Physician-Focused Payment Model Technical Advisory Committee
Public Meeting Minutes

June 15, 2026
9:31 a.m. – 5:00 p.m. EDT
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attendance

Physician-Focused Payment Model Technical Advisory Committee (PTAC) Members

Terry L. Mills Jr., MD, MMM, PTAC Co-Chair (Chief Medical Officer, Aetna Better Health of Oklahoma, and Owner, Strategic Health, LLC)
Soujanya R. Pulluru, MD, PTAC Co-Chair (President, CP Advisory Services, and Co-Founder, My Precious Genes)
Lindsay K. Botsford, MD, MBA (Market Medical Director, One Medical)
Lawrence R. Kosinski, MD, MBA (Founder and Chief Medical Officer, VOCnomics, LLC)*
Walter Lin, MD, MBA (Chief Executive Officer, Generation Clinical Partners)
Krishna Ramachandran, MBA, MS (Chief Information Officer, UnitedHealth Group)
David C. Tyson, MA (Senior Director, Policy & Regulatory Affairs, Public Affairs & Government Relations, Novant Health)

PTAC Member in Partial Attendance

Lauran Hardin, MSN, FAAN (Chief Integration Officer, HC^2 Strategies)*

PTAC Members Not in Attendance

Henish Bhansali, MD, FACP (Independent Consultant)
Jay S. Feldstein, DO (President and Chief Executive Officer, Philadelphia College of Osteopathic Medicine)
Joshua M. Liao, MD, MSc (National Associate Vice President of Clinical Transformation, Ascension)

Department of Health and Human Services (HHS) Guest Speakers

Samuel Watters (Counselor, Immediate Office of the Secretary, U.S. Department of Health and Human Services [HHS])
Abe Sutton, JD (Director, Center for Medicare and Medicaid Innovation [CMS Innovation Center], and Deputy Administrator, Centers for Medicare & Medicaid Services [CMS])

Office of the Assistant Secretary for Planning and Evaluation (ASPE) Staff

Marsha Clarke, PhD, MBA, COR III, PTAC Designated Federal Officer
Steven Sheingold, PhD

Via Zoom

List of Speakers and Handouts

1. **PCDT Presentation: Targeting Improvements in Patient Safety Through Alternative Payment Models**

   Soujanya Pulluru, MD, Preliminary Comments Development Team (PCDT) Lead

   Handouts

   - Public Meeting Agenda
   - PCDT Presentation Slides
   - Environmental Scan on Targeting Improvements in Patient Safety Through Alternative Payment Models

2. **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)
   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), 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*

   Handouts

   - Experts Biographies
   - Session 1 Presentation Slides
   - Session 1 Discussion Guide

3. **Session 2: Measuring Patient Safety in Value-Based Care**

   Jeffrey J. Geppert, Senior Research Leader, Battelle
   Patrick S. Romano, MD, MPH, Professor, Division of General Medicine and Division of General Pediatrics, University of California, Davis
   Commander Karen Chaves, MHS, Director, Division of Quality Measurement and Improvement, Center for Quality Improvement and Patient Safety (CQuIPS), Agency for Healthcare Research and Quality (AHRQ), and United States Public Health Service Commissioned Corps*
   David C. Classen, MD, MS, Professor of Medicine, University of Utah, Lead, Utah Center for Health AI and the Health IT Safety Program, and Senior Advisor, PascalMetrics*

   Handouts

   - Expert Biographies
   - Session 2 Presentation Slides
   - Session 2 Discussion Guide

4. **Session 3: Improving Patient Safety in Value-Based Care Through the Use of Health Information Technology and Data Analytics**

   Rollin J. (Terry) Fairbanks, MD, MS, Senior Vice President, Chief Quality and Safety Officer, MedStar Health, and Professor of Emergency Medicine, Georgetown University

Tejal Gandhi, MD, MPH, CPPS, Chief Safety and Transformation Officer, Press Ganey Associates LLC*
Melissa Swanfeldt, Senior Director, Quality & Regulatory Compliance, MEDITECH
Aneesh Chopra, MPP, Chair, Arcadia Institute

Handouts

- Expert Biographies
- Session 3 Presentation Slides
- Session 3 Discussion Guide

Via Zoom
[NOTE: A transcript of all statements made by PTAC members and public commenters at this meeting is available online: https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee].

Also see copies of the presentation slides, other handouts, and a video recording of the public meeting.

Welcome and Co-Chair Update

Soujanya Pulluru, PTAC Co-Chair, welcomed the Committee and members of the public to the June 15-16 public meeting. She explained that the Committee has been exploring themes that have emerged from proposals that the public has submitted to PTAC. Previous PTAC theme-based discussions have focused on topics such as reducing barriers to participation in Alternative Payment Models (APMs) and supporting primary and specialty care transformation; encouraging rural participation; using data and health information technology (health IT) to transparently empower consumers and support providers; and improving multi-payer alignment in value-based care. She explained that the current public meeting has brought together subject matter experts (SMEs) to gain perspectives on targeting improvements in patient safety through APMs. This topic is of interest to the Office of the Secretary of Health and Human Services (HHS) and the Center for Medicare and Medicaid Innovation (CMS Innovation Center).

Co-Chair Pulluru introduced Samuel Watters, Counselor in the Immediate Office of the Secretary at HHS, and Abe Sutton, Director of the CMS Innovation Center and Deputy Administrator at the Centers for Medicare & Medicaid Services (CMS), who gave the opening remarks. Mr. Watters shared a personal experience with patient safety, which has shaped his mission to improve patient safety. He explained that the Institute of Medicine's (IOM's) landmark report, *To Err Is Human: Building a Safer Health System*, launched a movement to improve patient safety. Since the report was published, there are better infection control practices, stronger reporting systems, safer surgical protocols, and greater awareness that harm in health care is not inevitable. Despite these advancements, patient safety remains one of the most significant challenges facing American health care. Preventable patient harm also contributes to health care waste and inefficiency. Approaches to improve patient safety have been fragmented. Reporting systems have been created without learning systems. Measures have been developed without timely feedback. There is a focus on compliance rather than on improvement. Measurement has focused on what is simple to count rather than what matters most to patients. Fear of punishment often discourages transparency.

Mr. Watters stated that patient safety improves when organizations are willing to learn from problems and share lessons broadly. Mr. Watters recommended striving for a culture that balances accountability with learning, transparency, and continuous improvement. Technologies are available to detect harm at

scale. Artificial intelligence (AI), large language models, and advanced analytics can identify safety events, detect emerging risks, automate quality measurement, and reduce the burden of data abstraction. However, AI can also introduce new risks. The safety of AI must be rigorously evaluated. He indicated that the knowledge and technology to improve patient safety are available; what is needed now is the will to act with urgency.

Mr. Sutton shared that he previously spoke about the CMS Innovation Center's three strategic pillars at the PTAC public meeting in September 2025. These pillars focus on evidence-based prevention, choice and competition in health care markets, and empowering people to achieve their health goals. Patient safety is core to each of the three pillars. Evidence-based prevention includes preventing harm. Improving efficiency and reducing unnecessary utilization that may actively be harmful to patients is a core philosophy in the Wasteful and Inappropriate Service Reduction (WISeR) Model, which focuses on reducing utilization in areas of low-value care that may pose risk for harm. Transparency and informed decision-making are key principles in patient empowerment. Mr. Sutton described the Long-term Enhanced ACO (Accountable Care Organization) Design (LEAD) and Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Models that support patient empowerment. The LEAD Model helps make information accessible and allows people to choose where they go in the health care system. The ACCESS Model allows patients to choose from consumer-facing technological solutions and digital therapeutics that will help them achieve their health goals. Patients should be able to choose providers and care models that deliver the best outcomes. Competition works best when patients, providers, and payers have access to meaningful information, including safety results.

Mr. Sutton indicated that the CMS Innovation Center monitors patient safety outcomes and is testing how technology can reduce burden on providers and increase patient quality. The Accelerating State Pediatric Innovation Readiness and Effectiveness (ASPIRE) Model will focus on pediatric high-needs populations in Medicaid. The model will change the incentives to interact with the pediatric population, including providing patients around-the-clock support to help them avoid emergency department (ED) utilization. Active leadership engagement is required to improve patient safety by ensuring that improvement efforts receive adequate attention and resources. Mr. Sutton explained that the CMS Innovation Center will continue to explore how payment and delivery can support patient safety goals. The CMS Innovation Center partners with entities such as the Agency for Healthcare Research and Quality (AHRQ), the CMS Center for Clinical Standards & Quality (CCSQ), the Assistant Secretary for Planning and Evaluation (ASPE), and PTAC, and with clinicians serving patients, patient advocates, health care systems, and other stakeholders to ensure that the CMS Innovation Center is patient-centered and focused on the right safety innovations. Mr. Sutton expressed interest in gaining insight from the public meeting on how to measure safety in value-based care, how technology can improve safety, and how payment models create opportunities rather than risks.

Following the opening remarks, Co-Chair Pulluru noted that a public comment period will occur on the second day of the public meeting. Public comments will be limited to three minutes each. She explained that the discussions, materials, and public comments from the public meeting will inform the report to the Secretary of HHS on Targeting Improvements in Patient Safety Through APMs. In April, PTAC posted a Request for Input (RFI) on the ASPE PTAC website to give stakeholders an opportunity to provide written comments to the Committee on targeting improvements in patient safety through APMs. To date, PTAC has received three responses that the Committee members may consider during their discussion over the next two days. Co-Chair Pulluru indicated that the Committee members are prepared to receive proposals on possible innovative approaches and solutions related to care delivery,

payment, or other policy issues from the public. More information about submitting a proposal is posted on the ASPE PTAC website.

Co-Chair Pulluru invited Committee members to introduce themselves and describe their experience with patient safety. Following Committee member introductions, Co-Chair Pulluru acknowledged three Committee members who were not in attendance but contributed to the preparation for the theme-based discussion: Henish Bhansali, Jay Feldstein, and Joshua Liao. Co-Chair Pulluru shared that two Committee members served on the Preliminary Comments Development Team (PCDT): Co-Chair Pulluru (Lead) and Lee Mills, PTAC Co-Chair. Co-Chair Pulluru presented the PCDT's findings from the background materials.

PCDT Presentation: Targeting Improvements in Patient Safety Through Alternative Payment Models

Co-Chair Pulluru delivered the PCDT presentation. For additional details, please see the presentation slides, transcript, and meeting recording (31:13-59:47).

- Patient safety is a core responsibility in health care, yet preventable harm remains a significant ongoing challenge. This presentation focuses on the prevalence and cost of patient harm and examines how payment models, measurement strategies, technology, and organizational design can create safer systems of care.
- Co-Chair Pulluru shared the objectives of the June theme-based discussion: establishing a common understanding of patient safety; reviewing the prevalence and economic burden of patient harm; examining the underlying causes of safety failures and opportunities for improvement; reviewing how patient safety can and should be measured; and discussing how participation in APMs can accelerate meaningful and sustainable improvements in patient safety.
- The objective of the theme-based meeting is to identify actionable opportunities to improve patient safety. The meeting will examine how APMs can create stronger incentives for safety where current measurement systems may be inadequate; how emerging technologies can improve reliability and fidelity to patient safety; and what payment methodologies might best reward organizations that prevent harm.
- PTAC has received 36 proposals for physician-focused payment models (PFPMs), including 28 proposals that Committee members have deliberated on during public meetings. Of the 28 proposals, 23 proposals met Criterion 9 (Patient Safety) established by the Secretary of HHS for PFPMs.
- PTAC's working definition of patient safety is, "Freedom from errors that could cause patient harm during the delivery of health care. Errors may be either errors of commission, in which an incorrect action was taken, or errors of omission, in which a correct action was not taken." The distinction between errors of commission versus errors of omission is critical, as many of the current safety opportunities in health care stem from what was missed.
- Preventable harm is estimated to cost over $600 billion annually across Organisation for Economic Co-operation and Development (OECD) countries. In the U.S., direct medical costs exceed billions of dollars each year. Indirect and societal costs of patient harm affect productivity, family stability, caregiver burden, workforce participation, disability, and overall quality of life. The societal costs often exceed the direct medical costs.
- Globally, more than one in 10 patients experience medical harm events, half of which may be preventable. Approximately one in four hospitalized Medicare beneficiaries experience a harm event. Nearly half of patient harm events may not be captured by existing incident reporting systems, potentially indicating that the visible problem may represent only part of the true burden of patient safety.

