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"
- Fla. Stat. § 395.0197(1)(b)(4):
  - 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 tends?
- Take notice of training procedures from larger facilities.
- Example:
  - Florida Hospital: Preventing Medical Errors
  - https://www.floridahospital.com/sites/default/files/campuses/mmc/preventing_med_errors_9-13-13.pdf

WHAT ARE "APPROPRIATE MEASURES TO MINIMIZE RISK"?

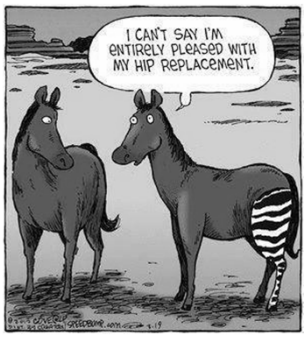
WHAT IS AN AI?

- 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?

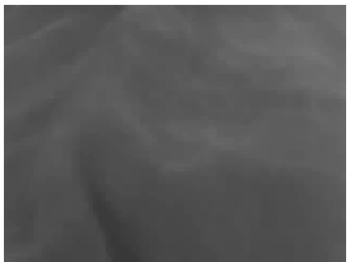
"Off hand, I'd say you're suffering from an arrow through your head, but just to play it safe, I'm ordering a bunch of tests."

WHAT IS AN AI?

- Basically…It's an incident that occurs during care; not what caused the need for care.
- <u>And</u> 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.

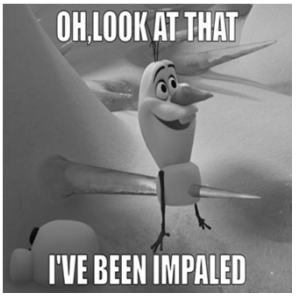
Am I required to report an adverse Incident?

- 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

*Florida Hosp. v. Agency for Health Care Admin., 823 So. 2d 844, 849 (Fla. 1st DCA 2002).



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

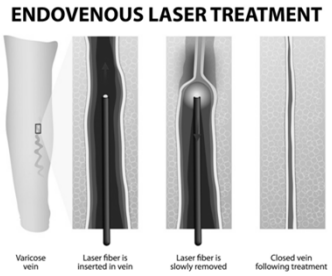
- Risk managers are immune from liability for implementing and overseeing internal risk management. Fla. Stat. § 395.0197(16).
- Statute provides the reports are privileged, absent bad faith or malice. Fla. Stat. § 395.0197(17).
- The annual reports are confidential, not discoverable in any civil or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

When not to report?

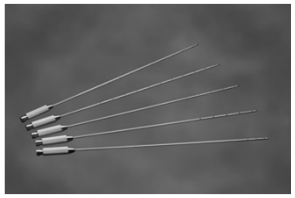
- Not every incident needs to be report
- Step #1:
  - Contact your attorn
- Step #2
  - Make sure you did step #1…

When not to report?

- Example:
  - A physician 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



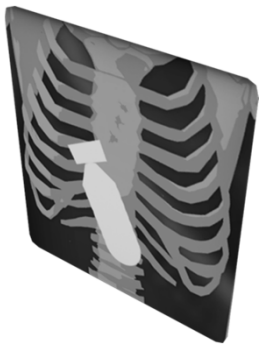
- Physician reported discovering—after a procedure—that one of the anesthesia cannulas appeared to be missing approximately 1cm of the tip.
- It was presumed that the missing piece was logged in a patient, but the identity of that patient was not known.
- **Report or Not to Report…That is the [legal]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

When not to report?

- 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 you 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 2: Compliance Rates Among Facility Types

Facility Report Type	Number of Reports	Percent in Compliance	Percent Late	Percent More than 10 days late	Average Number of Days from Incident to Submission to RMPS
Hospital/ ASC 15-day	46	72%	28%	17%	25 days[3]
ALF 1-day	76	45%	55%	11%	5 days
ALF 15-day	54	57%	43%	13%	22 days
NH 15-day	73	84%	16%	1%	11 days

Note: Our sample consisted of all hospital/ASC, and ALF reports filed in July 2012 and all NH reports of incidents in December 2012. There were no HMO reports filed in our selected time period.

For hospital and ASC reports, 72% were submitted in compliance with Chapter 395, F.S which includes five facilities that requested extensions[4] while 28% were filed after the required deadline of 15 days. RMPS did not take any action against the facilities that filed late.

