Patients For Patient Safety US

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Introduction

Patients for Patient Safety US (PFPS US) is a national patient-led initiative focused on advancing a safer, smarter, more patient-centered healthcare system. We welcome CMS's request for input on opportunities to reduce regulatory burden and modernize administrative processes — and offer the following responses with one overarching aim: **to reduce the true burden of preventable harm** borne by patients, families, and the system as a whole.

Our guiding principle: *"Reform, not retreat."* The public deserves a modernized regulatory approach that doesn't just preserve legacy programs, but actively aligns CMS's tools with today's knowledge and technologies — ensuring that safety improves, waste is reduced, and patients and families are empowered as partners, We urge CMS to view modernization not as a mandate to eliminate for its own sake, but as an opportunity to reinvest in infrastructure that works. Some current programs, while underpowered, offer foundational visibility and should be improved — not abandoned without viable replacements. We also believe that patients must be part of the modernization effort, not afterthoughts to it. FPS-US strongly encourages CMS to center its deregulatory strategy around the overarching goal that matters most: reducing the burden of preventable harm for patients and families, and eliminating the high expense from unsafe or substandard care to taxpayers. The following responses reflect that perspective.

We recommend that CMS evaluate any proposed regulatory change against the following criteria:

1. Will this increase the risk of preventable safety events?
2. Will this reduce the ability to identify and learn from error?
3. Will this reduce or increase the voice of patients and families in CMS data?
4. What is the economic consequence of increased harm to CMS?

We further urge CMS to:

- **Reform low-performing legacy programs** (e.g., QIOs and PSOs) and redirect investments to modern tools like AI-enabled surveillance, patient-reporting integration, and electronic quality infrastructure;
- **Center patient reporting** as a critical data stream, as other HHS agencies (FDA, CDC) already do;
- **Modernize financial incentives** to stop rewarding poor care or the concealment of harm.

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.

1A. Are there CMS regulations that are no longer needed or overly burdensome?

PFPS US Response: Yes — CMS should eliminate or radically restructure the following:

- **QIOs (especially BFCC-QIOs):** These were meant to be a mechanism for patients to report safety issues, but are widely viewed as nonresponsive. Hospitals frequently fail to turn over information when concerns are raised, impeding investigation. This concealment of harm must carry consequences.
- **PSOs:** These have largely become a legal vehicle to hide harm, not a learning mechanism. Most PSOs have not substantively improved safety, and patients are not permitted to report to them. Their structure is outdated and misaligned with transparency.
- **Multiple VBP programs with fragmented measures:** PFPS recommends unifying value-based payment (VBP) measures across all payors. The existing landscape — over 30 VBP programs with different metrics — creates unnecessary administrative burden and confusion without driving safety gains.

1B. What are the most burdensome processes related to Medicare quality data submission?

PFPS US Response:

- **Fragmented reporting infrastructure:** CMS should require all federally funded insurers to follow a single, unified standard for electronic clinical quality measures (eCQMs). This would eliminate duplicative or contradictory reporting.
- **Lack of patient reporting integration:** Patients' safety concerns remain absent from CMS quality infrastructure. BFCC-QIOs are ineffective, and there's no reliable way for patients to contribute to learning. We urge CMS to adopt a unified, interoperable patient-reporting mechanism that feeds directly into learning systems.
- **Manual chart abstraction:** Electronic, AI-enabled reporting is more accurate, more timely, and less burdensome. CMS should invest in eCQM infrastructure and analytics, reducing the resource-intensive burden of legacy methods.

1C. Are there measures that should be maintained, improved, or eliminated?

PFPS US Response: Preserve and Improve:

- **HCAHPS:** This remains the only CMS mechanism capturing patients' lived experience of care. It must be preserved and updated to reflect what patients value, including safety.
- **Hospital Star Ratings:** Imperfect but valuable, especially for patients seeking comparative quality information.
- **Readmissions Reduction Program (HRRP):** Performance has not "topped out." The measure should be improved (e.g., add Excess Days in Acute Care [EDAC]) to better address gaming through observation status.

3. Are there structural measures that could be replaced or refined?

PFPS US Response: Yes. Rather than eliminate structural measures outright, CMS should modernize them to reflect what we know about the organizational drivers of safety.

The new AHRQ "Making Healthcare Safer IV" report finds that key barriers to progress on safety interventions include lack of leadership commitment, lack of infrastructure, and lack of clear protocols. These are *structural issues*. Therefore, measuring leadership engagement and system infrastructure is essential.

Examples:

- Measures of leadership accountability for safety outcomes (e.g., whether safety performance is linked to executive compensation);
- Presence and effectiveness of harm detection infrastructure (e.g., use of eCQM, AI-enabled surveillance, real-time risk detection);
- Mechanisms to support patient reporting, track responsiveness to patients, and include patient-generated data in quality analytics.

In short, structural measures should evolve — not disappear.

Are there CMS requirements, policies, or operations that add unnecessary burden or barriers, or that create unintended consequences?

PFPS US Response: Yes. Several long-standing safety reporting programs — including CMS's Serious Reportable Events list, and data submitted to Patient Safety Organizations (PSOs) — have failed to yield the reductions in preventable harm that were envisioned at their inception. These programs are often siloed, retrospective, labor-intensive, and underutilized by the very clinicians and patients they are meant to serve. Specifically:

- **Absence of infrastructure to support patient reporting of harm.** In contrast to the FDA (VAERS, FAERS), Medicare lacks a mechanism for patients to easily and systematically report safety events. This limits innovation in transparency and learning.
- **Overreliance on retrospective, claims-based measures.** These encourage "compliance" behaviors instead of real-time learning and improvement.

The unintended consequence is two-fold:

- They **create a false sense of situational awareness**, leading healthcare organizations to believe they are safer than they are.
- They **divert time, staff effort, and financial resources** away from more modern, real-time, technology-enabled safety surveillance and prevention tools.

While these programs may have laid important groundwork for recognizing harm, CMS should now lead the transition toward next-generation tools — including AI-driven signal detection and meaningful,

actionable patient reporting mechanisms — that better reflect today's clinical and technological landscape.

Are there specific structural or process measures that CMS should consider removing or replacing in quality reporting or value-based purchasing programs?

PFPS US Response: Recent findings from AHRQ's *Making Healthcare Safer IV* report underscore that the primary barriers to safety improvement are not a lack of will or even a lack of evidence — but rather **gaps in leadership accountability, resourcing, and clear protocols for implementation**. In that context, CMS should view structural measures not as regulatory overhead, but as **vital tools for assessing whether the necessary foundations for safety are in place**.

Structural measures — such as whether an institution participates in a Patient Safety Organization, uses validated teamwork protocols, or meets criteria for age-friendly or equity-focused care — help answer the most important question: *Is the system built to support safe care?*

If we are not measuring whether leadership is creating the conditions for safety, we cannot expect better treatment outcomes, lower waste, or restored public trust. Structural measures provide the clearest available lens into an institution's **readiness and resolve** to improve — and remain indispensable until better, outcome-linked proxies are available.

We caution strongly against removing measures related to:

- Patient safety maturity or learning system readiness;
- Age-friendly care structures;
- Health equity infrastructure.

These are not mere reporting exercises — they represent **foundational commitments to safety for all patients, regardless of demographics.** If anything, CMS should **deepen its investment** in measures that help institutions become better learning organizations. Any removal or revision should be clearly justified and accompanied by an improved alternative, not a regulatory void.

Are there examples of successful burden reduction efforts that CMS should scale more broadly?

PFPS US Response: Yes. One promising model is the incorporation of **electronic clinical quality measures (eCQMs)** that pull data directly from EHRs, reducing the need for manual abstraction. Another is the use of **safety dashboards** that integrate patient experience data, near-miss tracking, and predictive analytics into a single platform for frontline teams.

However, we urge CMS to go further — **making safety data meaningful to patients**, not just administrators. For example, CMS could encourage the adoption of real-time, patient-facing dashboards that let patients know when errors are recognized and what corrective action is being taken. Again, this technology already exists. This builds trust, accountability, and transparency.

Are there new technologies or capabilities that CMS should leverage to improve care, reduce cost, or increase efficiency?

PFPS US Response: Absolutely. CMS should help catalyze a transition to a **modernized safety infrastructure** by investing in and incentivizing:

- AI-powered tools for early detection of clinical deterioration or procedural risk;
- NLP-driven analysis of free-text patient feedback to detect harm signals;
- Federated reporting systems that allow patients to submit concerns safely and confidentially, while routing actionable insights back to local care teams;
- Data integration platforms that combine clinical, claims, and patient-reported data for a more comprehensive view of safety and cost.

These are no longer theoretical innovations — they are **available, scalable, and ready for CMS to help normalize and standardize**.

Are there specific CMS regulations or administrative requirements that should be retained, improved, or expanded because they are critical to patient safety or health equity?

PFPS US Response: Yes. PFPS US urges CMS to **retain and strengthen** the following:

- **The Patient Safety Structural Measure and the Age-Friendly Structural Measure,** per above**.** These measures would be strengthened by public reporting of actual responses to the attestation statements required rather than a numerical score. More granular data would better empower patient decision-making and provide more targeted incentivization for healthcare providers to improve outcomes.
- **Patient experience and patient-reported outcome measures (PROMs)**, including a modernized H- CAHPS and C-CAHPS, which serve as essential counterweights to overly clinical or administrative views of quality and their free-text responses as recognized and important signals of valid patient safety concerns.
- **Social Drivers of Health screening measures**, including Screening and Screen-Positive Rates — which allow systems to better appreciate and respond to the real-life context of their patients.
- **Transparency requirements for safety events and hospital quality data**, including public reporting platforms.

These elements are vital not only to equity and accountability, but also to restoring patient trust — a form of capital the U.S. healthcare system can no longer afford to squander.

Are there requirements under the Medicare Conditions of Participation or Conditions for Coverage that could be revised or eliminated to reduce burden?

PFPS US Response: Rather than eliminate existing Conditions of Participation (CoPs), CMS should consider *augmenting them* to reflect modern safety expectations. PFPS US encourages CMS to create a

new CoP requiring hospitals and health systems to implement **modernized safety detection systems**, such as:

- **Real-time, AI-enabled surveillance** of clinical data to identify emerging harm or risk,
- **Trusted, patient-accessible harm reporting systems** at the local level, designed with feedback loops and data protections,
- **Inclusion of patient-reported data/insights** in root cause analyses and harm response protocols.

Such a requirement would drive adoption of technologies and structures that enhance awareness, speed response, and build accountability — all without increasing administrative burden on clinicians. Instead of outdated, low-yield reporting systems, this CoP would support smarter, higher-impact mechanisms for continuous improvement.

Are there forms that CMS uses that could be simplified or consolidated?

PFPS US Response: CMS should develop and centrally host a **streamlined universal form for patient harm reporting**, accessible to patients and families at any point during or after their care. This would:

- Ensure a *federal-level option* for patients uncomfortable reporting directly to their care providers,
- Provide consistent routing of information to CMS and relevant facilities or agencies,
- Enhance data consistency and usability across programs and systems.

The form should follow best practices in accessibility, plain language, and mobile-first design — and allow both named and anonymous submissions. While local reporting must remain actionable, CMS has a unique opportunity to unify and elevate these voices by creating a trustworthy, easy-to-navigate reporting mechanism

More generally, patients and their caregivers find many CMS forms – or mountains of forms for dually-eligible and/or medically complex family members -- unintelligible, at the most stressful point in our lives. This is not okay. If CMS is serious about reducing complexity and burden, this is an obvious, low-hanging fruit opportunity to learn from patients and families what would help.

Are there opportunities to improve interoperability and reduce duplicative submission requirements across CMS programs or with other payers and programs?

PFPS US Response: The current safety reporting landscape is fragmented, duplicative, and low yield. Hospitals may be required to report similar — or identical — harm events to CMS, state agencies, accrediting bodies, PSOs, and internal risk departments, often using different formats and timelines.

Instead, CMS should lead an effort to develop an **interoperable safety reporting ecosystem**, in which:

- A single event report could populate multiple downstream systems or registries;
- Patients and clinicians have one point of entry for harm documentation;

- Data fields and definitions are aligned across CMS, AHRQ, and accreditation requirements.

Such an approach would reduce reporting fatigue, improve data quality, and make it easier for frontline staff to contribute to real-time safety improvement. It would also give CMS broader situational awareness without additional data entry burden.

Prompt (Fraud/Audit/Claims Integrity): Are there other areas where CMS could reduce improper payments or strengthen claims review?

PFPS US Response: PFPS US encourages CMS to treat **non-reporting of serious, reportable harm** as a billing integrity concern. When hospitals fail to report preventable harm events that would render associated claims non-payable (e.g., surgical errors, hospital-acquired conditions), and still receive full reimbursement, this represents a **serious misalignment of policy and enforcement**.

Failure to disclose harm not only undermines transparency — it also drives **improper payment**. CMS should consider:

- Developing **audit triggers** based on known prevalence vs. reported incidence of harm;
- Encouraging use of AI tools to detect under-reported harm in claims data and EHRs;
- Accepting **patient harm reports** as part of fraud detection and post-payment review processes.

Ultimately, **hiding harm is fraud**. CMS must build visibility into harm detection and treat willful non-disclosure as a form of misrepresentation with financial consequences.