- The IOM's landmark report, *To Err is Human: Building a Safer Health System*, changed the national conversation on patient safety. The report demonstrated a high number of deaths from preventable medical errors in the U.S. Although some progress has been made to improve patient safety, recent evidence indicates that preventable harm remains persistent in the health care system and that safety improvement efforts have slowed.
- Patient safety is one of the six dimensions of health care quality. Quality of care is commonly described using the six STEEEP domains: safe, timely, effective, efficient, equitable, and patient-centered. When safety fails, every other dimension of quality is compromised. Safety should be considered a part of the entire quality continuum.
- The patient safety conceptual diagram shows that patient harm does not occur in isolation; patient harm is a systems problem. Systems, human factors, organizational culture, and technology contribute to patient safety errors. This framework encompasses errors of omission and commission, both of which result in altered patient outcomes. Although underutilized, there are mitigation strategies for patient safety, including communication, standardized protocols, care coordination, training, technology, patient engagement, and a culture of safety.
- Types of patient safety errors are medication errors, diagnostic lab and testing errors, surgical and procedural errors, communication failures, and health care-related errors such as infections, falls, and pressure injuries.
- Historically, health care has focused on errors of commission because these types of errors are more easily identified. However, errors of omission may be more common and more difficult to detect relative to errors of commission. Incentives may have a role in reducing errors of omission.
- Noncontrollable adverse events are not preventable and occur despite appropriate care. Controllable adverse events represent failures that could have potentially been avoided. The most serious controllable adverse events are sentinel events and never events. A never event is a serious preventable sentinel event that should never occur.
- A near miss occurs when there is no harm to the patient despite the potential for harm. Detection systems of near misses are foundational to patient safety. Near misses reveal vulnerabilities before a patient is injured. Organizations with strong safety cultures often learn as much from near misses as they do from actual harm events.
- There are many oversight organizations for patient safety. Patient safety is supported by CMS, AHRQ, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), The Joint Commission (TJC), National Committee for Quality Assurance (NCQA), The Leapfrog Group, and Institute for Healthcare Improvement (IHI).
    - CMS ensures mandatory minimum safety standards and conditions of participation in both Medicare and Medicaid. Additionally, CMS publicly reports safety data through the Care Compare tool. CMS also develops administrative APMs that promote patient safety, such as the Hospital-Acquired Condition (HAC) Reduction Program.
    - AHRQ is the primary federal agency that conducts patient safety research and develops patient safety measure resources and tools. Additionally, AHRQ oversees the quality and safety review system to track hospital adverse events. An important component to patient safety is AHRQ's hospital adverse event reporting system.
    - Together, the oversight organizations have created a regulatory measurement research and accountability infrastructure that supports safer care.
- Historically, patient safety efforts have focused on inpatient care; however, much of health care occurs in ambulatory settings. An analysis of 11 Massachusetts hospitals showed that nearly one in four inpatient admissions involved at least one adverse event. In Massachusetts outpatient

sites, 7% of patients had at least one adverse event. Of these events, one quarter were preventable, and 17.4% of the events were deemed serious events.

- Adverse events are more common among certain subgroups. Patients over 65 years old, patients with multiple chronic conditions, patients of color, and patients who are on Medicaid or are uninsured tend to experience adverse events. Improvements in patient safety have occurred due to a variety of factors, such as mandatory hospital adoption of standardized safety practices (e.g., hand hygiene protocols, security checklists) and financial penalties through value-based care incentive programs (e.g., CMS' Hospital Readmissions Reduction Program [HRRP]). Future safety strategies and payment models must include multiple populations and address the entire continuum of care, which currently excludes outpatient care.
- There have been measurable improvements in several Patient Safety Indicators (PSIs) over time. However, there remains substantial variation between hospitals. There are large differences in healthcare-associated infection (HAI) rates between the best- and worst-performing hospitals, where the best-performing hospitals consistently achieved better outcomes compared with the worst-performing hospitals. Findings from the analysis emphasize the importance of strong infection prevention and quality improvement initiatives targeting high-risk hospitals. This variation demonstrates that better performance is possible.
- Many patient safety categories improved between 2010 and 2019. Although there was a decrease during the COVID-19 pandemic, most indicator variables have remained relatively stable in recent years. While there are safety guardrails and processes in place, there has not been substantial improvement when examining the health care system in the aggregate. Large and persistent performance gaps exist across hospitals.
- There is a difference in scores between the best- and worst-performing hospitals. The best-performing hospitals achieved outcomes approximately 25% better than expected, while the lowest-performing hospitals performed approximately 40% worse than expected. These findings highlight substantial variation in quality and opportunities for improvement across hospital systems.
- A large share of hospitals with poor performance showed limited improvement over time. Nearly half (44%) of poorly performing hospitals remained in the bottom tertile according to results from a Care Compare study recently conducted by ASPE. Approximately one in four hospitals improved substantially and moved to the top tertile. A substantial portion of high-performing hospitals maintain strong performance over time. However, approximately 20% of initially high-performing hospitals declined to the bottom three deciles over time. While performance challenges persist, meaningful improvements are achievable. However, maintaining high patient safety performance can be challenging over time. These results highlight the importance of sustained quality improvement efforts, continuous monitoring, and measurement to preserve gains in performance.
- The causes of patient safety errors are multifactorial. Health care organizations face competing priorities. Measurement systems are retrospective and often lag behind reality. Workforce burnout is a problem, and staffing shortages introduce additional risk. Transparency across health care organizations remains inconsistent. Many safety systems that are retrospective and designed to identify harm after it occurs do not account for near misses or prevent harm before it occurs. The future of patient safety must be increasingly proactive, predictive, and preventive.
- Most patient harm originates from broad system vulnerabilities. Poor workflows, fragmented communication, physician and care team burnout, resource constraints, and technology challenges shift the focus of blame toward system redesign that can be incentivized.

- The Swiss cheese model of patient safety is a framework to understand how patient safety errors occur. A single safeguard is not perfect. Patient harm occurs when weaknesses align. It is important to design multiple systems that anticipate human imperfection.
- There are interventions for patient safety, such as standardization and operations (e.g., protocols), structured communication, care coordination, patient engagement, patient reporting tools, safety culture, and technology/data analytics. Technology can include data analytics, remote monitoring, predictive models that use AI to identify high-risk patients, and surveillance monitoring. It is important to foster a "just" culture that encourages reporting to capture adverse events and near misses. One challenge is creating adequate incentives and infrastructure to scale these interventions consistently.
- Technology has multiple roles in patient safety.
    - Technology can be the cause of harm, such as a malfunction.
    - Technology can contribute to harm, such as non-monitor defaults, burdensome documentation, and overdependence on technology.
    - Technology can also prevent harm. AI, predictive analytics, remote monitoring, clinical decision support, and data interoperability create opportunities to identify risk before adverse events occur and mitigate it. Important questions about the use of technology in patient safety include how it will be deployed thoughtfully and how it will be incentivized through advanced payment mechanisms.
- There are several challenges and opportunities to address patient safety.
    - Patient safety research and improvement efforts have focused on the inpatient setting. However, the volume of care is higher in the outpatient setting compared with the inpatient setting. It is important to create systems that track patient safety across the entire health care continuum.
    - Technology can be used to surface medical information to prevent errors of omission in real time. However, technology can also introduce new challenges.
    - There are opportunities to improve measurement systems using APMs.
- Patient safety measures include never events, adverse events, and safety processes.
- The gold standard to measure patient safety is retrospective chart review. Automating surveillance, using mandatory reporting mechanisms, and administering patient-reported safety surveys could better measure patient safety. The measurement of patient safety must move beyond counting adverse events. A balanced portfolio of measures should include measures of outcomes, processes, structures, and culture. The most commonly used patient safety measures are AHRQ's PSIs that assess potentially adverse events in hospitals. There are 26 PSIs, including 18 provider-level indicators. New patient safety measures include CMS' Patient Safety Structural Measure (PSSM) and the Errors of Care Omission Survey (ECOS). A shift from retrospective measurement to predictive measurement is an important advancement in patient safety.
- Additional measures of patient safety include CMS' electronic clinical quality measures (eCQMs), which use data extracted directly from electronic health records (EHRs) and health information exchanges (HIEs). CMS' eCQMs include patient safety measures and are reported by hospitals in the Hospital Inpatient Quality Reporting (IQR) program and the Medicare Promoting Interoperability Program. CMS also plans to add two additional measures.
- The CDC's National Healthcare Safety Network (NHSN) is developing electronic and automated safety measures called digital quality measures (dQMs). These measures build on eCQMs and are intended to improve validity and decrease reporting burden. dQMs will be reported using Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) Application Programming Interfaces (APIs).

- There continue to be challenges in patient safety measures, including determining whether an adverse event was preventable; reconciling differences in the definition of errors; a lack of standardized measures; immature safety measures for outpatient settings; a lag in safety measure information due to reliance on administrative data; and minimal availability of measures of omission errors. There are opportunities to increase use of patient-reported measures. The U.S. results from the 2023 Patient Reported Indicators Survey (PaRIS) and Medicare Current Beneficiary Survey (MCBS) showed that 13% of primary care patients reported that something went wrong over the course of their care in the last 12 months. This presents an opportunity to better identify errors of omission.
- The PCDT overview presentation outlined eight CMS programs and initiatives that have linked performance, including patient safety performance, to payment.
    - The Premier Hospital Quality Incentive Demonstration increased quality scores by nearly 19% between 2003 and 2006.
    - The HRRP reduced readmission rates, particularly for conditions such as acute myocardial infarction, heart failure, and pneumonia.
    - Patient safety is a high-priority category in the Merit-based Incentive Payment System (MIPS). CMS bases payment to providers across four categories. Safety net specialists were over 30% more likely to receive positive payment adjustments than non-safety net specialists.
    - The Bundled Payments for Care Improvement Advanced (BPCI-A) Model included safety and resulted in savings to Medicare by year 4.
    - When safety is embedded within quality and included within APMs, there are improvements in quality, safety, and savings.
    - The Transforming Episode Accountability Model (TEAM) is a new CMS model that will report on specific patient safety measures and will adjust payments based on performance.
- The focus areas of the public meeting are approaches to improve patient safety in APMs; measuring patient safety in value-based care; improving patient safety in value-based care using health IT and data analytics; and payment mechanisms and financial incentives to encourage patient safety in APMs.
- Co-Chair Pulluru concluded the presentation by summarizing three observations:
    - Preventable patient harm remains one of health care's most significant challenges;
    - Evidence demonstrates that safer care is achievable; and
    - APMs offer a unique opportunity to align financial incentives with prevention, reliability, transparency, and accountability.
- The goal is to create a health care system where every patient can trust that safety is embedded into every process, every decision, and every encounter.

Co-Chair Pulluru invited Committee members to ask questions about the PCDT presentation. Committee members discussed the following topics. For more details on the discussion, see the transcript and meeting recording (59:48-01:08:23).

