

Navigating the New CMS Attestation Requirements: Identifying and Addressing Potential Pitfalls

A Roadmap for the 2025 Patient Safety Structural Measures (PSSM)

January 22, 2025



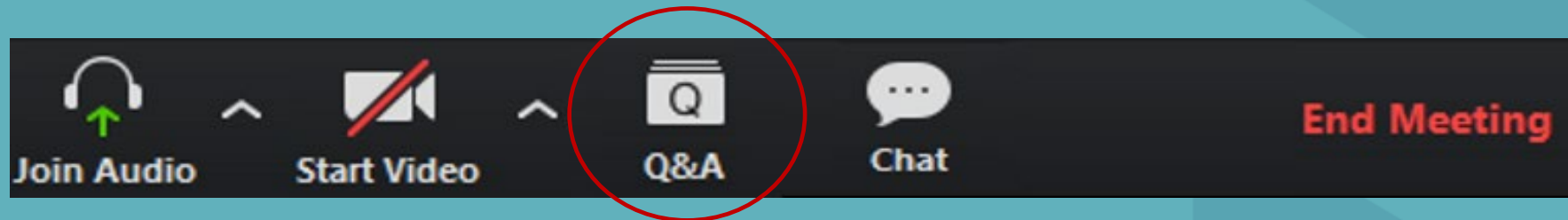
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APRIL 13 – 15, 2025
Denver, Colorado

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Part I

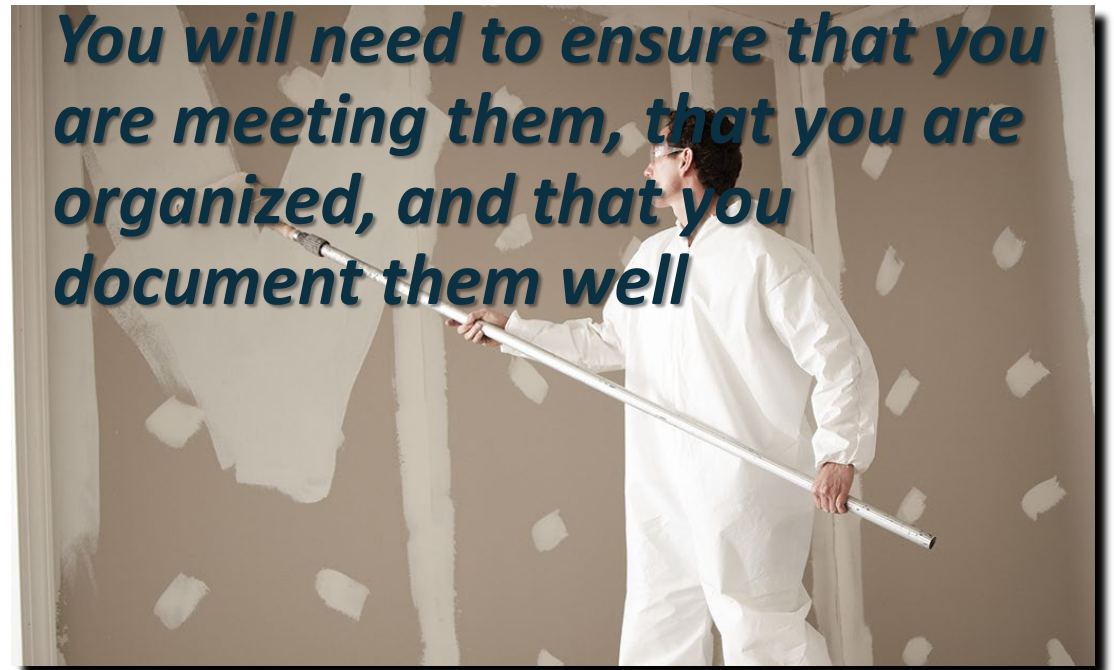
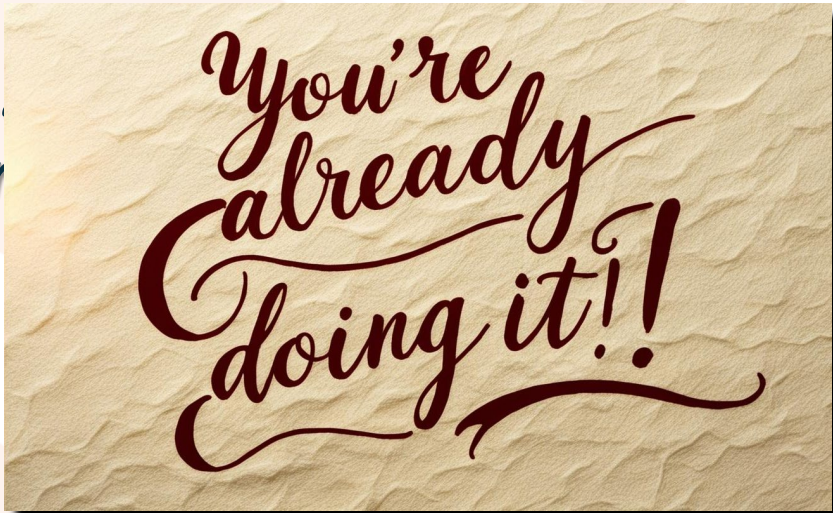
*A PSSM Primer – Why, What, and Whom – **and What Are the Consequences for Non-Compliance?***

