Patients For Patient Safety US

RE: HHS Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again (AHRQ-2025-0001-0001)

Dear Secretary Kennedy:

Patients for Patient Safety US (PFPS US) appreciates the opportunity to respond to the Department's call for public input on reducing regulatory burden and unleashing innovation in health care. PFPS US is a national network led by patients and families, working alongside healthcare providers, systems engineers, researchers, educators, and other key stakeholders to elevate patient safety as a national public health priority. Our network includes individuals, as well as nonprofit and for-profit organizations. Our shared goal is a healthcare system that centers the safety and well-being of patients in every setting, at every step of care. Our policy priorities align with the Administration's emphasis on transparency, measurement, and public reporting, fortified by patient/family engagement, as drivers of improvement. Improving safety and accountability for safety of care will also reduce unnecessary health care spending, waste, and associated taxpayer burden.

PFPS US) welcomes this moment of reevaluation. We believe health care urgently needs less complexity, more responsiveness, and better outcomes. We urge HHS, however, to begin with a clear and steady focus on what matters most: keeping patients safe from preventable harm in the healthcare system.

I. Reframing "Burden" with Patients at the Center

As you know, patients and families shoulder enormous burdens every day: navigating a fragmented and opaque healthcare system, managing medications in isolation and health records that are scattered across uncoordinated providers and platforms, and coping with avoidable harm that upends our lives. When errors occur — as they do with alarming regularity — patients also bear the consequences: physical injury, emotional trauma, lost income, and long-term disability. These are not theoretical harms; they are lived realities.

When patient safety measures, protections, or accountability structures are weakened in the name of provider convenience, the burden is not eliminated; it is simply shifted – onto patients, families, employers, the Medicare and Medicaid programs, and ultimately taxpayers. The foreseeable consequences include preventable injury and death, lives and livelihoods upended, and billions of dollars wasted in the form of inappropriate or unnecessary care, including extended patient stays and readmissions.

Efforts to reduce regulatory burden on providers and insurers must not come at the expense of critical evidence-based patient safety protections and organizational responsibility to implement and sustain such protections as baseline. Instead, they should recognize the disproportionate toll that unsafe care places on patients — and work to lighten it. PFPS US strongly encourages HHS to center its deregulatory strategy around the overarching goal that matters most: reducing the burden of preventable harm for patients, families, and taxpayers.

II. Streamlining Toward a Safer System: A Modernized Patient Safety Infrastructure

When harm is hidden from view, work to learn and improve is handicapped. Despite decades of investment in patient safety reporting systems, analyses using electronic medical record reviews and machine learning methods, e.g. "trigger tools," continue to reveal that while approximately 1 in 4 hospitalized patients experience a medical error, **fewer than 5% of these events are ever reported.**

Although efforts to hide harm can be intentional, the core challenge is not bad intent. It is the product of an array of reporting systems — including CMS's Serious Reportable Events, the Joint Commission's Sentinel Event program, CDC's National Heath Safety Network, State-level mandates, Healthcare provider organizations' internal incident reporting systems and AHRQ's Patient Safety Organization — that are fragmented, underpowered, siloed and retrospective. They also are dependent on manual input by clinicians who are overburdened. Because they so significantly underreport and underrepresent actual harm, these reporting systems create a false sense of situational awareness for health care providers and regulators, masking the true scope of harm and its staggering cost.

Notably, patients and our family caregivers are excluded from the reporting process almost entirely despite the value we could bring to continuous learning. We are often the first to notice when something has gone wrong in our care. We are frequently the most reliable coordination presence across fragmented episodes of care, and notice things others miss. Our reports can shed light on system level failure points, communication breakdowns, and latent safety risks that otherwise remain hidden. We are particularly well positioned to inform learning on missed or delayed diagnoses, where there are massive opportunities for improvement.

Instead of being given clear pathways to report patient safety events, patients are driven to litigate as an alternative. The desire to discover what happened and prevent future harm to others are primary reasons for filing medical liability claims.

The opportunity cost is enormous. Every dollar and hour spent propping up ineffective reporting mechanisms is a dollar and hour not spent advancing real-time tools for anticipation, detection, and prevention. Worse, this status quo leads to system-level inertia, where preventable injuries persist — not for lack of data, but for lack of usable insight and accountability.

HHS has the opportunity to catalyze a shift to a **next-generation safety infrastructure** that incorporates:

- AI as a "Central Nervous System" for safety in health care -- enabling detection of high-risk patterns and signals in real time, not dependent on manual input;
- Robust and easy-to-use mechanisms for patient and family harm reporting, designed to ensure insights are actionable within institutions but interoperable across systems;
- Integration of patient and caregiver insights, which often identify issues invisible to current surveillance systems and reflect the only continuous thread across care transitions;
- Culture change supports for hospitals and health systems to transition to proactive, data-rich safety strategies, rather than woefully inadequate, compliance-driven, post-hoc reporting.

As we move toward more technologically advanced, AI-enabled approaches for detecting safety threats in real time, it is imperative that we build — in tandem — meaningful pathways for patients and families to report harm events and contributing factors in our own words. While past efforts at patient-reported harm detection have struggled with signal-to-noise concerns, modern technology now makes it possible to elevate meaningful trends while filtering out non-actionable data. Creating a universal — but locally actionable — patient reporting mechanism must be a core element of the safety modernization effort.

