Preliminary Comments Development Team (PCDT) Presentation:

Targeting Improvements in Patient Safety Through Alternative Payment Models

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Agenda

Overview of Patient Safety

Costs and Prevalence of Patient Harm Events

Patient Safety Challenges and Opportunities

Patient Safety Measures

Value-Based Care and Patient Safety Improvement

Objectives of This Theme-Based Meeting

- Identify approaches and opportunities to improve patient safety through Alternative Payment Models (APMs)
- Ascertain areas to improve the measurement of patient safety
- Delineate the role of new technologies to improve patient safety
- Determine potential payment methodologies and financial incentives that can be used to promote improvements in patient safety

Context for This Theme-Based Meeting

- PTAC has received 36 proposals for physician-focused payment models (PFPMs), including 28 proposals that PTAC has deliberated on during public meetings.

- Committee members found that 23 of the 28 proposals met Criterion 9: Patient Safety established by the Secretary for PFPMs.

PTAC Working Definition of Patient Safety

- PTAC is using the following working definition of patient safety:
  - *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.*
- This definition will likely continue to evolve as the Committee collects additional information from stakeholders.

Cost Overview of Patient Errors / Patient Harm Events

- Avoidable adverse events that cause patient harm incur substantial cost
  - Direct costs (medical financial costs)
    - **Globally**: $606 billion estimated costs per year among OECD countries (2022)
    - **United States**: $17 billion estimated annual costs, $11,366 average cost per error (2008)
    - **Massachusetts**: $617 million estimated annual excess costs (2017)
      - Average incremental cost due to errors: $13,195 for pressure ulcers, $11,546 for post-op infection
  - Indirect/societal costs
    - Includes premature mortality, lost productivity and wages, reduced workforce participation, long-term disability or rehabilitation, caregiver burden/time, reduced quality of life, legal fees
    - Indirect costs are estimated to exceed direct costs
    - **United States**: $1.4 billion due to increased mortality rates; $1.1 billion due to lost productivity or short-term disability (2008)
    - **Massachusetts**: 33% decrease in an individual's income; 33% increase in household expenses (e.g., childcare, transportation) (2017)

Prevalence Overview of Patient Errors / Patient Harm Events

- Avoidable adverse events harm many patients
  - **Globally**:
    - More than 1 in 10 patients experience medical harm, of which 50% is preventable
      - 1 in 20 patients experience preventable medical harm
      - 12% of preventable harm is considered severe or results in death
    - Harm results in 3 million deaths and 64 million disability-adjusted life years
  - **United States**:
    - 25% of hospitalized Medicare patients experienced a harm event, of which 43% could have been prevented (2018)
    - The most common types of patient harm events are related to medication (43%), patient care (23%), procedures or surgery (22%), and infection (11%) (2018)
    - There may be significant under-reporting of patient harm events: an estimated 49% of patient harm events are not captured by hospital incident reporting or surveillance systems

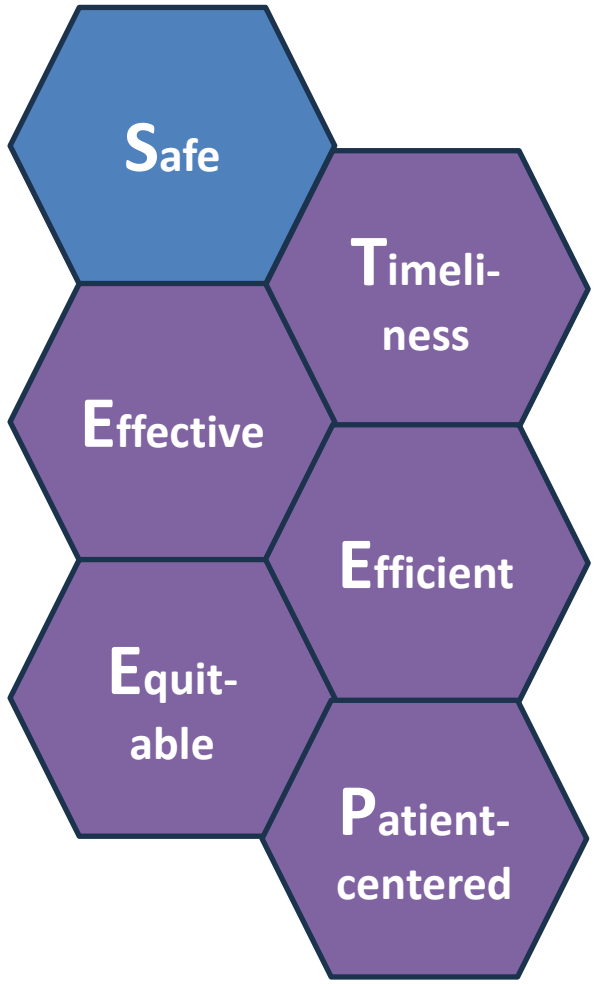
Patient Safety Efforts – A Very Brief History

- *To Err Is Human: Building a Safer Health System* is a landmark 1999 report by the Institute of Medicine that revealed the high number of deaths from preventable medical errors in U.S. hospitals, estimating it to be between 44,000 and 98,000 annually.
- Some progress has been made to improve patient safety
  - Problem recognition, public and private efforts, AHRQ's measurement efforts, Medicare payment policies (hospital VBP and HAC programs)
- Concern that patient safety improvement has not progressed rapidly enough and efforts have stalled
  - A 2025 report from the HHS Office of Inspector General (OIG) found little improvement in the percentage of patients experiencing harm events in hospitals

Patient Safety Versus Health Care Quality

- **Health care quality** refers to the degree to which health services increase the likelihood of the desired outcome
- Quality of care is commonly described using the **STEEEP** domains
- **Patient safety** is one component of health care quality

Six STEEEP Quality Domains



Avoiding patient harm from health care and treatment

Providing care and treatment consistent with current scientific evidence

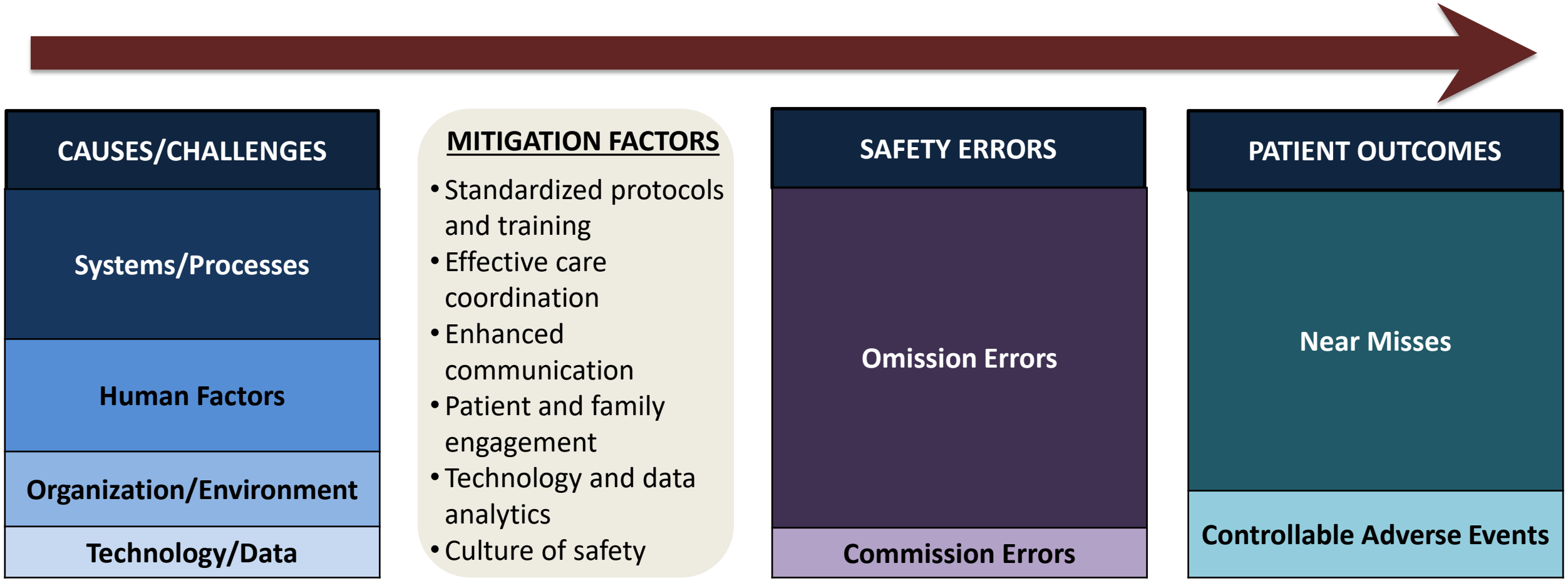
Delivering equal quality care regardless of patients' individual characteristics

Reducing wait times and other delays and barriers in delivering health care

Maximizing the benefit per unit of care delivered and avoiding waste

Providing care that meets patients' individual needs and preferences

Patient Safety Conceptual Diagram



Note: The size of the causes, errors, and outcomes bars reflect the approximate prevalence of the category, which are ordered most to least frequent.

Types of Patient Safety Errors

Type of Error	Examples of Commission Errors (Caused by Action)	Examples of Omission Errors (Caused by Inaction)
Medication errors	**Administration of the wrong medication**	**Failure to prescribe needed medication, not checking drug interactions**
Diagnosis/laboratory/test errors	Misdiagnosis of a health condition; ordering the wrong test	Failure to document abnormal test results; forgetting to order a lab test
Surgery and procedure errors	Wrong-site or wrong-procedure surgeries	Post-operative complications due to lack of preparation
Health care-related infections	Infections stemming from improper catheter insertion	Infections acquired through improper hand hygiene
Patient handling errors (falls, pressure injuries)	Incorrect positioning of bed/bed height	Inadequate monitoring of patient
Equipment, device, and technology errors	Malfunctioning medical equipment	Alarm fatigue leading to missed warnings
Communication, handoff, and follow-through errors	Taking incorrect actions due to misunderstanding verbal orders	Not following up with patients to have routine screening tests

