Corrective Action Plans and How to Mitigate Future Events

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Junior Mints
TOPICS TO BE COVERED

- Purpose
- What is an “adverse incident”?
- Do I have to report it?
- What is a Corrective Action Plan?
- Examples
- Mitigating Future Events
- Dealing with Problem Employees
- Questions?
WHY ARE WE DISCUSSING THIS?

- Florida law *requires* ASCs:
  - **Establish** internal risk management program;
  - **Investigate and analyze** the frequency and causes of adverse incidents; and
  - **Develop** appropriate measures to minimize the risks.

STEPS FOR INVESTIGATING

- **Plan ahead:**
  - Fla. Stat. § 395.0197(1)(d) requires you have a system for informing a patient that “was subject” to an adverse incident.
  - Take patient grievances seriously
  - An Incident Reporting System is required by statute.

- **Keep a dedicated record of patient grievances**
  - Don’t be afraid to notify your attorney
WHAT ARE “APPROPRIATE MEASURES TO MINIMIZE RISK”?

- Training:
  - Including non-physician personnel
  - Example: “Lunch n’ Learns”
  - Requires you to:
    - Develop, implement, and continually evaluate procedures, protocols, and systems to accurately identify patients, procedures, and correct sites of procedures to minimize risk.

WHAT ARE “APPROPRIATE MEASURES TO MINIMIZE RISK”?

- Does our in-house investigative plan:
  - Establish the incident categories?
  - Address incidents specific to our facility?
  - Are we continually updating?
  - Are we identifying incident trends?
- Take notice of training procedures from larger facilities.
- Example:
  - Florida Hospital: Preventing Medical Errors
What are “appropriate measures to minimize risk”?

An adverse incident is “an event over which the health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred” Fla. Stat. § 395.0197(7)

What did you say?
WHAT IS AN AI?

- Basically...It's an incident that occurs during care; not what caused the need for care.
- And the incident results in one of the following:
WHAT IS AN AI?

- Death;
- Brain or spinal damage;
- Permanent disfigurement;
- Fracture or dislocation of bones or joints;
- Limitation of neurological, physical, or sensory function;
- Any condition that required specialized medical attention or surgical intervention; or
- Any condition that required the transfer of the patient, to a unit providing a more acute level of care.

OTHER TRIGGERING EVENTS...

- Surgical procedure that occurred on the wrong patient, wrong surgical procedure, wrong-site surgical procedure, or unrelated surgical procedure;
- An incident requiring surgical repair of damage resulting from a planned surgical procedure; or
- A procedure to remove unplanned foreign objects.
AM I REQUIRED TO REPORT AN ADVERSE INCIDENT?

- Yes. Fla. Stat. § 395.0197(6)
  - Not all require immediate reporting.
- Fla. Stat. § 395.0197(7)
  - ASCs have 15 days to report adverse incidents.
  - Florida AHCA may grant extensions, if submitted in writing by the facility administrator.
- NOT EVERY INCIDENT NEEDS TO BE REPORTED

WHAT INCIDENT REQUIRE IMMEDIATE REPORTING?

- The following must be reported with 15 calendar days after occurrence:
  - Death
  - Brain/Spinal Damage (including “temporary conditions”)*
  - Surgery on wrong patient
  - Wrong-site surgery
  - Wrong procedure
  - Performance of unnecessary surgical procedure
  - Surgical repair or damage resulting from a planned procedure (if the damage was not recognized as a specific risk)
  - Surgical procedures to remove unplanned foreign objects

WHAT HAPPENS IF WE DON’T REPORT?

- Administrative Fines
- Civil Liability (Malpractice Action)
  - Potential for punitive damages and/or loss of insurance coverage
- AHCA has the authority to report incidents or conduct to your individual licensing board. (i.e. board of medicine)
- Individual civil fines apply for coercing, intimidating, or precluding a risk manager from lawfully executing their reporting obligations.
- Adverse Public Relations
**BENEFITS OF FLA. STAT. § 395.0197**

- Risk managers are immune from liability for implementing and overseeing internal risk management. *Fla. Stat.* § 395.0197(16).
- Statute provides the reports are privileged, absent bad faith or malice. *Fla. Stat.* § 395.0197(17).
- The annual reports are confidential, not discoverable in any civil or admin action, and not subject to public records requests. *Fla. Stat.* § 395.0197(6)(c).

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**WHEN NOT TO REPORT?**

- Not every incident needs to be reported.
- **Step #1:**
  - Contact your attorney!
- **Step #2**
  - Make sure you did step #1...
When Not to Report?

- Example:
  - A physician at an ASC reported discovering a broken instrument following a procedure.
  - Performs several endo-venous laser ablation procedures each day.
  - ELA is an advanced vein treatment using a micro-puncture and a specially designed cannula—guided by ultrasound—to heat the vein from inside.
  - Procedure uses an anesthesia cannula (originally designed for liposuction) to prep the vein.

Example

- Physician reported discovering—after a procedure—that one of the anesthesia cannulas appeared to be missing approximately 1cm of the tip.
  - It was presumed that the missing piece was logged in a patient, but the identity of that patient was not known.
  - Report or Not to Report...That is the [legal] question?
WHEN NOT TO REPORT?

- Not to report...not yet.
- Why?
  - Identity of the patient was not known;
  - Date of the incident was not known;
  - No hard evidence of an injury or adverse effect; and
  - Would need more information to even report the incident

HOW WE ADDRESSED THE ISSUE:

- Immediate patient contact;
- Re-examinations, including x-rays;
- Locate patients and/or rule out presumption; and
- Re-evaluate reporting.

Conclusion:

- Cannula was broken during sterilization and handling rather than the procedure.
WHAT NOT TO DO...

- Procrastinate on your planning; the importance of preventative care applies.
- Neglecting your written policies and procedures
- Ignore; never ignore an AI report
- Wait and see approach
- Attempt to handle internally
- Deny the possibility
- Instead:
  - Plan ahead
  - Contact your carrier
  - Cooperate with your attorney

AHCA Compliance Findings: 2013/2014

Some facilities did not submit reports within the statutory timeframes (see Table 2).

<table>
<thead>
<tr>
<th>Facility Report Type</th>
<th>Number of Reports</th>
<th>Percent in Compliance</th>
<th>Percent Late</th>
<th>Percent More than 10 days late</th>
<th>Average Number of Days from Incident to Submission to AHCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital ASC 1-day</td>
<td>46</td>
<td>72%</td>
<td>28%</td>
<td>17%</td>
<td>20 days</td>
</tr>
<tr>
<td>ALF 1-day</td>
<td>78</td>
<td>45%</td>
<td>55%</td>
<td>11%</td>
<td>5 days</td>
</tr>
<tr>
<td>ALF 3-day</td>
<td>54</td>
<td>57%</td>
<td>43%</td>
<td>33%</td>
<td>22 days</td>
</tr>
<tr>
<td>NRE 15-day</td>
<td>73</td>
<td>94%</td>
<td>6%</td>
<td>1%</td>
<td>11 days</td>
</tr>
</tbody>
</table>

Note: Data report includes only those reports with completed incident data and report submitted to AHCA.

For hospital and ASC reports, 72% were submitted in compliance with Chapter 395, F.S which includes five facilities that requested extensions while 28% were filed after the deadline of 15 days. RPMs did not take any action against the facilities that filed late.
DO I HAVE OTHER REPORTING REQUIREMENTS?

- Yes, AHCA has an annual reporting requirement:
  - Must summarize incident reports that have been filed in the facility, and include:
    - Number of AIs;
    - Listed by category;
    - Code number of licensed professional(s) involved;
    - A description of all malpractice claims filed against the facility (including pending and closed claims); and
    - A copy of the policies and procedures in place which govern the measures taken by the facility and risk manager.
DO I HAVE OTHER REPORTING REQUIREMENTS?

- Maybe more...
  - Medical device failures have separate reporting requirements to the FDA; Medical Device Reporting ("MDR")
  - Regulated by 21 CFR 803 – Provides mandatory requirements for manufacturers, importers, and device user facilities.
  - MDR “reportable event” for a device user facility is an event that the user facility became aware of that reasonably suggests that a device has or may have caused or contributed to death or serious injury.
  - "Serious injury" defined as either life-threatening, results in permanent impairment of body function or damage to structure, necessitates medical or surgical intervention to preclude permanent impairment. 21 CFR 803.3.
HOW TO REPORT AN AI?

WHAT HAPPENS AFTER?
WHAT HAPPENS AFTER?

- AHCA investigation may include:
  - Request for records/policies/procedures;
  - Evaluate statutory compliance;
  - Conduct interviews;
  - Unexpected inspections.
- AHCA may impose penalties, fines, and/or seek a written corrective action plan (CAP).
- Remember: AHCA has broad authority.

WHAT IS A CORRECTIVE ACTION PLAN?

- Step-by-step plan of action to prevent identified errors in responding to adverse incidents.
WHAT DOES THE CAP COVER?

- For single or isolated incidents, AHCA must first week to obtain a corrective action plan before penalties
- The extent of the CAP will depend on the AI and the facility’s history
- CAP may cover:
  - Policy or Procedure changes;
  - Report licensed employees to regulatory boards;
  - Provide time frames/deadlines for corrective actions
**STEPS TO A SUCCESSFUL CAP**

- Preemptive measures
- Maintain documentation
- Identify errors and deficiencies carefully from AHCA findings
- Brainstorm corrective actions for each error
- Have a plan for implementing corrective actions
- Continually evaluate and monitor progress
- Document your efforts

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**CAPs gone wrong...**

State Agency Fines Calhoun Liberty Hospital $45,000 in Barbara Dawson Case

Associated Press/FLP – Feb 17, 2010

TALLAHASSEE, Fla. (AP) - Florida's health care agency has issued a $45,000 fine to the hospital where a woman died after being forcibly removed.

In a 20-page document issued Wednesday, the Agency for Health Care Administration files five counts against Calhoun Liberty Hospital—three related to access to emergency care and services and two counts of failure to evaluate a patient's grievance.
Mitigating future events:

- Plan Ahead
- Review the requirements of Fla. Stat. § 395.0197
- Regular Training
  - Take notice of training procedures from larger facilities.
- Take patient grievances seriously
  - Incident Reporting System
  - Keep a dedicated record of patient grievances
- Document, Document, Document
- Don’t be afraid to consult your attorney

Handling the problem

Employee:
Appealing Agency Action...

- Can we legally appeal Agency action?
  - Yes (But...)

- State agencies are entitled to interpret law and the Courts must be "highly deferential" to an agencies interpretation. See e.g. Verizon Florida, Inc. v. Jacobs, 810 So.2d 906, 908 (Fla. 2002); Florida Hosp. v. Agency for Health Care Admin., 823 So. 2d 844, 847 (Fla. 1st DCA 2002).

Handling the Problem Employee:

- AHCA is required to report AI incidents involving licensed personnel to the appropriate regulatory board.
- Adverse Incidents often result in employee discipline, even discharge.
- Employee discipline/discharge presents its own legal considerations.
HANDLING THE PROBLEM
EMPLOYEE:

- Things to consider before taking action against employees:
  - Don’t act emotionally
  - Consider suspension before taking any permanent action
  - Wait for the AHCA investigation
  - Do you have HR procedures to address this?
  - Is additional training an option?
  - How will this effect employee moral?
  - DOCUMENT THE PROCESS

CONCLUSION

- Purpose
- What is an “adverse incident”?
- Do I have to report it?
- How/When to report
- What is a Corrective Action Plan?
- Mitigating Future Events
- Handling Problem Employees
- Examples
QUESTIONS?

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