- Technology must be used to decrease errors. For example, EHRs should be used to minimize human errors. Clinical decision support tools should become part of the care process.
- Errors of omission are more harmful than errors of commission.
- AI can be an effective tool to prevent misdiagnosis. Technology can support communication between providers.

- Providers must practice up to the level of their licensure. There is currently a heterogeneous provider profile that includes specialists, primary care doctors, mid-level staff, coaches, functional doctors, chiropractors, and naturopaths. While some providers are employed by hospital systems, some physicians are independent and not a part of the employee team. Processes should be used to minimize differences in the heterogeneity among providers.
- Mr. Watters explained that a payment model structured the right way can lead to long-term, sustained improvement. The current system penalizes failures and mistakes. The expert recommended considering a model that penalizes for failing to correct. A purely punitive approach can lead to hiding errors or focusing on one specific area of improvement. A payment approach that encourages organizations to correct errors could make it more desirable to invest in patient safety, particularly for systems that are in the bottom quartile of performance and have become used to being penalized.
- Different sites of care have different rates of errors of commission and omission. Errors of omission are common in ambulatory care. Patient safety and quality of care are flip sides of the same coin. Any gap in care is potentially an error of omission. The financial and management approaches for controllable adverse events are often disconnected in most payer and provider systems.
- Patient-reported events are often overlooked. At one of the Committee member's previous organizations, there were two patient reporting mechanisms. First, patients could share their complaints over the phone. Many patients did not use this mechanism, especially when a harm had not occurred. Second, a patient survey system administered a survey to one of five patients. Survey comments were reviewed weekly with the risk management team. The comments contained near misses that could be investigated. The surveys led to significant safety improvements and were an important part of the safety culture.

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

SMEs

- Susan E. Sheridan, MIM, MBA, DHL, President and Chief Executive Officer, Patients for Patient Safety US (PFPS 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), 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

Walter Lin moderated the session with five SMEs on approaches to improve patient safety in APMs. Full biographies and presentations are available.

Susan Sheridan presented on work conducted at Patients for Patient Safety US.

- Patients for Patient Safety US is a national organization and convener of patients, health care systems, HHS agencies, and specialty societies to address patient safety. The organization works with over 200 patient organizations, community-based organizations (CBOs), and consumer organizations.
- Ms. Sheridan serves as President and Chief Executive Officer (CEO) of Patients for Patient Safety US and Co-Chair of the National Academy of Medicine's Patient Safety in the Era of AI initiative. Previously, she was a director at the Society to Improve Diagnosis in Medicine, an advisor at

CCSQ, a director at the Patient-Centered Outcomes Research Institute (PCORI), and external lead at the World Health Organization's (WHO's) Patients for Patient Safety (PFPS) program.

- Ms. Sheridan shared her personal background with patient safety errors that led her to work in this space. Her family experienced two diagnostic errors. First, her son suffered brain damage at five days old from a failure to test and treat his newborn jaundice. This happened in 1995 when there were incentives for clinicians to withhold routine tests. Today, her son lives with hearing, speech, and mobility impairments. Second, her husband died of synovial cell sarcoma at age 45 due to the failure to communicate a malignant pathology report.
- Ms. Sheridan realized that what happened to her son and husband was invisible; there were no mechanisms to collect patient-reported experience or safety outcomes. Patients expect learning and immediate improvement from their losses.
- Diagnostic errors are the most common, costly, catastrophic, and underreported harms in the health care system. These types of errors cost the U.S. an estimated $200 billion annually and disproportionately affect vulnerable populations.
- Current APMs do not directly measure patient or diagnostic safety, and therefore miss important information and may result in delays in diagnosis and lack of care coordination. Ms. Sheridan quoted Peter Drucker, indicating that "If you can't measure it, you can't improve it."
- CMS and CDC are calling on the health care system to learn directly from patients and families to improve patient safety, including diagnostic outcomes, evident in CMS' new Patient Safety Structural Measure. Research demonstrates that patients can detect and report harm.
- Patients for Patient Safety US launched Project PIVOT (Patients Involved in deVeloping Outcomes Together) to improve patient and diagnostic excellence through the creation of patient-reported experience and outcome measures. Patient organizations, community organizations, patients and families, and professional stakeholders were convened to develop potential survey questions that patients would like to be asked. The stakeholders worked with AHRQ, CMS, Press Ganey, Geisinger, and ECRI (Emergency Care Research Institute) to prioritize survey questions.
- There are six questions that Press Ganey is currently piloting and validating. Press Ganey will pilot additional questions on diagnostic safety in September. The six questions cover whether, during a hospitalization, patients: experienced unexpected harm; were treated differently due to personal characteristics, which is especially important to older adults; felt their concerns were dismissed; were informed of how to report a concern about patient safety; were informed of how to escalate care or obtain a second opinion; and were given a list of pending test results upon discharge. Press Ganey has also refined these questions to apply to ambulatory care.
- Ms. Sheridan reviewed the benefits of adding validated PIVOT Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) into payment models:
    - Value: This measures what matters to patients.
    - Transparency: This makes hidden harms and near misses visible, measurable, and actionable.
    - Preventive: This is real-time and can identify safety risks before harm occurs.
    - Learning health system: These measures are available immediately; systems do not need to wait for claims data to take action.
    - Accountability: This creates C-suite accountability for patient and diagnostic safety.
    - Integrity: These measures are more difficult to game than many administrative measures.
- Patients for Patient Safety US' first proposal is to integrate these patient-reported measures into current ACOs such as the Medicare Shared Savings Program and the LEAD Model. Benefits to this approach are that the ACO infrastructure currently exists; the measures can be collected,

analyzed, and reported using AI; the approach will bring patient-centeredness and a safety lens to ACOs; the approach promotes diagnostic excellence; and the approach will reduce costs.
- PIVOT's "Earn Back" Value Model is a proposed model that uses withholds if benchmarks are not achieved. Ms. Sheridan noted that she planned to present additional information on the "Earn Back" Value Model during the second day (June 16) of the public meeting.
- Patients and families are the earliest detectors of safety breakdowns and the clearest judges of whether care was safe. The health care system should include patients' voices, learn from them, and reward health systems that respond to them.

For additional details on Ms. Sheridan's presentation, see the presentation slides (pages 2-15), transcript, and meeting recording (00:00-11:34).

Michelle Schreiber presented on targeting improvements in patient safety.

- Dr. Schreiber introduced herself as a general internal medicine physician who has served as a Chief Medical Officer (CMO), Chief Medical Informatics Officer (CMIO), and Chief Quality Officer (CQO) engaged in patient safety and quality throughout her career.
- Doing no harm is the fundamental principle of health care, and Dr. Schreiber is excited that PTAC is considering a model that focuses on patient safety. Patient safety is an urgent public health issue. During the pandemic, safety metrics in the U.S. plummeted, not only because of the pandemic but also because the systems of safety in place were not strong enough to withstand the public health burden. Results have improved but are returning to pre-pandemic levels and are not continuing to improve.
- CMS has quality and safety levers, but the health care system remains fragmented, even within CMS' programs.
- CMS quality and safety levers include:
    - Conditions of participation that establish the floor for quality and safety;
    - Coverage and payment determinations;
    - Audits and evaluation;
    - Survey and certification, largely to the conditions of participation;
    - Quality improvement organizations (QIOs) focused on improving safety mainly in skilled nursing facilities (SNFs), small clinician practices, and smaller hospitals;
    - Quality measurement, with CMS transitioning to digital measures to provide near real-time data for CMS and for organizations to learn how to use their data in real time to create learning health systems;
    - Value-based incentive programs that use quality measures through pay-for-reporting or pay-for-performance; and
    - Innovative advanced payment models.
- CMS works with agencies across and external to HHS, including CDC, AHRQ, FDA, Office of the National Coordinator for Health Information Technology (ONC), Department of Veterans Affairs (VA), and Department of Defense (DoD). CMS and CDC, as well as CMS and AHRQ, are working collaboratively on measures.
- Dr. Schreiber described CMS' recent efforts to advance accountability. These efforts include:
    - Transparency: CMS is publishing all data on Care Compare, a public website, to empower patients to make informed decisions and to empower providers and health systems to track their performance. Additionally, CMS is modifying Star Ratings to reduce ratings for facilities that rank in the lowest quartile for patient safety.
    - Technology and data: CMS is transitioning to digital measures, particularly eCQMs for organizations to use in real time. CMS is also considering using AI and large language

models to pull information from EHRs, including information on patient safety, and to potentially assess organizations' incident reporting systems.
    - Culture of safety: CMS is providing support for reporting errors. Dr. Schreiber recommended penalizing for failure to improve and for failure to report.
    - Payment: CMS is considering a patient safety model. CMS is assessing whether the Center for Medicare (CM) has levers that can be used for nonpayment for dangerous errors.
- Recent CMS accomplishments include the Birthing Friendly Designation to support maternal safety; the PSSM; the Age Friendly Measure; the QIO 13th Statement of Work; the updated weighting used in Star Ratings; and the suite of digital measures that includes new measures for diagnostic safety.
- Of over 400 quality measures, 122 are dedicated to patient safety both within and outside of hospital settings. These patient safety measures focus on medication safety, complications, HAIs, and organizational capacity. The PSSM includes five domains: leadership commitment to eliminating preventable harm, strategic planning and organizational capacity, culture of safety and learning health systems, accountability and transparency, and patient and family engagement. Dr. Schreiber emphasized the importance of leadership and governance to patient safety. A fundamental commitment to patient safety helps organizations improve patient safety. She also highlighted the vital importance of patient and family engagement, with patients able to report concerns directly.
- Dr. Schreiber presented a list of patient safety eCQMs. The goal of these measures is to achieve real-time reporting that facilities can use for continuous improvement. CMS is collaborating with CDC on these measures.
- Dr. Schreiber reviewed several future considerations, including the use of AI and the reporting of harm. There are over 100 patient safety organizations in the U.S. that are required to report to a national database maintained by AHRQ, but only approximately five of these organizations actually report harm. There is an opportunity to acquire additional national information on patient safety.
- Dr. Schreiber closed with safety considerations for APMs. First, she hopes there will be a model developed with a primary focus on safety. Second, there must be a focus on the system's capabilities, including governance, the ability to use real-time data to drive improvement, culture that allows individuals to speak up and report concerns in a safe environment, and training. There are opportunities to reframe and re-ask patients about their safety experience. Technology also offers opportunities, including wearable devices, monitoring, predictive analytics, and AI. Finally, it is important to create the will to change and accelerate patient safety.

For additional details on Dr. Schreiber's presentation, see the presentation slides (pages 16-52), transcript, and meeting recording (11:35-23:31).

Susannah Bernheim presented on approaches to patient safety in APMs.

- Dr. Bernheim shared that her presentation would focus on the CMS Innovation Center's authorities and opportunities related to patient safety. The CMS Innovation Center's portfolio does not include a patient safety model; however, across the portfolio, there are efforts to use the CMS Innovation Center's levers to advance fundamental changes and drive care coordination, which is a critical tool for improvement in patient safety. These efforts include coordination and communication between primary and specialty care, ambulatory and acute care, and patients and clinicians.

