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# Module H. Risk Management 101

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# Objectives

1. Discuss event reporting processes and structures
2. Discuss reporting culture
3. Define patient safety work product and structures that provide confidentiality
4. Define complaints versus grievances and understand the regulatory requirements for grievance process
5. Define claim types and discuss strategies to handle claims
6. Discuss how to conduct annual risk assessment and identify risk assessment tools
7. Discuss record retention recommendations

# Event Reporting

Intent: mechanism for sharing events from the perspective of those experiencing them in order to facilitate reflection and process improvement

Goals:

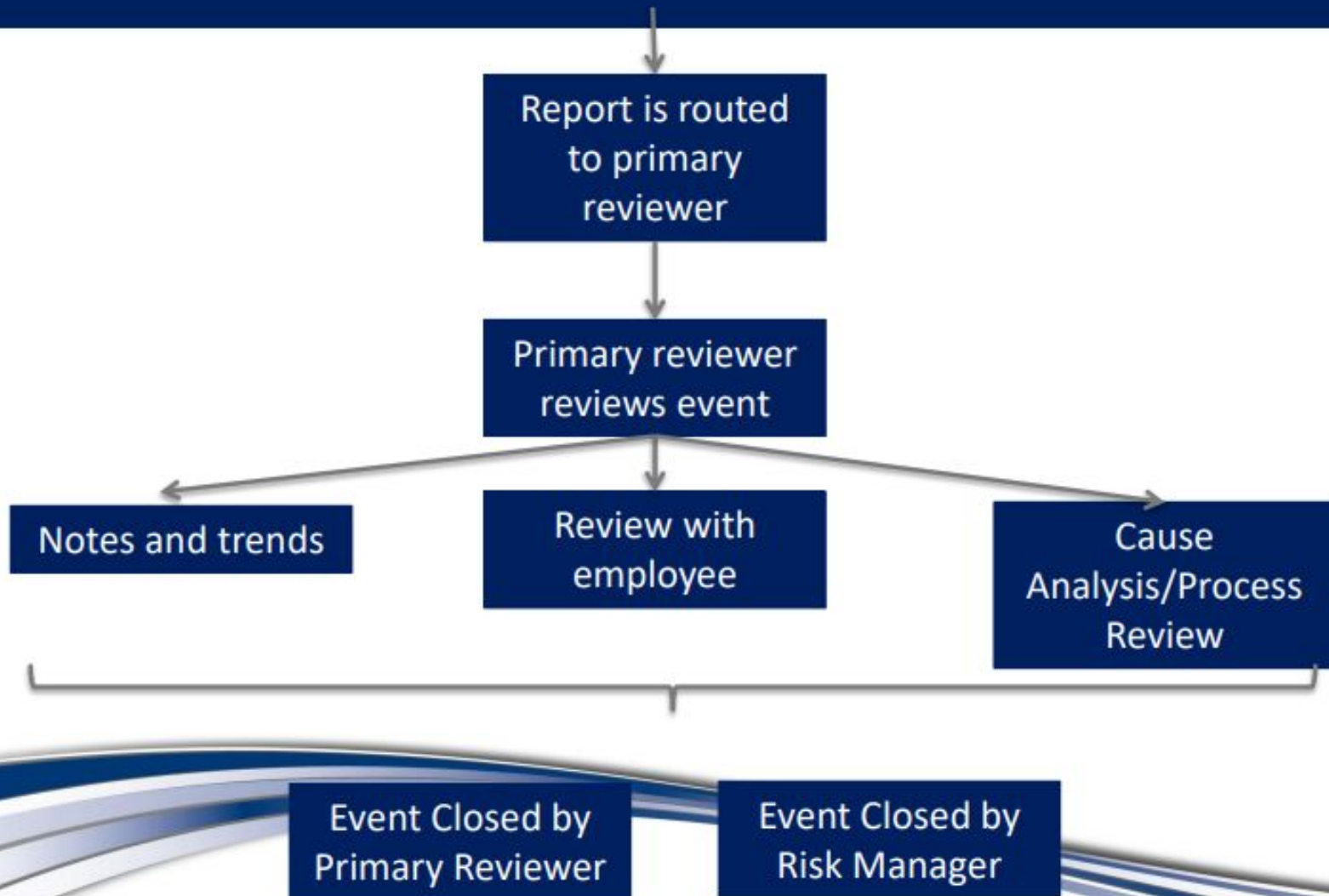
- Easy to use
- Data-driven
- Championed by leaders