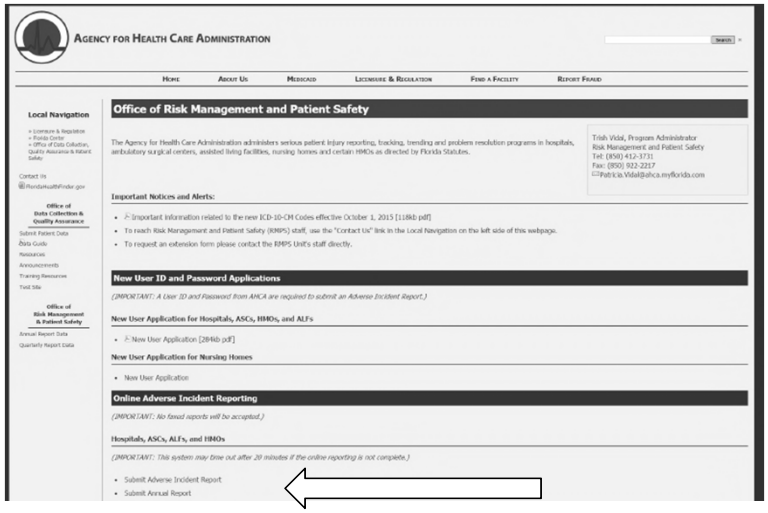
DO I HAVE OTHER REPORTING REQUIREMENTS?

- 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?



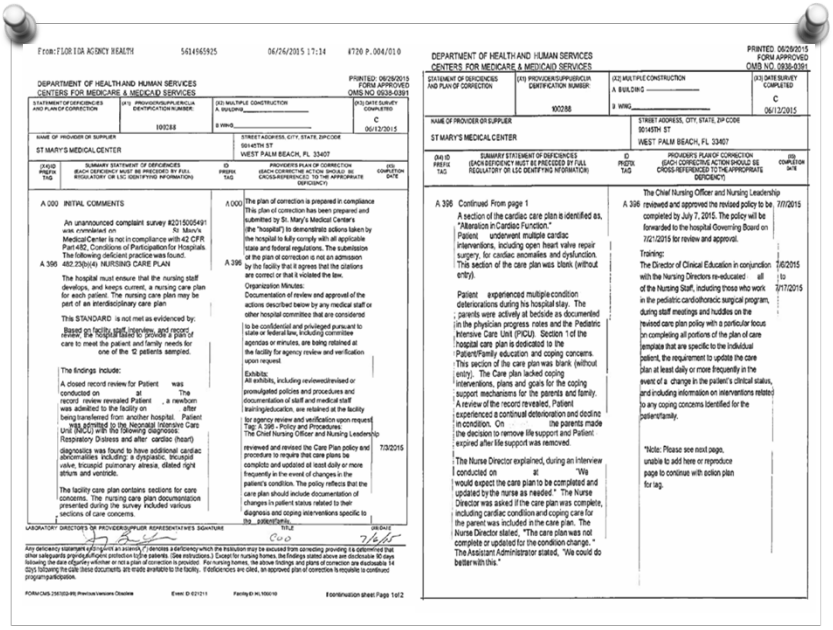
What happens after?

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.



From:FLORIDA AGENCY HEALTH 5614665925 06/26/2015 17:14 #720 P.004/010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 06/26/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	100288	A. BUILDING _____ B. WING _____	C 06/12/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST MARY'S MEDICAL CENTER	901 45TH ST WEST PALM BEACH, FL 33407

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS An unannounced complaint survey #2015005491 was completed on [illegible]. MedicalCenter is not in compliance with 42 CFR Part 482, Conditions of Participation for Hospitals. The following deficient practice was found. 482.23(b)(4) NURSING CARE PLAN	A 000	The plan of correction is prepared in compliance This plan of correction has been prepared and submitted by St. Mary's Medical Center's (the "hospital") to demonstrate actions taken by the hospital to fully comply with all applicable state and federal regulations. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.	
A 396	The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan This STANDARD is not met as evidenced by: Based on facility staff interview, and record review, the hospital failed to provide a plan of care to meet the patient and family needs for one of the 12 patients sampled. The findings include: A closed record review for Patient was conducted on at The record review revealed Patient , a newborn was admitted to the facility on after being transferred from another hospital. Patient was admitted to the Neonatal Intensive Care Unit (NICU) with the following diagnosis: Respiratory Distress and after cardiac (heart) diagnostics was found to have additional cardiac abnormalities including: a dysplastic, tricuspid valve, tricuspid pulmonary atresia, dilated right atrium and ventricle. The facility care plan contains sections for care concerns. The nursing care plan documentation presented during the survey included various sections of care concerns.	A 396	Organization Minutes: Documentation of review and approval of the actions described below by any medical staff or other hospital committee that are considered to be confidential and privileged pursuant to state or federal law, including committee agendas or minutes, are being retained at the facility for agency review and verification upon request. Exhibits: All exhibits, including reviewed/revised or promulgated policies and procedures and documentation of staff and medical staff training/education, are retained at the facility for agency review and verification upon request. Tag: A 396 - Policy and Procedures: The Chief Nursing Officer and Nursing Leadership reviewed and revised the Care Plan policy and procedure to require that care plans be complete and updated at least daily or more frequently in the event of changes in the patient's condition. The policy reflects that the care plan should include documentation of changes in patient status related to their diagnosis and coping interventions specific to the patient/family.	7/3/2015

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE COO (6) DATE 7/6/15

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide adequate protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

FORM CMS-2567(02-99) Previous Versions Obsolete Event ID: E21211 Facility ID: FL150018 If continuation sheet Page 1 of 2

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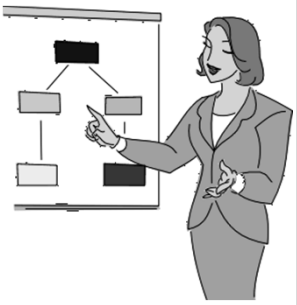
A 396	Continued From page 1 A section of the cardiac care plan is identified as, "Alteration in Cardiac Function." Patient underwent multiple cardiac interventions, including open heart valve repair surgery, for cardiac anomalies and dysfunction. This section of the care plan was blank (without entry). Patient experienced multiple condition deteriorations during his hospital stay. The parents were actively at bedside as documented in the physician progress notes and the Pediatric Intensive Care Unit (PICU). Section 1 of the hospital care plan is dedicated to the Patient/Family education and coping concerns. This section of the care plan was blank (without entry). The Care plan lacked coping interventions, plans and goals for the coping support mechanisms for the parents and family. A review of the record revealed, Patient experienced a continual deterioration and decline in condition. On the parents made the decision to remove life support and Patient expired after life support was removed. The Nurse Director explained, during an interview conducted on at "We would expect the care plan to be completed and updated by the nurse as needed." The Nurse Director was asked if the care plan was complete, including cardiac condition and coping care for the parent was included in the care plan. The Nurse Director stated, "The care plan was not complete or updated for the condition change." The Assistant Administrator stated, "We could do better with this."	A 396	The Chief Nursing Officer and Nursing Leadership reviewed and approved the revised policy to be completed by July 7, 2015. The policy will be forwarded to the hospital Governing Board on 7/21/2015 for review and approval. Training: The Director of Clinical Education in conjunction with the Nursing Directors re-educated all of the Nursing Staff, including those who work in the pediatric cardiothoracic surgical program, during staff meetings and huddles on the revised care plan policy with a particular focus on completing all portions of the plan of care template that are specific to the individual patient, the requirement to update the care plan at least daily or more frequently in the event of a change in the patient's clinical status, and including information on interventions related to any coping concerns identified for the patient/family. *Note: Please see next page, unable to add here or reproduce page to continue with action plan for tag.	7/7/2015 7/6/2015 to 7/7/2015

WHAT DOES THE CAP COVER?

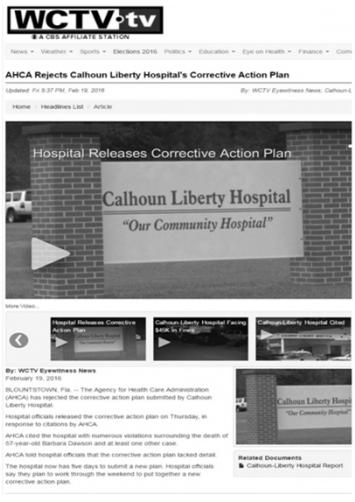
- For single or isolated incidents, AHCA must first week to obtain a corrective action plan before penalties
- The extent of the CAP will depend on the AI and the facility's history
- CAP may cover:
  - Policy or Procedure changes;
  - Report licensed employees to regulatory boards;
  - Provide time 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



CAPs gone wrong…



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

Associated Press/WTXL Feb 17, 2016

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 30-page document issued Wednesday, the Agency for Health Care Administration lists four counts against Calhoun-Liberty Hospital – three related to access to emergency care and services and one count of failure to evaluate a patient 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?

Contact Information:

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