Designing Trustworthy and Actionable Patient Reporting

While PFPS-US strongly supports the development of robust mechanisms for patient-reported safety concerns, we recognize a persistent tension that must be thoughtfully addressed: for reports to drive meaningful change, they must reach the local institution; but for patients to feel safe reporting, particularly after experiencing harm, they must trust that disclosure will not result in retaliation or compromised care. Many patients have told us directly that they would not feel comfortable reporting safety concerns to the very institutions where those concerns occurred. To resolve this, we encourage HHS to explore **independent intake and routing models** that collect patient reports through trusted third-party platforms and transmit structured, de-identified data to local institutions for learning and response. Patients should retain the option to disclose their identity if they choose, but should not be required to do so. These systems must be interoperable, locally actionable, grounded in patient trust. Building such a framework is not only feasible — it is essential to creating the safe, learning-oriented healthcare system the future demands.

To be clear, these platforms must be more than grievance portals. They should be designed to feed into a learning health system and provide a mechanism for patients to contribute directly to system improvement — not only when something goes wrong, but as a routine part of measuring what matters in care. Doing so will not only enhance safety surveillance but also reduce the reliance on the tort system as the only avenue for patients to be heard.

Redirecting resources from low-yield programs to these emerging models is a matter not of cutting, but of reinvesting. It is fiscally prudent, technically feasible, and morally essential.

III. Regulatory Restructuring Should Not Undermine Core Safety Goals

We understand the White House Executive Order guiding this initiative calls for agencies to identify regulations that could be eliminated or revised to reduce burden. But the ten-regulations-out-for-every-one-in approach is not a strategic blueprint for quality improvement. HHS must ensure that what is eliminated is not **essential scaffolding** for safety, equity, or patient trust.

For example, P4PS US is deeply concerned by suggestions being made to eliminate:

- Structural measures such as the Patient Safety Structural Measure and the Age Friendly Hospital Measure;
- Patient-reported outcomes and experience measures;
- Social Drivers of Health data collection and other measures that can inform closing disparities in outcomes experienced by more vulnerable populations.

Each of these represents a **system-level orientation** toward the future: where ALL patients regardless of economics, demographics, or the day of the week, receive the best of America's prevention-minded health care. They are not the source of burden; they are a proactive response to reducing the burden of bad outcomes patients continue to experience when systems are unsafe, unresponsive, or inequitable. Their removal would represent a step backward.

IV. The Economic Imperative of Prevention

Improving patient safety is not only a moral imperative — it is an economic one. If the true aim is to reduce waste and safeguard the American taxpayer, this Administration must reckon with the staggering cost of unsafe care. Medical harm is conservatively estimated to cost the U.S. healthcare system **more than $400 billion annually**, not including indirect costs such as lost productivity, legal expenses or the out-of-pocket costs and lost income that families absorb. Much of this waste is driven by care cascades following preventable events: readmissions, ICU stays, rehabilitation, long-term disability care. These costs are absorbed not only by hospitals, employers and patients, but by Medicare and Medicaid – and ultimately the taxpayer.

If HHS seeks to protect taxpayers, then regulatory simplification must be evaluated not only in terms of paperwork burden, but in terms of its impact on avoidable cost. Modernizing the safety infrastructure is **the clearest available pathway** to higher-value, lower-waste care. That effort should be framed not as additional burden — but as a strategic investment in better outcomes at lower cost.

V. A Rubric for Evaluating de-Regulatory proposals: Preventable Failure/Preventable Spend (PFPS) Framework

To ensure safety remains a central consideration in CMS's deregulatory deliberations, PFPS-US proposes a straightforward rubric for scoring proposed changes:

Domain	Guiding Question	Scoring Scale	Sample Criteria (to be evidence-backed)
1. Preventable Failures	Will changing or eliminating this regulation increase the risk of preventable patient harm?	-5 (High risk) → +5 (Risk mitigating)	- Regulation addresses known safety failure modes (e.g., wrong-site surgery, diagnostic error)- Aligns with WHO or AHRQ-defined harm types- Demonstrated reduction in harm with current rule

Domain	Guiding Question	Scoring Scale	Sample Criteria (to be evidence-backed)
2. Foregone Insight	Will this change reduce the ability to learn from error or adverse events?	-5 (Obscures insight) → +5 (Enables learning)	- Regulation supports data collection used for surveillance or prevention- Enables real-time or near-time feedback to clinicians- Evidence of under-reporting without mandate
3. Patient Voice	Does this change affect how patient and family experiences are captured or influence care?	-5 (Silences voice) → + 5 (Centers voice)	- Removes/integrates patient-reported outcome/experience measures- Impact on underserved/vulnerable populations- Supports culturally/linguistically concordant engagement
4. Systemic Cost / Preventable Spend	What are the economic consequences of preventable harm if protections are removed?	-5 (Increases cost) → +5 (Reduces waste)	- Linked to high-cost care cascades (ICU, readmission, post-acute care)- Studies quantifying cost avoidance from prevention- Downstream productivity/economic loss prevention

Conclusion

We appreciate HHS's openness to new ideas and innovations in this space, and we urge the agency to ensure that efforts to modernize do not result in unintended harms. Technology can and must play a central role — but always in service of **the core goal: to protect patients from preventable injury**. The future of health care safety depends on smarter systems, stronger patient-clinician partnerships, and clear, accountable investments in what works.

HHS has the leverage to transform patient safety at scale. We urge the Department to act boldly and lead the nation toward a future where avoidable health care harm is truly unthinkable.

PFPS-US stands ready to support HHS in designing and implementing that future. Thank you for the opportunity to comment.