- The CMS Innovation Center's models are required to reduce costs and improve quality. Improving safety is fundamental to a model's success. Adverse safety events and experiences are costly for the system. Care coordination is crucial for patient safety and remains a key gap in care that models can help address.
- Dr. Bernheim outlined the CMS Innovation Center's three pillars: prevention, patient empowerment, and choice and competition. Patient safety experts have advocated for the need to empower patients and beneficiaries. Currently, the focus is on how to give people more information, support, and incentives to take a more active role in their health. This includes equipping patients with tools to understand their health status, set goals, and make informed decisions. This idea is synergistic with work to advance patients' voices in the health care system.
- Dr. Bernheim acknowledged that hospital models have resulted in tremendous opportunities to strengthen incentives already in use in CMS. For example, the TEAM Model focuses on surgical bundles that will be mandatory in hospitals across the U.S. This model allows CMS to incorporate patient safety measures and increase financial accountability for the measures by driving coordination from the hospital through outpatient care. Coordination and the avoidance of complications are critical to lower the costs of procedure-based bundles, reduce use of acute care, and maintain positive outcomes for beneficiaries. The Comprehensive Care for Joint Replacement (CJR) Model showed success with preventing decreases in patient safety using bundled payments.
- Opportunities to improve safety in ambulatory care settings include addressing communication, medication safety, care coordination, and patient-centered care. There are opportunities in APMs to focus on interoperability, medication management, communication systems, and patient engagement, particularly with high-risk patients.
- Dr. Bernheim reviewed the CMS Innovation Center's authority to waive existing requirements to test new approaches. Examples include the SNF 3-day rule waiver; allowing for case management through a home visit waiver; and allowing for payment arrangements across participants that encourage and build coordination. The CMS Innovation Center also uses quality measurement tied to financial payment and often creates requirements for care management to instill changes in care delivery.
- Dr. Bernheim shared two models as examples. The Guiding an Improved Dementia Experience (GUIDE) Model is an ambulatory model focused on improving care for patients with dementia. Model features include supporting caregivers and attending to medication management given the risk of polypharmacy for dementia patients. The LEAD Model is the CMS Innovation Center's newest ACO model and will launch in 2027. The LEAD Model will test CMS-Administered Risk Arrangements (CARA). This approach creates infrastructure for ACOs to contract directly with specialists. The LEAD Model includes the Resilience and Independence in a Safe Environment (RISE) to Age in Place Episode. This will allow ACOs to build on the Community Aging in Place—Advancing Better Living for Elders (CAPABLE) Model by contracting directly to bring occupational therapists and nurses into patients' homes to focus on fall prevention. ACOs will be required to have a prevention intervention.
- Dr. Bernheim highlighted patient safety-related results from several CMS Innovation Center model evaluations. In episode-based payment models such as CJR that decrease acute and post-acute care use and costs, complications of care serve as a guardrail. The Oncology Care Model (OCM) embedded a multidisciplinary, multidimensional safety framework that showed an overall improvement in quality and safety. The Partnership for Patients early model resulted in national improvements in areas such as hospital-acquired conditions (HACs).

- Dr. Bernheim closed by inviting the Committee members' recommendations for how the CMS Innovation Center can use its authority to advance patient safety, including through building coordination functions, incorporating patient voices in care coordination, and expanding successful models.

For additional details on Dr. Bernheim's presentation, see the presentation slides (pages 53-62), transcript, and meeting recording (23:32-35:24).

Jason Mitchell presented on patient safety in APMs.

- Dr. Mitchell stated that safety matters, and zero harm is possible.
- Dr. Mitchell described opportunities to improve patient safety within current CMS APMs, most of which do not have a full, stand-alone incentive framework for patient safety. These models focus on outcomes such as utilization, admissions, and readmissions, yet patient safety extends beyond these outcomes. The TEAM Model will begin to assess key safety metrics. Medication events are critical for safety across settings, as are post-discharge falls, which often lead to multiple admissions. Additional areas where patient safety can be improved include post-discharge complications and ambulatory safety. People are most often at home, not in a hospital or clinic setting. Moving forward, CMS and health systems could consider how to address patients' needs at home.
- Dr. Mitchell explained that Geisinger now offers qualified patients warranties for certain procedures where Geisinger is personally at risk for poor outcomes. These warranties ensure that the organization is aligned with the best outcomes. For example, ProvenCare is a warranty for heart surgery.
- Dr. Mitchell described Geisinger's approach to organizational change to improve patient safety. Geisinger is committed to high reliability organization (HRO) principles:
    - Anticipating safety threats, which includes a preoccupation with failure mindset for every patient; a reluctance to simplify, given the complexity of health care; and sensitivity to operations where solving patient safety issues requires individuals to be present.
    - Responding and adapting to safety threats, which includes a commitment to resilience when failures occur; and deference to expertise where patients and clinicians are considered the experts in patient safety.
- Geisinger begins every meeting with a safety moment, which helps people focus on how their work ties back to care. Geisinger encourages and protects people who speak up to create a psychologically safe, no-blame culture. Finding harm is cause for celebration in that it allows an organization to conduct a root cause analysis and prevent it from occurring in the future. In every decision Geisinger makes, the organization considers how the decision will affect patients and their safety.
- Dr. Mitchell outlined opportunities for CMS models to advance patient safety:
    - First, advancing patient safety metrics to directly reward harm prevention, such as a safety composite score for ACOs; considering a safety-gated financial incentive in which an entity cannot earn savings without safety; and using bundled payments that include post-acute safety measures that extend beyond readmissions. There are additional ways to measure patient safety beyond assessing readmissions.
    - Second, aligning financial outcomes with zero harm by anchoring outcome-adjusted payments to patient safety; rewarding bundle adherence as a leading indicator to harm avoidance to allow systems time to ramp up to prevent harm; and integrating patient-

reported outcomes and safety measures to understand the patient and caregiver/family experience.
    - Third, deploying models to support ambulatory safety by establishing a framework of unified metrics and outcomes in the ambulatory setting; focusing on frailty and fall prevention, as frailty is an important predictor of poor outcomes in hospital settings; and reducing harm from medications, confusion about medications or medication benefits, and lack of access to medications.
- Dr. Mitchell concluded by reiterating that safety matters, and all harm is preventable.

For additional details on Dr. Mitchell's presentation, see the presentation slides (pages 63-70), transcript, and meeting recording (35:25-45:19).

Dheerendra Kommala presented on approaches to improve patient safety in APMs.

- Dr. Kommala introduced himself as representing 250 passionate people who work at ECRI, a federally qualified Patient Safety Organization (PSO) whose mission and vision is to reduce harm. ECRI is designated as an Evidence-based Practice Center (EBC) by AHRQ. For 60 years, ECRI has been testing medical devices and equipment. Its sister organization, Institute for Safe Medication Practices (ISMP), is the premier organization in the reduction of medication errors. ECRI recently acquired the Just Culture Company, which focuses on nonpunitive culture for transforming workplaces.
- Despite progress that has been made, including through innovative CMS models, there are still significant areas for improvement. One in four patients observe adverse events, with 50% or more underreporting. Implementing continuous learning systems is needed to learn from mistakes and improve patient safety outcomes.
- Dr. Kommala presented data on the last 10,000 safety events that were reported to ECRI, including over 1,000 near misses. For example, a pharmacist conducting rounds found that a patient on a heparin drip had not had any monitoring labs for nearly 48 hours, ordered the labs, and the heparin was titrated. There is no incentive for the pharmacist's intervention that caught and reported the problem. Near misses and safety signals need to be rewarded.
- One common safety problem is related to medication reconciliation, particularly at admission and discharge. Almost 73% of events happen during care transitions when there is not an accountable owner. This accountability needs to be clear, and reporting needs to be incentivized.
- Dr. Kommala described the role of technology in changing the patient safety paradigm. Almost 1,500 new devices were cleared through 2025, approximately 97% of which were cleared via the 510(k) process (i.e., no clinical outcomes data required). Almost 43% of AI device recalls occur within the first year of clearance. While there is a need to use new, innovative technologies, the technologies need to relate to outcomes and value-based frameworks. ECRI also supports enabling digital health access.
- In the last 10,000 safety events, there were 88 sepsis-related events, 15 of which were severe. In one case, there was an eight-hour delay between the patient's presentation to the hospital and the administration of the antibiotic. ECRI consistently observes system design failures in the context of ambiguous order sets, intravenous (IV) therapy access barriers, antibiotic scheduling defaults, and competing clinical priorities. Addressing these systematic problems requires examining systems design and human factors engineering.
- Dr. Kommala reviewed recommendations for redesigning APMs to drive structural safety. First, safety signals, particularly the ratio of near misses to adverse events, should be utilized to create the right culture and continuous learning system. Second, the use of technology in a value-based

framework should be incentivized, with outcomes as a parameter on which to measure technology. Third, care transitions, especially at high-risk points, continue to be a problem, and accountability is needed. Payment structures need to consider patient care transitions beyond the acute care setting. Finally, human factors engineering should be considered in care delivery design, shifting from reactive to proactive care. The patient should always remain the primary focus.

For additional details on Dr. Kommala's presentation, see the presentation slides (pages 71-82), transcript, and meeting recording (45:19-53:28).

Following the presentations, Committee members asked questions of the experts. For more details on this discussion, see the transcript and meeting recording (53:29-1:23:16).

Experts discussed whether it is possible for CMS Innovation Center models to focus solely on patient safety.

- It is possible to have models that focus on patient safety, but this focus should not distract from building patient safety into other models.

Experts discussed how to best engage low performers in improving patient safety, from initial point of intervention through outcomes.

- QIOs engage low performers. However, this is a voluntary program.
- There are opportunities for QIOs to serve as consultants and support low-performing participants who are not reaching their performance measures or benchmarks. CMS levers may be weaved into the Project PIVOT's "Earn Back" Value Model.
- Financial incentives and quality improvement can engage low performers. For example, the Continuous Improvement/Sustained Exceptional Performance (CI/SEP) measure in the ACO REACH Model rewards improvement. However, there can be challenges with using this approach in voluntary models. CMS is increasingly considering making models mandatory to achieve a more representative set of participants.
- It is important to meet people where they are and provide glide paths, such as up-front incentives that allow for investments. There are different tiers and timing in CMS models that help address barriers, avoid oversimplification, and provide low-performing pathways that work.
- ECRI meets with leadership at low- and high-performing organizations. There is a gap in connecting safety and quality to financials. There is a need for education on the link between patient safety and better financial outcomes. The right behaviors and outcomes should be financially incentivized.
- Project PIVOT's "Earn Back" Value Model is a continuous learning model within a payment model. Learning and improvement are shared with other hospitals as participants do not meet benchmarks, similar to CMS' Partnership for Patients. This learning collaborative could help low performers.

Experts discussed the importance of focusing on patient safety in ambulatory care and the creation of patient-reported outcome and safety measures in the ambulatory setting.

- Patients for Patient Safety US created PROMs and PREMs that mattered most to patients and families by using a new methodology that brought together over 100 CBOs and three populations (mothers of color, people with disabilities, and older adults). It conducted a systematic, rigorous qualitative analysis of the measures and mapped the measures to national

patient safety initiatives such as those from CMS, CDC, and AHRQ. It narrowed down the measures to a set of 18 measures, and the stakeholder groups and patients prioritized these measures. More measures will be developed. The measures are undergoing a pilot and validation by Press Ganey and may be deployed as performance measures in CMS payment models and in Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys.

- There are opportunities for more insights into patient safety in ambulatory care. There may be a lower percentage of errors in ambulatory care relative to hospitals because there are not acute changes in patients' conditions as there are in the hospital setting. CMS has introduced two diagnostic measures: timeliness of mammography and timeliness of colonoscopy. The timeliness of colonoscopy measure includes following up on positive first-line colon cancer screening tests, where follow-up rates are low because it is not part of the Healthcare Effectiveness Data and Information Set (HEDIS) measure or Star Rating. CMS is committed to incorporating patient safety measures into its 27 value-based programs that extend into all care facility types.

Experts discussed how patient safety measures are being applied and assessed in the behavioral health population, which experiences the same complications as other settings (e.g., failures in transitions of care, lack of evidence-based care, overprescribing, and unnecessary, high utilization).