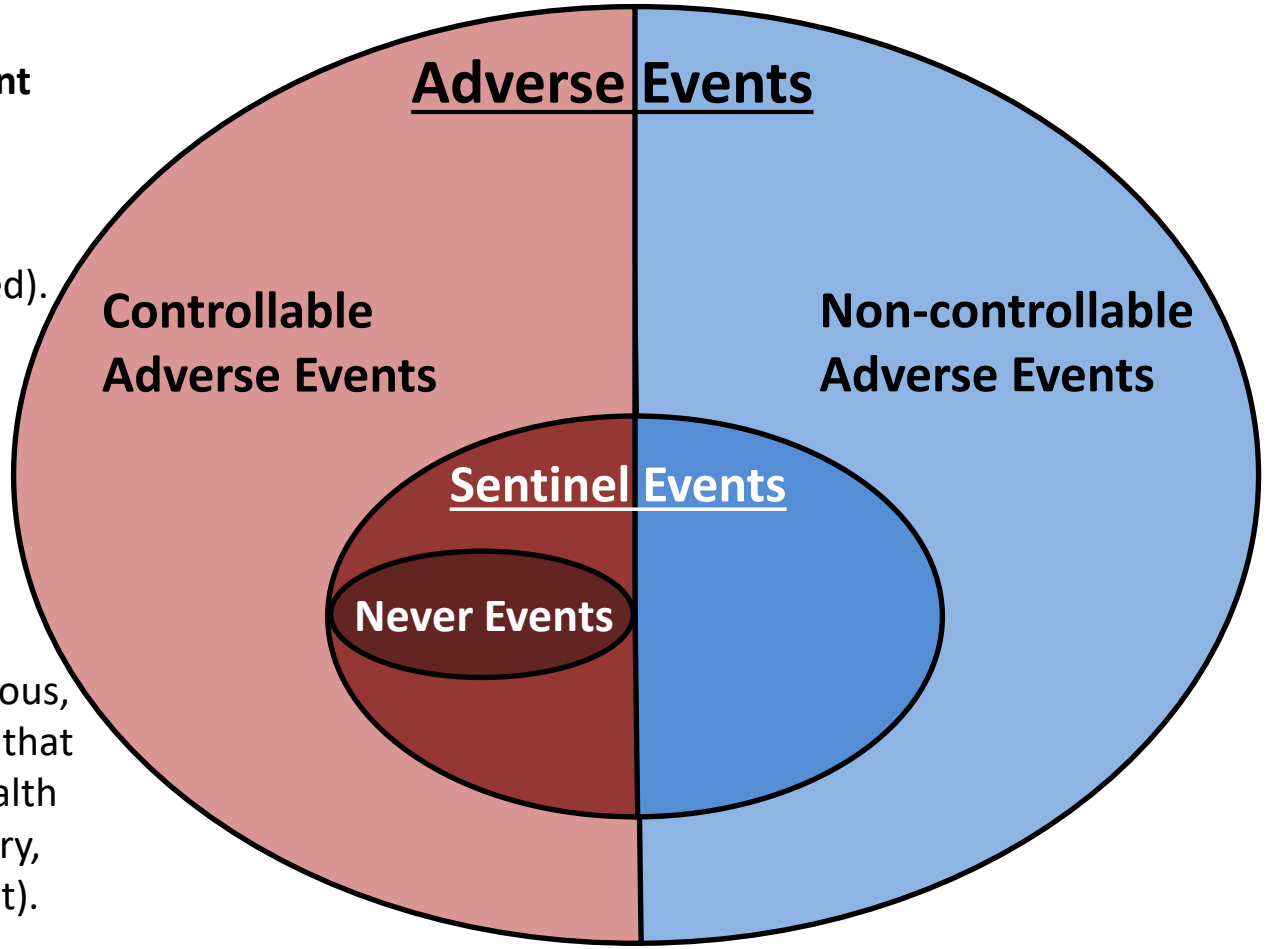
Adverse Events & Patient Safety

An **adverse event** is patient harm caused by medical care. Harm may be permanent or temporary, severe or non-severe, and may result in death.

A **controllable adverse event** is patient harm that could have been prevented with proper medical care (i.e., a patient safety error occurred).

A **sentinel event** is an adverse event where the patient experiences severe temporary harm, permanent harm, or death.

A **never event** is a very serious, preventable sentinel event that should never happen in health care (e.g., wrong-site surgery, foreign object left in patient).



A **non-controllable adverse event** is unavoidable patient harm that occurs despite proper medical care (i.e., no patient safety error occurred)

Non-controllable adverse events occur for reasons outside of the health system's control, such as patient biology and inherent treatment risks.

Outcomes of Patient Safety Errors

- There are two types of outcomes of patient safety errors:
  - Controllable adverse event
  - Near miss
    - A situation indistinguishable from a controllable adverse event except that it, by chance, does not result in a patient injury

Patient Safety Oversight

- Many organizations focus on overseeing and improving patient safety, including:
  - Federal Regulatory Oversight
    - **Centers for Medicare & Medicaid Services (CMS)**
    - **Agency for Healthcare Research and Quality (AHRQ)**
    - Food and Drug Administration (FDA)
    - Centers for Disease Control and Prevention (CDC)
    - Clinical Laboratory Improvement Amendments (CLIA)
    - Office of Inspector General (OIG)
  - Accrediting and Standards Setting
    - The Joint Commission (TJC)
    - National Quality Forum (NQF)
    - National Committee for Quality Assurance (NCQA)
    - American Board of Medical Specialties (ABMS)
  - Watchdog & Advisory Groups
    - The Leapfrog Group
    - Institute for Healthcare Improvement (IHI)
    - Patient Safety Organizations (PSOs)
    - ECRI & the Institute for Safe Medication Practices (ISMP)

CMS:

- Ensures **mandatory** minimum safety standards (conditions of participation) for Medicare and Medicaid providers
- Publicly reports hospital patient safety data through the Care Compare tool
- Administers alternative payment models that promote patient safety (e.g., Hospital Acquired Condition [HAC] Reduction Program)

AHRQ:

- Is the primary federal agency conducting patient safety research
- Develops patient safety measures, resources, and tools
- Oversees the *Quality and Safety Review System (QSRS)* to track hospital adverse events, the *Network of Patient Safety Databases (NPSD)* to track and analyze patient safety events, and the *Patient Safety Organization (PSO)* program

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Prevalence of Preventable Adverse Events: Inpatient Versus Outpatient

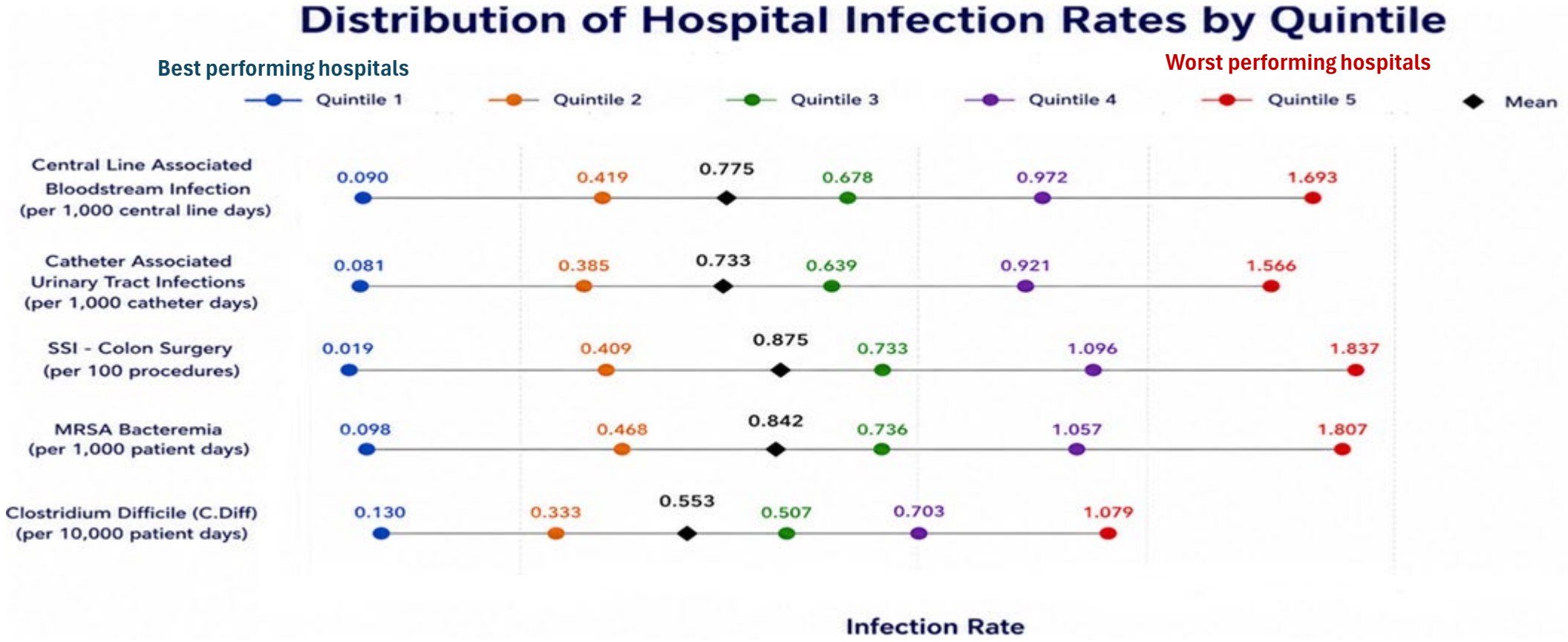
- Analyses of 2018 data from Massachusetts published in 2023 and 2024
  - **Inpatient**: Analysis of 11 Massachusetts hospitals found 23.6% of inpatient admissions involved at least one adverse event (AE)
    - 22.7% of the AEs were preventable and 32.3% were serious
    - 6.8% of all admissions involved a preventable AE
    - The most common AEs were adverse drug events (39.0%), surgical or procedural events (30.4%), patient care events such as falls and pressure ulcers (15.0%), and HAIs (11.9%)
  - **Outpatient**: Analysis of 11 outpatient sites in Massachusetts found 7.0% of patients had at least one AE (8.6 AEs per 100 patients annually)
    - 23.2% of the AEs were preventable and 17.4% were serious
    - 1.9% of patients had at least one preventable AE
    - The most common AEs were adverse drug events (63.8%), healthcare-associated infections (14.8%), and surgical or procedural events (14.2%)

Prevalence of Adverse Events By Patient Subgroups & Improvements in Patient Safety Outcomes

- Adverse events are more common among some subgroups of patients
  - **Patients over age 65 years**: higher overall likelihood of controllable adverse events
  - **Patients with chronic conditions**: more errors of omission, particularly among patients with diabetes; and more drug-drug interactions among cardiovascular patients who took more drugs and had multi-morbidity (vs. those who took fewer drugs and did not have multimorbidity)
  - **Non-white patients**: higher likelihood of pressure ulcers, post-op hemorrhages/hematomas, post-op pulmonary embolisms (PE) or deep vein thrombosis (DVT) among African American and Asian Pacific Islander (vs. white); and higher likelihood of accidental puncture/laceration among Hispanic/Latino
  - **Patients with Medicaid or who are uninsured**: higher likelihood of pressure ulcers, post-op respiratory failure and wound dehiscence, and death among surgeries among Medicaid patients (vs. private insurance) and higher likelihood of post-op PE or DVT among patients with Medicaid or uninsured
- Improvements in patient safety outcomes have occurred due to a variety of factors, including:
  - Mandatory hospital adoption of standardized safety practices such as hand hygiene protocols and surgical checklists
  - Financial penalties through value-based incentive programs such as CMS's Hospital Readmissions Reduction Program (HRRP)

Hospital Safety Results From CMS's Care Compare Tool

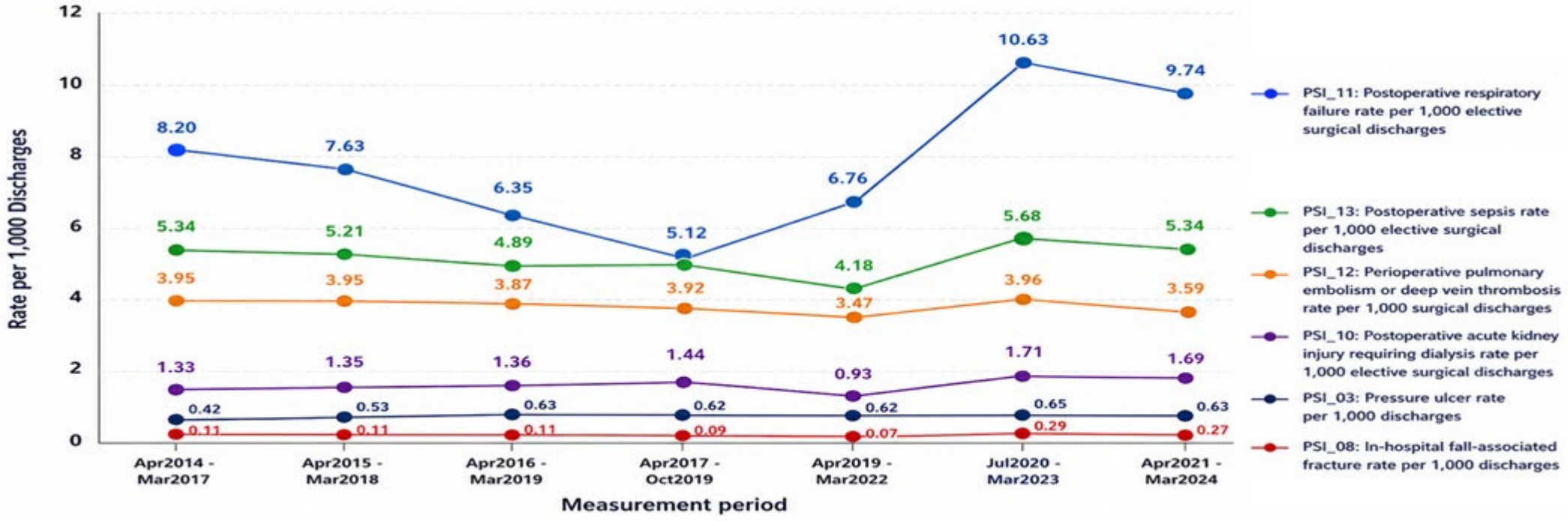
- Large differences in HAIs between best and worst performing hospitals



Note: Data sourced from CMS Care Compare. Reported statistics are weighted by total hospital discharges and include all measurement periods. Values represent average rates within each quintile. Based on analysis by ASPE.

