of Patient Safety Databases (NPSD).

Currently there are only 100 AHRQ Listed PSOs. FAH members have been able to reduce serious safety events by more than 80%. HHS and AHRQ should consider how to more fully leverage the PSO infrastructure – through standardized data collection and data definitions, education and training and cross-organization collaboration, this may also be a mechanism to identify new preventable harms.

Distinguish between non-preventable and preventable harms.

The Office of the Inspector General (OIG) noted in its May 2022 report, 56 percent of harm events studied were not preventable and occurred even though providers followed proper preparation and procedures. Additionally, they noted that events were determined not preventable for several reasons, including that the older patients were found to be highly susceptible to the event due to poor health status. With this in mind, HHS should consider ways to detect and address non-preventable harm.

Adjust hospital policy program methodologies to account for small numbers.

CMS should use rewards instead of penalties, which have not moved the needle on harms. For example, the Hospital-Acquired Condition Reduction Program (HACRP), is a CMS initiative that ties Medicare reimbursement to hospital-related patient safety issues. Specifically,

the program strives to improve health care quality by reducing the incidence of hospital-acquired infections (HAIs) and other adverse events. Every year, the lowest performing twenty-five percent of all subsection (d) hospitals are penalized with a one percent reduction in Medicare payments. Although statutorily defined, this flawed methodology results in catastrophic consequences for hospitals with smaller volumes, such as small and rural hospitals. CMS should explore options within its current authority to adjust for lower patient volumes wherein one event would place a hospital in the lower performance quartile.

Expand the list of patient safety harms outside of the hospital setting.

While there are robust mechanisms for reporting some harms via the CDC, nationally there is a lack of focus for common causes of harm, especially for settings of care outside of the hospital. Most of the quality measures on patient safety focus on hospitals, yet most care is delivered in the ambulatory setting, which limits insights into the risks in that setting, as well as in home care. For children, newborns, and mothers, the situation is worse, with little national data because these groups largely receive care through Medicaid. More meaningful measures or frameworks for eliminating harms are needed that focus on every point of care that touches patients and caregivers. State Medicaid data should also be integrated to provide insights into maternal, neonatal, and child harms.

Remove barriers to innovation.

The burden of clinical documentation has been shown to have a negative effect on the provision of care even prior to the COVID pandemic, having been linked to job attrition and burnout among health care professionals and to an increase in medical errors and hospital-acquired conditions. Health care professionals, including nurses and physicians, may spend up to twice as much time completing electronic documentation and administrative tasks as they do engaging in direct bedside care.

Reducing regulatory requirements for documentation would relieve some of the burden on the clinical workforce. Earlier this year, the American Medical Informatics Association (AMIA) announced an effort to reduce clinical documentation burden by 25% by 2025 through a collaborative effort with providers, health IT vendors, policy and advocacy representatives. Support for these and other similar efforts would assist in efforts to support our health care workforce and enhance patient safety.

Additionally, the continued use of administrative data is an inadequate data source and collecting manually abstracted data from hospitals is burdensome. Data should be collected and analyzed in real-time to proactively identify and prevent harm. The introduction of data collection efforts that don't impede care processes and workflow is essential to encourage the bidirectional exchange of information. Automated systems and artificial intelligence (AI) generated algorithms, present untested opportunities that should be studied.

Additional flexibilities, such as those in the current Public Health Emergency (PHE) waivers, such as the expanded utilization around the provision of telemedicine services, enabling

the provision of acute or post-acute care within the home, and other innovations, potentially supported through CMS' Centers for Medicare and Medicaid Innovation or other agencies, should be considered.

****

The FAH appreciates the opportunity to offer these insights. If you have any questions, please contact me or a member of my staff at 202-624-1534.

Sincerely,