- The CMS Innovation Center's Innovation in Behavioral Health (IBH) Model focuses on how to integrate physical and behavioral health care, which creates a safety net for patients with serious mental illness. These patients often do not have an adequate system for their physical health. Recently, the CMS Innovation Center has focused on how to incorporate patients' voices and goals as a feature of the care required in this model.
- People with both behavioral health and medical diagnoses have two to three times the utilization of health care services for their medical diagnosis compared to patients without both a behavioral health and medical diagnosis. Treating behavioral health can improve individuals' mental and physical health. There are not enough psychiatrists, psychologists, and therapists to treat everyone with behavioral health diagnoses. There is a need for more ambulatory clinicians who can treat behavioral conditions, including depression, anxiety, and substance use disorder, which could help make available behavioral health resources for more complex patients. This can happen through collaborative care models in which primary care and specialty clinicians engage in diagnosis and treatment for simpler behavioral health diagnoses with clinical pharmacists for support. There are also opportunities to diagnose and treat behavioral health conditions within specific specialties, such as postpartum depression and depression after heart attack or stroke.
- There are adverse events related to lack of timely follow-up post-discharge and medication reconciliation. There must be systematic incentives for timely follow-up to allow for detecting and treating behavioral health issues such as postpartum depression. In addition, patient and family education is critical to identify red flags.
- It is important to include patients and families in identifying what matters most to patients and understanding what problems look like from the behavioral or mental health perspective. Project PIVOT is creating behavioral and mental health-specific PROMs and PREMs.

Experts discussed the role of AI in identifying and understanding harms, as well as how AI can be used safely and responsibly.

- CMS is looking into whether an AI engine on top of a facility's electronic medical record (EMR) can use a large language model to pull unstructured data from text-based documents, such as

radiology reports, pathology reports, and clinical notes. It is important to make sure that the AI systems are correct and pulling information appropriately.

- In many organizations, incident reports are not directly under the purview of many quality organizations; some incident reports are considered risk and risk management, which is distinct from quality and quality management. There are opportunities for AI to address this issue.
- AI and predictive models can monitor an entire unit for early warning signs and intervene early for patients who may need intervention.
- CMS aligned its initial digital measures with ECRI on the most common types of harm; however, once these systems were turned on, they resulted in an overwhelming volume of errors. Some organizations have started to turn the systems off because the organizations do not know how to manage the large quantity of information. There are opportunities for AI to help process large volumes of information about safety events to evaluate and prioritize the events.
- There is an opportunity to use large language models through AI overlays to capture near misses. Given the large amount of information captured, it is important to be able to decipher the information and capture what is relevant and important to allow for a continuous learning system.
- AI and chart synthesis can provide clinicians with a better picture than clinicians can do on their own. This tool can help doctors, advanced practice clinicians, nurses, and help desk employees to identify and prevent harm before it occurs and identify near misses. AI and chart synthesis are needed given the large number of events.
- There is an opportunity to automate and use AI to capture safety information from the patient. For example, a bot could ask patients five questions about safety every night in the hospital to create immediate feedback and alerts. AI can also alert patients of safety risks, such as leaving the hospital without a newborn bilirubin test.

Experts discussed how to improve safety without disproportionately harming the most vulnerable providers (i.e., those with the most room to improve) through penalties, withholds, or reduced payments, especially considering that administrative and reporting burden is already high.

- Shared savings work well because quality and safety reduce the cost of care. When systems reduce harm, there should be savings that can be measured and shared with entities. Entities that are having difficulty with CMS metrics and mostly care for Medicare and Medicaid patients are unlikely to succeed in a model with a fee-for-service (FFS) withhold in which they are expected to invest, especially if it is a voluntary model. A mandatory model could give a pay cut to a system that is having difficulty. Instead, shared savings for every harm prevented decreases utilization and allows everyone to succeed. Funding that would otherwise be spent on hospitalizations can be used to fund these types of programs.
- CMS is considering how measures can work well; however, measures are not the be-all, end-all of improvement. The agency would like to assess and reward capabilities to build a fundamental layer. Additional tools include prospective or early payment, which can be useful for models with multiple years of pre-implementation. These types of payment can support some of the system transformation that must occur before incentives come into play.
- Even in traditional Medicare models with a withhold, there must be a way to earn those dollars back if there is improvement.
- The transition to digital measures reduces burden significantly and allows for real-time learning and improvement.

- EMR vendors must have eCQMs built in with workflows that allow systems, smaller practices, and independent doctors to participate in the transition to digital measures. Recommendations should consider what is expected of EMR vendors to facilitate this work.

Session 2: Measuring Patient Safety in Value-Based Care

SMEs

- Jeffrey J. Geppert, Senior Research Leader, Battelle
- Patrick S. Romano, MD, MPH, Professor, Division of General Medicine and Division of General Pediatrics, University of California, Davis
- Commander Karen Chaves, MHS, Director, Division of Quality Measurement and Improvement, Center for Quality Improvement and Patient Safety (CQuIPS), Agency for Healthcare Research and Quality (AHRQ), and United States Public Health Service Commissioned Corps
- David C. Classen, MD, MS, Professor of Medicine, University of Utah, Lead, Utah Center for Health AI and the Health IT Safety Program, and Senior Advisor, PascalMetrics

David Tyson moderated the session with four SMEs on measuring patient safety in value-based care. Full biographies and presentations are available.

Jeffrey Geppert presented on measuring patient safety in value-based care.

- Mr. Geppert described Battelle as a CMS-certified consensus-based entity that leads the Partnership for Quality Measurement, which includes more than 1,200 health care stakeholders, and supports three consensus-based entity processes: endorsement and maintenance, pre-rulemaking measure review, and measure set review.
- Mr. Geppert discussed challenges in determining whether patient safety measures are fit for purpose in accountability settings, emphasizing that measures should drive system-level improvement, be explicitly linked to meaningful patient outcomes, and provide value that outweighs data collection burden.
- Mr. Geppert questioned whether current measurement approaches generate sufficient value, noting that differences between high- and low-performers may reflect only a small number of events and that links between measures and outcomes are often highly attenuated across the system and over time.
- Feasibility and reliability are limited because patient safety measures often rely on data in unstructured fields or external systems (e.g., laboratory, pathology, radiology), and adverse events may be too rare at the clinician or organization level to support consistent performance assessment.
- Accountability requires demonstrating that an entity is the primary cause of a safety event; however, causal relationships are often unclear, with multiple contributing factors that complicate attribution and increase risk for both entities and patients.
- Measures are often not explicit about how they function, for whom, or under what conditions, and measurement strategies may be misaligned in scope, scale, and timing to produce meaningful results.
- Mr. Geppert proposed shifting from compliance-based to goal-oriented accountability, noting that traditional retrospective measurement remains important for detecting harm and benchmarking performance but may be insufficient as care delivery becomes more complex and technology-driven.
- Drawing on other safety-critical industries, Mr. Geppert introduced assurance cases as a complementary approach—structured arguments that identify hazards, define safety controls,

and evaluate residual risk—to move from retrospective measurement toward prospective safety assurance.
- Mr. Geppert outlined three approaches: (1) integrate assurance cases with traditional measures as part of governance; (2) use advanced analytic tools to make measurement more predictive and evidence-informed; and (3) align financial incentives with transformation through community engagement, value generation, and phased implementation.
- Mr. Geppert concluded that there is an opportunity to reframe the focus from improving individual metrics to improving overall reasoning about safety, strengthening accountability, connecting to AI governance and socio-technical systems, explaining why current quality measure debates persist, and positioning assurance cases as a complementary governance infrastructure rather than just another reporting burden.

For additional details on Mr. Geppert's presentation, see the presentation slides (pages 2-9), transcript, and meeting recording (00:00-11:07).

Patrick Romano presented provider perspectives on measuring patient safety in value-based care.
- Dr. Romano described his experience leading the AHRQ Quality Indicators (QI) Program and PSIs over the past two decades. He also served as clinical lead for eCQMs for eligible clinicians in CMS' Quality Payment Program, contributed to hospital harms measure development, and has served on The Leapfrog Group's Hospital Safety Grade technical expert panel.
- He grounded his perspective in the IOM/National Academy of Medicine (NAM) framework, emphasizing that equity and value are cross-cutting dimensions that intersect with effectiveness, safety, timeliness, patient-centeredness, accessibility, and efficiency. This framing is also reflected in CMS' Meaningful Measures framework.
- Dr. Romano encouraged broadening PTAC's definition of patient safety from events occurring "during the delivery of health care" to those "associated with health care," to better capture harms that emerge after care transitions across settings, providers, and organizations. He emphasized a goal of zero preventable harm.
- Dr. Romano noted limitations of Donabedian's structure–process–outcome framework, explaining that it may be overly linear. In practice, process improvement can drive structural change, and even strong structures only enable better care. He emphasized that outcomes are most meaningful to patients because they reflect not only what care was delivered, but also how well it was delivered, and may not be fully captured by traditional structural and process measures.
- Dr. Romano questioned the role of financial incentives in improving patient safety, noting that safe care is an ethical and legal expectation embedded in professional norms. He cited clinical training (e.g., "primum non nocere"), malpractice risk, and clinician distress following errors as strong intrinsic motivators for safe care.
- Dr. Romano used the Hospital-Acquired Condition (HAC) Reduction Program as an example, noting that while it focuses attention on patient safety through outcome measures and a 1% Medicare penalty for the lowest-performing hospitals, it does not reward improvement, is sensitive to small numbers of events, and may produce unintended consequences such as underreporting, risk avoidance, and disadvantages for teaching and safety net hospitals. He noted limited evidence of impact on improving safety.
- Dr. Romano emphasized attribution challenges in measuring patient safety, noting that care is delivered by multidisciplinary teams, harm events are relatively rare and multifactorial, and outcomes may occur outside the measured episode. These factors complicate linking outcomes to specific entities, though ACO structures may better align accountability with care delivery.

- There is growing interest in linking process and outcome measures to strengthen measurement approaches, including pairing related indicators (e.g., hypoglycemia and hyperglycemia for diabetes management, hand hygiene with HAI rates, fall prevention with functional status and injury outcomes, and diagnostic processes with timely diagnosis and treatment). CMS Hospital Harm measures and AHRQ's work on timely follow-up after abnormal cancer screening reflect this direction.
- Dr. Romano recommended a cautious, deliberate approach to incorporating patient safety into payment models, noting that such models have had a limited track record of improving safety. He emphasized that intrinsic motivation may be as important as, or more important than, extrinsic incentives. Transparency can promote improvement with or without financial incentives.
- Accountability must be aligned with actionability at the entity level, such that the organization held accountable has the ability to influence outcomes. Dr. Romano concluded that improving patient safety requires strengthening professionalism, continuous quality improvement, and a culture of safety, while anticipating and monitoring unintended consequences such as underreporting, risk avoidance, and undertesting or overtesting.

For additional details on Dr. Romano's presentation, see the presentation slides (pages 10-22), transcript, and meeting recording (11:08-23:27).

Commander (CDR) Karen Chaves presented on AHRQ's patient safety measurement activities.