Hospital Safety Results From CMS's Care Compare Tool, Continued

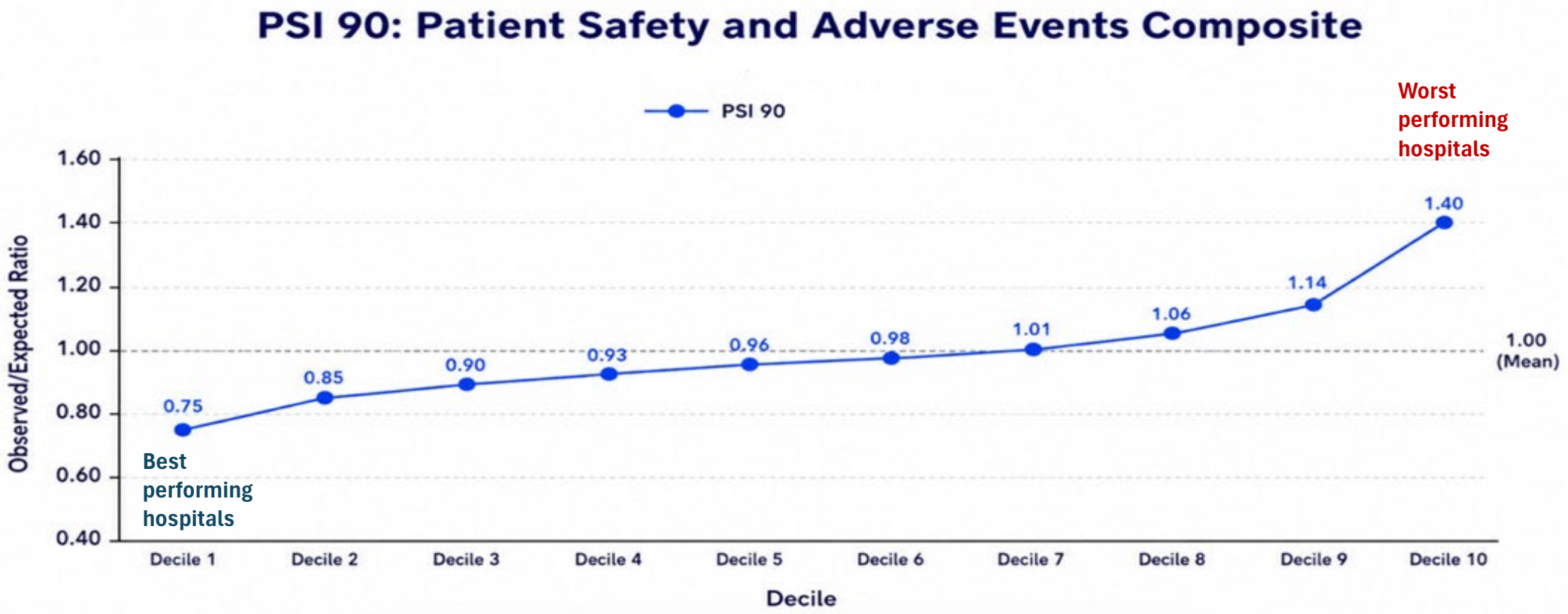
- Patient safety and adverse event indicators were relatively stable over this period



Note: Data sourced from CMS Care Compare. Reported statistics are weighted by total hospital discharges. Based on analysis by ASPE. Increase in Postoperative respiratory failure rates during the 2020-2024 measurement period may be attributed to broader definition changes or COVID. PSI 08 expanded to include a broader definition of fractures to be included such that the rate increased beginning in the version released in 2023.

Hospital Safety Results From CMS's Care Compare Tool, Continued

- Large differences in Composite Patient Safety Measures between best and worst performing hospitals



Note: Data sourced from CMS Care Compare and include measurement periods from 2014-2024. Reported statistics are weighted by total hospital discharges and represent average rates within each decile. Based on analysis by ASPE.

Hospital Safety Results From CMS's Care Compare Tool, Continued

- A large share of hospitals with poor performance did not improve over time, while about one in four moved into the top three deciles
- A substantial proportion of high-performing hospitals maintained their performance, while approximately 20% dropped to the bottom three deciles

	Hospitals in Bottom Decile in 2014-2017			Hospitals in Top Decile in 2014-2017		
	Remained in **Bottom** 3 deciles in 2021-2024	Remained in the **Middle** 4 deciles in 2021-2024	Moved to **Top** 3 deciles in 2021-2024	Remained in **Top** 3 deciles in 2021-2024	Remained in the **Middle** 4 deciles in 2021-2024	Moved to **Bottom** 3 deciles in 2021-2024
PSI 90: Patient safety and adverse events composite	**44%**	**30%**	**26%**	**54%**	**27%**	**19%**
PSI_03: Pressure ulcer rate	43%	32%	25%	56%	20%	24%
PSI_08: In-hospital fall-associated fracture rate	39%	36%	25%	52%	16%	32%
PSI_10: Postoperative acute kidney injury requiring dialysis	47%	18%	35%	49%	11%	40%
PSI_11: Postoperative respiratory failure rate	47%	37%	16%	52%	35%	13%
PSI_12: Perioperative pumonary embolism or DVT	52%	24%	24%	54%	23%	23%
PSI_13: Postoperative sepsis rate	47%	27%	26%	47%	25%	28%

Note: Data sourced from CMS Care Compare. The average PSI-90 score for the bottom three deciles remained largely unchanged between the earliest and latest time periods (1.19 vs. 1.21). The average PSI-90 score for the top three deciles remained largely unchanged between the earliest and latest time periods (0.843 vs. 0.837). Based on analysis by ASPE.

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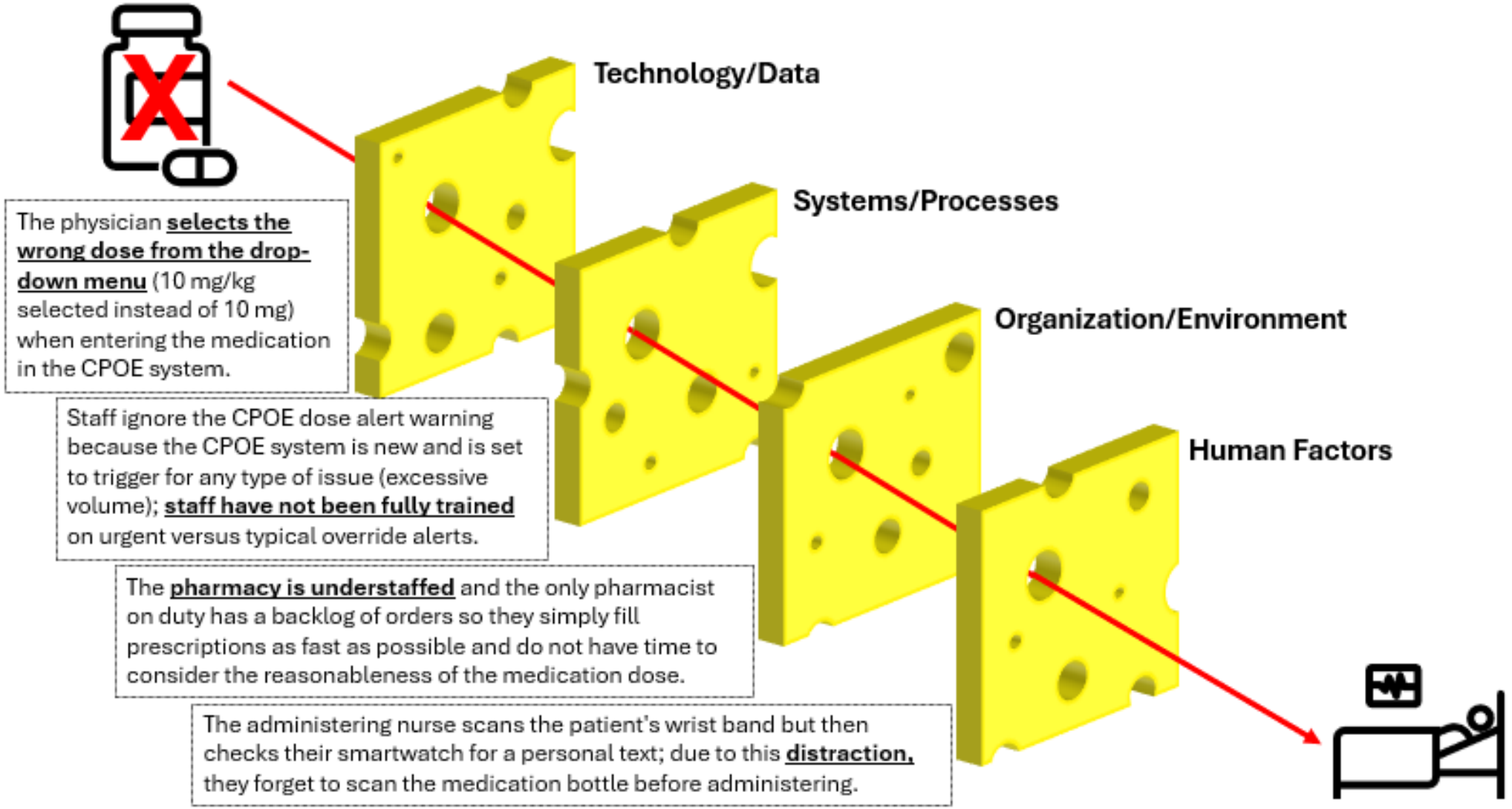
Causes of Patient Safety Errors

Cause/Challenge	Examples
Systems/Processes	• Lack of standardized protocols and procedures • Poorly designed medication administration processes • Poorly defined oversight and management of EHR tools • Ineffective handoffs during transitions • Inadequate exchange of information between clinical staff regarding medical orders or test results
Human Factors	• Burnout/fatigue • Information overload and frequent interruptions • Lack of experience and training
Organization/ Environment	• Negative work environments and a lack of transparency • Inadequate supervision and monitoring of staff • Resource limitations and staffing shortages • Poorly designed spaces, inadequate lighting, and limited space for visitors
Technology/Data	• Burdensome clinical documentation methods and complex data entry forms • Overdependence on technology • Lack of data interoperability • Equipment malfunction and mishandling