Patient Safety Structural Measure



This is a primer – an introduction to the PSSM

While there is a lot here, you are already doing (or should be doing) many of these measures.



Patient Safety Structural Measure



Background

- Part of CMS's FY 2025 Inpatient Prospective Payment System Final Rule
- Applies to hospitals participating in CMS's Hospital Inpatient Quality Reporting Program & the PPS-Exempt Cancer Hospital Quality Reporting Program
- Consists of 5 Domains
 - Each with distinct components
 - Includes 25 separate attestation statements
- Developed with extensive input (*Institute for Healthcare Improvement*)
- **A response to the recognition that despite extensive efforts only modest improvements in patient safety have taken place**
- Designed to shift quality reporting from **outcome** metrics (e.g., infection rates) to organizational **structures and policies** focused upon patient safety

Patient Safety Structural Measure



5 Domains

- Leadership Commitment
- Strategic Planning & Organizational Policy
- Safety Culture & Learning Health System
- Accountability & Transparency
- Patient & Family Engagement

2025 – Hospital Reporting / Attestation Starts

2026 – CMS Publishes Information

2027 – Reimbursement cuts for those not reporting...



Domain

1

Leadership Commitment to Eliminating Preventable Harm



- The senior leadership and governing board at hospitals sets the tone for commitment to patient safety.
 - Accountable for patient safety outcomes
 - Ensure that patient safety is the highest priority for the hospital
- The most senior governing board must oversee all safety activities.
 - Must hold the organizational leadership accountable for outcomes
- Patient safety should be central to all strategic, financial, and operational decisions.



Leadership Commitment to Eliminating Preventable Harm

Domain

1

Attestations

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

Statement-Specific Guidance

- “System-wide assessment on safety” refers to a hospital self-assessment of safety practices and capacity
- Example – Institute for Healthcare Improvement’s Self-Assessment Tool that accompanies the National Action Plan to Advance Patient Safety
- Designed to be implemented by hospital leaders to evaluate organizational practices and capacity – and is different than a safety culture survey that targets frontline hospital staff



Medical Staff Professionals

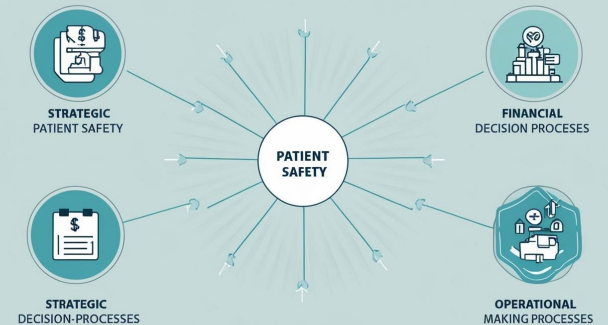
Patient safety should be central to all strategic, financial, and operational decisions

- Dedicated time on agendas
- Templates for minutes
 - Ensures accurate reflection of discussions and data presentation
 - If it wasn't documented . . .