- CDR Chaves explained that the AHRQ QIs program aims to produce scientifically sound measures and software for health care users to identify the potential for quality improvement. She emphasized that AHRQ is a research agency—not a regulatory agency—which distinguishes its role from agencies such as CMS and FDA. AHRQ has developed approximately 70 QIs organized into six modules and maintains technical specifications, conducts ongoing refinements, and produces open-access software. She noted that AHRQ's work in measure development typically precedes implementation in quality improvement initiatives, public reporting, and payment models.
- CDR Chaves noted that AHRQ QIs are used by a broad range of stakeholders, including hospitals, health care systems, hospital associations, health plans, third-party vendors, nonprofit quality improvement organizations, and federal agencies. She emphasized that AHRQ QIs are intended primarily for quality improvement rather than accountability, though AHRQ works with implementation partners to address the scientific basis for these measures.
- CDR Chaves focused on findings from the PSIs Gap Analysis Report, concluded in December 2025. She explained that PSIs focus on potentially avoidable safety events, including in-hospital complications and adverse events following surgeries, procedures, and childbirth, and are widely used in pay-for-performance and public reporting programs. The gap analysis included a literature review, public comment analysis, and stakeholder listening sessions conducted in collaboration with CMS.
- CDR Chaves highlighted themes from the study, noting that the proliferation of measures since the IOM report, *Crossing the Quality Chasm,* has led to overlap across measures developed by AHRQ, CDC, CMS, and NCQA. While this proliferation contributes to measurement burden, gaps remain in several areas, including the availability of standardized measures and access to robust data sources.
- CDR Chaves identified diagnostic safety as a gap in the PSIs. The current PSI module does not include measures specific to diagnostic safety, and AHRQ is working to expand into diagnostic excellence. Key gaps include missed laboratory tests, imaging results, and follow-up care, all of

which can lead to delayed or missed diagnoses. Measurement challenges include long-time horizons, variation between generalist and specialist diagnoses, limitations of claims-based data, and the fact that many diagnostic processes occur in outpatient settings. She also noted challenges in rural areas with limited access to diagnostic services. Potential solutions include the use of proxy measures, such as late-stage diagnoses, which AHRQ is exploring in cancer care.

- CDR Chaves noted that adverse drug events (ADEs) represent the most common form of patient harm in the U.S. but are not currently included in the PSI module. While related measures exist (e.g., HEDIS measures), claims data often lack sufficient clinical detail to capture issues such as medication reconciliation errors, dosing errors, or adverse reactions. She highlighted patient-reported data as a potential complementary data source and suggested focusing on serious events and high-risk medications such as opioids, anticoagulants, and insulin.
- HAIs are the second most common outpatient adverse safety event. CDC's NHSN provides extensive infrastructure for tracking these events. Given this existing ecosystem, AHRQ is considering retiring PSI 07 (central venous catheter-related bloodstream infection rate) while maintaining and potentially expanding PSI 13 (postoperative sepsis rate).
- CDR Chaves explained that HACs are the third most common source of patient harm. The PSI module includes many measures, but all are inpatient. The gap analysis identified opportunities to expand measurement for maternal and neonatal care, with potential to reduce preventable harms during pregnancy and infancy.
- CDR Chaves summarized four recommendations: (1) review and streamline existing PSIs to reduce overlap with other federal measures; (2) expand PSIs to ambulatory surgical centers and develop measures for perioperative care; (3) broaden maternal and neonatal safety measures beyond hospital settings; and (4) continue efforts to identify data sources to support measurement of preventable harm from diagnostic errors. She noted that ongoing work includes development of diagnostic excellence measures, maternal health measures, and outpatient surgery measures.

For additional details on CDR Chaves' presentation, see the presentation slides (pages 23-48), transcript, and meeting recording (23:28-43:45).

David Classen presented on AI-enabled patient safety measurement from a PSO perspective.

- Dr. Classen introduced himself as a medical informaticist at the University of Utah, an advisor to a PSO (PascalMetrics), chair of the AHRQ Common Formats PSO Committee, and leader of The Leapfrog Group's EHR Safety Standard. He noted his involvement in an NAM effort examining the future of patient safety in the era of AI, including questions about the continued role of retrospective measurement.
- Dr. Classen described the development of the IHI Global Trigger Tool to measure all-cause harm, noting that traditional patient safety measures significantly under-detect harm. Over more than a decade of implementation in the U.S., Europe, and Asia, the tool consistently found safety events occurring in one-quarter to one-third of all hospital patients, confirmed by David Bates' 2023 *New England Journal of Medicine* study showing that one in four patients in 11 teaching hospitals experienced harm.
- Dr. Classen provided a comparison illustrating this gap: In one sample, the Global Trigger Tool identified 354 adverse events, compared with 35 detected through AHRQ PSIs and four identified through hospital reporting systems. He emphasized that commonly used measurement approaches capture only a small fraction of actual harm.
- The Global Trigger Tool has since been automated and embedded in EHR systems, enabling real-time identification of harm. These automated approaches can detect substantially more events

and allow organizations to intervene at the point of care. CMS' hospital harm measures reflect this shift toward more comprehensive, real-time measurement.

- Dr. Classen described PSO-led implementation of automated safety monitoring using eCQMs, now deployed in more than 100 hospitals. These systems have substantially increased hard detection (e.g., 20 to 25-fold) and enable unit-level monitoring, supported by analytic approaches that reduce false positives and enable daily review.
- Improved detection enables a more complete understanding of the types and causes of harm, which is necessary to evaluate which interventions are effective—a long-standing gap in patient safety improvement efforts.
- Dr. Classen described advances in predictive analytics, noting that AI-enabled systems have been used to identify patients at risk of harm up to 72 hours in advance, creating opportunities to prevent adverse events rather than only measure them retrospectively.
- Dr. Classen also highlighted efforts to improve transparency and patient engagement, including real-time safety dashboards that provide information to patients and families. Early findings suggest that these tools may improve outcomes such as readmissions, mortality, and patient activation.
- Dr. Classen discussed applications in risk management, where automated detection systems can identify potentially compensatory events within 36 hours, compared with approximately 50 days using traditional approaches, with implications for reducing malpractice costs.
- Dr. Classen concluded by recommending that the field shift toward real-time, AI-enabled patient safety measurement, emphasizing that technical barriers have largely been addressed. He noted that the primary challenges to adoption are organizational, including reliance on legacy reporting systems and reluctance to adopt approaches that may reveal substantially higher rates of harm.

For additional details on Dr. Classen's presentation, see the presentation slides (pages 49-68), transcript, and meeting recording (43:46-1:01:47).

Following the presentations, Committee members asked questions of the experts. For more details on this discussion, see the transcript and meeting recording (1:01:48-1:34:52).

Experts discussed recommendations for scaling automated, AI-enabled patient safety monitoring nationwide, including barriers to implementation and strategies for broader adoption.

- Automated, AI-enabled patient safety monitoring has already been scaled across more than 100 hospitals in the U.S. and Australia, suggesting that technical barriers are not the primary constraint on broader adoption. Organizational and cultural barriers predominate, including reliance on voluntary reporting systems that tend to capture errors that do not result in patient harm rather than actual harm events. Some organizations have expressed concern that more sensitive detection methods would reveal substantially higher rates of harm; in some cases, hospitals observed increases in detected events of 20 to 25-fold but subsequently discontinued use of these systems.
- The infrastructure to ensure that AI tools perform as expected is still emerging. Agentic AI is nondeterministic—small input changes can result in large output changes—and exhibits the same human-factor errors observed in safety-critical situations. AI is manifesting as complex systems with multiple agents running multiple models, where errors may spread through connected systems. There is uncertainty about building APMs on an AI foundation. While value-based payment could simply reward adoption of well-established AI tools, given current

uncertainty about how AI tools integrate to improve patient outcomes, value-based payment models still have a role in uncovering these unknowns.

- Testing of AI-enabled functionality within EHR systems has demonstrated variability in outputs, including auto-population of medication fields. Repeated testing of identical scenarios has produced substantially different results, including unsafe recommendations. This variability raises concerns about the reliability and predictability of AI tools in clinical decision-making environments.

Experts discussed how to measure systems-based errors at the team level rather than the individual level, addressing the cultural challenges of implementing automated safety measurement and the team-based nature of both care delivery and error occurrence.

- Early implementation of automated triggers relied on sending alerts directly to frontline providers; however, this approach proved ineffective because providers were often too overwhelmed to respond. Effective implementation requires a dedicated team to manage, analyze, and act on safety signals, allowing frontline providers to be supported rather than responsible for monitoring and responding to alerts.
- APMs can support accountability at the entity level, reflecting the team-based nature of care delivery; however, these structures must be supported by fully engaged providers and functioning care teams. Without this foundation, accountability mechanisms risk appearing financially motivated rather than driving meaningful improvements in care. Effective systems-based approaches require organizational structures that align with care teams, facilitate shared accountability, and enable providers to act on performance data to address safety issues.

Dr. Schreiber joined the Session 2 experts to provide additional comments.

- CMS is transforming measures to digital formats, which helps with data standardization needed both for measures and to train AI models. While CMS may not provide real-time feedback, organizations can use these tools in real time on their units and floors to create real-time feedback monitoring systems and ongoing learning systems for change. AI can help manage and make actionable the huge volume of data, but it is equally important to monitor AI systems to ensure that the AI systems are learning correctly. CMS mandating that every facility implement automated safety monitoring systems would likely face resistance because it would be burdensome and expensive. An APM is valuable because it can evaluate whether these systems work before translating them to national participation. The approach needs to be studied first through a model.

Experts discussed why patient safety measurement has historically focused on inpatient settings and emerging approaches to address ambulatory patient safety.

- The historical focus on hospital-based patient safety measurement stems from the health care system being hospital-centric. In hospitals, care changes frequently, and effects are immediately visible, whereas in ambulatory settings, patients are at home and not in front of providers to observe immediate effects. However, health care is changing, with more surgery now performed in ambulatory settings. Traditional harms such as falls with injury are more common in facilities than at home; it was not until diagnostic excellence came to the foreground that health care began considering ambulatory harm. AHRQ started work in this area, and CMS is introducing measures, but stakeholders are just starting to see progress. Health care must transform and recognize that the system is shifting to ambulatory settings and to local patient control, ensuring that patients have information and are making decisions.

- From a measurement perspective, ambulatory settings are more difficult because the sample sizes may become too small to support reliable measurement. Accountability is essentially about causality, and causality is more difficult to establish when patients enter and leave care through many different pathways. The evidence base is much sparser.

Experts and Committee members discussed whether payment models are effective at improving patient safety or whether transparency alone may be a better intervention.

- Hospital payment programs have had some impact in reducing readmissions and reported events, but demonstrating true care improvement has been more difficult. Providers sometimes engage in behaviors to improve reported performance without improving care. The mixed record exists because the focus has been narrow, rather than on building robust systems. Developing more effective payment models involves building on work with composites, linking processes and outcomes through assurance cases, and implementing systems within organizations. When financial incentives are too large, they may create unintended incentives for providers to focus on reducing reported events rather than building robust systems that prevent errors affecting broader patient populations.
- The challenge is not primarily a technology challenge but an issue of organizational commitment. The health care sector has identified effective improvement strategies, and other industries have demonstrated that safety improvements are achievable; however, health care organizations have not consistently adopted these strategies. Medicare Advantage (MA) Star Ratings, which have substantial financial incentives, have shown measures change, though they may have been subject to substantial gaming. Most value-based programs have small amounts of money tied to them, making it a business decision where organizations would choose to absorb the penalty rather than change capabilities. The question is how to create the organizational commitment needed to support change. This is cultural and requires everyone—from the government to commercial payers—to speak consistently on how important this change is. High-quality health care should be the product in health care, but financial performance may be prioritized over quality and safety.
- One Committee member shared that payment attached to large-scale initiatives has proven successful—Meaningful Use drove EMR adoption, and the Bundled Payments for Care Improvement (BPCI) initiative reduced costs for joint procedures while improving quality and shifting care to outpatient settings. To be relevant, patient safety incentives must be embedded into the infrastructure of how payment cuts across all lines, similar to mandatory programs such as MIPS, rather than optional APMs.
- Another Committee member remarked that the question is not whether to create these incentives but how and when.
- Mr. Watters remarked that a new approach could create strong incentives for system leadership to invest in patient safety by allowing systems to recover withheld funds only when devoted to improvement, rather than simply accepting penalties as a business decision. This structure would create a clear leadership obligation to invest, creating responsibility for adopting a culture of patient safety. The approach should avoid a narrow focus on a limited set of metrics that organizations focus on while other contributors to patient harm remain unaddressed. A more flexible system should promote continuous improvement and transparency through automated reporting systems passing through PSOs, real-time feedback systems to identify effective interventions, and funding for practice improvement activities allowing multiple hospitals to test different approaches simultaneously.

