Session 1: *Approaches to Improve Patient Safety in Alternative Payment Models*

Presenters:

Subject Matter Experts

- **Susan E. Sheridan, MIM, MBA, DHL** – President and CEO, Patients for Patient Safety US
- **Michelle Schreiber, MD** – Deputy Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Quality Measurement and Value-Based Incentives Group (QMVIG), Centers for Medicare & Medicaid Services (CMS)
- **Susannah Bernheim, MD, MHS** – Chief Medical Officer, CMS Innovation Center, CMS
- **Jason W. Mitchell, MD** – Executive Vice President and Chief Medical Officer, Geisinger
- **Dheerendra Kommala, MD** – Chief Medical Officer, ECRI

Session 1: *Approaches to Improve Patient Safety in Alternative Payment Models*

Susan E. Sheridan, MIM, MBA, DHL

President and Chief Executive Officer
Patients for Patient Safety US (PFPS US)

Patients for Patient Safety US

Sue Sheridan, MBA, MIM, DHL

President and CEO

PTAC Meeting, June 15, 2026

Session 1: *Approaches to Improve Patient Safety in Alternative Payment Models*

Organization Vision And Mission

Organization Vision

A world in which no one is harmed in health care, and every patient receives safe and respectful care every time, everywhere.

Organization Mission

To unite patients, families, and stakeholders to improve diagnostic accuracy, advance patient safety, and eliminate health disparities through research, policy, advocacy, and technology.

Sue Sheridan

Current Roles:

President and CEO, Patients for Patient Safety US

Co-chair, National Academy of Medicine, Patient Safety in the Era of AI

Previous Leadership Experience:

Director Patient Engagement, The Society to Improve Diagnosis in Medicine

Patient and Family Engagement Advisor, CCSQ, CMS

Director Patient Engagement, PCORI

External Lead, Patients for Patient Safety, the World Health Organization

What brings me here?

THE NATION'S NEWSPAPER

USA TODAY

NO. 1 IN THE USA . . . FIRST IN DAILY READERS

Test delayed: Pat Sheridan sued a Boise hospital and pediatrician, saying son Cal wasn't given a blood test soon enough after birth to detect dangerously high levels of bilirubin. Cal, now 5, has brain damage.

Porous safety net allows lethal medical mistakes

Care has failed to keep up with technological advances

By Robert Davis and Julie Appleby
USA TODAY

An overworked nurse infuses the wrong type of blood into a patient. An experienced pharmacist puts the wrong drug in a child's medicine bottle. A less experienced surgeon blows a heart procedure that is performed more frequently, and flawlessly, down the street.

All the patients die, victims of medical errors. Up to 98,000 such deaths a year — perhaps the nation's most disturbing health care statistic — have health officials scrambling to find fixes. They are spurred by an Institute of Medicine report last November that named errors made by doctors, nurses and hospital workers the USA's eighth-leading killer.

What they have discovered are glaring problems in the health care system, many of which are expected to be at the heart of a new institute report in the next few months. Among them:

► Too many modern drugs and treatments for doctors to keep in mind as they rush from patient to patient.

► Nurses taking on more work as pharmacies and other hospital departments close early or reduce their staffs to save money.

Special Report
To err can be deadly

► Sharing data could save lives. Story, 1B

► Talk live at 1 p.m. ET today at talk.usatoday.com

► A shift toward performing more surgeries in less regulated facilities outside hospitals, such as doctors' offices and clinics, putting patients at greater risk.

► In perhaps the most worrisome development, a slowness by the medical community to embrace technology that could help doctors avoid errors. Not only does the situation create more risk for patients, but it has slowed progress. The federal government has declined to approve some drugs, for example, because it can't trust doctors to remember their complexities.

"Medicine, the way it's practiced in the United States today, can be pretty unsafe," says Andrew Wiesenthal, a Permanente Federation doctor who is overseeing the development of a computer system to help Kaiser Permanente practice safer medicine.

Improvements must be made, he says. "There is a moral imperative about it."

He and others are following the technological success of the Veterans Affairs hospital in Washington, D.C., where physicians use a $365,000 computer system that scans bar codes on patient bracelets and medicines.

If a doctor is about to make a mistake,

Please see COVER STORY next page ►

The Problem

- Preventable harm in healthcare is the **3rd leading cause of death** in the United States
- Diagnostic errors contribute to death or serious harm of approximately **900,000 Americans** annually at a cost of approximately $200 billion annually
- There have been **few measurable reductions** in adverse events over the past decade (OIG)
- Hospitals **do not capture half** of preventable or potentially preventable patient harm events. Of the patient harm events captured**…..few led to hospitals making improvements for patient safety** (OIG)
- Current **APMs do not directly measure patient or diagnostic safety from the patient perspective,** thereby missing many patient safety breakdowns, communication failures, and delays in diagnosis

What We Know

“If you can’t measure it, you can’t improve it.” Peter Drucker

CMS and CDC are calling on health care systems to **learn directly from patients and families** to improve patient experiences and outcomes related to patient and diagnostic safety

*“Through published work on patient-reported incidents, researchers demonstrated **patients can detect and report harm and safety concerns** occurring during their healthcare trajectory that **may go otherwise unnoticed by clinicians**.”* https://pubmed.ncbi.nlm.nih.gov/37830363/

Project PIVOT:

(Patients Involved in deVeloping Outcomes Together)

Improving patient safety, diagnostic excellence, and reducing biases in care by learning from **patient-reported experience and outcome measures (PROMs and PREMs)** that matter most to patients, families, and communities

Project PIVOT was partially funded through a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award (EASCS-34604).

Project PIVOT Patient and Diagnostic Safety PROM and PREM Safety Questions

(Currently being refined by Press Ganey and they will begin piloting and validating 3rd quarter of 2026)

- During your hospitalization, did you **experience unexpected harm** from the care and/or treatment that you received? If YES, please describe.
- During your hospitalization, did you feel that you were **treated differently due to personal characteristics**? If YES, please describe.
- During your hospitalization, did you feel that any of your **concerns were dismissed** by healthcare team members? If YES, please describe.
- During your hospitalization, were you **informed of how to report a concern** about your safety, quality of your care, or your experience?
- During your hospitalization, were you **informed of how to escalate care** with a rapid response team or how to seek a second opinion?
- Before left the hospital, were you **given a list of pending test results** and instructions how to get them?

Stakeholders on the Table

PressGaney, The Leapfrog Group, CMS Centers for Medicare & Medicaid Services, National Academy of Medicine, ECRI, MedStar Georgetown University Hospital, HOMERuN Hospital Medicine ReEngineering Network, Dana-Farber Cancer Institute, Institute for Healthcare Improvement, UW Medicine, Johns Hopkins Medicine, Oracle, Stanford Health Care, Beauregard Health System, Geisinger, apsf Anesthesia Patient Safety Foundation, Kaiser Permanente, UCSF, AHRQ Agency for Healthcare Research and Quality

Benefits of Adding Validated PIVOT PROMs and PREMs into Payment Models (A new data layer)

VALUE

Measures what matters most to patients.

TRANSPARENCY

Makes hidden harms and near misses visible, measurable and actionable.

PREVENTIVE

Real-time patient-reported measures identify safety risks before harm occurs.

LEARNING HEALTH SYSTEM

Supports earlier intervention and continuous improvement.

ACCOUNTABILITY

Creates C-suite accountability for patient and diagnostic safety.