Domain

1



Medical Staff Professionals

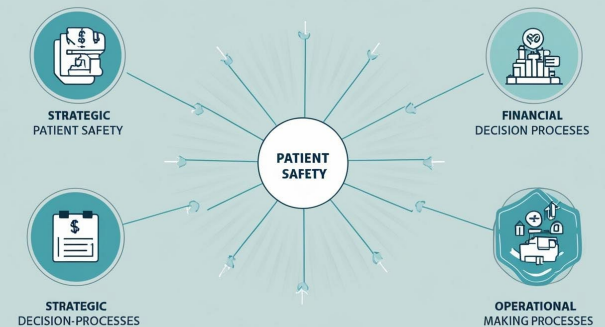


Patient safety should be central to all strategic, financial, and operational decisions

- *Reporting on patient safety and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event cause analysis, infection outbreak, culture of safety, or other patient safety topics) accounts for **at least 20% of the regular board agenda** and discussion time for senior governing board meetings.*
- *C-suite executives and individuals on the governing board are **notified within 3 business days** of any confirmed serious safety events resulting in significant morbidity, mortality, or other harm.*

Domain

1



Domain 2

Strategic Planning and Organization Policy



- Hospitals must leverage strategic planning and organizational policies to demonstrate a commitment to safety as a core value.
 - Written policies & protocols that demonstrate patient safety is a priority
 - Goals, metrics, & practices to advance progress
- Hospitals should acknowledge the ultimate goal of zero preventable harm.
 - Requires a continual process of improvement and commitment
- Patient safety and equity in care are inextricable, and therefore equity, with the goal of safety for all individuals, must be embedded in safety planning, goalsetting, policy, and processes.

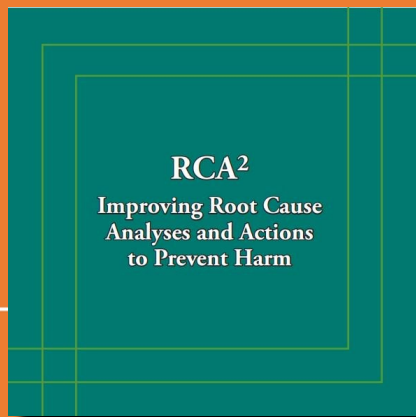


Strategic Planning and Organizational Policy

Domain

2

Attestations



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

Statement-Specific Guidance

- Patient safety curriculum & competencies (skills & behaviors) vary based upon role
- Training should be based on **validated, industry-standard competencies**
- Examples
 - Comprehensive-Unit-based-Safety-Program (CUSP)
 - AHRQ's CANDOR (Communication and Optimal Resolution) Toolkit
 - CDC's Infection Control Assessment & Response program & tool
 - IHI's Root Cause Analyses and Action (RCA2) resources
 - Etc.

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The use of written policies and protocols that demonstrate patient safety is a priority...

- *Our hospital has implemented **written policies and protocols** to cultivate a just culture that balances no-blame and appropriate accountability and reflects the distinction between human error, at risk behavior, and reckless behavior.*
- *Our hospital requires implementation of a patient safety curriculum and competencies **for all clinical and non-clinical hospital staff, including C-suite executives and individuals on the governing board**, regular assessments of these competencies for all roles, and action plans for advancing safety skills and behaviors.*



Domain

2



Many responsibilities you have, but not much time

Domain

3

Culture of Safety and Learning Health System



- Hospitals must utilize evidence-based practices and protocols that cultivate a **culture that prioritizes safety** & establishes a learning system both within and across hospitals.
 - Establish information flows to develop a proactive, hospital-wide approach to optimizing safety and eliminating preventable harm
- Hospitals must establish an integrated infrastructure (*people & systems working collaboratively*) and foster **psychological safety** among staff to effectively and reliably implement these practices.

Culture of Safety and Learning Health System



D. Our hospital implements a minimum of 4 of the following high reliability practices:

Domain

3

Attestations



Statement-Specific Guidance

- “High reliability practices” refer to activities that apply principles of high reliability organizations (HROs) – which achieve safety, quality and efficiency by applying 5 key principles.
- A “tiered & escalating huddle” system involves a series of brief focused conversations that rapidly identify & escalate safety, quality, and operational issues from a broad array of frontline staff to a focused group of senior leaders.
 - Outcomes align with organizational goals of patient safety & high reliability
 - Include rapid identification & resolution of safety issues and optimal employee engagement at all levels

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Hospitals must integrate a suite of evidence-based practices & protocols ...culture that prioritizes safety...