The Swiss Cheese Model of Patient Harm

- Barriers (slices) prevent errors from occurring
- Gaps (holes) in those barriers allow mistakes to slip through
- When a series of gaps occur across barriers, the result is a patient error
- Example: the patient receives the wrong dose of medication



Strategies and Tools to Improve Patient Safety

Strategy/Tool	Examples
Standardized Protocols and Training	• Standardized checklists • Simulation training • Training tools and resources
Effective Care Coordination	• Structured tools improve handoff communication and discharge processes (see Enhanced Communication) • Screening tool for providers in ambulatory care to predict patient anesthesia needs
Enhanced Communication	• Structured communication framework tools • Tools to improve communication during transitions of care • Closed-loop communication

Patient and Family Engagement	• Evidence-based resources that promote collaboration among clinicians, patients, and families
	  • AHRQ's Guide to Patient and Family Engagement in Hospital Quality and Safety
	  • AHRQ's Questions are the Answer Initiative

Technology and Data Analytics	• EHRs with embedded clinical decision support systems (CDSS) that use electronic alerts/alarms/reminders
	• Medication safety technologies
	  • Computerized provider order entry (CPOE) systems
	  • Barcode medication administration (BCMA)

Culture of Patient Safety	• Assessing safety culture perspectives of clinical staff across hospitals (e.g., AHRQ's Hospital Survey on Patient Safety Culture)

Technology and Patient Safety

- Technology has multiple roles in patient safety
  - Direct patient safety error (e.g., medical device malfunction causes patient injury)
  - Cause of patient safety errors (e.g., overdependence on technology)
  - Tool to improve patient safety (e.g., AI real-time prediction of high risk)
- Critical technology to promote patient safety
  - Electronic Health Records (EHRs) – a digital patient record that provides accessible, continuous, and comprehensive patient data to reduce medical errors
  - Clinical Decision Support Systems (CDSS) – provide real-time patient information to assist in decision-making and reduce medical errors
  - Computerized Provider Order Entry (CPOE) – structured order entry of medications reduce medical errors
  - Barcode Medication Administration (BCMA) – scanning patient wristbands and medications reduces medication errors

Broad Patient Safety Challenges and Issues

- Patient safety research and improvement efforts have focused predominantly on the inpatient setting rather than the outpatient setting
  - The volume of patient care is far higher in the outpatient setting
  - Procedures previously performed in hospitals have shifted to outpatient settings
  - More focus is needed on patient safety in the outpatient setting as well as the long-term care (e.g., nursing homes) and transitions between care settings
- Technology has both improved patient safety and introduced new challenges
- Patient safety efforts have focused most heavily on errors of commission rather than errors of omission
  - Errors of omission are estimated to be more common than errors of commission but can be more difficult to recognize
- Patient safety interventions have emphasized piecemeal reactive strategies rather than proactive system-wide approaches

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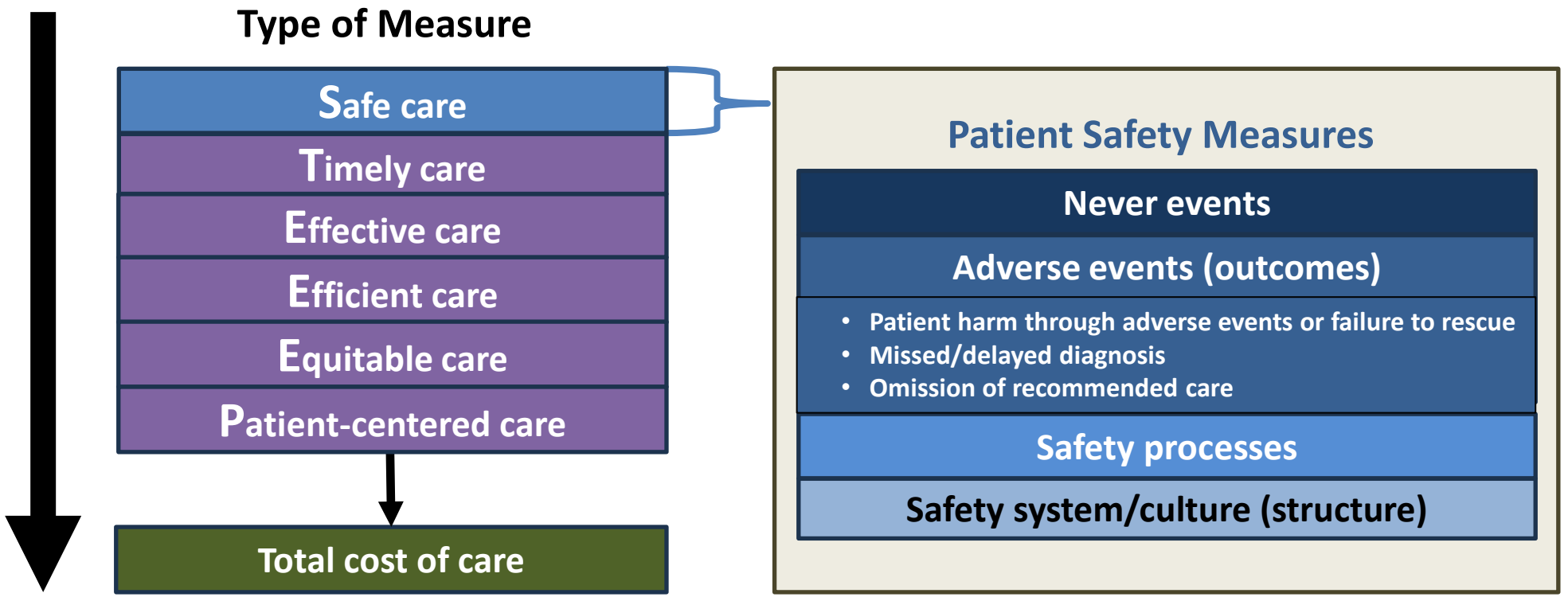
Patient Safety Versus Quality & Other Performance Measures

- Patient safety measures are a subset domain of health care quality (STEEEP) measures



Patient Safety Measurement

- Patient safety can be measured in multiple ways:
  - Retrospective chart review: gold standard (clinically rich) but costly
  - Other methods include voluntary error reporting systems, automated surveillance, administrative claims, EHRs, patient/family reports, and safety culture surveys
- Commonly used measures
  - AHRQ's Patient Safety Indicators (PSIs) assess potentially avoidable adverse events in hospital: 26 indicators including 18 provider-level indicators
    - Examples: PSI 03 Pressure Ulcer Rate; PSI 05 Retained Surgical Item or Unretrieved Device Fragment Count
- Newer measures
  - CMS's Patient Safety Structural Measure (PSSM)
    - Hospital attestation, five safety domains: leadership commitment to eliminating preventable harm; strategic planning & organizational policy; culture of safety & learning health system; accountability & transparency; patient & family engagement
  - Errors of Care Omission Survey (ECOS)
    - PCPs, 31 item survey instrument with four subscales: self-management support, follow-up, emotional health support, and care integration

Patient Safety Measurement, Continued

- Electronic clinical quality measures (eCQMs)
  - Use electronic data extracted directly from EHRs/HIEs
  - CMS's eCQMs include patient safety measures (e.g., pressure injury) and are reported by hospitals in the Hospital Inpatient Quality Reporting (IQR) program and Medicare Promoting Interoperability Program
  - CMS plans to add two additional patient safety measures to the measure set in 2026: 1) Hospital Harm–Falls with Injury; and 2) Hospital Harm–Postoperative Respiratory Failure
- Digital quality measures (dQMs)
  - CDC's National Healthcare Safety Network (NHSN) is creating electronic and automated patient safety measures called dQMs
  - dQMs build on eCQMs and are meant to improve validity and decrease reporting burden, and will be reported using HL7 FHIR APIs
  - NHSN identified five areas for dQMs: 1) medication safety; 2) improved HAI definitions; 3) respiratory pathogen surveillance; 4) adult sepsis events; and 5) healthcare-associated venous thromboembolism

Patient Safety Measurement, Continued

- Challenges and gaps
  - Determining whether an adverse event was preventable
  - Differences in definitions of errors (e.g., medication errors)
  - Lack of standardized measures (especially for diagnostic errors)
  - Immature safety measures for outpatient settings
  - Lag in safety measure information due to reliance on administrative data
  - Minimal availability of measures of omission
- Opportunities include greater use of patient-reported measures
  - U.S. results (aged 65+ years) from the 2023 Patient Reported Indicators Survey (PaRIS) / Medicare Current Beneficiary Survey (MCBS) revealed that 13% of primary care patients reported that something went wrong over the course of their care in the last 12 months

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CMS Programs and Initiatives That Promote Patient Safety and Link Performance to Payment

Program	Years	Description	Results
Premier Hospital Quality Incentive Demonstration	2003-2009	CMS and Premier (national organization of non-profit hospitals) partnered to **award bonus payments** to hospitals **providing high quality of care** in several clinical areas (e.g., acute myocardial infarction, heart failure, coronary artery bypass graft); **AHRQ patient safety indicators** (e.g., postoperative hemorrhage) are included as part of the overall quality measures assessed	Quality scores **increased** almost 19% from 2003 to 2006
Surgical Care Improvement Program (SCIP)	2005-2015	CMS and CDC partnered to **improve surgical infectious complication rates** by measuring and reporting on several infection-prevention process-of-care measures; in 2013, the program started tying **performance to payment**	High performance on SCIP measures **has not been associated** with improved clinical outcomes
Hospital Value-Based Purchasing (VBP) Program	2012-present	CMS **redistributes 2% Medicare payment withholds as value-based incentives** to hospitals based on performance; the program uses performance measures used for the Hospital Inpatient Quality Reporting (IQR) program, and includes **incentives for reducing adverse events** and adopting evidence-based care standards and protocols	**No impact** on patient outcomes; safety-net hospitals **performed worse** on quality and cost measures compared to non-safety-net hospitals

CMS Programs and Initiatives That Promote Patient Safety and Link Performance to Payment, Continued

Program	Years	Description	Results
Hospital Readmissions Reduction Program (HRRP)	2012-present	CMS applies a **payment reduction for hospitals with excess readmissions** for select conditions (AMI, CABG surgery, COPD, heart failure, pneumonia, hip/knee surgery); goal to improve communication and care coordination and reduce avoidable readmissions	Readmission rates **decreased**, especially for AMI, heart failure, and pneumonia
Hospital-Acquired Condition (HAC) Reduction Program	2014-present	CMS **reduces payments to hospital in the worst-performing quartile** on measures of HACs; HAC scores are based on a composite and five healthcare-acquired infection (HAI) measures	**Did not improve** patient outcomes; risk adjustment not done appropriately leading to unfair penalties for teaching hospitals and hospitals treating disadvantaged patients
Comprehensive Care for Joint Replacement (CJR) Model	2016-2024	CMS determines **payment to providers based on a composite quality score** derived from two quality measures, **complication rate** and patient perspectives (using the Hospital Consumer Assessment of Healthcare Providers and Systems survey measure). **Hospital participation was required** in selected Metropolitan Statistical Areas (MSAs).	The model **reduced hospital discharges** to institutional post-acute care facilities and lowered total expenditures within the first two performance years. By performance year 7, resulted in **almost $113 million in savings** to Medicare

CMS Programs and Initiatives That Promote Patient Safety and Link Performance to Payment, Continued

Program	Years	Description	Results
Merit-Based Incentive Payment System (MIPS)	2017-present	CMS bases payment to providers on performance across four categories; **patient safety is a MIPS high priority category** (e.g., % of patients with history of falls who have a documented plan of care for falls; % of patients with a surgical site infection)	Safety-net specialists were **more than 30% likely to receive positive payment adjustments** compared to non-safety-net specialists; MIPS incentives are substantially lower than the estimated administrative costs for physicians
Bundled Payments for Care Improvement Advanced (BPCI-A)	2018-2025	Model participants are responsible for **coordinating patient care across all providers** for a given patient; model **includes specific patient safety measures**, such as PSI-90 (composite) and complication rate; participants receive a Composite Quality Score (CQS) and **payment is adjusted by a maximum of 10% (positive or negative)** based on the CQS	Did not result in savings to Medicare in first three years of inception; **resulted in net savings** to Medicare in model year 4
Transforming Episode Accountability Model (TEAM)	2026-present	Acute care hospitals will **coordinate care for certain surgical procedures** from day of surgery to 30 days post-hospitalization; participants will **report on certain patient safety measures**, including PSI-90 (composite), hospital-wide readmissions, surgical complications, mortality, falls with injury, failure to rescue; participants receive a CQS and **payment is adjusted** based on the CQS (varies depending on participant track)	No results yet

PTAC Public Meeting Focus Areas

- Approaches to Improve Patient Safety in Alternative Payment Models
- Measuring Patient Safety in Value-Based Care
- Improving Patient Safety in Value-Based Care Through the Use of Health Information Technology and Data Analytics
- Payment Mechanisms and Financial Incentives to Encourage Patient Safety in Alternative Payment Models

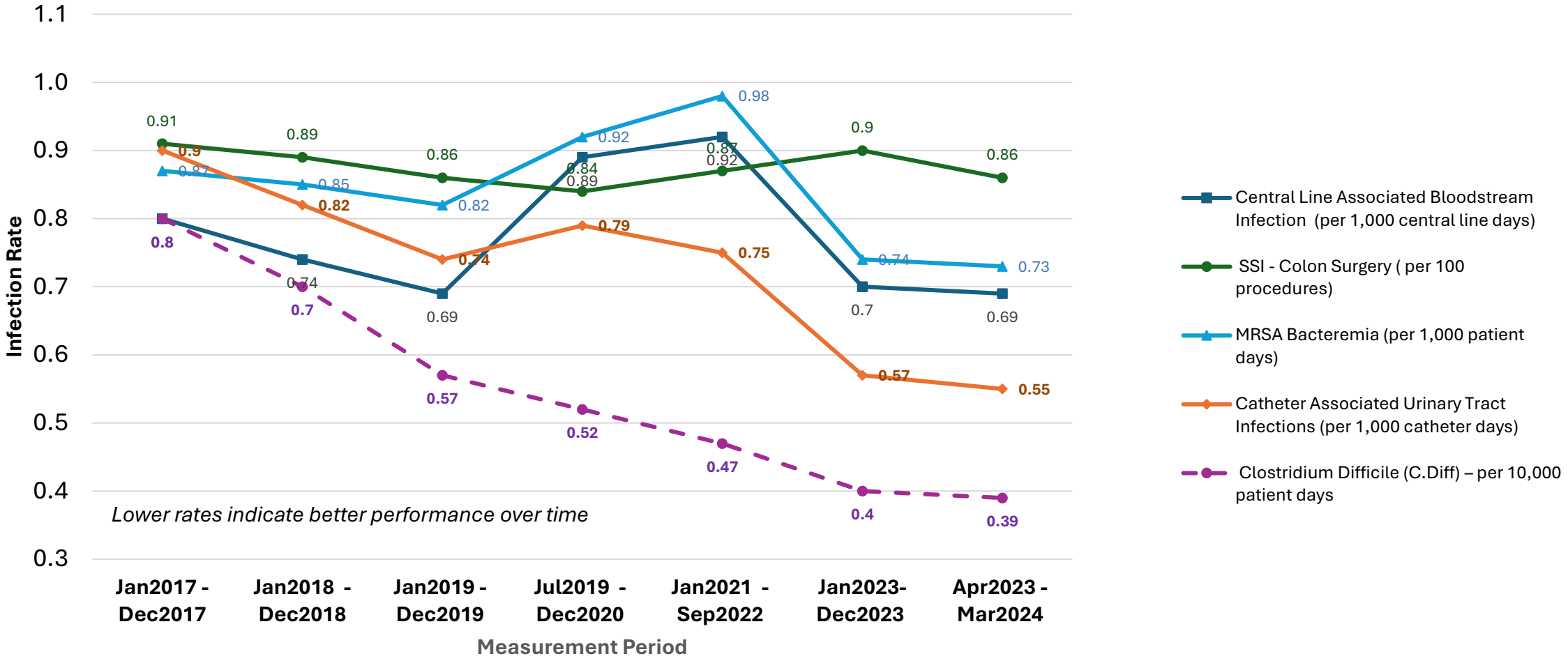
Appendix A
Supplemental Background
Patient Safety Information

Improvements in Patient Safety Outcomes

- Medicare Patient Safety Monitoring System Measures of Adverse Events
  - Between 2010 and 2019, the rate of adverse events per 1,000 hospital discharges decreased:
    - From 218 to 139 for acute myocardial infarction
    - From 168 to 116 for heart failure
    - From 195 to 119 for pneumonia
    - From 204 to 130 for major surgical procedures
- Healthcare-associated infections (HAIs)
  - The rate of HAIs in hospitals has been decreasing over the past 10-20 years
  - Today, 1 in 31 hospital patients has an HAI on any given day

Hospital Safety Results From CMS's Care Compare Tool

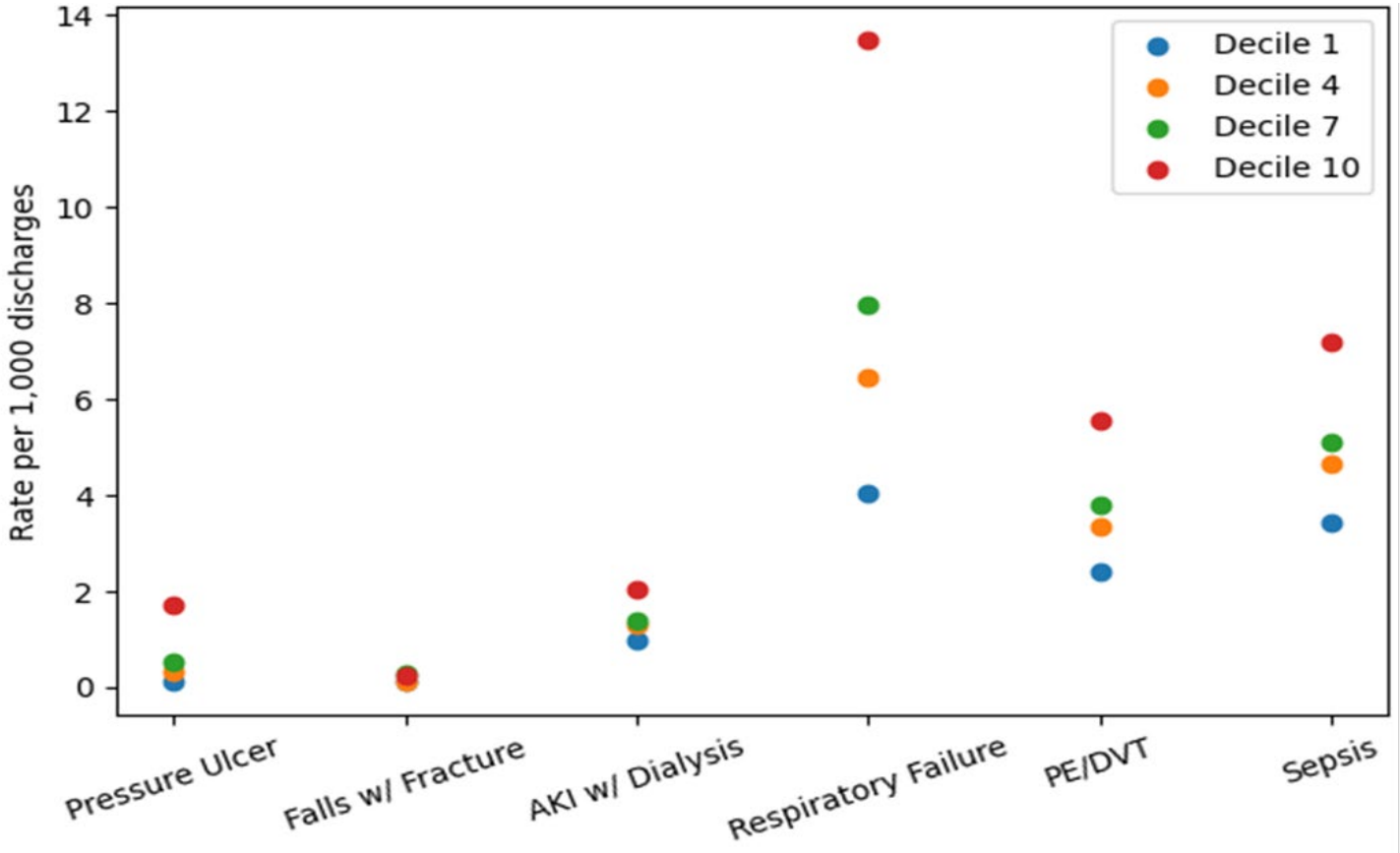
- Healthcare-Associated Infections (HAIs) are generally improving over time



Note: Data sourced from CMS Care Compare. Reported statistics are weighted by total hospital discharges. Based on analysis by ASPE.

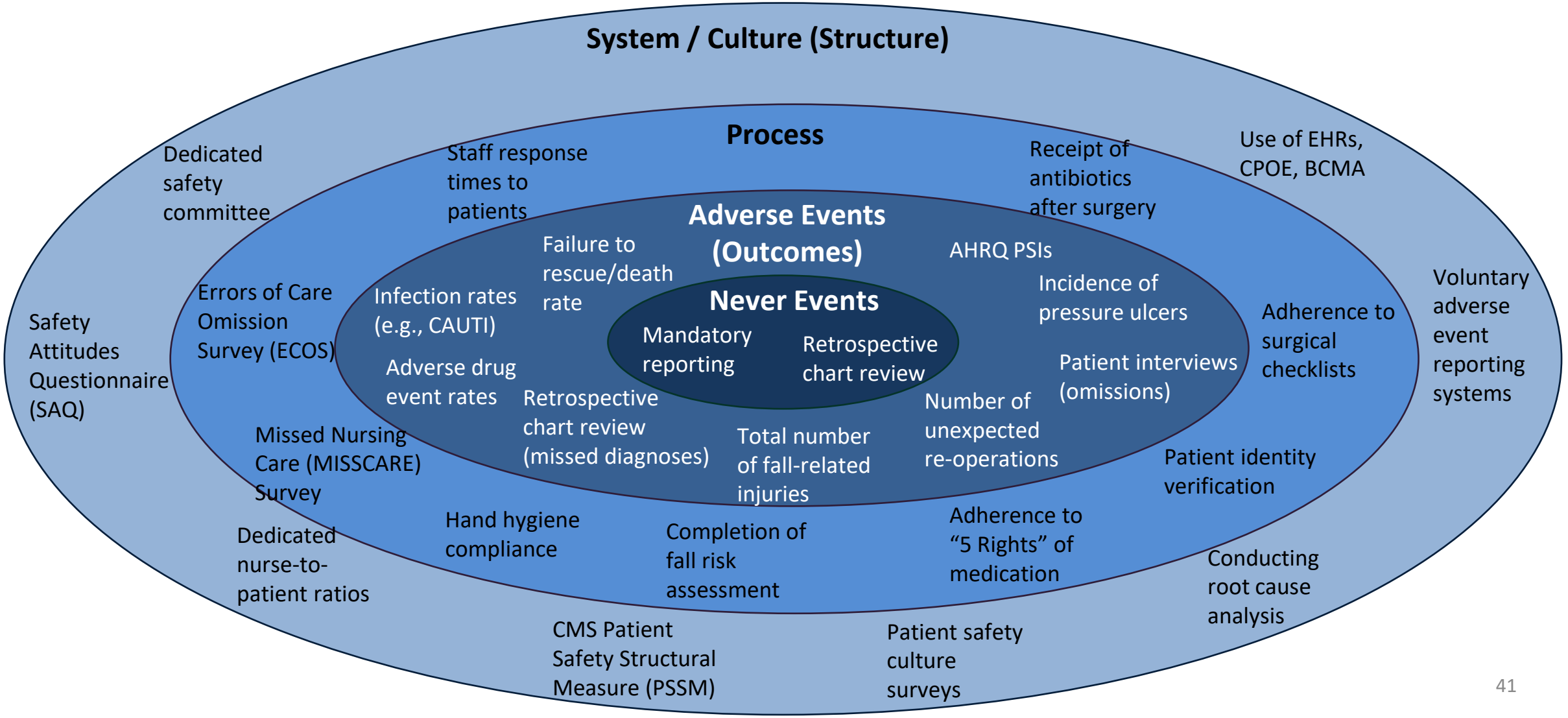
Hospital Safety Results From CMS's Care Compare Tool, Continued

- Other major patient safety and adverse event indicators show similar levels of dispersion



Note: Data sourced from CMS Care Compare and include measurement periods from 2014-2024. Reported statistics are weighted by total hospital discharges. Decile 1 represents the best-performing hospitals, and Decile 10 represents the worst-performing hospitals. Based on analysis by ASPE.