Session 3: Improving Patient Safety in Value-Based Care Through the Use of Health Information Technology and Data Analytics

SMEs

- Rollin J. (Terry) Fairbanks, MD, MS, Senior Vice President, Chief Quality and Safety Officer, MedStar Health, and Professor of Emergency Medicine, Georgetown University
- Tejal Gandhi, MD, MPH, CPPS, Chief Safety and Transformation Officer, Press Ganey Associates LLC
- Melissa Swanfeldt, Senior Director, Quality & Regulatory Compliance, MEDITECH
- Aneesh Chopra, MPP, Chair, Arcadia Institute

Krishna Ramachandran moderated the session with four SMEs on improving patient safety in value-based care through the use of health IT and data analytics. Full biographies and presentations are available.

Terry Fairbanks presented on improving patient safety through safety science and human factors engineering.

- Dr. Fairbanks introduced himself as Senior Vice President and Chief Quality and Safety Officer at MedStar Health and Professor of Emergency Medicine at Georgetown University. He described three career phases: first as a safety engineer with a master's degree in human factors engineering in high-risk industries outside health care; second as an emergency physician who brought safety science into health care, starting the National Center for Human Factors in Health Care; and third, for the past eight years, as MedStar Health's Chief Quality and Safety Officer.
- MedStar Health is the largest health system in the Washington, D.C., and Baltimore area with 10 hospitals, 500 outpatient sites, and 35,000 associates. MedStar Health has prioritized safety for two decades, including open and honest communication with families, deep patient and family engagement, and deep human factors integration with 20 to 25 human factors and safety engineers embedded in the health system.
- Dr. Fairbanks explained that he conducted 30 qualitative interviews with safety experts to understand why safety is not progressing faster in health care than in other industries. Five emerging themes resulted: avoid the conflation of quality and safety; deliberately infuse true safety science; preempt harm with a proactive focus; prioritize new safety culture drivers using incentives; and engage the entire health care industry in the systems approach. He stated that even the best systems cannot achieve zero harm in the current structure. EHR designers, medical device companies, and others need to work collaboratively.
- Dr. Fairbanks described the difference between quality and safety in relation to defining patient safety. Quality metrics are quantitative while safety is qualitative. From the patient's perspective, he noted that quality asks, "how does my care measure up?" while safety states, "please don't harm me." Dr. Fairbanks referenced the utility of tools such as Kaizen, Standard Work, and Lean Six Sigma in defining harm. Safety, on the other hand, requires understanding human factors, such as safety design, team training, and psychological safety. It is important to establish a culture that does not inhibit people from talking about risks and near misses in care.
- The most common health care error is skill-based error, also referred to as an automaticity error. He provided an example of defibrillator design where pressing the "on" button instead of the "shock" button turns the device off, which could delay providing lifesaving care to the patient. He noted that consumer electronics, such as projectors, have mitigated this type of error, but defibrillator companies have not. He stated that health care believes that it will

become safer by telling people not to make errors instead of designing the health care environment and tools to mitigate risks from occurring.

- Dr. Fairbanks provided the example of a door with a pull handle and a sign that says push. People pull the handle because they follow the design, not the sign. A push plate on the door makes it difficult to take the wrong action. There are two concepts of basic safety engineering: know where the risks and hazards occur and then mitigate them with safety science-based solutions.
- Dr. Fairbanks cautioned against Committee members recommending or supporting incentives that reduce or inhibit reporting. Stakeholders must create an environment where people can report near misses without fearing the repercussions of reporting these errors. Aviation became safe not from reducing human errors, but from understanding human error and mitigating the design around it.
- Dr. Fairbanks concluded that stakeholders must use hazard, risk, and error data and encourage reporting to facilitate the study of errors before they injure patients. Health care may benefit from the inclusion of safety engineering experts. For example, medical schools and nursing schools do not teach how to lead safety practices in the clinical setting. Data must be the facilitator of change and not a disincentive to change.

For additional details on Dr. Fairbanks' presentation, see the presentation slides (pages 2-15), transcript, and meeting recording (00:00-14:42).

Tejal Gandhi presented on AI and its role in improving patient safety.

- Dr. Gandhi introduced herself as Chief Safety and Transformation Officer at Press Ganey Associates. She started her career as a health services researcher studying how technology can improve quality and safety and has been a Safety Officer at a large academic medical center, a Chief Quality Officer at a large system, CEO of the National Patient Safety Foundation, and served as the Chief Clinical and Safety Officer at IHI. Dr. Gandhi added that she also brings knowledge about what worked and did not work well with EMR adoption 20 years ago.
- Dr. Ghandi outlined four primary questions to ask related to AI's role in improving patient safety: Is the technology designed to be safe, is it being implemented safely, is it being used safely, and how can the technology improve patient safety? The fourth question is the focus of her presentation.
- Dr. Gandhi explained that AI can improve safety by decreasing administrative burden and cognitive load. She identified specific areas in patient safety where AI has opportunity, including diagnostic errors; medication reconciliation; supporting predictive, upstream, and proactive approaches to identifying harm; measuring and analyzing harm; and patient engagement.
- Health care is too often reactive in patient safety. For example, harm is analyzed only after someone is harmed. AI can help improve patient safety by uncovering where risk occurs and moving approaches upstream to reduce harm. AI must be tied to clinical workflows and actionability.
- AI presents an opportunity to help solve issues such as medication reconciliation and test result follow-up. Particularly in areas such as radiology and pathology, results fall through the cracks, diagnoses are delayed, and patients are harmed. Studies are starting to show that AI implementation can identify abnormal test results, determine whether follow-up occurred, and ensure follow-up occurs for test results flagged as still needing follow-up. In addition, large language models can conduct chart reviews to identify gaps.

- Dr. Gandhi stated that health systems should start leveraging AI for patient engagement, particularly by asking patients about safety. For example, AI can extract safety themes from patient comments, complaints, and online websites. Press Ganey is developing systems for reporting direct safety feedback that can feed directly into event reporting systems. She highlighted the importance of this work because what patients report is different than what clinicians report.
- Dr. Gandhi stated that she is very positive about the value of AI but noted concerns regarding design, implementation, and use. Health care must understand the impact of these tools on humans. For example, there is a need to understand whether the tools lead to de-skilling or automation bias and how clinicians should be trained to use them. She stated that AI can exhibit cognitive bias and produce errors, and that relying on a human to identify those errors is insufficient given the complexity of AI models. She noted that even reviewing AI-generated content can add cognitive burden on clinicians.
- Dr. Gandhi concluded that health care needs to incentivize adoption of tools that augment safety, starting with test result management, medication reconciliation, adverse event detection, and patient-reported safety concerns. Health care needs metrics to ensure safety improvement and to evaluate clinician experience with technology. Measures also need to be balanced and monitored to prevent unintended consequences. She stated that health care learned with EMRs 25 years ago that every new technology introduces new problems. Health care should acknowledge this and measure it in a smart and safe manner.

For additional details on Dr. Gandhi's presentation, see the presentation slides (pages 16-35), transcript, and meeting recording (14:43-28:52).

Melissa Swanfeldt presented on EHR technology opportunities for patient safety.

- Ms. Swanfeldt introduced herself as Senior Director of Quality & Regulatory Compliance at MEDITECH, the oldest software company and EHR in the nation.
- As an EHR company, MEDITECH views technology as a tool to improve the systems around the care team. Technology should be embedded in and augmenting provider workflows.
- Ms. Swanfeldt noted certain system-level contributors to patient safety events, including disrupted workflows, cognitive overload, and fragmented patient histories. Systems should be improved around the care team model by identifying risk early, standardizing care quality, supporting patient and physician decision-making, and augmenting workflows.
- Ms. Swanfeldt underscored the abundance of health care data available. She explained that MEDITECH aims to improve the data life cycle in three ways:
    - Capturing data using tools such as ambient listening, computer vision, smart sensors, and wearables;
    - Making data more useful by leveraging AI and machine learning for pattern recognition, clinical decision support, and care prioritization; and
    - Making data more accessible through interoperability, FHIR and FHIR APIs, and workflow integration.
- Ms. Swanfeldt highlighted examples of clients that use clinical decision support and EHR-supported protocol standardizations to improve patient safety. Examples included:
    - North Country Healthcare in New Hampshire, which used surveillance tools to track indwelling catheters;
    - Southern Ohio Medical Center, which used clinical decision support to ensure that specific criteria are met; and

    - Appalachian Regional Healthcare, which used nurse-driven protocols for diabetes ketoacidosis management.
- Ms. Swanfeldt discussed where data can be better leveraged through the care journey, including pre-visits and intake, real-time monitoring regardless of care setting, AI-enabled clinical decision support, well-timed surveillance alerts, care transfers using AI-generated nurse handoffs, outreach, follow-up education, telehealth, and remote patient monitoring.
- Ms. Swanfeldt highlighted one client's outcomes from using AI ambient listening tools. Eighty percent of users reported a reduction in cognitive load when completing discharge documentation, a 20 to 30% reduction in documentation time, and a savings of 40 hours per month in their Quality and Infection Control Department on abstracting data for quality measure reporting.
- Technology can be thought of as a clinician force multiplier, helping providers reclaim capacity, augmenting their intuition as clinicians, and extending their expertise through virtual nursing, telehealth, and training simulations.
- Ms. Swanfeldt emphasized the need to establish guardrails for responsible AI use in health care. Doing so will help build trust and transparency with patients, ensure equity in access to AI human autonomy and not replacement of human clinical judgement, provide risk management support, and ensure regulatory alignment with state laws.
- Ms. Swanfeldt recommended continued investment in technology-driven solutions and AI. She highlighted the importance of cross-agency collaboration on regulatory requirements related to technology adoption, especially for clinical decision support and AI. She noted that the FDA released guidance stating that any clinical decision support tool used to manage and support clinicians in identifying high-risk patients for sepsis or stroke is considered a medical device. She emphasized the importance of taking a risk-based approach to regulation. Additionally, regulatory oversight should not be the same for a low-risk AI use case and a high-risk tool that requires medical device clearance.

For additional details on Ms. Swanfeldt's presentation, see the presentation slides (pages 36-49), transcript, and meeting recording (28:53-46:16).

Aneesh Chopra presented on improving patient safety in value-based care using health IT and data analytics.

- Mr. Chopra introduced himself, stating that he served as Chief Technology Officer for President Barack Obama and as Virginia's Secretary of Technology. In the last decade, he founded a firm that became one of the largest research organizations that uses CMS data, which he sold to Arcadia. He currently serves as Chair of the Arcadia Institute and operates a large longitudinal data platform focused on value-based care.
- Mr. Chopra highlighted the 2023 President's Council of Advisors on Science and Technology (PCAST) report on patient safety, which emphasized the importance of longitudinal data sharing for promoting patient safety and encouraging patients to contribute data on the patient safety journey. He explained that it is important to include the patient's entire journey and not just care that takes place in a hospital.
- Mr. Chopra provided a sepsis case example to illustrate the patient-centered view. Because the measure starts when the patient is admitted to the hospital, the current Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) measure could miss capturing information two weeks prior to hospital admission when symptoms were communicated to the provider. This gap also occurs in the eCQM measure. The goal is to have a safety learning network that has a

full trajectory of the patient's story from initial symptoms through outcome. Health care misses the patient's trajectory by design because there is no mechanism to track it.