- Tiered and escalating... **safety huddles** at least 5 days a week, with 1 day being a weekend, that include key clinical and non-clinical units and leaders, with a method in place for follow-up on issues identified.
- Hospital leaders participate in monthly **rounding for safety** on all units, with C-suite executives rounding at least quarterly, with a method in place for follow up on issues identified.
- A data infrastructure to measure safety, based on patient safety evidence... **These data are shared with C-suite executives at least monthly, and the governing board at every regularly scheduled meeting.**



Scheduling & Holding
Accountable

Domain

3

Data Collection,
Working with Quality

Domain

4

Accountability and Transparency



- Accountability for outcomes, as well as transparency around safety events and performance, represent the cornerstones of a culture of safety.
- All involved (caregivers, leaders, patients, & families) can learn from safety events & prevent harm if:
 - There must exist a culture that promotes event reporting without fear or hesitation
 - Safety data collection & analysis with the free flow of information

Accountability and Transparency



Domain

4

Attestations



- B. Our hospital voluntarily works with a **Patient Safety Organization** listed by the Agency for Healthcare Research and Quality (AHRQ) to carry out patient safety activities as described in 42 CFR 3.20, such as, but not limited to, the collection and analysis of patient safety work product, dissemination of information such as best practices, encouraging a culture of safety, or activities related to the operation of a patient safety evaluation system.

Statement-Specific Guidance

- Patient Safety Organizations (PSOs) authorized by the Patient Safety & Quality Improvement act of 2005 (PSQIA) have been created to drive improvements in patient safety.
- Hospitals positively attesting to this statement are those working with an AHRQ-listed PSO.
 - These PSOs have been approved by AHRQ and provide the **confidentiality and privilege protections** of the PSQIA

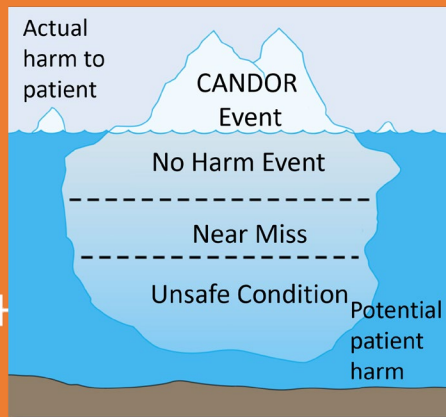
Accountability and Transparency



Domain

4

Attestations



- D. Our hospital has a defined, evidence-based communication and resolution program reliably implemented after harm events, such as AHRQ's Communication and Optimal Resolution (CANDOR) toolkit.

Statement-Specific Guidance

- Communication and Optimal Resolution (CANDOR) is a patient-centered process that hospitals can use to respond in a timely, thorough, and just way to unexpected events causing patient harm.
- CANDOR emphasizes early disclosure of adverse events and a proactive method to achieving amicable & fair resolution for patients, their families, & involved health care providers.
- AHRQ provides a CANDOR toolkit to assist hospitals in implementing these programs.

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The use of written policies and protocols that demonstrate patient safety is a priority . . .

- *Our hospital has a **confidential safety reporting system** that allows staff to report patient safety events, near misses, precursor events, unsafe conditions, and other concerns, and prompts a feedback loop to those who report.*
- *Patient safety metrics are **tracked and reported** to all clinical and non-clinical staff and made public in hospital units (for example, displayed on units so that staff, patients, families, and visitors can see).*
- *Our hospital uses standard measures to track the performance of our communication and resolution program and **reports these measures to the governing board at least quarterly.***



Feeds into Quality,
Safety, & Peer Review

4

Data Collection,
Organization, &
Communication

Domain 5

Patient and Family Engagement



- The effective and equitable engagement of patients, families, and caregivers is essential to safer, better care.
- Hospitals must embed patients, families, and caregivers as coproducers of safety and health through meaningful involvement in safety activities, quality improvement, and oversight.