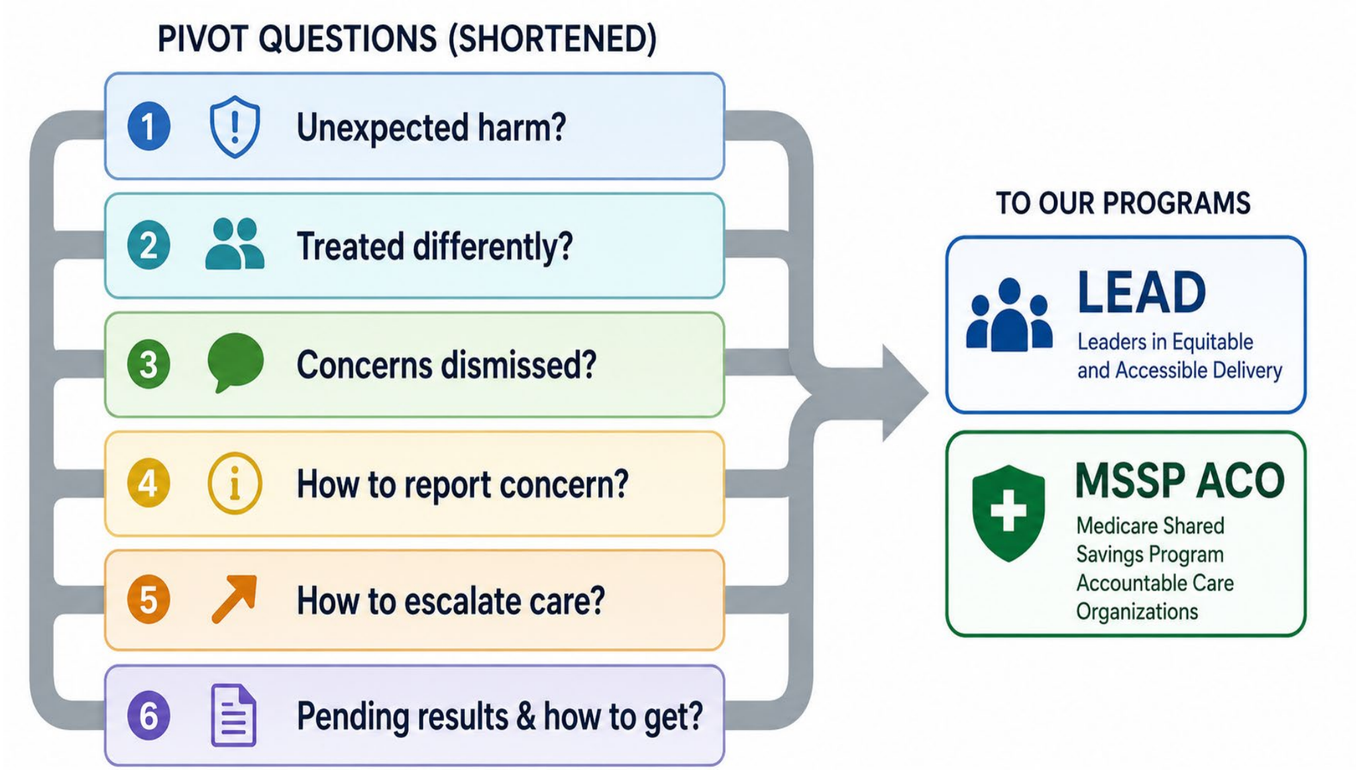
INTEGRITY

Harder to game than many administrative measures.

PIVOT patient-reported measures strengthen transparency, accountability, and safer care.

Recommendation (Phase 1)

Add the validated patient-reported PIVOT measures to quality measures of existing ACO models such as the LEAD and/or MSSP models



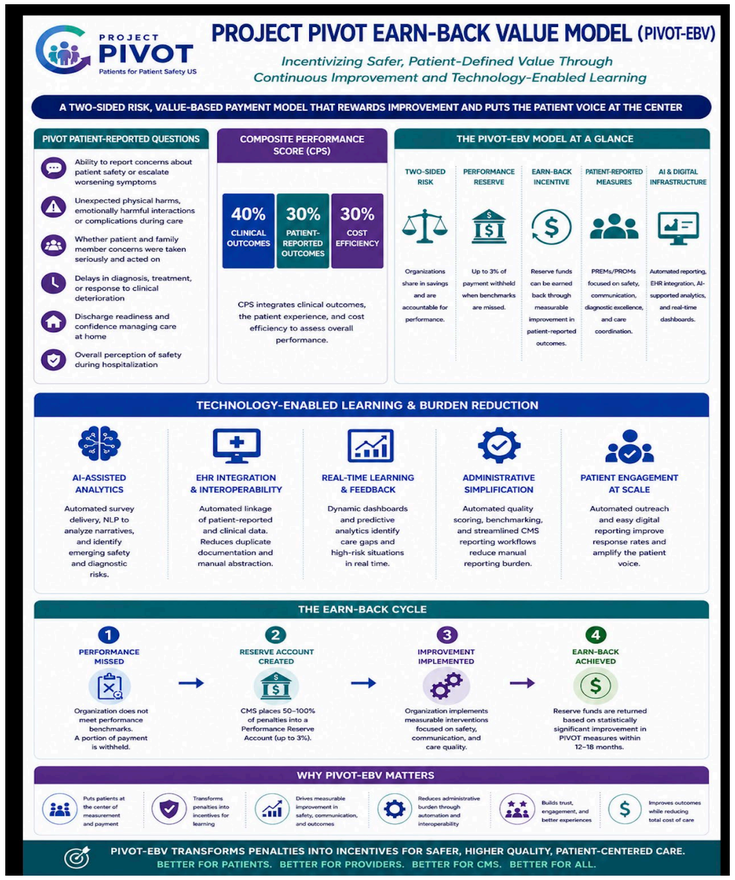
Phase 1 PIVOT Model

Benefits:

- ACO infrastructure already exists
- Minimal burden of collection (using AI)
- Patient centered
- Safety oriented
- Promotes diagnostic excellence
- Reduces costs

The Next Generation: The PIVOT “Earn Back” Value Model

(For tomorrow’s discussion)



- Withhold % earned shared savings for missing performance (safety) measures
- Withheld funds put in reserve account
- ACO implements safety improvements
- ACOs earn back % of withheld funds based on performance on PIVOT measures

Benefits:

- Allows “second chance” to reinvest and recover performance losses

- Reinforces continuous improvement in patient safety rather than one-time penalty cycles. (National learning collaborative?)

References/Supporting Documents

- **Adverse Event Report: Office of Inspector General** https://oig.hhs.gov/reports/featured/adverse-events/
- **Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer** https://oig.hhs.gov/reports/all/2025/hospitals-did-not-capture-half-of-patient-harm-events-limiting-information-needed-to-make-care-safer/
- **How safe is the diagnostic process in healthcare?** https://qualitysafety.bmj.com/content/33/2/82
- **Using Patient Experience Surveys to Identify Potential Diagnostic Safety Breakdowns: A Mixed Methods Study** https://pubmed.ncbi.nlm.nih.gov/39283602/
- **The benefits and opportunities: Engaging patients in identifying and reporting patient safety incidents** https://pubmed.ncbi.nlm.nih.gov/37830363/
- **Family Input for Quality and Safety (FIQS): Using Mobile Technology for In-Hospital Reporting from Families and Patients** https://pmc.ncbi.nlm.nih.gov/articles/PMC12179642/
- **Patient and Family-Initiated Safety Event Reporting: A Scoping Review** https://patientsafetyj.com/article/156234-patient-and-family-initiated-safety-event-reporting-a-scoping-review
- **OECD (2018), "Measuring patient safety: Opening the black box"**, OECD Publishing, Paris, https://doi.org/10.1787/4a764a70-en.

Thank You

Session 1: ***Approaches to Improve Patient Safety in Alternative Payment Models***

Michelle Schreiber, MD

Deputy Director, Center for Clinical Standards and Quality (CCSQ)
Director, Quality Measurement and Value-Based Incentives Group (QMVIG)
Centers for Medicare & Medicaid Services (CMS)

Targeting Improvement in Patient Safety

PTAC Advisory Meeting – June 2026

Michelle Schreiber, MD

Deputy Director, Center for Clinical Standards and Quality

Director Quality Measurement and Value Based Incentives Group

Centers for Medicare and Medicaid Services (CMS)

Safety: An Urgent Public Health Issue

- Prior to 2019, progress was made to improve safety. Safety metrics significantly declined 2019-2023.
- The National Action Alliance for Patient and Workforce Safety coordinated through AHRQ is taking a collaborative and comprehensive approach to improve patient and workforce safety.
- July 2025 OIG report “Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer”
- CMS is committed to advancing patient safety through Innovation, Collaboration and Evidence Based Practices.

When a patient is admitted to hospital, harm occurs 24% of the time; more than 40% determined to be preventable (HHS, 2018).

Between 2010-2019 rates of adverse events for heart failure, pneumonia, and major surgical procedures significantly decreased (JAMA, 2022).

Performance on a range of other key safety metrics from 2019 to 2021 also showed significant worsening (CMS, 2024).

From 2020 – 2023 healthcare-acquired infections, falls, and pressure ulcers increased (AHRQ, 2023).