Patient Safety Measures Conceptual Diagram



CMS Efforts to Promote Patient Safety

- CMS incentivizes patient safety through hospital quality Star ratings and safety program payments
  - CMS hospital quality star ratings
    - Hospitals receive from 1 to 5 stars based on quality performance
    - CMS's Overall Star Rating is a weighted summary of five measure groups: mortality, safety (includes HAIs and serious complications), readmission, patient experience, and timely & effective care
    - Starting in 2026, hospitals in the lowest quartile of the Safety of Care measure group will be capped at a 4-star maximum
    - Starting in 2027, hospitals in the lowest quartile of the Safety of Care measure group will receive a blanket 1-star reduction
  - CMS programs that promote patient safety
    - Multiple CMS programs focus on improving patient safety (e.g., Hospital Value-Based Purchasing Program [HVP], Hospital-Acquired Condition [HAC] Program)
    - These programs incentivize patient safety by adjusting payments received by providers based on patient safety performance
    - For some programs, safety is one type of quality component included in the program

Patient Safety Oversight

Organization	Description
Federal Regulatory Oversight	
Centers for Medicare & Medicaid Services (CMS)	Ensures **mandatory** minimum safety standards (conditions of participation) for Medicare and Medicaid providers; publicly reports hospital patient safety data through the Care Compare tool
Agency for Healthcare Research and Quality (AHRQ)	Primary federal agency conducting patient safety research; develops patient safety measures, resources, tools; oversees the Quality and Safety Review System (QSRS) to track hospital adverse events, the Network of Patient Safety Databases (NPSD) to track and analyze patient safety events, and the Patient Safety Organization (PSO) program
Food and Drug Administration (FDA)	Ensures safety and effectiveness of drugs and medical devices; **mandatory** approval before marketing
Centers for Disease Control and Prevention (CDC)	Leads patient safety efforts to prevent HAIs; manages the National Healthcare Safety Network (NHSN) to track HAIs (**mandatory** reporting by facilities to comply with Medicare requirements and many state mandates)
Clinical Laboratory Improvement Amendments (CLIA)	CLIA certification is **mandatory** for all laboratories performing non-research testing on human specimens (e.g., for health purposes); the CLIA program is led by CMS along with the CDC and FDA
Office of Inspector General (OIG)	OIG supports HHS agencies by reporting the incidence of adverse events among Medicare patients, identifying the impact of harm events, and producing recommendations to improve patient safety

Patient Safety Oversight, Continued

Organization	Description
Accrediting & Standards Setting	
The Joint Commission (TJC)	Conducts independent **voluntary** evaluations of healthcare organizations' safety and quality; offers accreditation (to hospitals) and certifications for specific programs including ASCs; accredits more than 22,000 organizations and programs; monitors sentinel events
National Quality Forum (NQF)	Creates multi-stakeholder consensus and endorses standard safety and quality measures; partners with TJC
National Committee for Quality Assurance (NCQA)	Promotes patient safety and quality through **voluntary** accreditation and certification programs; oversees the Healthcare Effectiveness Data and Information (HEDIS) performance measures; HEDIS is generally **mandatory** for health plans
American Board of Medical Specialties (ABMS)	Integrates patient safety education in modules and assessments in certification exams

Patient Safety Oversight, Continued

Organization	Description
Watchdog & Advisory Groups	
The Leapfrog Group	Collects and analyzes patient safety and quality data for hospitals and ASCs; assigns public safety grades; **voluntary** participation
Institute for Healthcare Improvement (IHI)	Provides education, training, and evidence-based tools, and engages in collaborative initiatives to promote patient safety and quality
Patient Safety Organizations (PSOs)	Collect and analyze patient safety and quality data, and provide feedback to help providers prevent future safety events; **voluntary** and confidential; there are 127 PSOs; managed by AHRQ
ECRI & the Institute for Safe Medication Practices (ISMP)	ECRI develops evidence-based guidance, tools, and reports to promote patient safety; ISMP provides the gold standard for medication safety information and runs a national **voluntary** medication error reporting program; ECRI/ISMP is an AHRQ PSO

CMS Patient Safety Programs and Initiatives That Do Not Link Performance to Payment

Program	Years	Description	Results
Hospital Inpatient Quality Reporting (IQR) Program	2004-present	CMS requires hospitals to **annually report on quality measures**, including specific patient safety measures (e.g., death rate among surgical inpatients with complications, new Patient Safety Structural Measure); hospitals are subject to a **payment reduction** (25%) if they **do not meet reporting requirements**; serves as the foundation for other value-based programs (e.g., HRRP, HAC Reduction Program)	Public reporting of hospital performance on CMS Care Compare
Home Health Care Quality Improvement National Campaign	2007-2017*	Initiated by CMS, home health agencies (HHAs) engaged in a national campaign along with other stakeholders (e.g., CMS staff, Quality Improvement Organization [QIO] leaders, home care leaders) to **gather and implement best practices** (e.g., hospitalization risk assessments, emergency care planning, medication management) and HHA success stories to **reduce avoidable acute care hospitalizations**	Participating HHAs acute care hospitalization rate **slightly improved** while non-participating HHAs rate worsened

*The Home Health Care Quality Improvement National Campaign ran for approximately a decade. The Campaign evolved into Value-Based Purchasing models and other CMS quality initiatives.

CMS Patient Safety Programs and Initiatives That Do Not Link Performance to Payment, Continued

Program	Years	Description	Results
Hospital Outpatient Quality Reporting (OQR) Program	2009-present	CMS requires short-term acute hospitals to **annually report on quality measures** specific to outpatient care, emergency department, and surgical procedures, including patient safety measures (e.g., hospital visit within 7 days of hospital outpatient surgery); hospitals are subject to a **payment reduction** (2%) if they **do not meet reporting requirements**	Public reporting of hospital performance on CMS Care Compare
Partnership for Patients (PfP)	2011-2016	Two objectives: 1) federal and private organizations worked together to **develop policy to reduce preventable Hospital Acquired Conditions (HACs);** and 2) Hospital Engagement Networks (HENs) **provided hospitals with technical assistance to implement best practices**	Almost **9% reduction** in harm rates; approximately **$4 billion in estimated cost savings** for 2011-2012
Quality Improvement Network-Quality Improvement Organization (QIN-QIO)	2014-present	Partnership for Patients integrated with QIN-QIO in 2016; HENs, renamed to Hospital Improvement Innovation Networks (HIINs) **provided hospitals with best practices to reduce harm**	HACs rate **dropped 13%**; about **$7.7 billion in estimated cost savings** for 2014-2017

Appendix B
Value-Based Care Components of PTAC Proposals That Include Patient Safety

Value-Based Care Components of PTAC Proposals That Include Patient Safety

PTAC has received 36 proposals for physician-focused payment models (PFPMs), including 28 proposals that PTAC has deliberated on during public meetings. Committee members found that 23 of the 28 proposals met Criterion 9: Patient Safety.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American Academy of Family Physicians (AAFP) **(Provider association and specialty society)** **Advanced Primary Care: A Foundational Alternative Payment Model (APC-APM) for Delivering Patient-Centered, Longitudinal, and Coordinated Care** **Recommended for limited-scale testing, 12/19/2017**	Clinical Focus: Primary Care Providers: Physicians with a primary specialty in family medicine, general practice, geriatric medicine, pediatric medicine, or internal medicine Setting: Primary care practices Patient Population: Medicare FFS beneficiaries	Overall Model Design Features: APC-APM builds on concepts tested through CPC and CPC+ models. Primary care medical homes work closely with patients' other health care providers to coordinate and manage care transitions, referrals, and information exchange. Financial Methodology: Capitated per-beneficiary-per-month (PBPM) with shared risk options for accountability How Payment is Adjusted for Performance: Participants assume performance risk. APMs that meet or exceed agreed-upon benchmarks retain incentive payment. Failure to meet benchmarks would involve repaying all or part of the incentive payment. Approaches to Address Patient Safety: Entities would be required to report on selected quality measures from the Core Quality Measures Collaborative's PCMH/ACO/Primary Care Core Set that are tied to payment. However, the proposal does not mention specific patient safety measures. The authors also state that the model would support patient safety by making the primary attribution method be patient choice. Patients may leave the model at any time.
American Academy of Hospice and Palliative Medicine (AAHPM) **(Provider association/specialty society)** **Patient and Caregiver Support for Serious Illness (PACSSI)** **Recommended for limited-scale testing, 3/26/2018**	Clinical Focus: Serious illness and palliative care Providers: Palliative care teams (PCT) Setting: Inpatient; outpatient; other palliative care settings Patient Population: Patients with serious illness	Overall Model Design Features: PACSSI proposes palliative care medical home services for high-need patients not yet eligible or not wanting hospice care. Financial Methodology: Monthly care management payments adjusted based on geographic location and site of care. There are two tracks: Track 1 – payment incentives and Track 2 – shared savings and shared risk. How Payment is Adjusted for Performance: Payments would be adjusted based on performance on quality and spending. Approaches to Address Patient Safety: Participants would be required to report on two quality measures regarding hospice election rates, patient-reported surveys, and certain processes of care. These measures would be linked to payment.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American College of Allergy, Asthma & Immunology (ACAAI) **(Provider association/specialty society)** **Patient-Centered Asthma Care Payment (PCACP)** **Referred for other attention by HHS, 6/22/2020**	**Clinical Focus: Asthma care** **Providers: Allergists, immunologists, pulmonologists, PCPs, other providers** **Setting: Emergency department** **Patient Population: Patients with asthma and asthma-like symptoms**	**Overall Model Design Features:** Supports asthma specialists, PCPs, and other providers to coordinate treatment of patients with asthma **Financial Methodology:** Bundled payments based on the severity of patient symptoms **How Payment is Adjusted for Performance:** Asthma Care Teams receive the default payment level for each patient if the team scored "good" on all performance measures; payments are increased or decreased (up to +/-5% to increase over time to +/-9%) if team scored "high" or "low" on some performance measures. **Approaches to Address Patient Safety:** Quality standards must be met to receive full bundled payments. However, the proposal does not list specific patient safety measures. The authors also mention providing patient education about proper use of medications.
American College of Emergency Physicians (ACEP) **(Provider association/specialty society)** **Acute Unscheduled Care Model (AUCM): Enhancing Appropriate Admissions** **Recommended for implementation, 09/06/2018**	Clinical Focus: Emergency medicine Providers: Emergency medicine physicians and advanced practice professionals Setting: Hospital emergency departments (EDs) Patient Population: Medicare FFS beneficiaries presenting in the ED	Overall Model Design Features: AUCM aims to coordinate care post-discharge from the ED. Several elements are adapted from the CJR and the BPCI Advanced Models. Financial Methodology: Episode-based, bundled payment; if spending for eligible and attributed episodes is less than the bundled payment target price, the participant is eligible for a positive reconciliation payment; if it is more, the participant will have to reimburse CMS. Also includes payment waivers for ED acute care transition services, telehealth services, and post-discharge home visits. How Payment is Adjusted for Performance: A composite quality score, including post-ED event rates and patient safety measures, determines whether participants are eligible for a reconciliation payment or if repayment to Medicare is warranted. Approaches to Address Patient Safety: Specific patient safety measures will be required, such as post-discharge falls, adverse drug events, and post-surgery complications and will be tied directly to payment.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American College of Physicians-National Committee for Quality Assurance (ACP-NCQA) **(Provider association and specialty society/other)** **The "Medical Neighborhood" Advanced Alternative Payment Model (AAPM) (Revised Version)** **Recommended for testing to inform payment model development, 9/15/2020**	**Clinical Focus: Improved coordination in primary and specialty care practices** **Providers: Primary and specialty care practitioners** **Setting: Primary and specialty care practices** **Patient Population: Medicare FFS beneficiaries with multiple chronic conditions**	**Overall Model Design Features: The model builds on the CPC+, PCMHs, and PCSP concepts.** **Financial Methodology:** Participants receive a monthly PBPM care coordination fee and a retrospective positive or negative payment adjustment. Track 1 includes fee-for-service payments, while Track 2 has a reduced fee-for-service payment and a comprehensive specialty care payment (CSCP). **How Payment is Adjusted for Performance:** Performance-based payment adjustment is based on spending relative to a financial benchmark, adjusted for performance on quality and utilization metrics. **Approaches to Address Patient Safety:** NCQA would regularly review patient-centered specialty practice (PCSP) standards and rescind PCSP status if the review identified a patient safety threat. The model would include various patient experience measures as well as National Healthcare Safety Network measures to detect if patients acquired MRSA bacteria and/or other HAIs when in the hospital.
The American College of Surgeons (ACS) **(Provider association/specialty society)** **The ACS–Brandeis Advanced Alternative Payment Model** **Recommended for limited-scale testing, 4/11/2017**	Clinical Focus: Cross-clinical focus with sets of procedural episodes of care Providers: Single or multispecialty practices and groups of small provider practices Setting: Inpatient, outpatient, ambulatory Patient Population: Medicare FFS beneficiaries from over 100+ conditions or procedures	Overall Model Design Features: Focused on procedural episodes, leveraging the EGM software developed by CMS and Brandeis University, the model is based on shared accountability, integration, and care coordination. Financial Methodology: Retrospective payment that compares episode target prices to the actual cost of the care provided How Payment is Adjusted for Performance: Performance (e.g., unacceptable, acceptable, good, excellent) determines the shared savings retained by the APM entity or the amount to repay CMS for losses. Approaches to Address Patient Safety: ACS proposed to monitor and compare care levels and outcomes across participants to identify participants with potential gaps in care that may be indicative of delayed or missed care. The authors also suggested creating a potentially avoidable adverse event measure.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American Society of Clinical Oncology (ASCO) **(Provider association/specialty society)** **Patient-Centered Oncology Payment Model (PCOP)** **Recommended for testing to inform payment model development, 9/15/2020**	**Clinical Focus: Oncology** **Providers: Clinicians, including hematologists and oncologists** **Setting: Oncology specialty practices** **Patient Population: Oncology practice patients**	**Overall Model Design Features:** The model proposes to create PCOP communities that include several providers, payers, and other entities to provide high-quality, coordinated care. **Financial Methodology:** Providers receive three payments: monthly care management payments (CMP), performance incentive payments (PIP), and adjustments to FFS reimbursement. A portion of the CMP will be allocated to a PIP. PIPs will be positively or negatively adjusted based on provider success in adherence to clinical treatment pathways, quality metrics, and cost reduction. There are two tracks: Track 1 participants continue to receive FFS reimbursement in addition to the CMPs; Track 2 participants participate in the Consolidated Payments for Oncology Care (CPOC) where practices can bundle 50% or 100% of the value of specified services. 10% of the amount bundled will be subject to the same performance adjustment as PIPs times a 1.4 multiplier. **How Payment is Adjusted for Performance:** If providers do not meet minimum expectations, CMP and PIP amounts may be suspended, and providers will need to develop an improvement plan. **Approaches to Address Patient Safety:** Entities would be required to follow ASCO's Quality Oncology Practice Initiative (QOPI) safety standards for chemotherapy administration. Entities must also have a process for implementing follow-up visits and tests as the authors cite failure to follow-up as an important patient safety issue.
Avera Health **(Regional/local multispecialty practice or health system)** **Intensive Care Management in Skilled Nursing Facility Alternative Payment Model (ICM SNF APM)** **Recommended for implementation, 3/27/2018**	Clinical Focus: Geriatric primary care for residents in long-term care Providers: Geriatric care teams that include geriatricians, PCPs, nurses, social workers, pharmacists Setting: Skilled nursing homes and long-term care facilities Patient Population: Medicare FFS beneficiaries in skilled nursing homes or long-term care facilities	Overall Model Design Features: Provides access to a geriatrician-led care team through telemedicine, provides geriatric care management and management of care transitions, and mentors and trains long-term care staff. Financial Methodology: One-time payment for new admission care and a PBPM payment for post-admission care. Two payment method options are proposed for the model: 1) a performance-based payment adjusted on quality performance; and 2) a shared savings model with an annual financial reconciliation. How Payment is Adjusted for Performance: In the performance-based payment option, payments are adjusted positively or negatively by the ability to meet performance criteria. Approaches to Address Patient Safety: The model would require patient safety metrics, such as percentage of patients who had a catheter left in their bladder, who were physically restrained, who fell and sustained a major injury, or who have pressure ulcers. Entities must be above the 50th percentile or not decrease more than five percent per year for at least eight of the 13 required measures or they will be removed from the model.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Coalition to Transform Advanced Care (C-TAC) **(Coalition)** **Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model** **Recommended for limited-scale testing, 3/26/2018**	**Clinical Focus: Advanced illness, palliative care, end-of-life care** **Providers: PCPs, specialists** **Setting: Hospitals, health systems, hospices, home health** **Patient Population: Medicare FFS beneficiaries with advanced illness in the last year of life**	**Overall Model Design Features:** An interdisciplinary care team implements the ACM care delivery services. **Financial Methodology:** A non-tiered PMPM payment with downside risk for TCOC and an upside bonus for quality, subject to maximum payment and loss amounts **How Payment is Adjusted for Performance:** Pay-for-quality structure, where participants are eligible for a quality-based bonus funded by shared savings and determined by performance measure performance **Approaches to Address Patient Safety:** The model proposes to address patient safety by offering care coordination approaches and monitoring quality measures. However, the proposal does not include specific patient safety measures.
Dialyze Direct **(Regional/local single specialty practice)** **APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities** **Recommended for attention, 9/6/2018**	Clinical Focus: End-stage renal disease (ESRD) Providers: Nephrologists Setting: SNFs Patient Population: Geriatric dialysis patients residing in SNFs	Overall Model Design Features: Nephrologists provide ESRD beneficiaries that reside in SNFs with home hemodialysis services Financial Methodology: Bundled payment model with ability to receive shared savings, as well as a one-time additional payment for efforts related to educating patients on the benefits of on-site staff-assisted home dialysis in the nursing home. How Payment is Adjusted for Performance: N/A Approaches to Address Patient Safety: Complications of transportation, such as falls or fractures that occur would be a measure. The authors mention that they would perform a study to accurately develop other measures that pertain specifically to the ESRD population that resides in SNFs, which is known to have a higher prevalence of comorbidities, be older, and more frail.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Hackensack Meridian Health and Cota, Inc. (HMH/Cota) *(Regional/local multispecialty practice or health system; Device/technology company)* Oncology Bundled Payment Program Using CNA-Guided Care Recommended for limited-scale testing, 9/8/2017	**Clinical Focus:** Oncology **Providers:** Clinicians with admitting privileges in the Hackensack Meridian Health (HMH) health system **Setting:** HMH health system that includes hospitals, home health, rehabilitation clinics, skilled nursing facilities, and mental health facilities **Patient Population:** Medicare patients with breast, colon, rectal, or lung cancer attributed to clinicians in the HMH health system	**Overall Model Design Features:** This is an oncology bundled payment model in which care choices are modulated by the prior outcomes of similar patients from real-world data. This process is called Cota Nodal Address (CNA) guided care. **Financial Methodology:** Prospective payment is provided to HMH for patients participating in the model. HMH bears the risk of bundled payments and distributes payments to physicians. **How Payment is Adjusted for Performance:** Compensation is, in part, incentive-based and determined by the achievement of clinical quality and patient satisfaction outcomes. **Approaches to Address Patient Safety:** HMH performed analysis and learned that patients who see their doctors before starting chemotherapy treatment have fewer occurrences of toxicity compared to those patients who do not see their provider or see their provider not right before starting chemotherapy. There are also several patient safety measures included, such as biopsy review completed within 48 hours, documentation of post-operation vomiting and pain scores, presence of pressure sores, monitoring for infections, and falls/falls with injury.
Johns Hopkins School of Nursing and the Stanford Clinical Excellence Research Center (Hopkins/Stanford) *(Academic institution)* CAPABLE Provider Focused Model Recommended for testing as specified in PTAC comments, 9/6/19	**Clinical Focus:** Chronic conditions and functional limitations **Providers:** Interdisciplinary team of an occupational therapist, registered nurses, and a handy worker **Setting:** Home and community-based settings **Patient Population:** Medicare FFS beneficiaries with at least two chronic conditions and difficulty with at least one activity of daily living	**Overall Model Design Features**: A time-limited intervention performed by an interdisciplinary team to target specific functional goals, perform limited home repairs and modifications, and address common geriatric concerns. **Financial Methodology:** Partial bundled payment with partial upside, moving toward a fully capitated model of care. **How Payment is Adjusted for Performance:** A bonus for meeting quality metrics would be awarded. **Approaches to Address Patient Safety:** The authors highlighted that the CAPABLE Model is a patient safety approach because it aims to improve the ability for older adults to take care of themselves at home. It has been approved by the National Council on Aging as a fall prevention program. The model would include metrics such as home hazard or fall risk.
Illinois Gastroenterology Group and SonarMD, LLC (IGG/SonarMD) *(Regional/local single specialty practice; Device/technology company)* Project Sonar Recommended for limited-scale testing, 4/10/2017	**Clinical Focus**: Chronic disease (Crohn's disease) **Providers**: Specialty physicians **Setting**: Outpatient settings and specialty care practices **Patient Population**: Medicare FFS beneficiaries	**Overall Model Design Features**: The model integrates evidence-based medicine with proactive patient engagement. It allows physicians to participate in chronic disease management that is not triggered by a surgical procedure or on an inpatient or outpatient basis. **Financial Methodology**: Add-on PBPM payment with two-sided risk, plus a payment to support remote monitoring **How Payment is Adjusted for Performance**: Payments would be adjusted based on quality and financial performance. **Approaches to Address Patient Safety:** Project Sonar references patient engagement to aid in decreasing patient safety concerns.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Innovative Oncology Business Solutions, Inc. (IOBS) *(For-profit corporation)* Making Accountable Sustainable Oncology Networks (MASON) Referred for further development and Implementation, 12/10/2018	**Clinical Focus**: Oncology **Providers**: Oncologists, surgeons, PCPs, pathologists, radiologists **Setting**: Oncology practices **Patient Population**: Medicare FFS beneficiaries	**Overall Model Design Features**: Builds off the Community Oncology Medical Home (COME HOME) CMS Innovation Center project **Financial Methodology**: Determined by the oncology payment category (OPC), consisting of FFS payments for physician visits, imaging, lab, radiation therapy, surgery; infusion with a facility fee; ambulatory payment classifications (APCs) for hospital outpatient care; diagnosis-related groups (DRGs) for inpatient care; and the PCOP for medical home infrastructure **How Payment is Adjusted for Performance**: 2% of the OPC, which includes all expenses related to cancer care except drugs, is reserved for a quality pool. If quality measures are not met, the 2% is not rewarded. **Approaches to Address Patient Safety:** COME HOME, the program with which this model builds from, measured patients who went to different care sites than expected (e.g., office instead of ED) and found that patients experienced no harm when visiting the doctor's office versus the ED.
Large Urology Group Practice Association (LUGPA) *(Provider association and specialty society)* LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer Not recommended, 2/28/18	**Clinical Focus:** Urology/Oncology (treatment of prostate cancer) **Providers:** Eligible professionals (including urologists) at large and small urology and multispecialty practices **Setting:** Large and small urology and multispecialty practices **Patient population:** Newly diagnosed prostate cancer patients with localized disease	**Overall Model Design Features**: The model aims to identify those newly diagnosed prostate cancer patients with low-risk localized disease to receive active surveillance rather than active intervention. **Financial Methodology**: An episode-based payment that would retrospectively compare actual initial episode spending against a target amount **How Payment is Adjusted for Performance**: Participants earn performance-based payments or owe performance-based repayments based on the number of quality performance targets achieved/exceeded. **Approaches to Address Patient Safety:** LUGPA proposes several quality measures, such as biopsy follow-up and avoidance of overuse of bone scan. However, the proposal does not list specific patient safety measures.
Icahn School of Medicine at Mount Sinai (Mount Sinai) (*Academic institution*) "HaH-Plus" (Hospital at Home-Plus): Provider-Focused Payment Model Recommended for implementation, 9/17/2017	**Clinical Focus**: Inpatient services in the home setting **Providers**: Physicians and HaH-Plus providers, including nurse practitioners, registered nurses, social workers, and physical, occupational, and speech therapists **Setting**: Patient homes **Patient Population**: Medicare FFS beneficiaries who have one of the 44 acute conditions	**Overall Model Design Features**: Multidisciplinary care around an acute care event to reduce complications and readmissions **Financial Methodology**: Bundled payment covering the acute episode and an additional 30 days of transition services. Two components are in the payment model: 1) a new DRG-like HaH-Plus payment to substitute for the acute inpatient payment to the hospital and attending physician; and 2) the potential for a performance-based payment linked to the total Medicare spend for the entire HaH-Plus episode and the APM performance on quality metrics. **How Payment is Adjusted for Performance**: The APM entity's performance on quality metrics influences payment. **Approaches to Address Patient Safety:** The authors propose to track adverse events metrics, such as occurrence of various infections, pressure ulcers, falls, and adverse drug reactions. Furthermore, all adverse events must be reported within 24 hours of occurrence for review by a medical director as well as an independent provider.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
New York City Department of Health and Mental Hygiene (NYC DOHMH) *(Public health department)* Multi-provider, bundled episode of care payment model for treatment of chronic hepatitis C virus (HCV) using care coordination by employed physicians in hospital outpatient clinics Not recommended, 12/18/2018	**Clinical Focus**: Hepatitis C virus (HCV) **Providers**: Primary care and internal medicine physicians (infectious disease specialists, gastroenterologists) **Setting**: Hospital-based outpatient clinics **Patient Population**: Patients with HCV	**Overall Model Design Features**: The Project INSPIRE Model proposes integrated medical, behavioral, and social services for patients with HCV. **Financial Methodology**: Bundled payment with the opportunity for shared savings. **How Payment is Adjusted for Performance**: Additional shared savings are awarded for being a "high-performing facility" based on their sustained virological response (SVR) score. **Approaches to Address Patient Safety:** The proposal references that patient safety is addressed through the use of a care coordinator as well as the ability to modify shared savings rates to incentivize provider behavior and decrease potential care stinting. The proposed model does not list specific patient safety measures. It also does not include patient-reported outcome measures.
Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group Inc. (PMA) (*Regional/local single specialty practice*) The COPD and Asthma Monitoring Project (CAMP) Not recommended, 4/11/2017	**Clinical Focus:** COPD and/or asthma **Providers:** Pulmonary physicians **Setting:** Patient home **Patient Population:** COPD and asthma patients	**Overall Model Design Features**: The model proposes remote interactive monitoring for patients with COPD, asthma, and other chronic lung diseases. **Financial Methodology**: Two-sided risk arrangement that would permit CMS to recoup up-front costs first and then allow participants to share in remaining savings or losses up to a stop loss percentage amount **How Payment is Adjusted for Performance**: The proposal does not specify how quality measures would affect payment. **Approaches to Address Patient Safety:** The proposal mentions that there will be several checks in place to ensure that patients are not neglected; however, specific details are not provided. The proposal also does not include specific patient safety measures.
Personalized Recovery Care (PRC) (*Regional/local single specialty practice*) Home Hospitalization: An Alternative Payment Model for Delivering Acute Care in the Home Recommended for implementation, 3/26/2018	**Clinical Focus**: Inpatient services in the home setting or skilled nursing facility **Providers**: Admitting physicians at facilities receiving personalized recovery care (PRC) payments; on-call physicians; recovery care coordinators **Setting**: Patient home or skilled nursing facility **Patient Population**: Commercial and Medicare Advantage patients with one of 150 acute conditions	**Overall Model Design Features**: This is a home hospitalization care model that proposes to provide inpatient hospitalization-level care and PRC at home or a skilled nursing facility for patients with certain conditions through an episodic payment arrangement. **Financial Methodology**: Bundled episode-based payment not tied to an anchor admission, replacing FFS with shared risk. Bundled payment has two components: 1) risk payment for delivering care compared to the targeted cost of care; and 2) a per-episode payment made for care provided instead of an acute care hospitalization. **How Payment is Adjusted for Performance**: To be eligible for shared savings, providers must meet or exceed benchmarks for performance measures. Participants are eligible to receive 20% of savings for each measure that meets or exceeds the benchmark. Participants receive 100% of savings if all five performance measures are met (0% if none are met). **Approaches to Address Patient Safety:** The authors cite that because the care takes place at home and not in a hospital, hospital-acquired infections and other conditions are avoided. Care coordinators would have substantial involvement and engagement with patients to ensure patient safety. The proposed model would also offer a compliance hotline number where patients can formally report patient safety concerns and issues. Specific patient safety measures are also included, such as the percentage of episodes with adverse events (e.g., pressure ulcers, falls with injury) and medication reconciliation.