Patient and Family Engagement



Domain

5

Attestations



- A. Our hospital has a Patient and Family Advisory Council that ensures patient, family, caregiver, and community input to safety related activities, including representation at board meetings, consultation on safety goal-setting and metrics, and participation in safety improvement initiatives.
- B. Our hospital's Patient and Family Advisory Council includes patients and caregivers of patients who are diverse and representative of the patient population.

Statement-Specific Guidance

- The Patient and Family Advisory Council should adequately represent the population of your specific hospital, in terms of age, race, ethnicity, and other social and demographic characteristics deemed important to health outcomes for your patient population.

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...embed patients, families, & caregivers... involvement in safety activities, quality improvement, & oversight.

- *Our hospital has a Patient and Family Advisory Council that ensures patient, family, caregiver, and community input to safety related activities, including representation at board meetings, consultation on safety goal-setting and metrics, and participation in safety improvement initiatives.*
- *Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via patient portals and other options, and the hospital provides support to help patients interpret information that is culturally and linguistically appropriate as well as submit comments for potential correction to their record.*



Domain

5



Part II

Eat Your Wheaties – The Heavy Lifting



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Patient Safety Structural Measure Responsibilities



- MSPs will be relied upon to ensure compliance with the PSSM.
- Degree of involvement will depend upon institutional size, resources, and culture.
- You will be using, and likely adding to, the “MSP Swiss Army Knife” set of tools.



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PSSM Responsibilities

- ***Closer*** integration with Quality Team, Peer Review, & Credentials Committee
- Information gathering, organization, & dissemination
- Holding people accountable – *e.g., C-Suite, Physician Leaders*
- Increased and closer interaction with quality team
- Minutes for a number of meetings will be very important (and subject to audit) – *including 20% of dedicated time with each Board meeting.*

MSPs will be at the center of the communication crossroads



Act like a traffic cop, not as a stop sign



Medical Staff Professionals

Patient Safety Structural Measure Responsibilities

- Get organized now
- Nail down flow of crucial information
- Timelines help with documentation
- Make use of technology when it makes sense (*AI scribing for meeting minutes*)
- Build a robust team, and plan for absences & departures
 - Quality Team
 - Patient Safety Team
 - Medical Staff Leaders
 - C-Suite Allies
 - Board members



Part III

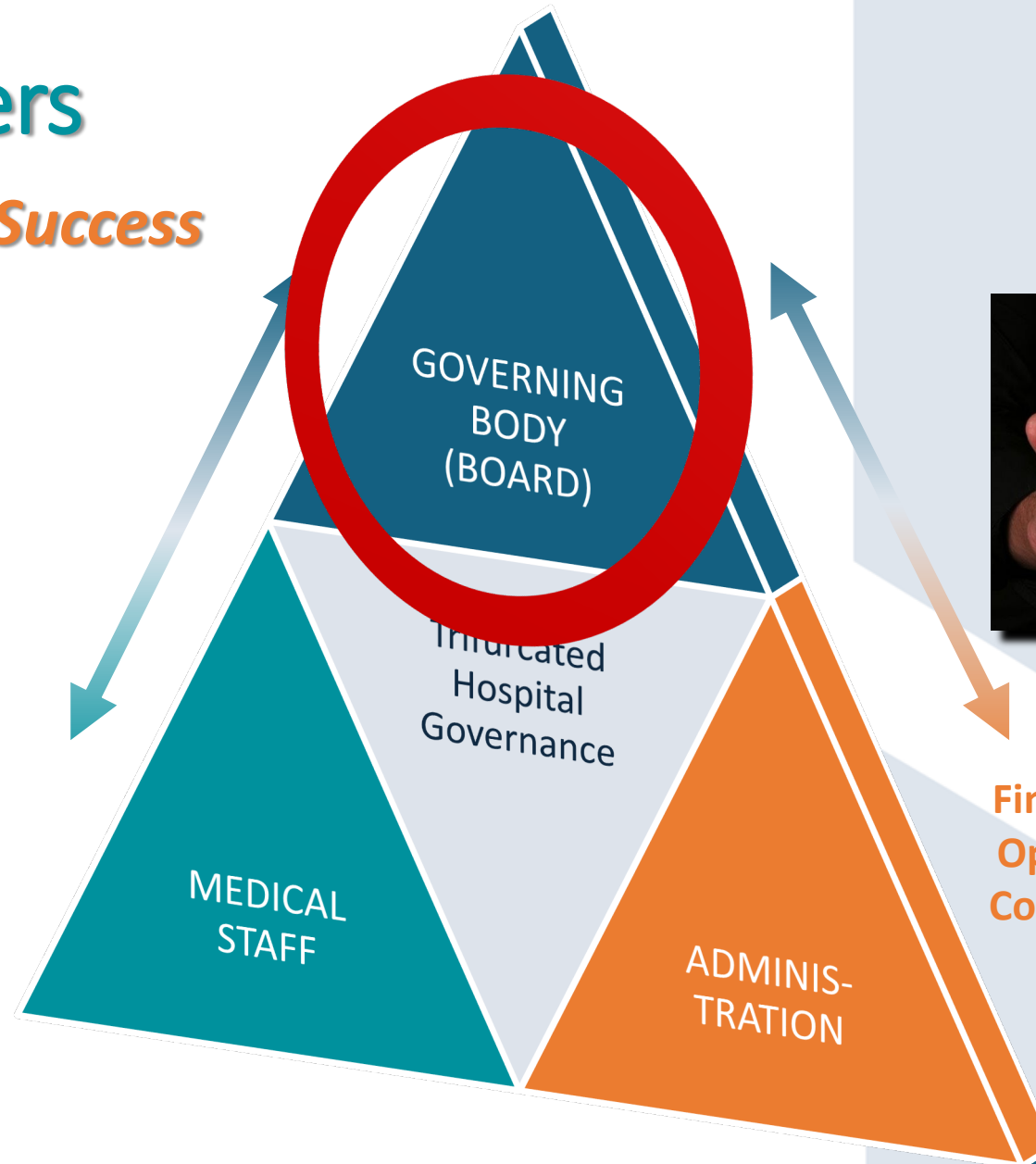
The Secret Sauce? Leveraging Physician Leader Engagement