Cause for Optimism

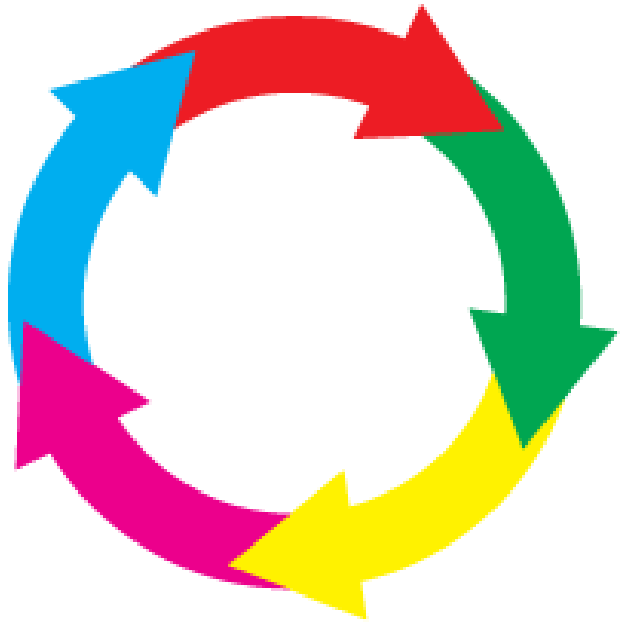
CDC “Current HAI Progress Report” shows improvement from 2021-2022

- 9% decrease in CLABSI with 21% decrease in ICU’s
- 12% decrease in CAUTI with 27% decrease in ICU’s
- 19% decrease in VAE; 37% decrease in non-ICU
- No significant changes in SSI (except 8% increase for SSI in hip arthroplasty)
- 16% decrease in hospital onset MRSA
- 9% decrease in CDI for IRF but otherwise no significant change
- No significant change for LTCH

CDC “Current HAI Progress Report: 2022 National and State Healthcare Associated Infections Progress Report, Division of Healthcare Quality Promotion, 12/1/2023

CMS Quality and Safety Levers An interconnected system to support patient safety

- **Conditions of Participation:** Establishes the “floor” for what is needed for quality and safety
- **Coverage and Payment:** Determinations of what is covered for payment
- **Audit and Evaluation:** Post participation evaluation and auditing for compliance
- **Survey and Certification:** On site surveyors from CMS or other Accrediting Organizations to observe compliance
- **Quality Improvement Organization:** Hands on assistance to improve quality – Hospitals, Clinicians, Skilled Nursing Facilities
- **Quality Measurement:** The structured definitions for the data to evaluate performance. CMS Inventory of approximately 470 measures. Of these, there are 98 Safety measures EXTERNAL to hospital settings.
- **Value Based Incentive Programs:** 27 Quality Incentive and/or Penalty Programs to promote quality and safety
- **Payment and Innovative Advanced Payment Models:** Current and new policies and models for payment



Cross Government Efforts to Support Patient Safety

- AHRQ – Research and education, PSO reporting, Safety measures (PSI), patient experience measures (but no specific safety questions), Leadership Alliance to Promote Patient Safety, Diagnostic Safety
- CDC – NHSN reporting network (healthcare acquired infections) and multiple initiatives such as prevention, smoking cessation, maternal safety
- PCAST – President's Council of Advisors on Science and Technology
- VHA – High reliability
- FDA – Medication Safety
- IHI – National Steering Committee for Patient Safety (several Federal representatives)

CMS Efforts to Advance Patient Safety

TRANSPARENCY

- Quality measurement provides the foundation for driving meaningful improvement
- Empower patients to make informed care choices through Public Reporting
- Modification of Hospital Star ratings to support safety (One Star reduction for poor safety performance)

TECHNOLOGY & DATA

- Transition to Digital measures for rapid data and lower burden
- Use of AI and Advanced Analytics for better, faster identification and deeper understanding of harm
- Real time use of data/data analytics to prevent or mitigate harm

CULTURE OF SAFETY

- Provide expert support from QIO networks to help providers improve care
- Encourage patient engagement, high reliability and leadership/governance commitment
- Culture of safety surveys
- Communication and Resolution Programs

PAYMENT

- Evaluation of payment/non-payment for dangerous mistakes that should never occur such as Serious Reportable Events
- Conditions of Participation establish minimum quality and safety standards – failure results in loss of participation in Medicare/Medicaid.

National Quality Forum updating list of “Never Events”

Recent Accomplishments

- Birthing Friendly Designation for safe maternal care in hospitals
- Patient Safety Structural Measure (PSSM) to ensure organizational structures and capacity for safety (hospital)
- Age Friendly Measure – to ensure organizational alignment around safe care for the elderly (hospital)
- Quality Improvement Organization 13th Statement of Work
- Stronger weighting for Safety in Hospital Stars Program
- Suite of digital, all payer measures for patient safety (hospital)
- Newer diagnostic safety metrics (MIPS)

Quality Measurement

- Portfolio of 476 measures – 122 dedicated to Patient Safety, of which 98 are EXTERNAL to hospital (clinicians and post acute care)
- Safety focus areas: Medication Safety, Complications, Healthcare Acquired Infections, Falls, Pressure Injuries, Diagnostic Safety, Organizational Structures for Safety
- Many but not all Value Based Programs include safety measures
- Penalties for Patient Safety performance minimal (1% penalty for Hospital Associated Safety Conditions – HAC program)
- Models and Advanced Payment (CMMI, MSSP) include few safety metrics and no model is specifically focused on safety as the primary goal

Patient Safety Structural Measure

- Leadership commitment to eliminating preventable harm
- Strategic planning and organizational policy
- Culture of safety and learning health systems
- Accountability and transparency
- Patient and family engagement

Electronic Clinical Quality Measures for Safety

Measure	Status
Hyper and Hypoglycemia	Finalized
Opioid Overdose – Naloxone Administration	Finalized
Acute Kidney Injury	Finalized
Pressure Injury	Finalized
Severe Maternal Morbidity	Finalized
Falls With Injury	Finalized
Post Operative Respiratory Failure	Finalized
Sepsis Outcome	MUC 2025
Venous Thromboembolic Events	Proposed 2026
Medication Related Bleeding	In progress
Death Among Surgical Inpatients	Finalized

**Measures begin in IQR before being considered for Hospital Acquired Condition (HAC) Program.

Successes and Shortfalls

Successes	Shortfalls/Challenges
Quality Measurement has drawn focused attention to patient safety	Measurement sometimes perceived as compliance not improvement, burdensome and not timely
Demonstrable Improvement in Some Areas, especially Infection Prevention and some Complications	Most patient safety efforts have been in the Acute Care Setting
Quality Improvement Organization assistance has lead to success	Direct assistance programs can be costly and time intensive
Newer digital measures more timely and more robust data	Current Measure reporting is retrospective and data may be old by the time it is made public
High Reliability Organizations often perform better in safety	Serious Reportable Event data is difficult to obtain especially in a standardized format
Most effective change when leadership and governance fully support safety	Safety is not always the first leadership priority – in measures, clinical practice, or in model development
Incentives/penalties can be effective	Limited incentives/penalties barrier to full implementation

Future Considerations

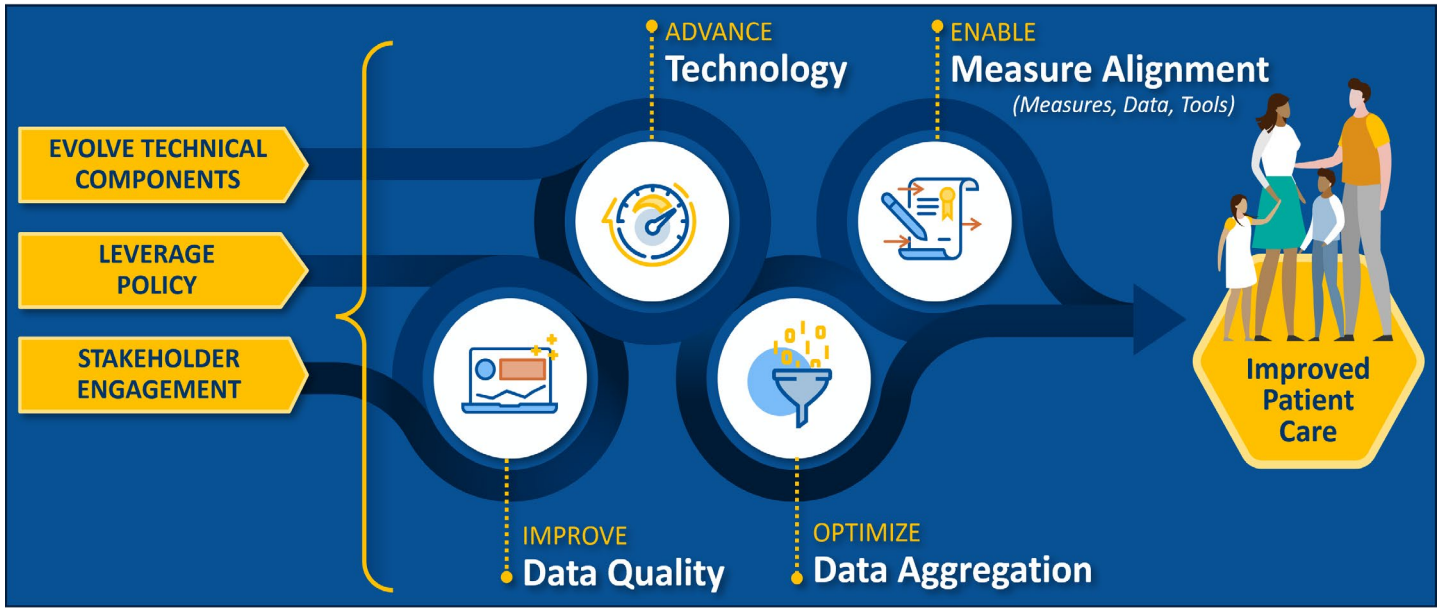
- New Measure Concepts
  - Diagnostic Safety
  - Safety of EMR and AI
- Use of Artificial Intelligence
- Reporting of Harm
  - Patient Safety Organizations
  - Serious Reportable Events
  - Direct Patient Reporting of Harm
- Incorporation of Patient Voice and Patient Reported Outcomes

