June 10, 2025

Honorable Mehmet Oz, MD, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: RIN 0938-AV45 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes

Dear Dr. Oz,

Patients for Patient Safety US (PFPS US) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed changes to the FY 2026 Inpatient Prospective Payment System (IPPS) rule.

PFPS US is a patient and family led network of individual patient safety advocates and strategic partner organizations working to elevate patient safety as a public health priority in the United States. Although led by users of care, our nationwide network includes a wide range of stakeholders: patients, family caregivers, healthcare providers, researchers, educators, employers, systems safety experts and stakeholder organization leaders, all dedicated to expediting the systemic changes needed to reduce preventable health care harm.

PFPS US and its partners strive to create a healthcare system that prioritizes the safety and well-being of every patient across health care settings. Improving safety and accountability for safety of care also will also reduce unnecessary health care spending, waste, and associated taxpayer burden. Our policy priorities align with CMS's emphasis on transparency, measurement, and public reporting—reaffirmed in this Proposed Rule – fortified by patient/family engagement, as drivers of improvement.

General Comments

PFPS US urges CMS to strengthen its commitment to systemic patient safety and quality for all patients as both a harm reduction and cost savings strategy.

Patients and families shoulder enormous burdens every day, navigating a fragmented and opaque healthcare system, managing care needs for our loved ones or ourselves that upend our lives, as well as managing health records that are spread across uncoordinated providers and platforms.

Approximately one in four hospitalized adults suffers a medical error according to research studies as well as analysis by the DHHS Office of Inspector General, with many experiencing significant preventable harm as a result. 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 our lived realities. This is well-being lost.

We also shoulder the burden of unsafe care as taxpayers. Medical harm is conservatively cited by the NIH to cost the U.S. healthcare system $20 billion annually, though estimates are wide ranging. Other analyses have found that up to $45 billion is spent annually on hospital-acquired infections alone, and that costs attributed to missed or delayed diagnoses in the U.S. are $100 billion annually.[i] Much of this is preventable waste, driven by preventable problems in care is devastating for patients and increases readmissions, ICU stays, rehabilitation, long-term disability care. These costs are absorbed not only by patients and families, but also by payors including Medicare and Medicaid – and ultimately the taxpayer. When preventable unsafe care occurs, it is almost always hidden and still billed to payors and patients. PFPS strongly supports CMS's strategy to advance safety and accountability for the cost and quality of care. PFPS calls on CMS to advance incentives toward quality care and create better disincentives for hiding harm while charging government payors for that substandard care.

Identifying Patient Safety Events

PFPS US urges CMS to address a foundational flaw in our national health care quality and patient safety data infrastructure: the absence of a mechanism for patients and families to directly report harm events they experience in healthcare settings. PFPS calls for CMS to establish a national mechanism that would enable patients and families to directly report harm events or flag safety concerns for improvement, a long-overdue step to help improve the data quality and close the massive gap between actual safety and quality metrics reported by providers.

We could not agree more with CMS's statement that:

> "Poor data quality poses direct threats to patient safety, especially when providers, including eligible hospitals and CAHs, treat patients based on inaccurate or incomplete information. Accountability, transparency, and improvement efforts also suffer when health care actors evaluate—or are evaluated based on—care quality and outcomes that don't reflect true performance due to unreliable or low-quality data."

Harm is hidden and costly. Peer-reviewed research based on medical record reviews indicates that only about 5% of patient harm events are ever formally reported by providers. Missed or delayed diagnosis that contribute to preventable death or harm are especially under-reported, harming up to 795,000 patients annually. Current patient safety incident reporting systems rely almost entirely on internal hospital documentation, yet patients and families are often the most reliable observers of lapses in care coordination across the continuum of care. Studies show that, if given access to a reporting system, patients identify patient safety events that providers do not. One such study showed that when given an app to report patient safety events in hospitals, patients reported 52 events that met required reporting criteria, only 1 of which was reported by hospital staff.[ii]

Patients and families need a formal mechanism to report safety concerns and events to CMS. CMS should use its guidance to ensure that all entities that accredit or receive payment are held to a standard of better reporting, including patient reporting, of quality and safety. This should include the CDC's NHSN database, CMS's CoP guidance, The Joint Commission, Patient Safety Organizations at AHRQ and other safety oversight and payment entities.

When patient harm is hidden, taxpayers pay for the excess cost of this hidden harm. Given the Trump Administration's commitment to government accountability, PFPS US hopes that HHS leadership will address hidden, yet paid for, harm and create patient access to report safety concerns and stop the silencing of patients.

We understand that a priority of CMS is 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 and safety improvement. PFPS US urges CMS to continue to ensure that what is eliminated is not essential scaffolding for patient safety and public trust. For example, PFPS US is deeply concerned by suggestions being made to eliminate HCAHPS surveys as burdensome. We agree that HCAHPS survey instruments can be improved in both content and mode of administration. We are active, engaging both patient groups and health systems, in identifying patient-reported outcomes and experience measures that contribute to continuous improvement.[iii] Improving HCAHPS to better inform strategies that improve clinical outcomes should be the focus, not eliminating this established pathway for patient reporting altogether.

Modernizing Safety Data

As part of modernization of patient safety infrastructure in the United States, PPFS US also supports advancing the use of interoperable electronic clinical quality measures (eCQM) at CMS and responsibly developed and managed AI in tracking patient safety events as well as predictive conditions that are precursors to patient safety events. Since eCQM and AI is only as good as the data it collects, we believe including patient-reported data around harm and quality of care is essential to feed into the data pulls and models. Without patient input, AI and eCQM generated safety and quality data is incomplete and often misleading, impeding both learning and improvement as well as contributing to waste in health care spending.