Physician Leaders

Partners for PSSM Success

CMS Condition of Participation §482.22 - The hospital must have an organized medical staff ... *which is responsible for the quality of medical care provided to patients by the hospital.*



With competing priorities, patient safety can get lost in the shuffle



Financial Viability, Operations, Meet Community Needs



Physician Leaders

Partners for PSSM Success

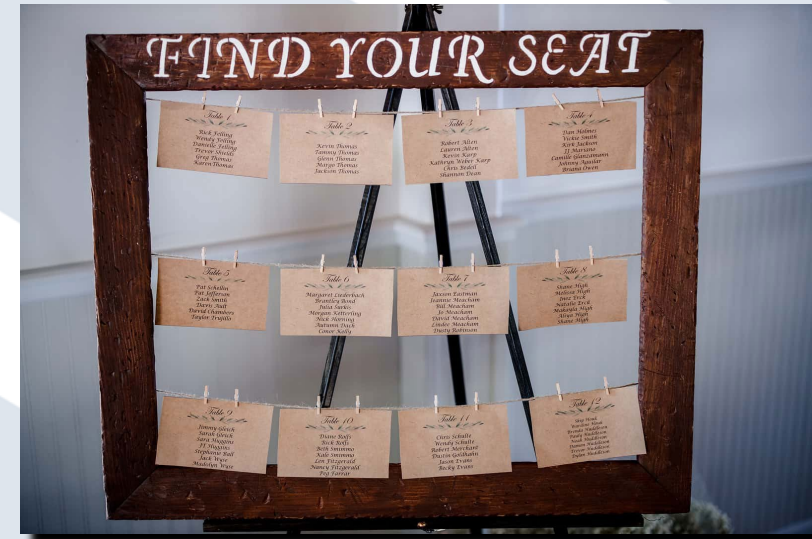
- Personal and professional interest in quality care delivery and patient safety
 - *As well as a regulatory requirement*
- Community ties
- Your best translators of clinical information for Board Members
 - *Most effective lobbyists for necessary changes*
- Institutional knowledge
 - *The “Whole (hi)story”*
 - *Average C-Suite member tenure...3-5 years?*



Physician Leaders

Partners for PSSM Success

- Encourage Board Member & Physician Leader interactions
 - *Establish dedicated time to meet and establish rapport*
 - *Ensure Physician Leader participation in Board retreat activities*
- Expand physician membership in your Hospital Board – ***they need a seat at the table***
- Specific physician-delivered quality metric discussions at all Board Meetings