**Reporting is essential to identification and resolution of safety issues and to promoting a healthy culture of safety!**

# Keys for Success

- Non-punitive
- Confidential/Protected
- Actioned
- Form follows function—can be formal or informal, the system houses the data, the program promotes reporting

# Example of Reporting Workflow



# What's in a review?

- Confirms details of event or adds pertinent information
- Identifies if the event diverged from expectations and if so, WHY and HOW with a focus on process and system
- Indicates action taken in response

# Where to share?

- Daily safety huddles
- Quality committee
- Process Improvement Committees
- Individual cause analysis
- Board reports

# How to share?

- Focus on the data, deidentified and aggregate is best
- Never use names when sharing publicly
- Encourage reporter to use roles vs names when reporting
- Always about the process/system



# Non-punitive vs Accountability

## Just Culture Approach

- Console
- Coach
- Discipline

(Marx/Outcome Ingenuity)

# Protecting Patient Safety Work

Patient Safety & Quality Improvement Act  
(2005)

Patient Safety Rule (2008)

Nebraska Patient Safety Improvement Act (2005)

# Protecting Patient Safety Work

The Intent: provide a system for providers to share patient safety work, without fear of liability, for the goal of improving patient care and safety

- **Disclosure:** the act of releasing, transferring, providing access to or otherwise divulging patient safety work to another legally separate entity or person EXCLUDING, an affiliated PSO, provider on the medical staff
- **Patient Safety Evaluation System (PSES):** collection, management or analysis of information for reporting to or by a PSO
- **Patient Safety Work Product (PSWP):** developed for reporting to a PSO, developed by a PSO, analysis of PSES

# Confidentiality in the Wild

- Can you share PSWP with a private provider affiliated with your facility?
- Should you place copies of patient safety reports into files such as HR or medical staff files?
- Can you share the results of an RCA with another hospital or with a clinic practice?
- Can you share PSWP with state surveyors?
- Should you email event reports or RCA documents?

# Patient Rights: Grievances

The CMS Conditions of Participation state that patients have the right to file a grievance without fear of retaliation from the healthcare provider.

- Hospitals must have a grievance process and inform patients of how to use that process
- Report grievances to governing board OR a grievance committee

# What is considered a grievance?

- **CMS definition:** written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by staff present) by a patient or the patient's representative regarding the patient's care, abuse or neglect, issues related to the hospital's compliance with the CMS hospital CoP, or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 C.F.R. § 489, or issues related to compliance with Nondiscrimination in Health Programs and Activities regulations at 45 CFR Part 92.

**In other words...**

- Verbal complaint **when the verbal complaint about patient care is not resolved at the time of the complaint by staff present**
  - Any written complaint, including patient experience feedback if the patient requests a response or if the hospital would normally treat the content as a grievance
    - Any complaint about abuse or neglect
    - Any complaint about discrimination
    - Any complaint about privacy/HIPAA

# What is not a grievance?

- **Verbal complaint that can be resolved** to the patient's satisfaction at the time of the complaint by the staff present
- **Any complaint concerning billing** is not a patient grievance unless the complaint is related to rights and limitations provided by 42 C.F.R. § 489, or discrimination under 45 CFR Part 92. *Does the billing complaint contain a quality of care or other covered concern?*
- **Complaints about durable medical equipment** dispensed by the hospital. *There is a separate process for this with a 14 day response timeframe.*
- **Discussions or other interactions between a patient and hospital care staff, medical staff, or ancillary care providers** concerning treatment methods, protocols, alternatives, care plan development, and other specifics which may form the basis for informed consent and the patient's exercise of his/her rights of self-determination are not patient grievances.