Advancing Digital Quality Measurement

Enables a future in which **care quality is entirely measured digitally**, using standardized, interoperable data

Provides **usable, timely, detailed data** from multiple sources to support delivery of high-quality care, quality improvement and patient use

Produces **reliable and valid measurement results** common across multiple programs and payers



Maximizes value of electronic health record (EHR) data mapping and reporting workflows by leveraging Fast Healthcare Interoperability Resources (FHIR®) application programming interface (API) technology that is already required for interoperability

Considerations for Advanced Payment Models - Safety

- Model development with primary focus on safety, including ROI for safety calculations?
- Expansion of patient safety beyond hospital walls
- Should all models include an element of patient safety?
- Weighting of patient safety and quality in model evaluation
- Ensuring direct patient voice in model design and ability to report events
- Advance technologies to support safety (monitoring, predictive analytics, devices and device safety)

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

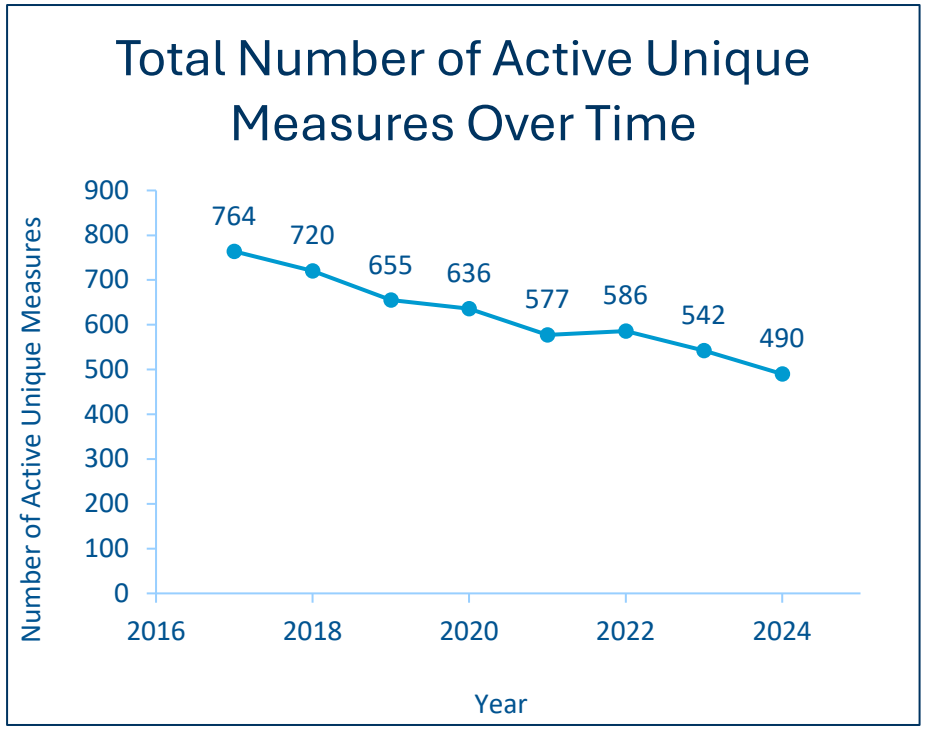
APPENDIX

Additional slides for further information on patient safety

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

Measure Portfolio

- Portfolio of 490 quality measures. Increase in outcome measures (40%) and digitally sourced measures (88%)
- CMS funds the Endorsement & Maintenance process, Measure Set Review and Pre-Rulemaking Measure Review
- Most recent focus for measure development has been maternal health, safety, behavioral health, dialysis and organ transplantation, and cost measures



27 CMS Statutory Value-Based Programs (VBP)

(not including CMMI models)

Hospital	Clinician and Other	Post Acute Care and Other
Hospital Inpatient Quality Reporting**	Merit-based Incentive Payment System/Quality Payment Program*	Skilled Nursing Facility Quality Reporting**
Hospital Readmissions Reduction*	Medicare Shared Savings Program/Accountable Care Organizations (*CM*)*	Skilled Nursing Facility Value-Based Purchasing*
Hospital Value-Based Purchasing*	Medicare C&D Quality (*CM*)*	Expanded Home Health Value-Based Purchasing Model*
Hospital-Acquired Conditions*	Clinician Promoting Interoperability*	Home Health Quality Reporting**
PPS-exempt Cancer Hospital**	End Stage Renal Disease Quality Incentive Program*	Inpatient Rehabilitation Facility**
Inpatient Psychiatric Facility**	Medicaid Adult Core Set (*CMCS*) **	Long-Term Care Hospital**
Hospital Outpatient Quality Reporting**	Medicaid Pediatric Core Set (*CMCS*) **	Hospice Quality Reporting**
Promoting Interoperability – Hospital*	Medicaid Behavioral Health Core Set *(CMCS)* **	Electronic Prescribing for Controlled Substances**
Rural Emergency Hospital**	Ambulatory Surgical Center**	Marketplace Quality Reporting**

Red* = PAY FOR PERFORMANCE; Blue** = PAY FOR REPORTING

Quality Programs: Public Reporting

New Change to Hospital Stars – Reduction of One Star for Poor Patient Safety Performance – this year only for 5-star hospitals; 2027 for ANY hospital

Hospitals	Clinicians and Plans	Post Acute Care
Hospital Compare (including Birthing Friendly designation)	Physician Compare – Doctors and Clinicians	Nursing Home Compare
Hospital Stars* (Quality, Outcomes, Safety and Experience)	Clinician Stars at a Measure Level*	Nursing Home Stars* (Overall, Healt h Inspection, Staffing, Quality)
Long Term Care Hospital Compare	Medicare Advantage Stars*	Home Health Stars* (CAHPS and Overall)
Dialysis Facility Compare	Marketplace Stars*	Hospice Compare (CAHPS)
Dialysis Facilities Stars*		Inpatient Rehabilitation Facility Compare

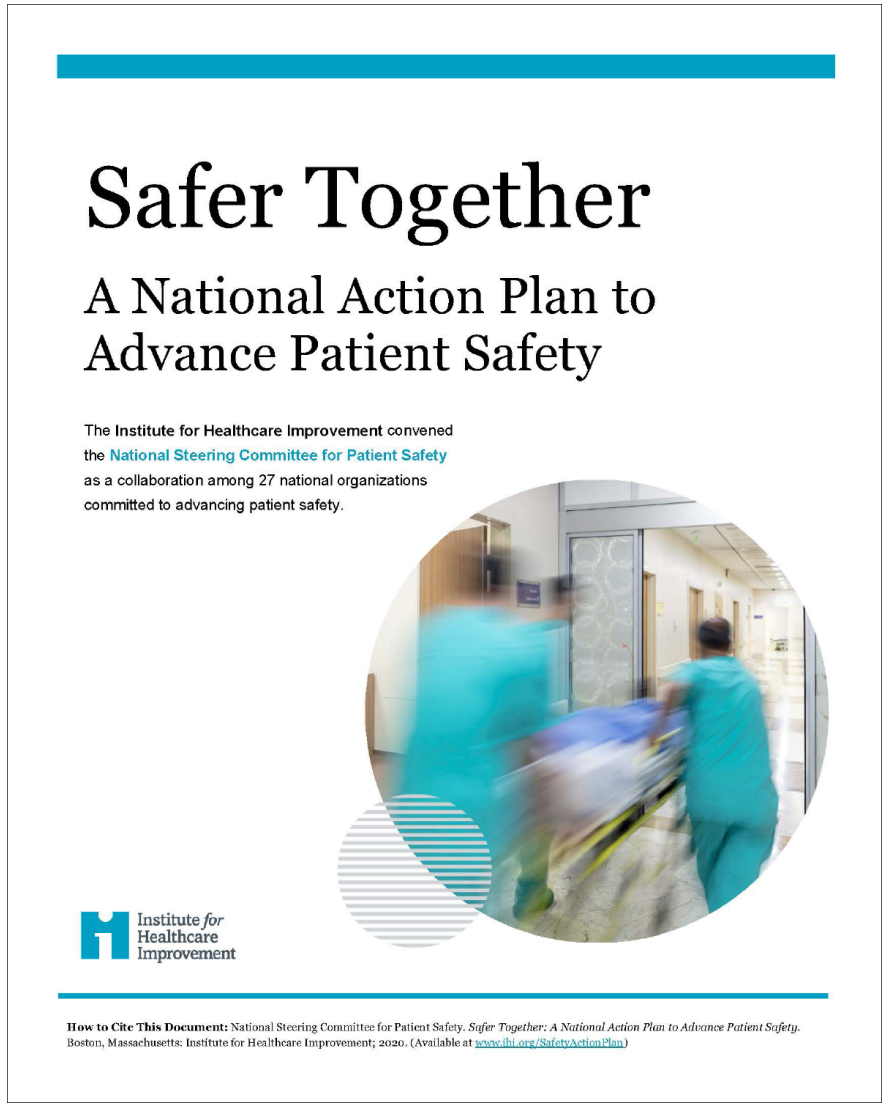
All Star Programs also have Care Compare information; not all Care Compare programs have Stars information. Additional public-facing information is also available via the Provider Data Catalog.
Red* connotes Stars Program.