Physician Leaders

Hospital Board Relationships



 Hardenbergh Group



Physician Leaders

“Suits to Scrubs” with
Administrative Team

“Take Your Board
Member to Work Day”





Part IV

Takeaways – AKA, Your To-Do List

Patient Safety Structural Measure



Preparation To-Dos

- Start talking
 - To each other
 - To Administrative Leaders
 - To Physician Leaders
 - To your Quality and Patient Safety Teams
- Engage with the Hospital Board – ***now is not too early***
- Make a plan and a timeline
 - Identify weaknesses, and bolster your strengths
- Lean on your available resources



Q & A

Roundtable Discussion



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Parkland Health and Hospital
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Mark Smith, MD, MBA, FACS
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**TALK IS CHEAP. GET
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Chris Thomson, MD, MBA, FACEP
Nicholas Testa, MD, FACEP

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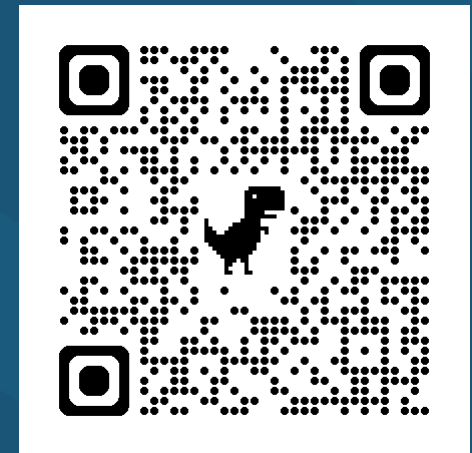
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Please reach out with additional questions.
Scan this QR code for a 15-minute
consultation with a Senior Consultant.



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Appendix

Domain Attestation Statements

Domain

1

Attestations

Leadership Commitment to Eliminating Preventable Harm

Attestation statements

- A. Our hospital senior governing board prioritizes safety as a core value, holds hospital leadership accountable for patient safety, and includes patient safety metrics to inform annual leadership performance reviews and compensation.
- B. Our hospital leaders, including C-suite executives, place patient safety as a core institutional value. One or more C-suite leaders oversee a system-wide assessment on safety and the execution of patient safety initiatives and operations, with specific improvement plans and metrics. These plans and metrics are widely shared across the hospital and governing board.
- C. Our hospital governing board, in collaboration with leadership, ensures adequate resources to support patient safety (such as equipment, training, systems, personnel, and technology).
- D. Reporting on patient safety and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event cause analysis, infection outbreak, culture of safety, or other patient safety topics) accounts for at least 20% of the regular board agenda and discussion time for senior governing board meetings.
- E. C-suite executives and individuals on the governing board are notified within 3 business days of any confirmed serious safety events resulting in significant morbidity, mortality, or other harm.

Domain

2

Attestations

Strategic Planning and Organizational Policy

Attestation statements

- A. Our hospital has a strategic plan that publicly shares its commitment to patient safety as a core value and outlines specific safety goals and associated metrics, including the goal of “zero preventable harm.”
- B. Our hospital safety goals include the use of metrics to identify and address disparities in safety outcomes based on the patient characteristics determined by the hospital to be most important to health care outcomes for the specific populations served.
- C. Our hospital has implemented written policies and protocols to cultivate a just culture that balances no-blame and appropriate accountability and reflects the distinction between human error, at risk behavior, and reckless behavior.
- D. Our hospital requires implementation of a patient safety curriculum and competencies for all clinical and non-clinical hospital staff, including C-suite executives and individuals on the governing board, regular assessments of these competencies for all roles, and action plans for advancing safety skills and behaviors.
- E. Our hospital has an action plan for workforce safety with improvement activities, metrics and trends that address issues such as slips/trips/falls prevention, safe patient handling, exposures, sharps injuries, violence prevention, fire/electrical safety, and psychological safety.