Structural Measures

One incentive that CMS has employed to advance safety is the Patient Safety Structural Measure (PSSM). PFPS US strongly supports CMS's patient safety structural measure to advance patient safety leadership commitment and accountability for safe standards of care. From Demming to Donebedian, structural measures have been critical to complement outcomes and process measures by actively engaging leadership and governance boards of health care organizations in establishing and maintaining organizational best practices. Sustainability is a stubborn challenge that historically has undermined continual progress in reducing preventable harms such as surgical site infection, falls with injury, pressure ulcers and other costly patient safety events. A new Agency for Healthcare Research and Quality (AHRQ) white paper issued just last month reviewed the evidence on the effect of patient safety best practices, found that a lack of leadership

engagement and maintenance of clear protocols in healthcare provider organizations were barriers to improved safety. CMS advancement of the patient safety structural measure incents leadership commitment and high reliability processes for patient safety improvement.

Accordingly, we are pleased to see that there is no recommendation to remove the Patient Safety Structural Measure (PSSM) or the Age Friendly Hospital Measure in the FY 2026 Proposed Rule.

We are disappointed, however, to see recommendations for the removal of the Social Determinants of Health (SDOH) and Hospital Commitment to Health Equity structural measures. Most hospitals collected SDOH data because it better helps them understand their variance in their patients' needs and to connect with community organizations that can support patients. Removing these measures now would signal that CMS no longer views leadership commitment and infrastructure as essential to delivering safe care for each and every patient. This would be a retreat on the promise to advance every American's well-being. We note that structural measures do not have financial penalties nor do they divert frontline healthcare workers from patient care. They create an incentive for good processes and establish standards that hospitals should strive to meet. The result is motivation for fewer variations in care, more good outcomes, less waste, and lower costs from savings in extended stays or readmissions. To Make America Healthy Again, CMS should strengthen the connection between screening and care coordination for All Americans. Hospitals need support in making this data actionable, not leeway to avoid it. All Americans deserve to be supported in their care and receive safe, quality care.

Additional Comments on Specific Proposed Provisions

PFPS US Supports the proposal to include data from Medicare Advantage (MA) patients in the Hospital Inpatient Quality Reporting (IQR) Program safety measure set and shortening the performance period. Including MA beneficiaries in hospital safety and outcome measures will provide consumers with more robust and reliable information about the care Medicare beneficiaries receive in specific hospitals and enable better-informed decisions about where to seek healthcare. PFPS believes that all government funded payment should be held to accountability for safety performance standards.

PFPS US Supports publicly reporting PPS-Exempt Cancer Hospital (PCH) data on the Care Compare webpage. Displaying data submitted by PCHs under the PCH Quality Reporting Program in the more user-friendly format of the Compare website and making data more widely available would promote greater transparency and better support patient and family decision-making about where to seek intensive cancer care.

PFPS US strongly supports CMS's attention to Delirium as a significant and potentially preventable patient safety issue across all health care settings. Delirium is a common complication of illness or injury that can also be induced by long exposure to the artificial environment of inpatient health care settings. Delirium is recognizable and, most often, treatable. Left unrecognized, uninvestigated, and untreated, it can lead to a host of poor outcomes including

death. We urge CMS to consider measure concepts that apply to all inpatient care settings, not just long-term care hospitals.

Medicare Promoting Interoperability Program (formerly Meaningful Use)

- **PFPS US supports modifying the Security Risk Analysis measure** to require eligible hospitals, including Critical Access Hospitals to attest "yes" to having conducted security risk management of electronic Protected Health Information associated with the implementation and use of Electronic health Records (EHR) as required under the HIPAA (Health Insurance Portability and Accountability Act) Security Rule, in addition to the existing measure requirement to attest "yes" to having conducted security risk analysis.
- **PFPS US supports modifying the EHR SAFER Guides measure** to require eligible hospitals to attest "yes" to completing an annual self-assessment using the updated SAFER Guides published in January 2025.

In closing, and on behalf of patients and their family members across the nation, we appreciate the opportunity to share our insights and concerns. This Public Comment was crafted by a work group of PFPS US members active in contributing the patient voice and lived experience to public policy.

Patients for Patient Safety US

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[i] Rodziewicz TL, Houseman B, Vaqar S, et al. Medical error reduction and prevention. [Updated 2024 Feb 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK499956/; Epner, P. Diagnostic Error: Common, Catastrophic and Costly, The Pathologist, Apr 2021, available at: https://thepathologist.com/issues/2021/articles/apr/diagnostic-error-common-catastrophic-and-costly

[ii] Bardach N, et al, Family Input for Quality and Safety (FIQS): Using mobile technology for in-hospital reporting from families and patients, *Journal of Hospital Medicine*, 2022, 17:6, 456-465. See also, Sharm A, et al, Incorporating Family and Patient Voices into Safety Efforts: Implementation of a Multi-Hospital Pediatric Safety Collaborative to Learn from Patient-Reported Safety Events, AcademyHealth Presentation, June 30, 2024, available at: https://academyhealth.confex.com/academyhealth/2024arm/meetingapp.cgi/Paper/63220

[iii] See PFPS US Project PIVOT, available at https://www.pfps.us/project-pivot.