Patient Safety Structural Measure

- Finalized for use in acute hospitals and PPS exempt cancer hospitals in FY 2025 Inpatient Payment Final Rule
  - Excludes children's hospitals, inpatient psychiatric facilities, long term care or rehabilitation hospitals
- Reporting began for hospitals January 1, 2025
- First reporting is due Spring, 2026. Reporting is through CDC NHSN. Public reporting October 2026 on CMS Hospital Care Compare
- Hospitals who fail to report face reduction in annual payment update beginning in 2027
- This is a structural/attestation measure
  - Meant to ensure that hospitals have structural components and operational policies/processes that support patient safety
  - Evidence based, reviewed extensively by Technical Expert Panel
  - More information: https://qualitynet.cms.gov/inpatient/iqr/measures#tab2

National Alignment for Safety

- Domains reflect the “Safer Together: A National Action Plan to Advance Patient Safety” (IHI and AHRQ)
  - Leadership commitment to eliminating preventable harm
  - Strategic planning and organizational policy
  - Culture of safety and learning health system
  - Accountability and transparency
  - Patient and Family Engagement



Patient Safety Structural Measure

- Leadership commitment to eliminating preventable harm
- Strategic planning and organizational policy
- Culture of safety and learning health systems
- Accountability and transparency
- Patient and family engagement

Domain 1: Leadership Commitment to Eliminating Preventable Harm

Hospital senior governing board prioritizes safety as a core value, holds hospital leadership accountable for patient safety, and includes patient safety metrics to inform annual leadership performance reviews and compensation.

Leaders place patient safety as a **core institutional value**. One or more C-suite leaders oversee a system-wide assessment on safety and the execution of patient safety initiatives and operations, with specific improvement plans and metrics. These plans and metrics are widely shared across the hospital and governing board.

Governing board, in collaboration with leadership, ensures **adequate resources** to support patient safety (such as equipment, training, systems, personnel and technology)

Reporting on patient safety and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event cause analysis, infection outbreak, culture of safety, or other patient safety topics) **accounts for at least 20% of the regular board agenda** and discussion time for senior governing board meetings.

C-suite executives and individuals on the governing board are **notified within 3 business days** of any confirmed serious safety events resulting in significant morbidity, mortality or other harm.

Domain 2: Strategic Planning & Organizational Policy

Hospital has a **strategic plan** that publicly shares its commitment to **patient safety as a core** value and outlines specific safety goals and associated metrics, including the goal of "zero preventable harm"

Safety goals include the use of **metrics to identify and address issues in safety outcomes** based on the patient characteristics determined by the hospital to be most important to health care outcomes for specific populations served.

Implemented written policies and protocols to **cultivate a *just* culture** that balances no-blame and appropriate accountability and reflects the distinction between human error, at-risk behavior, and reckless behavior.

Hospital requires **implementation of patient safety curriculum and competencies** for all clinical and non-clinical hospital staff, including C-suite executives and individuals on the governing board, regular assessments of these competencies for all roles, and action plans for advancing safety skills and behaviors.

Has an **action plan for workforce safety with improvement activities**, metrics, and trends that address issues such as slips/trips/falls prevention, safe patient handling, exposures, sharps injuries, violence prevention, fire/electrical safety and psychological safety.

Domain 3: Culture of Safety & Learning Health System

Conducts a hospital wide **culture of safety survey** using a validated instrument annually, or every two years with pulse surveys on target units during non-survey years. Results are shared with governing board and hospital staff and used to inform unit-based interventions to reduce harm.

Has a dedicated team that conducts event analysis of serious safety events using an evidence-based approach, such as the National Patient Safety Foundation's **Root Cause Analysis and Action**.

Has a **patient safety metrics dashboard** and uses external benchmarks (such as CMS Star Ratings or other national databases) to monitor performance and inform improvement activities on safety events (such as: medication errors, surgical/procedural harm, falls, pressure injuries, diagnostic errors, and healthcare-associated infections).

Participated in **large-scale learning network(s) for patient safety improvement** (such as national or state safety improvement collaboratives), shares data on safety events with these network(s) and has implemented at least one best practice from the network or collaborative.

(Continued on next slide)

Domain 3 Continued: Culture of Safety & Learning Health System

Implements a minimum of **4 of the following high reliability practices**:

1. Tiered and escalating (e.g., unit, department, facility, system) **safety huddles** at least 5 days a week, with one day being a weekend, that includes key clinical and non-clinical (e.g., lab, housekeeping, security) units and leaders, with a method in place for follow-up on issues identified.

2. Hospital leaders participate in **monthly rounding** for safety on all units, with the C-suite executives rounding at least quarterly, with a method in place for follow-up on issues identified.

3. A **data infrastructure to measure safety**, based on patient safety evidence (e.g., systematic reviews, national guidelines) and data from the EMR that enables identification and tracking of serious safety events and precursor events. This data is shared with C-suite executives at least monthly, and the governing board at every regularly scheduled meeting.

4. Technologies, including a CPOE system and BCMA system, that promote **safety and standardization of care** using evidence-based programs.

5. The use of a **defined improvement method** (or hybrid of proven methods), such as Lean, Six Sigma, PDSA, and/or high reliability framework.

6. Team **communication and collaboration training** of all staff.

7. The use of **human factors engineering principles** in selection and design of devices, equipment and processes.

Domain 4: Accountability & Transparency

Has a **confidential safety reporting system** that allows staff to report patient safety events, near misses, precursor events, unsafe conditions and other concerns, and prompts a feedback loop to those who report.

Voluntarily works with a **Patient Safety Organization** listed by AHRQ to carry out patient safety activities, such as, but not limited to, the collection and analysis of patient safety work product, dissemination of information such as best practices, encouraging a culture of safety, or activities related to the operation of a patient safety evaluation system.

Patient safety metrics are tracked and reported on to all clinical and non-clinical staff and made public in hospital units (e.g., displayed on units so that staff, patients, families, and visitors can see).

Uses standard measures to **track the performance of our communication and resolution program**, and reports these measures to the governing board at least quarterly

(Continued on next slide)

Domain 4: Accountability & Transparency (Continued)

Has a defined, evidence-based communications and resolutions program reliably implemented after harm events, such as AHRQ's Communication and Optimal Resolution (CANDOR) toolkit, that contains the following elements:

1. Harm event identification
2. Open and ongoing communication with patients and families about the harm event
3. Event investigation, prevention, and learning
4. Care-for-the-caregiver
5. Financial and non-financial reconciliation
6. Patient-family engagement and on-going support

Domain 5: Patient & Family Engagement

Has a **Patient and Family Advisory Council (PFAC)** that ensures patient, family, caregiver, and community input to safety-related activities, including representation at board meetings, consultation on safety goal-setting and metrics, and participation in safety improvement initiatives

PFAC includes patients and caregivers of patients who are **representative of the patient population**.

Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via **patient portals** and other options, and the hospital provides support to help patients interpret information that is appropriate, as well as **submit comments for potential correction to their record**.