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Renal Physicians Association (RPA) (*Provider association and specialty society*) Incident ESRD Clinical Episode Payment Model Recommended for implementation, 12/18/2017	**Clinical Focus**: End-stage renal disease (ESRD) **Providers**: Nephrologists, PCPs **Setting**: Dialysis centers **Patient Population**: Medicare patients with ESRD	**Overall Model Design Features**: Condition-specific, episode-of-care payment model for ESRD patients during the first six months of dialysis therapy that promotes coordination, patient choice for treatment, CKD patient education, quality of life, and advanced care planning. **Financial Methodology**: Episode of care payment model with shared savings achieved over the entire 6-month episode of care. There is also a one-time bonus payment for nephrologists to facilitate a patient receiving a kidney transplant preemptively or during the episode of care. **How Payment is Adjusted for Performance**: Physicians' quality scores based on performance on patient-centered quality measures determine the percentage of overall shared savings the physician receives. The higher the quality score, the higher amount of shared savings received. **Approaches to Address Patient Safety:** The proposal describes that interventions, such as this proposed model, that keep patients out of the hospital improve patient safety because there is decreased risk of hospital-acquired infections. Additionally, avoiding use of hemodialysis catheters decreases risk of catheter infections. RPA also developed a kidney patient safety resource for nephrologists. The proposal references quality measures specific to the care of ESRD patients, including home dialysis percentage and patient experience measures, but does not list specific patient safety measures.
University of Chicago Medicine (UChicago) *(Academic Institution)* The Comprehensive Care Physician Payment Model (CCP-PM) Recommended for limited-scale testing, 9/7/2018	**Clinical Focus**: Frequently hospitalized patients **Providers**: Inpatient and outpatient providers **Setting**: Home care and rehabilitation **Patient Population**: Medicare beneficiaries who are at high risk for hospitalization	**Overall Model Design Features**: The model seeks to coordinate care for patients at risk for hospitalization by having one physician to provide inpatient and outpatient care. **Financial Methodology**: Add on PBPM payment with shared risk **How Payment is Adjusted for Performance**: Providers will continue to be incentivized or penalized for quality outcome measures based on their APM or MIPS participation. **Approaches to Address Patient Safety:** The proposal describes that it ensures patient safety by reducing the transitions of care between inpatient and outpatient settings and providing coordination (e.g., one provider responsible for both inpatient and outpatient care).

Value-Based Care Components of PTAC Proposals That Include Patient Safety, Continued

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
The University of New Mexico Health Sciences Center (UNMHSC) (*Academic institution*) ACCESS Telemedicine: An Alternative Healthcare Delivery Model for Rural Emergencies Recommended for implementation, 9/16/2019	**Clinical Focus**: Cerebral emergency care; telemedicine **Providers**: Neurologists, neurosurgeons, and providers in rural and community systems **Setting**: Inpatient, outpatient, or emergency department **Patient Population**: Patients with neurological emergencies	**Overall Model Design Features**: Rural EDs can consult neurologists via teleconsultation and assess patients' condition when they present at the hospital ED. The model aims to reduce costs in hospital transfers and ambulatory medicine. **Financial Methodology**: Additional one-time payment without shared risk **How Payment is Adjusted for Performance**: Performance is monitored but does not impact payment. **Approaches to Address Patient Safety:** The authors propose that there would be a process in place to verify patient identification and to obtain written consent for telemedicine. Additionally, education and resources, such as neuroscience workshops and technology education, would be provided to all clinical staff to ensure competency of staff. Model leaders would perform a systematic review to ensure clinical guidelines are being followed.
Upstream Rehabilitation (Regional/local single specialty practice) CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients Not recommended, 5/11/2019	**Clinical Focus:** Chronic wound care **Providers:** Physical and operational therapists **Setting:** Physical and occupational therapy centers **Patient Population:** Medicare patients with chronic wounds	**Overall Model Design Features:** Physical and occupational therapists will provide chronic wound care services in outpatient therapy clinics. **Financial Methodology:** Providers would track the total cost of and time in treatment for each patient, to include wound care supplies. CMS would allow providers to be reimbursed $250 per patient for wound care supplies and to bill for advanced therapeutics (e.g., bioengineered dressings). **How Payment is Adjusted for Performance:** Claim refunded to CMS if minimum standards of improvement are not met. Clinicians can receive a 3% savings bonus for achieving average reimbursement costs below risk-adjusted thresholds. **Approaches to Address Patient Safety:** The proposal would measure rates of infection, patient level of pain, and patient satisfaction.

Appendix C
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Slides 43-45 – Patient Safety Oversight

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