# What is required?

- **Notify** patients of their right to file a grievance
- When a grievance is received:
  - Send the patient an initial letter acknowledging receipt of the grievance, explaining the process and letting them know when they will receive feedback **within 7 days**
  - Conduct an investigation
  - Document findings and follow up actions, if indicated
  - Send the patient a final written response **within 30-45 days**
  - Maintain a log of grievances

**A best practice is for Risk to review grievances and responses**



# Investigation

- -Interview involved staff, as indicated
- -Review relevant documentation
- -Identify and act upon opportunities for improvement, document these
  
- **\*\*Your investigation documentation may (and should) go beyond what you might disclose to the patient in a response.\*\***

# Response Letter

- The response letter **must** contain:
  - The name of the hospital contact person
  - The steps taken on behalf of the patient to investigate the grievance
  - The results of the grievance process, and the date of completion.
  
- The hospital is **not** required to:
  - Include information that could be used against the hospital in a legal action
  - Provide exhaustive explanation of every action taken to investigate and resolve the grievance

# Section 1557: Discrimination

**1557 Complaints:** complaints alleging discrimination due to race, color, national origin, sex, age, or disability

- Designate a 1557 Coordinator to keep a specific log of 1557 complaints
- Include required due process information with the final response
- Follow the appeal process, if activated by the patient

# Dos and Don'ts

- **DO**
- Listen to the patient. Most people just want to feel heard.
- Express regret that we did not meet the patient's expectations
- Ensure that the timelines are always met
  
- **DON'T**
- Redirect or "argue" with the patient's perceptions
- Admit fault or liability
- Offer compensation without first reviewing with carrier or claims support

Complete	Patient Name	Encounter Number	Date of Admission	Date Received	Response Due Date	Date of Final Response	Timely per Policy	If no, why?	Responsible Leader	Service Area	Provider Named	Requested billing adjustment?	Referred for claim?	Administrative adjustment made?	Concerns as stated by patient/family	Received from: pt, family, social media, other	If other, indicate source	Behavior/Customer Service- Staff	Behavior/Customer Service- Behavior/Customer Service-	Quality of Care- Staff	Quality of Care- Provider	Communication	Environmental	Billing	HIP AA/Privacy	Other
#																										

# Claim Management

- Types of Claims
- Claim Investigation 101
- Strategies for intake and management of claims

This does not constitute formal claim handling advice. Participants are encouraged to see specific advice from insurance carrier or claim support.

# Common Types of Claims

- Medical Malpractice aka Professional Liability
- General Liability (property, bodily injury)
- Auto
- Privacy/Cyber
- Administrative Proceeding
- Small Claims

# Claim Investigation

## Investigate early and often!

### Claim File Checklist:

- Copy of medical record
- Copy of billing record
- Staffing sheets
- Interview notes
- Timeline
- Device Information
- List of pertinent witnesses
- Other evidence
- Surveillance Video
- Witness Statements
- Photographic Evidence
- Maintenance records



# Claim Management Strategies

- COMMUNICATION IS KEY
- Be a listener, pace the response
- Know the basics of your policy coverage and how it applies OR know who your experts are

# Disclosure

Disclosure is communication with patients and families about unanticipated outcomes or errors.

- Regulatory requirement
- Decreases claim potential
- Right thing to do

Who should disclose? Provider and/or hospital representative

When should disclosure occur? ASAP and ongoing

Apologies are ok!

# Record Retention

## How determined:

- Statutory
- Facility Policy
- Statue of Limitations
- Litigation Hold

## Key considerations:

- Medical Records: 10 years or patient age 21 + 10 years
- Malpractice Statute of Limitations: 2 years\*\*
- General Liability Statute of Limitations: 3 years

## Recommendations:

- Risk Files: 5 years or 3 years post closure
- Abuse records: 10 years or patient age 21 + 10 years
- Case Investigations: same as medical records

# FMEA

## Failure Mode Effects Analysis

- Proactive instead of reactive
- Process examination
- Detectability / Criticality = Prioritize the Response

What makes for a good FMEA?

# Discussion/Questions

# References/Resources

- Patient Safety Statute and Rule:  
<https://www.hhs.gov/hipaa/for-professionals/patient-safety/statute-and-rule/index.html>
- Just Culture: <https://outcome-eng.com/>
- Grievance Regulation: <https://www.law.cornell.edu/cfr/text/42/482.13>
- Candor Program: <https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html>
- NE Apology Act: <https://nebraskalegislature.gov/laws/statutes.php?statute=27-1201>
- VA FMEA Resources: <https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp>