



Science & Management Symposium



LOWE & EVANDER, P.A.

707 Monroe Road
Sanford, FL 32771



Presented by
Mike Lowe, Esquire

Prevention of Medical Errors To Err is Human & Costly & Deadly & Stressful. . .

Lake Buena Vista, FL
January 18, 2020
3:30 p.m. – 5:30 p.m.





LOWE & EVANDER, P.A.

707 Monroe Road
Sanford, FL 32771



This presentation provides education on record management and related legal *principles*, not specific legal advice

The presenters advise vetting of all your Legal Health Record activities with your legal counsel



20 years since 1999 Institute of Medicine (“IOM”) Report - To Err is Human: Building A Safer Health System

- The release of the Institute of Medicine's *To Err Is Human* in 1999 represented a seminal moment in patient safety and is considered by many to have launched the modern patient safety movement. It brought the problem of medical errors into the public eye and highlighted why every health care organization in the US must consider safety as a priority. Before the report's release, many—including leaders in major health care organizations—simply did not.



20 years since 1999 Institute of Medicine (“IOM”) Report - To Err is Human: Building A Safer Health System

- Since 1999, additional types of hospital errors that need addressing include errors during handoffs between units, failure to rescue, misidentification of patients, pressure ulcers, and falls. Safety gaps from discontinuous care have been addressed by a standardized intervention bundle called I-PASS (for illness severity, patient summary, action list, situation awareness and contingency plans, and synthesis by receiver), which is now being implemented in hundreds of hospitals across the US and internationally. Failure to rescue, defined as the death of a patient after one or more potentially treatable complications, is being used as a surgical quality indicator to account for potentially preventable postoperative complications.



20 Years since 1999 Institute of Medicine (“IOM”) Report - To Err is Human: Building A Safer Health System

- New safety challenges have emerged in the last 20 years. In the past two decades additional areas of safety risk have been identified and targeted for intervention, those areas include addressing harm related to as outpatient care, diagnostic errors, and the use of health information technology as well as using newly available electronic data to improve safety.
- In sum, the frequency of preventable harm remains high, and new scientific and policy approaches to address both prior and emerging risk areas are imperative.
- The next challenge in patient safety is the development and implementation of tools and strategies that enable organizations to measure and reduce harm both inside and outside the hospital, continuously and routinely.



Medical Errors- Progress Over The Last 20 Years

- The systems and cultural factors that contribute to preventable medical harm events are well understood, at least by patient safety and quality professionals.
- An extensive array of evidence-based best practices for reducing the risk of human error and preventing patient harm when errors do occur are now available.
- A number of transparency initiatives and financial incentives, mainly at the national level, now promote safety and quality improvement.



Defining Medical Errors

- Medical errors are a serious public health problem and a leading cause of death in the United States. "What constitutes a medical error?" The answer to this basic question has not been clearly established. Due to unclear definitions, "medical errors" are difficult to scientifically measure.
- Patient Safety- the prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors.
- Healthcare error- is an unintended healthcare outcome caused by a defect in the delivery of care to a patient. Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting.



Defining Medical Errors

- Types of Medical Errors:
 - a. Diagnostic
 - b. Treatment
 - c. Prevention
 - d. Communication
 - e. Medication



Defining Medical Errors

- Other terms or words used to identify a medical error include:
 - a. Adverse event, adverse outcome
 - b. Commission vs. omission
 - c. Medical mishap, unintended consequences
 - d. Unplanned clinical occurrence; unexpected occurrence; untoward incident
 - e. Therapeutic misadventure; bad call
 - f. Peri-therapeutic accident
 - g. Sentinel event
 - h. Iatrogenic complication; iatrogenic injury
 - i. Hospital acquired complication



How Do Medical Errors Occur/Contributing Factors

- A. Busier physician schedules.
- B. Sloppy documentation.
- C. Increased pressure to perform, see more patients and produce due to skyrocketing overhead costs and decreasing reimbursement rates across the board.
- D. Failure to properly supervise physician extenders, nursing staff and surgical teams (remember you as the physician are ultimately accountable as the captain of your “ship”).
- E. Failure to communicate among multiple specialists involved in complex cases.
- F. Lack of nursing support due to nursing shortages.



How Do Medical Errors Occur/Contributing Factors

- G. Misunderstood verbal communications and orders.
- H. Failure of all caregivers to coordinate patient care, and in particular, preoperative care and obtainment of informed consents.
- I. Lack of time (and sometimes effort) to develop an appropriate and well-thought out differential diagnosis.
- J. Performing back-to-back surgical procedures without sufficient intermissions between them.
- K. Interruptions during the pre-operative process.
- L. Poor communication or poor communication skills with patients – failure to listen carefully or to obtain a full and detailed history of the patient’s chief complaint or illness.
- M. Lack of a coordinated medical record keeping system – having records spread over many providers and physicians.



Medication Errors

- A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.
- Such events may be related to:
 - Professional Practice
 - Health Care Products
 - Procedures and Systems
 - Product Labeling, Packaging, and Nomenclature
 - Dispensing
 - Distribution
 - Administration
 - Education
 - Monitoring
 - Use



Medication Errors

- This definition is broad and suggests that errors are preventable at different levels. Medication error has also been defined as a reduction in the probability of treatment being timely and effective, or an increase in the risk of harm relating to medicines and prescribing compared with generally accepted practice.



Classifying Medication Errors

- There are a number of different approaches to classifying medication errors:
 - base the classification on the stage in the sequence of medication use process, such as prescribing, transcribing, dispensing, administration or monitoring.
 - consider the types of errors occurring, such as wrong medication, dose, frequency, administration route or patient.
 - according to whether they occur from mistakes made when planning actions (knowledge-based or rule-based mistakes) or errors in the execution of appropriately planned actions (action-based errors, known as “slips”, or memory-based errors, known as “lapses”).
 - according to their level of severity.
- The approach taken will depend on the setting and the purpose of the classification.



Prevention of Adverse Drug Events

- According to the Office of Disease Prevention and Health Promotion (“ODPHP”), “An adverse drug event (ADE) is an injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reactions, allergic reactions, and overdoses”.
- Preventable adverse drug events result from a medication error that reaches the patient and causes any degree of harm.
- ADEs can happen anywhere: in hospitals, long-term care settings, and outpatient settings.
- The good news is that large majority of ADEs are preventable. Reducing ADEs is expected to result in safer and higher quality health care services, reduced health care costs, more informed and engaged consumers, and improved health outcomes.



Prevention of Adverse Drug Events

- The widespread use of electronic health records has helped avert errors at the ordering and transcribing stages, but these errors still persist, and studies have found a high rate of medication administration errors.
- Avoid unnecessary medications by adhering to conservative prescribing principles.
- Computerized provider order entry, especially when paired with clinical decision support systems.
- Medication reconciliation at times of transitions in care.



What is the Opioid Epidemic?

- In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to opioid pain relievers and healthcare providers began to prescribe them at greater rates.
- Increased prescription of opioid medications led to widespread misuse of both prescription and non-prescription opioids before it became clear that these medications could indeed be highly addictive.
- In 2017 HHS declared a public health emergency and announced a 5-Point Strategy To Combat the Opioid Crisis.



THE OPIOID EPIDEMIC BY THE NUMBERS



130+

People died every day from
opioid-related drug overdoses³
(estimated)



11.4 m

People misused
prescription opioids¹



47,600

People died from
overdosing on opioids²



2.1 million

People had an opioid use
disorder¹



886,000

People used heroin¹



81,000

People used heroin
for the first time¹



2 million

People misused prescription
opioids for the first time¹



15,482

Deaths attributed to
overdosing on heroin²



28,466

Deaths attributed to
overdosing on synthetic
opioids other than
methadone²

SOURCES

1. 2017 National Survey on Drug Use and Health, Mortality in the United States, 2016
2. NCHS Data Brief No. 293, December 2017
3. NCHS, National Vital Statistics System. Estimates for 2017 and 2018 are based on provisional data.



The Opioid Crisis

- According to U.S. Department of Health and Human Services (“HHS”) and the Centers for Disease Control and Prevention (“CDC”), Opioid overdoses accounted for more than 47,000 deaths in 2017, more than any previous year on record. An estimated 36% of opioid overdose deaths involved a prescription opioid. On average, 130 Americans die every day from an opioid overdose.
- Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Deaths from drug overdose are up among both men and women, all races, and adults of nearly all ages.
- The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare.
- Devastating consequences of the opioid epidemic include increases in opioid misuse and related overdoses, as well as the rising incidence of newborns experiencing withdrawal syndrome due to opioid use and misuse during pregnancy.



The Opioid Crisis

- In response to the opioid crisis, the U.S. Department of Health and Human Services (“HHS”) is focusing its efforts on five major priorities:
 1. Improving access to treatment and recovery services.
 2. Promoting use of overdose-reversing drugs.
 3. Strengthening our understanding of the epidemic through better public health surveillance.
 4. Providing support for cutting-edge research on pain and addiction.
 5. Advancing better practices for pain management.



The Opioid Crisis

- The National Institutes of Health (NIH), a component of HHS, is the nation's leading medical research agency helping solve the opioid crisis via discovering new and better ways to prevent opioid misuse, treat opioid use disorders, and manage pain.
- On March 19, 2018, The Trump administration outlines an initiative to stop opioid abuse. The three areas of concentration are law enforcement and interdiction; prevention and education via an ad campaign; and job-seeking assistance for individuals fighting addiction.
- On May 15, 2018, The Florida Attorney General's Office filed an action in state court against some of the nation's largest opioid manufacturers and distributors for their role in the opioid crisis.
- On October 24, 2018, President Donald Trump signed opioid legislation into law. The SUPPORT for Patients and Communities Act includes provisions aimed at promoting research to find new drugs for pain management that will not be addictive. It also expands access to treatment for substance use disorders for Medicaid patients.



The Opioid Crisis

- On January 14, 2019, The National Safety Council finds that, for the first time on record, the odds of dying from an opioid overdose in the United States are now greater than those of dying in a vehicle crash.
- On March 18, 2019, More than 600 cities, counties and Native American tribes from 28 states file a federal lawsuit against eight members of the Sackler family, the family that runs Purdue Pharma. The suit says the family increased sales by creating a "new 'health care' narrative, one in which opioids are considered safe and effective for long-term use, and pain is aggressively treated at all costs."
- On May 28, 2019, A major opioid trial, the first of its kind, begins in Oklahoma. The trial is expected to determine whether states and municipalities can hold drug companies accountable for the opioid crisis. The defendant in the case is Johnson & Johnson.
- On July 17, 2019, The Centers for Disease Control and Prevention (CDC) releases preliminary data showing a 5.1% decline in drug overdoses during 2018. If the preliminary number is accurate, it would mark the first annual drop in overdose deaths in more than two decades.



The Opioid Crisis Florida Law

- March 19, 2018, Florida Governor Rick Scott signed House Bill 21 into law, Chapter No. 2018-13.
- Take a ways:
 - Compliance with the new federal and Florida laws and regulations effective March 2018.
 - Taking continuing medical education courses particularly in the required areas of laws and rules and prevention of medical errors.
 - The 3-day limit on opioid prescriptions, unless certain criteria are met.



The Opioid Crisis Florida Law

- Chapter 2018-13 is an act relating to controlled substances; creating Section 456.0301, Florida Statutes; requiring certain boards to require certain registered practitioners to complete a specified board-approved continuing education course to obtain authorization to prescribe controlled substances as part of biennial license renewal and before a specified date; providing course requirements; providing that the course may be offered in a distance learning format and requiring that it be included within required continuing education hours; prohibiting the Department of Health from renewing the license of a prescriber under specified circumstances; specifying a deadline for course completion; providing an exception from the course requirements for certain licensees; requiring such licensees to submit confirmation of course completion; authorizing certain boards to adopt rules.



The Opioid Crisis Florida Law

- Chapter 2018-13 amends Section 465.0276, Florida Statutes; prohibiting the dispensing of certain controlled substances in an amount that exceeds a 3-day supply unless certain criteria are met; providing an exception for the dispensing of certain controlled substances by a practitioner to the practitioner's own patients for the medication-assisted treatment of opiate addiction; providing requirements for practitioners for the dispensing of controlled substances to persons not known to them; defining the term "proper identification".
- Chapter 2018-13 amends Section 456.44, Florida Statutes; defining the term "acute pain"; requiring the applicable boards to adopt rules establishing certain guidelines for prescribing controlled substances for acute pain; providing that the failure of a prescriber to follow specified guidelines is grounds for disciplinary action; limiting opioid drug prescriptions for the treatment of acute pain to a specified period under certain circumstances; authorizing such prescriptions for an extended period if specified requirements are met; requiring a prescriber who prescribes an opioid drug for the treatment of pain other than acute pain to include a specific indication on the prescription; requiring a prescriber who prescribes an opioid drug for the treatment of pain related to a traumatic injury with a specified Injury Severity Score to concurrently prescribe an emergency opioid antagonist.



Accountability of Medical Errors

- While it is true that individual providers should be held accountable for their decisions, there is a growing realization that the majority of errors are out of the clinician's control.
- The potential for errors in healthcare is very high. Due to cost control measures, are individuals accountable, or is increased workload and staff fatigue the reason for errors?
- Why report? Failure to report errors may subject clinicians to disciplinary action and increased risk for legal liability. Beneficence and nonmaleficence are ethical concepts that are violated when an error is not reported.



Consequences of Medical Errors

A. Civil litigation

1. Medical malpractice/professional negligence lawsuits
2. Battery
3. Wrongful death lawsuits

B. Administrative Action

1. Professional licensure complaint from Florida Department of Health/ Florida Board of Medicine or Florida Board of Osteopathic Medicine
2. Disciplinary action (revocation or suspension of license, fines, probation, reprimand, required CME, payment of investigative costs, etc.).

C. Criminal litigation – some aggressive state prosecutors have or may bring charges against physicians for reckless endangerment, negligent homicide, or manslaughter.

D. Loss or suspension of clinical or medical staff privileges at hospitals or ambulatory surgical centers.



Consequences of Medical Errors

- E. Reports to the physician's State of Florida practitioner profile and the federal National Practitioner Data Bank/Healthcare Integrity Protection Data Bank (permanently on a physician's record and accessible by all future credentialing entities including hospitals and managed care insurance companies).
- F. Increased medical malpractice insurance premiums or inability to obtain insurance.
- G. Costly attorney's fees to defend legal actions.
- H. Loss of or damage to professional reputation.



Preventing Medical Errors (a Legal Perspective)

- A. Get off of or at least slow down the treadmill (is the lifestyle really worth the stress and risk; perhaps seeing a few less patients or performing a few less procedures each year is worth it).
- B. Repeat all verbal orders and obtain confirmation of them from the receiver.
- C. If you are not satisfied with a hospital's or other facility's pre-operative checklist and informed consent procedures, then recommend changes in writing to the medical executive committee and hospital administration.
- D. Always double-check prescriptions including the amount and frequency of all dosages.
- E. Implement and coordinate appropriate prescribing procedures within your practice especially if you rely on physician extenders to call in prescriptions for you.



Preventing Medical Errors (a Legal Perspective)

- F. Dictate procedures, medical record entries, operative reports and notes whenever possible. If your staff tells you that your documentation is illegible, listen to them. Always make medical record entries and complete medical records and reports as soon thereafter as possible (no one likes paperwork until you don't have any to rely upon to defend yourself).
- G. Slow down and listen carefully when seeing and treating patients.
- H. Avoid hallway medicine at all costs.
- I. Obtain appropriate consults whenever necessary and if providing consults be sure to provide the results to all caregivers involved in a patient's care and treatment (particularly in complex cases with multiple specialists involved).
- J. SLOW DOWN! SLOW DOWN! SLOW DOWN! (one more reimbursable procedure or patient visit will not pay for the costs of a medical malpractice lawsuit).
- K. Document! Document! Document!



Preventing Medical Errors: Wrong-Site Surgery

- Wrong-Site Surgery Definition encompasses surgery performed on the wrong side or site of the body, wrong surgical procedure performed, and surgery performed on the wrong patient.
- Includes any invasive procedure that exposes patients to more than minimal risk, including procedures performed in settings other than the OR [operating room], such as a special procedures unit, an endoscopy unit, and an interventional radiology suite.
- Despite focused attention and protocols, provider preventable patient harm continues to be a problem.
- Examples can include wrong site or wrong procedure surgery, and retained objects.
- Researchers from Johns Hopkins reported an analysis of data from the National Practitioner Data Bank suggesting these events may occur in the United States at least 80 times per week.
- Patient safety in surgery can be influenced by decision based errors, including inadequate knowledge, mistakes in judgment, or cognitive bias. Often, however, communication errors may be an important cause of adverse events. Another study found that almost one-third of operating room communication resulted in partial failure, such as poor timing, missing or inaccurate information, or failure to resolve an issue.



Preventing Medical Errors: Wrong-Site Surgery

- Several approaches are recommended in an attempt to reduce risk and improve communication:
 - Preoperative initial timeout to review informed consent and confirm patient identity, planned surgical location, and procedure. This should include the patient or surrogate, at least two medical professionals and be documented in the medical record.
 - In the operating room, implement a timeout with the entire team to review patient identity, review diagnostic studies, and confirm the planned surgical site and procedure again.
 - Standardized checklist as a cognitive aid to ensure necessary information and safety measures are available. This may include a surgeon-led, pre-operative briefing outlining the surgical plan, anticipated intra operative needs (equipment, blood, etc.) and risks.
 - Techniques to reduce distractions and interruptions. Limiting extraneous personnel in and out of the room, reducing the noise level, assigning coverage for beeper calls, and limiting extraneous interruptions to the surgeon to only time-sensitive, vital issues.
 - At the completion of the procedure, a formal debriefing may include review of any equipment or supply concerns, correct processing of any pathology samples, and arrangements for transition and handoff of post-operative care.
 - Consistent utilization of a preoperative review of the surgical plans, standardized checklists, and continued open communication throughout the team may help to further reduce the risk of surgical adverse events.



Preventing Medical Errors: Take a Pause

- **Rule 64B8-9.007, Florida Administrative Code**
- This rule outlines requirements for taking a pause prior to beginning surgery to ensure you have the right patient, the right site and are performing the right surgery as described in the Informed Consent signed by the patient.
- Physicians are required to confirm the patient's identity, confirm the procedure being performed and confirm the correct surgical site with another healthcare practitioner.
- “Pause” must be performed again if the physician leaves the room at any time during the procedure or surgery.
- Clarification of the definition of surgery; means the removal, incision or curettage of tissue or an organ, insertion of natural or artificial implants, electro-convulsive therapy, endoscopic procedure or other procedure requiring the administration of anesthesia or an anesthetic agent.
- This rule is intended to prevent wrong site, wrong side, wrong patient and wrong surgeries/procedures by requiring the team to pause prior to the initiation of the surgery/procedure to confirm the side, site, patient identity, and surgery/procedure.



Preventing Medical Errors: Informed Consent

- Being well versed in the basic components of a properly executed informed consent is the first step toward compliance.
- **1. Patient-specific information:**
 - Consent information documented on the form must be specific to the patient and include the name of the specific procedure or treatment, as well as the name of the responsible practitioner who will perform the surgery or administer the treatment. The best consent forms will also list the practitioner who obtained consent (if different from the responsible practitioner) and include a listing of the material risks associated with the contemplated treatment or procedure. At a minimum, the consent form must state that the procedure description, risks, benefits, and alternatives were explained to the patient. Organizations must further ensure that their processes support the attestations made on the consent form.
- **2. Proper execution:**
 - Hospitals must obtain a properly executed, written, and signed patient consent for nonemergent procedures. (A chart note stating that the patient gave his or her consent for the treatment or procedure is insufficient.) This documentation must have complete information, legible writing, and appropriate abbreviations. Another area of compliance is form consistency, making it important to ensure all providers have access to the most up-to-date versions.



Preventing Medical Errors: Informed Consent

➤ 3. Date and time:

- Consent forms must include the date and time along with the appropriate signatures. Signatures such as a witness signature must include the date and time separate from the date and time that the patient signed the consent form. (Note that the time of day should be written in military time or include the AM or PM designation.)

➤ 4. Present at preop:

- Consent forms must be complete and placed in the patient's medical record prior to the time of surgery. This requirement is waived for emergent procedures; CMS is silent on consent for anesthesia (although hospitals are advised to contemplate anesthesia consents in their policies). The surgical team will confirm the presence of the consent form prior to the start of a case. This means that lost or missing consent forms can delay operating room (OR) start times, resulting in scheduling issues as well as decreased satisfaction if patients or family members are asked to sign a replacement consent form.

➤ 5. Address consent for multiple or possible procedures:

- Ensure that the consent process includes disclosure and documentation of possible or contemplated procedures that might be performed based on intraoperative findings. Possible procedures with a reasonable likelihood of being performed should be clearly listed on the consent form. While many consent forms contain language that authorizes a provider to perform additional, necessary procedures based on that practitioner's clinical judgment, this permission should apply only to unanticipated, emergent procedures.



Preventing Medical Errors (a Legal Perspective)

Documentation

- Provides proof you did the correct thing
- Supports idea you gave adequate thought and consideration to the case
- Document your advice to patient
- Document thought process and differential



What To Do When a Medical Error Occurs (or When You Think One Has Occurred)

- A. Patient care comes first – admit the error to yourself and provide appropriate care and treatment to the patient in order to protect their health and well-being (even if this means involving other physicians and caregivers in the process and allowing them to discover your mistake). Information about errors should never be withheld from patients.
- B. Immediately document all relevant care and treatment.
- C. All personnel involved should participate in the review of the error and in solving any systems problems that contributed to the occurrence of the error.
- D. Notify your medical malpractice carrier as necessary.
- E. Notify legal counsel as necessary.
- F. Follow appropriate reporting procedures for the applicable facility (i.e., notifying risk management in a timely manner, Code 15 Reports, etc.).



As of September 15, 2003, Florida law requires physicians to inform patients of any adverse incident (hospitals are also required to inform patients in the same situations).

1. Do not wait until a medical error or adverse incident occurs to develop your strategy, policies and procedures for informing patients of such adverse incidents. Do it now!
2. Face-to-face communications v. telephonic or written notification.
3. How much should you tell the patient? (Being informative vs. setting yourself up for a lawsuit).
4. Who should be present when you inform the patient?
5. Be sure to memorialize your conversation with the patient through medical record documentation or other appropriate written means.
6. When to inform your insurance carrier and legal counsel?
7. Bedside manner is critical at this stage.
8. How soon must you notify the patient after the adverse incident?



Reportable Events

- Florida's Mandatory Reporting for Every Licensed Facility, Section 395.0197 (5)(a), Florida Statutes
- For purposes of reporting to the agency pursuant to this section, the term “adverse incident” means an event over which 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, and which:
 - (a) Results in the following injuries:
 1. Death;
 2. Brain or spinal damage;
 3. Permanent disfigurement;
 4. Fracture or dislocation of bones or joints;
 5. A resulting limitation of neurological, physical or sensory limitation post discharge;
 6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or



Reportable Events

➤ Florida's Mandatory Reporting for Every Licensed Facility, Section 395.0197 (5)(a), Florida Statutes

7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

(b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

(c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or

(d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.



Reportable Events

- Florida's Mandatory Reporting for Every Licensed Facility, Section 395.0197 (7), Florida Statutes
- Any of the following adverse incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence:
 - (a) The death of a patient;
 - (b) Brain or spinal damage to a patient;
 - (c) The performance of a surgical procedure on the wrong patient;
 - (d) The performance of a wrong-site surgical procedure;
 - (e) The performance of a wrong surgical procedure;
 - (f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
 - (g) The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
 - (h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.



Reportable Events

- Florida's Mandatory Reporting for Every Licensed Facility, Section 395.0197 (7), Florida Statutes
- The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency. The agency may require an additional, final report. These reports shall not be available to the public pursuant to Section 119.07(1) or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of Section 456.073 shall apply.



Claims and Allegations by Patients

- According to the Medical Malpractice Center, in the United States, there are between 15,000 and 19,000 medical malpractice suits against doctors every year.

- Four elements must be proven to have existed in order to succeed in a medical malpractice claim:
 1. A duty was owed by the health care provider or hospital.
 2. A duty was breached, because the health care provider or hospital did not conform to the expected standard of care.
 3. The breach resulted in an injury, and it was closely linked to the injury.
 4. Considerable damage resulted for the patient, whether physical, emotional, or financial.



Claims and Allegations by Patients

- In evaluating allegations, your defense is dependent upon the medical record, and your ability to defend it is their sole vehicle for counterattack.
- A well-documented, meticulous chart is key.
- A separate section of the chart should be designated for fees and reimbursements.



Claims and Allegations by Patients

- Claims and allegations by patients of improper treatment, improper surgical technique, and unnecessary surgery are credited as the primary area of question in the majority of law suits. Whereas "poor results" are listed as the major reason for Litigation in liability cases. Some of the non-technical allegations made by plaintiffs and their attorneys are: lack of informed consent, fee disputes, error in medication, and fraud.



Addressing Claims and Allegations by Patients

- Open communication with patients is paramount in reducing the risk of a malpractice allegation. Patients are more likely to become angry or frustrated if they sense a physician is not listening to or addressing their concerns. These patients are in turn more likely to file a complaint if they are harmed or experience a bad outcome.
- Of course, when evaluating and treating patients, the Practitioner should always take the time to listen to the patient's concerns during the encounter to ensure his or her needs have been addressed. In the event of a patient allegation or complaint, the Practitioner should make the effort to explore and de-escalate the situation before the patient is discharged.
- It's essential to verbally communicate the risks before a procedure, not after—and to include this information in a written consent form that the patient signs. The patient must receive a proper explanation of the form's purpose that clearly spells out the risks inherent in the procedure.



Addressing Claims and Allegations by Patients

- Get the facts about an adverse event to determine whether an apology or an expression of empathy is needed.
- Plan and schedule the disclosure/apology discussion so that it will be as beneficial as possible to the patient and other participants.
 - Hold the discussion as soon as possible after immediate healthcare needs are addressed.
 - Choose a quiet, private, comfortable place for the discussion suited to the patient's and family's needs and conducive to conversation.
 - Consider who should participate; ask the patient who should be included.
- Get assistance if you feel you need help preparing for a disclosure discussion. Members of a hospital's risk management department or patient safety team can usually aid healthcare providers who want or need assistance with facets of the disclosure task. It is also appropriate to discuss a disclosure situation with a risk management or claims representative from your liability insurance company to get advice or answers to questions you may have about going through a disclosure process.



Addressing Claims and Allegations by Patients

- Elicit patient and family responses after a poor outcome, and listen to and acknowledge the responses.
- View a disclosure/apology discussion as an education opportunity.
 - Honestly educate the patient and family by telling them all the facts you know about what happened.
 - Don't use jargon or talk down to the patient/family.
 - Ask the patient or a family member to summarize the information back to you if you think he or she may not fully comprehend what you're saying, and you want to check understanding.
 - Do not include subjective information or conjectures.
 - Don't blame other providers.



Addressing Claims and Allegations by Patients

- Document in the patient's record about the disclosure/apology discussion.
 - Include the known facts associated with how the event happened, care given in response to the adverse outcome, the key issues in the disclosure conversation, and plans for future care and future discussions.
 - Preferable documentation of an apology is brief and objective; for example, "Expressed sympathy to patient about outcome."
 - If you are required to complete an incident report for an adverse event, do not refer to this report in the patient's record or include a copy of the report in the record; incident reports should be used for a facility's internal communication only.



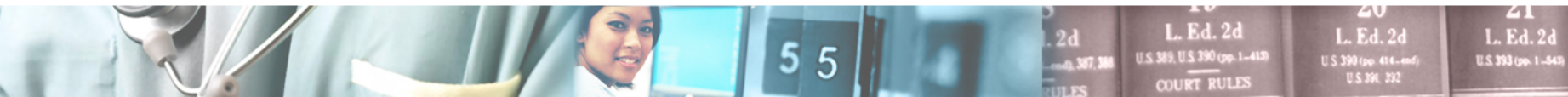
Pricing and Transparency

- In 2019, the Trump Administration announced the promulgation of an Executive Order establishing criteria for transparency in the pricing of health care goods and services including procedures and pharmaceuticals.
- At first glance this Executive Order appears to place another overwhelming compliance burden on health care professionals and providers, it also presents a tremendous opportunity for them.
- Transparency and pricing presents an opportunity for health care professionals and providers to connect with their patients and discuss the costs and benefits of a recommended procedure, drug therapy, course of treatment, etc.



Pricing and Transparency

- This in and of itself is a tremendous marketing opportunity for health care professionals and providers to distinguish themselves from the competition, and a keen understanding of a patient's health insurance/third-party payor programs, goals and desires for their care and treatment, and ability to pay represents a chance to build stronger physician-patient relationships and foundations for trust by eliminating surprise bills and obtaining a clear understanding of the patients desired goals and outcomes and achieving them within their ability to pay.
- It also presents an opportunity for the development of innovative fee schedules and payment structures.



Pricing and Transparency

- Providers and professionals must be aware of applicable federal and Florida laws and regulations including the advertising and marketing rules promulgated by the licensing boards, consumer protection laws, and balance-billing and transparency laws and regulations when developing their marketing materials, fee schedules and payment structures.
- This will require not only a keen awareness and understanding of those laws and regulations, but also an ability to implement them, and by necessity the retention of qualified legal counsel, marketing consultants and billing staff and personnel to advise on them.



Health Care Price and Quality Transparency

- The United States is experiencing significant changes in health care payment and delivery.
- Record numbers of newly-insured persons are enrolled in both public and private health insurance.
- Americans bear a greater share of health care costs, and more participate in high deductible health plans.
- Clear, factual information about the cost and quality of health care is necessary for consumers to select valuedriven health care options and for consumers and providers to be involved in and accountable for decisions about health and health care services.
- To promote consumer involvement, health care pricing and other data should be free, timely, reliable, and reflect individual health care needs and insurance coverage.



Health Care Quality Transparency

- According to the *Henry J. Kaiser Foundation, Peterson-Kaiser Health System Tracker, Health Spending Explorer-U.S. Health Expenditures 1960- 2017*, “Although the U.S. spends more than \$3 trillion a year on health care, roughly 18% of the gross national product, research shows that the quality of health care in America is, at best, imperfect, and, at worst, deeply flawed”.
- **Issues with health care quality fall into three categories:**
- **Underuse:** Many patients do not receive medically necessary care.
- **Misuse:** Each year, more than 100,000 Americans get the wrong care and are injured as a result. More than 1.5 million medication errors are made each year.
- **Overuse:** Many patients receive care that is not needed or for which there is an equally effective alternative that costs less money or causes fewer side effects.