Domain

3

Attestations

Culture of Safety and Learning Health System

Attestation statements

- A. Our hospital conducts a hospital-wide culture of safety survey using a validated instrument annually, or every 2 years with pulse surveys on target units during non-survey years. Results are shared with the governing board and hospital staff and used to inform unit-based interventions to reduce harm.
- B. Our hospital has a dedicated team that conducts event analysis of serious safety events using an evidence-based approach, such as the National Patient Safety Foundation's Root Cause Analysis and Action (RCA2).
- C. Our hospital has a patient safety metrics dashboard and uses external benchmarks (such as CMS Star Ratings or other national databases) to monitor performance and inform improvement activities on safety events (such as: medication errors, surgical/procedural harm, falls, pressure injuries, diagnostic errors, and healthcare-associated infections).

Domain

3

Attestations

Culture of Safety and Learning Health System

D. Our hospital implements a minimum of 4 of the following high reliability practices:

- 1) Tiered and escalating (for example, unit, department, facility, system) safety huddles at least 5 days a week, with 1 day being a weekend, that include key clinical and non-clinical (for example, lab, housekeeping, security) units and leaders, with a method in place for follow-up on issues identified.
- 2) Hospital leaders participate in monthly rounding for safety on all units, with C-Suite executives rounding at least quarterly, with a method in place for followup on issues identified.
- 3) A data infrastructure to measure safety, based on patient safety evidence (for example, systematic reviews, national guidelines) and data from the electronic medical record that enables identification and tracking of serious safety events and precursor events. These data are shared with C-suite executives at least monthly, and the governing board at every regularly scheduled meeting.
- 4) Technologies, including a computerized physician order entry system and a barcode medication administration system, that promote safety and standardization of care using evidence-based practices.
- 5) The use of a defined improvement method (or hybrid of proven methods), such as Lean, Six Sigma, Plan-Do-Study-Act, and/or high reliability frameworks.
- 6) Team communication and collaboration training of all staff.
- 7) The use of human factors engineering principles in selection and design of devices, equipment, and processes.

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

Domain

4

Attestations

Accountability and Transparency

Attestation statements

- A. Our hospital has a confidential safety reporting system that allows staff to report patient safety events, near misses, precursor events, unsafe conditions, and other concerns, and prompts a feedback loop to those who report.
- B. Our hospital voluntarily works with a **Patient Safety Organization** listed by the Agency for Healthcare Research and Quality (AHRQ) to carry out patient safety activities as described in 42 CFR 3.20, such as, but not limited to, the collection and analysis of patient safety work product, dissemination of information such as best practices, encouraging a culture of safety, or activities related to the operation of a patient safety evaluation system.
- C. Patient safety metrics are tracked and reported to all clinical and non-clinical staff and made public in hospital units (for example, displayed on units so that staff, patients, families, and visitors can see).

Domain

4

Attestations

Accountability and Transparency

- D. Our hospital has a defined, evidence-based communication and resolution program reliably implemented after harm events, such as AHRQ's Communication and Optimal Resolution (CANDOR) toolkit, that contains the following elements:
 - 1) Harm event identification
 - 2) Open and ongoing communication with patients and families about the harm event
 - 3) Event investigation, prevention, and learning
 - 4) Care-for-the-caregiver
 - 5) Financial and non-financial reconciliation
 - 6) Patient/family engagement and on-going support
- E. Our hospital uses standard measures to track the performance of our communication and resolution program and reports these measures to the governing board at least quarterly

Domain

5

Attestations

Patient and Family Engagement

Attestation statements

- A. Our hospital has a Patient and Family Advisory Council that ensures patient, family, caregiver, and community input to safety related activities, including representation at board meetings, consultation on safety goal-setting and metrics, and participation in safety improvement initiatives.
- B. Our hospital's Patient and Family Advisory Council includes patients and caregivers of patients who are diverse and representative of the patient population.
- C. Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via patient portals and other options, and the hospital provides support to help patients interpret information that is culturally and linguistically appropriate as well as submit comments for potential correction to their record.
- D. Our hospital incorporates patient and caregiver input about patient safety events or issues (such as patient submission of safety events, safety signals from patient complaints or other patient safety experience data, patient reports of discrimination).
- E. Our hospital supports the presence of family and other designated persons (as defined by the patient) as essential members of a safe care team and encourages engagement in activities such as bedside rounding and shift reporting, discharge planning, and visitation 24 hours a day, as feasible.