- After a decade of Meaningful Use, there is opportunity to propose a unified, open data model that brings payers, providers, and patients to the same platform. He explained that the 21st Century Cures Act called for information to be accessible to all stakeholders without special effort. The patient safety community also can benefit from these legislative principles embodied by the health technology ecosystem.
- Mr. Chopra stated that health care must move away from eCQMs because these measures use the wrong technical architecture. He noted that even blood pressure reporting is typically only 60% accurate in the Medicare ACO program because externally sourced data enter the EHR like a static Portable Document Format (PDF). With AI, health care can move to a third generation using Conversational Interoperability (COIN), the next generation of Cures Act standards. COIN allows AI agents to reason rather than requiring hard-coded if-then logic. He referenced a University of California, San Diego AI team that used AI reasoning agents for SEP-1 reporting, extracting necessary information and transmitting it to CMS without requiring doctors to micromanage documentation.
- Mr. Chopra explained that health care has used a framework where EHR suppliers are told what to build; however, this approach does not reflect the full needs of stakeholders. Health care can move toward a use-case-driven model, similar to what CMS has done with the health technology ecosystem. For example, organizations pledge to be early adopters and test new technical approaches. Once there is evidence of industry adoption, ONC and CMS can standardize and scale what works. U.S. policy on standards requires evidence of industry adoption.
- Mr. Chopra referenced the Healthcare Innovation Challenge he released during his tenure with the Obama Administration, highlighting the High Value Healthcare Collaborative awarded to James (Jim) Weinstein, DO, at the Dartmouth-Hitchcock Health System. Among other entities, Dr. Weinstein recruited Cleveland Clinic, Providence, and Intermountain Health to pool their EHR data. CMS also contributed to the pooled data by providing longitudinal claims history. This collaboration resulted in a better protocol for sepsis.
- Mr. Chopra proposed funding "Star Alliances for Safety," which are collaboratives where competitors work together. If there are measurable savings, those savings could be reinvested or used to support more evidence generation. He stated that health care can start with all risk-bearing networks such as the Medicare Shared Savings Program, ACO REACH Model, and LEAD Model; bring the CMS FHIR API infrastructure for daily claims information; move to open COIN models; and enable collaboration so that stakeholders can learn and regulators can scale what works.

For additional details on Mr. Chopra's presentation, see the presentation slides (pages 50-58), transcript, and meeting recording (46:17-1:00:50).

Following the presentations, Committee members asked questions of the experts. For more details on this discussion, see the transcript and meeting recording (1:00:51-1:25:03).

Experts discussed how to scale innovation to a national level in an isolated health care system.

- Patients for Patient Safety US incentivized hospital systems to create a learning environment with leadership accountability.

- Human factor safety engineers should be incorporated in health care environments to inform the board of every case of patient harm.
- Models should encourage proactivity instead of reactivity. People should be encouraged to be proactive by implementing new processes and understanding where patient safety risks are found.

Experts discussed Maryland's Quality Based Reimbursement Program.

- Maryland reimbursement is similar to CMS reimbursement in that the reimbursement is based on quality metrics, not particularly safety. Currently, many human errors and AI use errors are not accounted for in quality measures.
- It is important for all providers to focus on risk.
- Providers are not trained in safety even though it is part of their duty. Medical education should highlight medical safety.
- Organizations should implement training on accountability and transparency in reporting adverse events.
- Financial punishment for reporting adverse events continues the trend for hospitals and providers to deny and defend decisions instead of promoting transparency.

Experts discussed opportunities for EHRs to minimize safety errors by providing organizations better tools.

- EHRs should be implemented into the workflow and centered around the user to reduce burden. A balance is needed between customization and standardization of approaches applied across facilities or providers.
- User-centered design is important and can be achieved by including providers in the implementation and design stages. The manual extraction required to submit Meaningful Use data was burdensome, and has since been placed on providers in clinical coding processes. New technologies should reduce administrative burden for clinicians. It is important to receive input from various types of health care providers.

Experts discussed opportunities for EHR vendors to collaborate to improve patient safety.

- The EHR Association is a national industry trade group that collaborates weekly to identify opportunities to influence policy and engineer better tools. The health care technology ecosystem fosters innovation and collaboration across vendors.
- EHR vendors should not be expected to collaborate unless there is clear demand from health systems. Health systems should actively use and contribute to protocols rather than rely solely on EHR vendor-provided defaults, as EHR customization is essential for effective care. Incentives for health systems to contribute to, publish, and adopt guidelines could drive vendor collaboration.

Experts discussed how to fund a large-scale concept such as the Star Alliance on a large scale.

- The CMS Innovation Center has the capacity to fund health system collaboration initiatives focused on patient safety without a change to the federal statute. Examples include the 2012 High Value Healthcare Collaborative, WISeR Model, which is a technology-focused model, and the Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence (MAHA ELEVATE) Model. By design, the CMS Innovation Center models identify successful models of care.

- Basic safety engineering concepts that work in other industries can work in health care if they are adopted by the health care industry. Aviation operates under conditions that have high risk to human safety. The aviation industry holds meetings that solve safety concerns identified by federal regulations. In health care, hospitals should not compete but should collaborate on safety.
- Implementation of best practices is an area in need of improvement. EHRs need to be improved to support patient safety advancements using known and effective strategies.

Committee Discussion

Co-Chair Mills opened the floor to Committee members to reflect on the day's presentations and discussions. The Committee members discussed the topics noted below. For additional details, please see the transcript and meeting recording (00:00-22:10).

- There may be opportunities to use waivers to create a model.
- AI should be used responsibly to advance patient safety, such as increasing reporting and supporting follow-up. AI should be incorporated into model features.
- One Committee member expressed interest in the evolution of an automated trigger tool to identify and measure patient safety. There may be opportunities to incorporate these types of trigger tools into model features.
- While some SMEs recommended incorporating patient safety into all models, other SMEs recommended that patient safety be considered distinct from quality and be the focus of a model. One Committee member inquired whether patient safety metrics and approaches should be incorporated into CMS programs or whether a stand-alone patient safety model should be developed.
- Patient safety should be embedded into APMs either as a core objective or as the primary focus of a model.
- Safety is broader than avoiding adverse events; patient safety includes errors of omission, diagnostic errors, communication failures, and unsafe transitions of care across settings.
- One Committee member summarized potential solutions to improve patient safety that SMEs shared during the public meeting. Patients and families observe safety risks that the system often misses. PROMs and PREMs can serve as important safety signals for providers. One organization improved patient safety by committing to HRO principles. Doing so enabled the organization to provide a warranty for certain procedures such as heart surgery.
- AI can improve patient safety by decreasing cognitive burden, identifying risk earlier, and increasing the predictability of safety issues before they become harm events.
- Value-based care and APMs have a unique opportunity to make patient safety risks visible and actionable. Historically, however, payment models have not improved patient safety. Improvements in patient safety depend on professionalism, continuous quality improvement, a culture of safety, and learning. A strong safety culture depends on transparency, psychological safety, and encouraging clinicians and organizations to report harm, adverse events, near misses, and unsafe conditions without fear of blame.
- One Committee member inquired how to design payment models that reinforce rather than undermine intrinsic motivation and safety culture. Payment models should reward reporting, learning, corrective action, and measurable improvement. Models should also align with what matters most to patients, families, and purchasers without encouraging underreporting, risk avoidance, or stinting on care.
- Process measures and systems may be more important than outcome measures to drive a culture of safety.

- Linking payment to patient safety may hinder improvement in patient safety, as some payments can incentivize the wrong action and encourage gaming the system. Although payment models have historically not substantially improved patient safety, funding or payment is still needed to improve patient safety. This funding or payment could be provided through a payment model or through a different type of investment, such as investment in tools and systems that support a culture of safety. For example, AI, EHR investment, and human factors designs could potentially lead to more improvements in patient safety relative to payment models.
- Errors of omission may be more significant than errors of commission.
- Shifting the focus of patient safety away from the hospital environment and toward the ambulatory environment will support a more longitudinal view of patient safety. Understanding patient safety can be difficult in the ambulatory environment because of small sample sizes. Capturing some types of patient safety errors requires longitudinal assessment because the results of some errors can take time to appear.
- Provider experience should be addressed. A more positive term, such as a "safety quotient," should be used in place of the term "error." A negative focus on errors may delay improvement in safety culture.
- The technology necessary for improving patient safety already exists. One Committee member emphasized the importance of improving safety culture, integrating AI, and monitoring errors.
- Lessons on patient safety can be learned from other industries, such as the airline industry, law enforcement, and athletics.
- One Committee member recommended taking an incremental approach to improving patient safety. Providers would benefit from having tools, not more regulations. There is a need to convene EHR vendors, as well as those who will implement and pay for EHRs. Doing so could help develop a solution to incrementally employ and build a culture of change.
- There is a need to standardize data and infrastructure. Data should be more easily accessible. One Committee member indicated that CMS could drive standardization efforts.
- EHRs should be provider- and patient-centric and not contribute to provider burden. Cognitive burden from documentation can increase safety risks.
- Collaboration and coordination are needed to improve patient safety.
- An incentive structure is needed to support individuals being trained in patient safety.
- One Committee member expressed interest in using shared savings for patient safety rather than financially penalizing providers.
- Current measures of patient safety show improvement. However, in the aggregate, patient safety is not improving. Only a percentage of what should be measured is actually measured.
- One Committee member inquired how to incentivize tactical, on-the-ground full-time equivalents (FTEs) and how to include safety officers as part of an incentive structure.
- Patients should have a role in safety reporting structures. One Committee member shared that patients can report near misses. However, the current infrastructure does not have a standard mechanism to capture, measure, respond to, or assign accountability to patients' safety reports.
- Patient safety should be integrated into all CMS models and programs. There is also merit in developing a specific patient safety model.
- PROMs and PREMs should be a standard part of the dataset for patient experience, monitoring, and quality data reporting. There are opportunities to increase the use of standardized questions for different domains of patient safety.
- One Committee member explained that practicing clinicians may not consider patient safety a part of clinical quality. Making a distinction between quality and safety may be more useful for clinicians compared with wider audiences.

- Shared savings may serve as a mechanism to improve patient safety.
- There may be a need for initial investment in patient safety to increase process and capability performance.
- Incentive structures should not make penalties less expensive than implementing safety programs. It should be difficult to take the wrong action and easy to take the right action. It is currently too easy for Chief Financial Officers (CFOs) to take, penalties without building systems that support patient safety.
- There are potential benefits of collaborating with CEOs and CFOs to encourage patient safety. These individuals run large health systems and employ physicians across the country. Safety issues that occur in integrated delivery systems are often subsumed into risk management. Chief counsels, compliance officers, and the risk safety community should be included in efforts to improve patient safety.
- The preconditions to improve patient safety, such as technology, information, and regulatory framework policies, already exist. What is needed to improve patient safety is willpower.

Closing Remarks

Co-Chair Mills adjourned the meeting.

The public meeting adjourned at 5:00 p.m. EDT.

Approved and certified by:

//Marsha Clarke//
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Marsha Clarke, PhD, MBA, COR III
Designated Federal Officer
Physician-Focused Payment Model Technical Advisory Committee

7/21/2026
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Date

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Terry L. Mills Jr., MD, MMM, Co-Chair
Physician-Focused Payment Model Technical Advisory Committee

7/20/2026
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