Incorporates patient and caregiver input about patient safety events or issues (such as patient submission of safety events, safety signals from patient complaints or other patient experience data, or patient reports of discrimination).

Supports the presence of family and other designated persons (as defined by the patient) as essential members of a safe care team, and encourages engagement in activities such as bedside rounding and shift reporting, discharge planning, and visitation 24 hours a day, as feasible

Scoring & Performance

- Must attest YES to each statement in order to receive one point for Domain
- Scoring 1-5 scale; 1 point per domain; total possible score of 5
- Data submitted to NHSN
- Guidance document for more specifics and references available
  - See: https://qualitynet.cms.gov/inpatient/iqr/measures#tab2
- Total score will be public on Care Compare

Maternal Safety

- American maternal mortality still ranks high (worse) globally
- Top causes of maternal death: bleeding, infection, hypertension and cardiovascular disease
- Key components of maternal safety:
  - Clinical Protocols – evidence based “bundles” such as to prevent/treat hemorrhage, hypertension, sepsis
  - Early and continuous care
  - Patient Education and respectful communication, consent and supportive environment
  - Teamwork & Communication

Performance Improvement Initiatives

- Alliance for Innovation on Maternal Health (AIM) – national effort by HRSA and others to implement evidence patient safety bundles
- Transforming Maternal Health (TMaH) CMMI model – promotes state Medicaid accountability for maternal health, integrating behavioral health and expanding support such as doulas and midwives
- Joint Commission Maternal Levels of Care
- MOM model to combat opioid use
- Medicaid Maternal and Infant Health Initiative (MIHI) technical assistance

Other CMS Actions to Improve Maternal Safety

- Expanded Medicaid waiver to pay for post-partum care (1 year)
- Mandatory electronic quality measures for C-section rates and severe OB morbidity (first national data collected)
- “Birth Friendly” hospital designation – 94% of hospitals that provide OB care received BF designation.
- Plan to refine BF designation to include outcomes performance
- Exploring opportunities to better capture patient experience
- Cross agency committee evaluating additional options (such as focus on hypertension)

The Graying of America

- Over 54 million Americans age 65+ … by 2060 estimate is 95 million
- Medicare insurance covers most all
- Many have one or more chronic condition and take multiple medications
- Although many are independent, many are facing transitions to greater dependency and reliance on others
- Often community and family support lacking
- Support and practice of the 4M’s of care may reduce readmissions, reduce length of hospital stay, and promote better outcomes

Promoting Age Friendly Healthcare

- What Matters
- Medication
- Mentation
- Mobility
- 5th M – Multicomplexity

Evidence based framework for assessing and acting upon critical issues in the care of older adults across care settings and transitions of care

Age Friendly Structural Measure

- Eliciting Patient Healthcare Goals
- Responsible Medication Management
- Frailty Screening and Intervention
- Social Vulnerability
- Age Friendly Care Leadership

President's Council for Science and Technology
A Transformational Effort on Patient Safety - Recommendations

- Establish National Leadership and Oversight
- Implement Evidence Based Practices focused on High Priority Harms
- Improve Accountability and Transparency
- Leverage Technology and Data, including Advancing Health IT
- Engage Patients and Families
- Support Healthcare Workers and Promote "Just Culture"

Session 1: *Approaches to Improve Patient Safety in Alternative Payment Models*

Susannah Bernheim, MD, MHS

Chief Medical Officer, CMS Innovation Center
Centers for Medicare & Medicaid Services

Approaches to Patient Safety in Alternative Payment Models

Presentation to PTAC

Susannah Bernheim
Chief Medical Officer
CMS Innovation Center
June 2026

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Agenda

- CMS Innovation Center Overview
- Ambulatory Safety Priorities and CMMI Authority
- Examples from CMMI models
- Summary

CMS Innovation Center Strategy

Ambulatory Safety Priorities

Challenges

- **Fragmented communication** and poor electronic health record interoperability
- **Medication safety** problems, especially reconciliation and adherence
- **Care coordination gaps** with specialists
- **Patients often feel unheard** or excluded from safety purposes
- Outpatient adverse events are common, **under detected**, and frequently preventable

Opportunities

- Improve EHR interoperability
- **Strengthen medication management** with pharmacists and clinician decision making
- Expand **team-based care** and transition-of-care coordination
- **Increase patient engagement** through portals, education, and shared-decision making
- Focus interventions on **high-risk populations**, especially older adults and patients with complex care needs

CMS Innovation Center Authority

(1) WAIVER AUTHORITY. – The Secretary may waive such requirements of titles XI and XVII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be **necessary solely for purposes of carrying out this section with respect to testing models.**

Waiver Examples

Skilled Nursing Facility 3-Day Rule Waiver

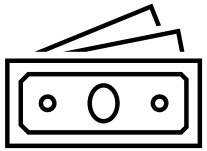
Allows for patient to be admitted to a SNF without a prior 3-day hospital stay

Care Management Home Visits Waiver

Allows a home visit by a clinician in advance of a potential hospitalization

Payment Related Waivers

Allows for payment arrangements across participants necessary for program participation that would normally be prohibited



Medication Management & Reconciliation in GUIDE

Dementia patients are often prescribed medications by multiple clinicians across multiple care settings, **increasing risk of polypharmacy, duplicate therapies, conflicting instructions, and adherence challenges**.

Clinicians **required to review and reconcile medications** during initial assessment, future assessments, and when concern arises from care team, beneficiary, or caregiver

GUIDE **financially incentivizes medication management** assessing participant performance on Use of High-Risk Medications in Older Adults measure

GUIDE supports **intentional de-prescribing** when medications are no longer clinically beneficial, duplicative, or cause side effects or safety concerns

Participants required to communicate recommendations and changes with **primary care providers, specialists, and other relevant clinicians**

Care navigators play a key role by helping beneficiaries and caregivers **maintain safe medication routines**

LEAD Model: Resilience and Independence in a Safe Environment (RISE) to Age in Place Episode

LEAD tests new structures for payment arrangements with specialists through CMS-Administered Risk Arrangements (CARA).

Global Risk Option ACOs can participate in CARA to contract directly with specialists for specific quality and cost outcomes, reducing barriers for ACOs to establish meaningful **episode-based risk arrangements** with specialists.

Resilience and Independence in a Safe Environment (RISE) to Age in Place Episode

- The RISE to Age in Place Episode aims to increase **activities of daily living** (ADLs) and decrease acute events for Medicare beneficiaries.
- Provides a **bundled payment** for an **interdisciplinary care team** (Occupational Therapists (OTs) and Registered Nurses (RNs)) to deliver comprehensive **fall prevention** interventions.

Quality Measures

- **Performance adjustments will be based on quality measures** – Q484 Risk-Standardized Admissions or other Merit-Based Incentive Payment System (MIPS)-comparable measures. Adjustments range 10-100%, **negotiated between ACOs and specialists**.

Evaluation Results

Innovation Center models improved or maintained quality and patient safety

Episode-Based Payment Models

- Embedded **mandatory safety metrics** – complication rates, ED visits, unplanned readmissions – into episode-based payment model evaluations
- Served as **guardrails against financial incentives** driving harmful care shortcuts

Oncology Care Model

- Included **multi-dimensional safety framework for high-risk population** tracking ED use, hospitalizations, patient experience, and end-of-life care quality, including chemotherapy use in final 14 days of life
- OCM demonstrated **improvements in quality of care**

Partnership for Patients Early Model

- Patient safety as **primary outcome** targeting 40% reduction in preventable hospital-acquired conditions (HAC) and 20% reduction in 30-day readmissions
- **Meaningful reductions in HAC rates** across hospital participants

Summary

- CMMI models (not categorized as “patient safety models”) utilize **quality measures, care delivery requirements, and CMMI authorities to include important patient safety aspects** in inpatient and outpatient care
- **CMMI authorities allow for more novel approaches to improve patient safety** by (1) changing current limitations in clinician payment rules and (2) creating more flexible pathways to advance care coordination
  - Care coordination is *instrumental* for safety and a common finding across many models
- **Critical to monitor patient safety in evaluation** of new models that put downward pressure on cost and utilization

Session 1: *Approaches to Improve Patient Safety in Alternative Payment Models*

Jason W. Mitchell, MD

Executive Vice President and Chief Medical Officer
Geisinger

Patient Safety in Alternative Payment Models

June 2026

Geisinger

Jason W. Mitchell, MD
Executive Vice President and
Chief Medical Officer, Geisinger

Patient safety matters

In the United States alone, we lose an estimated
165,000 years of life and burden patients with
49,000 future years of disability each year
through patient harm events[1]

1) Estimate uses University of Washington's IHME Global Burden of Disease Adverse Effects of Medical Treatment as a proxy for treatment-related patient harm. This includes adverse drug events, surgical complications, transfusion-related injury, and device-related complications. Source for GBD weights: https://www.healthdata.org/research-analysis/gbd-data

Current CMS models are light on safety, heavy on opportunity

	Model	Safety-Related Metrics & Incentives
Episode -based	**TEAM** *(mandatory surgical episodes, 2026–2030)*	**Explicit safety measures:** • Hybrid Hospital-Wide Readmission (30-day) • **PSI-90** Patient Safety Composite (e.g., pressure injuries, thromboembolism, etc.) • **Hospital Harm** eCQMs – Falls with Injury, Postop Respiratory Failure • **Failure-to-Rescue** • **THA/TKA PRO-PM** (hip/knee outcomes, specific to LEJR)
	CJR / CJR-X *(Comprehensive Joint Replacement bundle)*	**Limited quality linkage:** • Original CJR used **THA/TKA Complications** (90-day risk-adjusted complication rate including some infections, revision surgery, etc.) and **HCAHPS** survey as quality adjusters • **CJR-X** (proposed 2027 expansion) expected to continue similar measures; exploring **PRO** metrics
Longitudinal	**MSSP ACO** *(Shared Savings Program)*	**Indirect safety via utilization:** • Uses **All-Cause Unplanned Readmission** rate and **ambulatory care-sensitive admission** measures • Patient experience surveys (CAHPS) include safety culture items
	LEAD ACO *(Next-generation 10-year ACO, starts 2027)*	**Quality measures TBD** • Likely to build on ACO REACH core set (readmissions, unplanned admissions, timely follow-up, CAHPS)

- *Most CMS-driven alternative payment models still lack a complete incentive framework to reward patient safety on its own*
- *Utilization (avoidable admissions / readmissions) is still the dominant lens for safety*
- *Strongest signal of safety measurement to-date is through the CMS TEAM model*
- *Remaining opportunities:*
  - *Medication events*
  - *Post-discharge falls*
  - *Post-discharge complications (e.g., wound infections)*
  - *Ambulatory safety*

Individual organizations can lead the way in tying safety to financial outcomes

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Tech Markets & Finance Opinion Free Expression Arts Lifestyle Real Estate

A Warranty for Heart Surgery

By Jacob

May 17, 2007 8:52 am ET

Aa

A central Pennsylvania health system is offering patients and their insurers a flat fee for elective bypass surgery -- and the price includes all follow-up treatment for 90 days after the procedure, even if a patient needs to be re-admitted for complications, the New York Times reports.

The warranty gives Geisinger Health System, which runs several hospitals in central Pennsylvania, a strong incentive to reduce the kinds of errors that can send patients back to the hospital in the weeks after surgery. Insurers

Geisinger ProvenCare® in action:

- Multi-step checklists, embedded in Epic workflow
- Reduction in mortality and readmissions
- Lifetime guarantee for qualified patients and procedures

Geisinger is fortifying our commitment to zero harm through high reliability practices

High Reliability Organization (HRO) Principles[1]

Anticipate
safety threats

- Preoccupation with failure
- Reluctance to simplify
- Sensitivity to operations

Respond and Adapt
to safety threats

- Commitment to resilience
- Deference to expertise

1) Weick, Karl E., and Kathleen M. Sutcliffe. *Managing the unexpected: Sustained performance in a complex world*. John Wiley & Sons, 2015.

Every layer of leadership has been tasked with cultivating and reinforcing a culture of safety

1. **Start every meeting with a safety moment**
2. **Encourage, recognize and protect those that speak up**
   - Promote a psychologically safe environment
     - Transparency
   - No-blame culture
   - Celebrate Great Catches that prevented harm because someone spoke up
3. **Link decisions to safety**
   - Think about impacts to our patients and community with every decision
   - Build safety and reliability into every discussion and action

Everyone has a role in advancing patient safety

CMS Model Opportunities

Expand patient safety metrics to directly rewarding harm prevention

- **Safety composite score** for ACOs
- **Safety-gated financial incentives** - “no savings without safety”
- **For bundled payments, introduce post-acute safety measures** beyond readmissions

Align financial outcomes with zero harm

- **Anchor outcome-adjusted payments to safety** (e.g., episode guarantees)
- **Reward bundle adherence** as leading indicators of harm avoidance
- Expand integration of **Patient-Reported Outcomes and Safety Measures (PROMs, PRMs)** into payments

Deploy models to support ambulatory safety

- **Establish a framework,** unified metrics and outcomes in the ambulatory setting
- **Focus on frailty and fall prevention,** leading causes of preventable hospital admissions
- **Reduce harm from medications**, reducing polypharmacy, patient confusion, and lack of access to chronic disease medications

Session 1: *Approaches to Improve Patient Safety in Alternative Payment Models*

Dheerendra Kommala, MD

Chief Medical Officer
ECRI

ECRI | The Most Trusted Voice in Healthcare

Approaches to Improve Patient Safety in Alternative Payment Models

PTAC June 2026 Public Meeting

Monday, June 15, 2026

Physician-Focused Payment Model Technical Advisory Committee (PTAC)

ECRI | The Most Trusted Voice in Healthcare

REDUCING PREVENTABLE HARM

ECRI is an independent, nonprofit organization improving the safety and quality of healthcare.

- ✓ Federally certified Patient Safety Organization (PSO) by HHS
- ✓ Evidence-based Practice Center (EPC) designated by AHRQ
- ✓ Independent evaluator of medical devices & health tech
- ✓ Acquired ISMP to reduce medication errors
- ✓ Acquired Just Culture Company to transform workplaces

ISMP Institute for Safe Medication Practices

The JUST CULTURE Co.

SERVING ENTIRE CARE ECOSYSTEM

ECRI

Advancing Payment Models

A Foundation To Build On and Improve

Through the CMS Innovation Center, the U.S. is making progress advancing the testing and implementation of models that reward outcomes and value.

- ACCESS Model
- LEAD Model
- AHEAD Model
- Home Health Value-Based Purchasing Expanded Model

Areas of Improvement Needed

- ❑ Improve Patient Safety Outcomes
- ❑ Implement Continuous Learning Systems

NEAR MISSES: Reward them as safety signals

- **Problem: No incentive to better capture near-misses and decrease adverse events.**
- **10% of the 10K+ safety events analyzed were NEAR MISSES.**

10,000+ Safety Events*

Analyzed from ECRI & ISMP PSO Database

1,336

Documented near-miss events

In this PSO dataset alone

459

Medication near misses

Largest single category

309

Lab & radiology near misses

Critical value gaps, wrong patient imaging

116

High-alert drug interceptions

Insulin, anticoagulants, opioids, chemo

REAL PATIENT EXAMPLE

Harm *prevented* for 85-year-old patient

Pharmacist conducting rounds found heparin drip monitoring labs had not been obtained for 48 hours. Therapeutic status unknown. Labs ordered immediately; heparin titrated.

Would bill for the heparin drip but not incentivize the intervention that caught the problem.

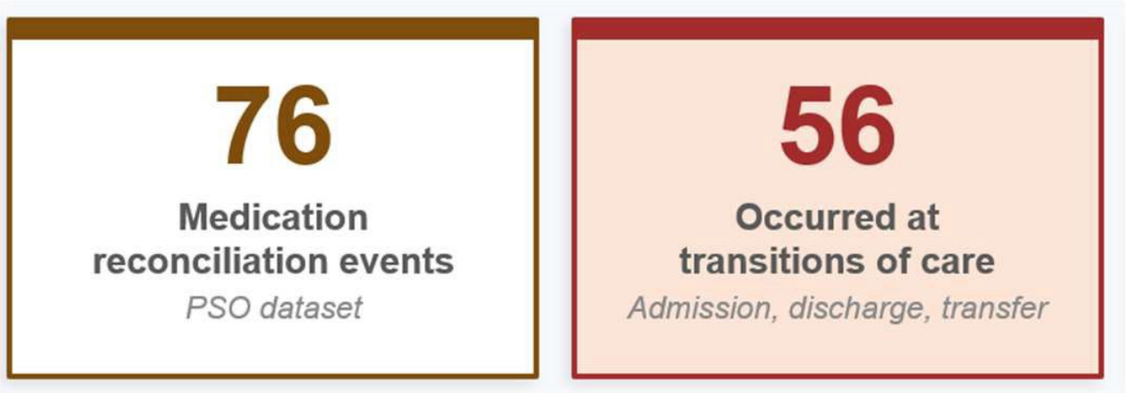
*Evaluated most recent 10,000+ safety events

MEDICATION RECONCILIATION:
Transition failures with no accountable owner

73% of medication reconciliation errors took place during care setting transitions

Analyzed ECRI & ISMP PSO Database

- **Problem: No single entity is financially accountable for the accuracy of the medication list across all transitions between care settings.**
- Transitions are a risky point in care delivery:
  - At admission (e.g., from home to hospital)
  - During inpatient care (e.g., from ICU to step down unit)
  - At discharge (e.g., from hospital to SNF)



REAL PATIENT EXAMPLE

Incomplete medications for elderly patient

Six home medications were omitted from a patient's admission reconciliation, including thyroid supplement, aspirin, vitamins B12 and D.

Discovered at discharge when patient's husband asked about her aspirin. System workflow for transitions failed to capture critical details.

*Evaluated most recent 10,000+ safety events

Incentivize Utilization of Technology with Value-based Framework (ACCESS Model)

Technology with Proven Outcomes

1,451

AI/ML medical devices cleared through 2025

Up from just 6 clearances per year in 2015. Record 295 cleared in 2025 alone.

97%

Cleared via 510(k) — no clinical outcomes data required

Substantial equivalence to a predicate device. Only 1.6% of AI devices had RCT data at clearance.

43%

Of AI device recalls occur within 1 year of clearance

Concentrated in devices that lacked clinical validation at market entry. Class I recalls at a 15-year high in 2024.

ACCESS Model Strengths

- ❑ **Quality over volume**
- ❑ **Outcome-aligned payments**

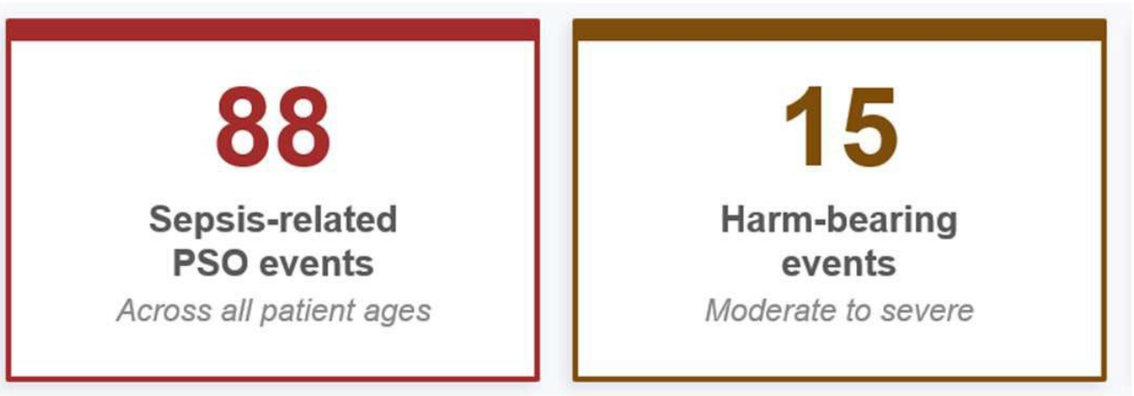
Quality over Volume.

- Scale payment with outcomes (e.g. conditional coverage with evidence development)
- Physician selection shifts toward what is evidence-based, rather than best margin

Enable Digital Health Access.

- Expand RPM and telehealth incentives. Tie to outcomes.

SEPSIS: High Harm Events that Require System Redesign and HFE



- PSO data shows failures of sepsis prevention bundles are system design failures.
  - Ambiguous order sets
  - IV access barriers
  - Antibiotic scheduling defaults
  - Competing clinical priorities
- **Problem: SEP-1 bundle compliance is tracked publicly, but there is no payment consequence for the 492-minute door-to-antibiotic delay in the example shown.**

REAL PATIENT EXAMPLES

Moderate harm to patient 65+ years old

Patient presented hypoxic and altered from nursing home with fever and foul-smelling urine. Door to antibiotic: 492 minutes. The sepsis clock ran. The payment clock did not.

*Evaluated most recent 10,000+ safety events

RECOMMENDATIONS: Redesign APMs to Drive Structural Safety

1. **Increase Utilization of Near-Miss to Adverse Event Ratio**
   - APMs that treat event counts as liabilities create punitive pressure that suppresses reporting.
   - Drive cultural change that boosts near-miss reporting to better capture data for improvement.
2. **Incentivize Utilization of Technology in Value-Based Framework**
   - Tech must be evaluated through a lens of safety, evidence and **outcomes.**
   - PPM should be procedure and outcomes oriented. (Access model)
   - Remote monitoring improves access. Incentivize and reimburse accordingly.
3. **Enhance Safety of Patient Care Transitions**
   - Patient handoffs between care settings are a high-risk point (e.g. medication reconciliation).
   - Incentivize transition improvements. Data interoperability.
   - Design payment structures to make transitions more visible, accountable and interoperable.
4. **Implement Human Factors Engineering (HFE) in Design of Care Delivery**
   - Move upstream from harm and outcomes. Shift from reactive to proactive via HFE-informed design.
   - The care delivery system is the primary failure point.

APPENDIX

PTAC June 2026 Public Meeting

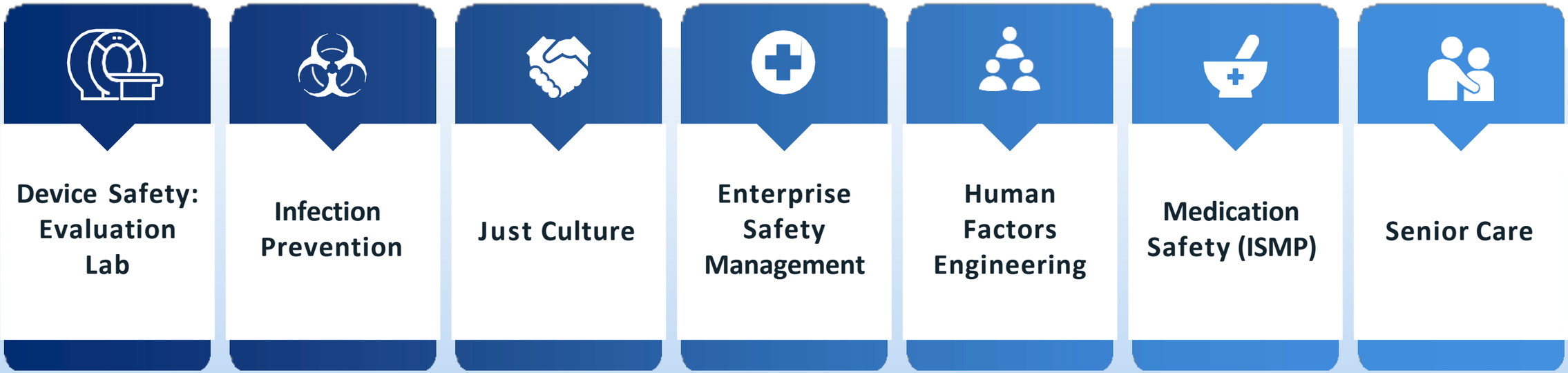
Monday, June 15, 2026

Physician-Focused Payment Model Technical Advisory Committee (PTAC)

ECRI: What We Do

Reducing Preventable Harm & Improving Quality Through Data-Driven Clinical Expertise

SafeSystem℠ Solutions



Patient Safety Organization (PSO): One of nation's largest. 8M+ safety incident dataset.

Safety Transformation is Urgent

Despite decades of effort, patient safety in the U.S. has not significantly improved—a troubling trend that reflects a broader global challenge.[1]

- 1 in 4 inpatient admissions involve an adverse event
- 22.7% of these events are preventable
- 32.3% of adverse events are serious or worse

Preventable adverse events in hospitals cost the U.S. $20 billion a year[2]

This is a call to action.

[1] Source: Bates, D. W., Levine, D. M., Salmasian, H., Syrowatka, A., Shahian, D. M., Lipsitz, S., Zebrowski, J. P., Myers, L. C., Logan, M. S., Roy, C. G., Iannaccone, C., Frits, M. L., Volk, L. A., Dulgarian, S., Amato, M. G., Edrees, H. H., Sato, L., Folcarelli, P., Einbinder, J. S., Reynolds, M. E., & Mort, E. (2023). The safety of inpatient health care. *The New England Journal of Medicine*, 388(2), 142–153. https://doi.org/10.1056/NEJMsa2206117

2Ahsani-Estahbanati, E., Sergeevich Gordeev, V., & Doshmangir, L. (2022). Interventions to reduce the incidence of medical error and its financial burden in health care systems: A systematic review of systematic reviews. Frontiers in medicine, 9, 875426. https://doi.org/10.3389/fmed.2022.875426

ECRI