Health Care Price and Quality Transparency

- There are hundreds of health care quality measures developed, maintained, and evaluated for relevancy and accuracy by many different organizations, including the federal Agency for Healthcare Research and Quality, the National Quality Forum, and the National Committee for Quality Assurance. In general, health quality measures can be sorted into four categories:
 - **Structure measures**- assess the aspects of the health care setting, including facility, personnel, and policies related to the delivery of care.
 - Example- What is the nurse-to-patient ratio in a neonatal intensive care unit?
 - **Process measures**- determine if the services provided to patients are consistent with routine clinical care.
 - Example- Does a doctor recommend prostate-specific antigen testing for his male patients at average risk for prostate cancer beginning at age 50?
 - **Outcome measures**- evaluate patient health as a result of care received.
 - Example- What is the infection rate of patients undergoing cardiac surgery at a hospital?
 - **Patient experience measures**- provide feedback on patients' experiences with the care received.
 - Example- Do patients recommend their doctor to others following a procedure?



Health Care Price and Quality Transparency

- Standardized healthcare performance measures are used by a range of healthcare stakeholders for a variety of purposes.
- Measures help clinicians, hospitals, and other providers understand whether the care they provide their patients is optimal and appropriate, and if not, where to focus their efforts to improve.
- Public and private payers also use measures for feedback and benchmarking purposes, public reporting, and incentive-based payment.
- As more and more health care consumers shop for their health care, value becomes more important than price alone.
- Determining value means comparing the cost of care with information on the quality or benefit of the service.



Florida Center for Health Information and Transparency

- The Florida Center for Health Information and Transparency (the Florida Center) provides a comprehensive health information system (information system) that includes the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of health-related data.
- The Florida Center is housed within AHCA and is funded through appropriations in the General Appropriations Act, through grants, gifts, and other payments, and through fees charged for services.
- The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, ambulatory surgery center (ASC), emergency department, and comprehensive rehabilitation hospital on a quarterly basis.
- Florida statute requires the Florida Center to identify available data sets, compile new data when specifically authorized by the Legislature, and promote the use of extant health-related data and statistics.



Florida Center for Health Information and Transparency

- The Florida Center maintains www.FloridaHealthFinder.gov , which was established to assist consumers in making informed health care decisions and lead to improvements in quality of care in Florida.
- The website provides a wide array of search and comparative tools to the public that allows easy access to information on hospitals, ambulatory surgery centers, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida.
- The website also provides tools to researchers and professionals to allow specialized data queries, but requires users to have some knowledge of medical coding and terminology.
- Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator, hospital and ambulatory surgery centers performance data, data on mortality, complication, and infection rates for hospitals, and a facility/provider locator.



Technology Innovation

Healthcare technology in 2019 is set to take a huge step forward

Technological advances continue to grow exponentially, and the healthcare industry is no exception. Whether streamlining healthcare operations through new system designs and software, lowering costs and enhancing quality of care through new devices and procedures, or utilizing new solutions in marketing personalization such as through artificial intelligence or blockchains, healthcare technology in 2019 is set to take a huge step forward.

For instance, the telehealth industry is on the rise both in Florida and the nation as a whole. The ability to receive clinical care long-distance has been warmly received by patients. The increased accessibility to health care providers, coupled with the ability to sidestep potential delays they might otherwise face due to busy lifestyles if the patient were required to travel to a provider to receive care, has led to exponential growth in the telehealth field. The telehealth industry is projected to reach \$3.5 billion in revenue by 2022.



Technology Innovation

- Computer–assisted diagnostic expert systems may also help to avoid diagnostic errors. Clinicians could use these systems for unusual or complex diagnostic challenge.
- As providers and professionals continue to turn more to technology innovations and the care and treatment of their patients, they need to be aware of such security and safety risks and ensure that they have proper insurance coverage for these risks and potential liabilities such as cyberliability insurance and riders for amendment to their professional liability insurance policies to cover advanced health care technological innovations such as artificial intelligence and the internet of things.
- Cybersecurity, HIPAA, and risk management policies and procedures.



With new innovations comes new risk

- Telehealth, IoT integration, artificial intelligence and blockchain all represent ways in which healthcare technology has evolved and will continue to advance in the coming months. With new innovations comes new risks, however.
- While telehealth raises the bar on convenience for patients, it likewise raises concerns among governmental agencies and entities overseeing the safe administration of healthcare such as the Florida Department of Health, and the specifics of the telemedicine system of a practice or practitioner are crucial to analyzing whether or not such a system, and the care and treatment provided remotely to patients via same, is compliant with applicable state and federal law.



With new innovations comes new risk

- While blockchain can securely store a virtually immeasurable amount of data in tamper-proof records, a breach of the blockchain's security (for instance, through access credentials being compromised due to human error caused by lack of proper education and training by the covered entity of its employees) could allow that virtually immeasurable amount of data to fall into unauthorized hands, creating a “megabreach” scenario and triggering extensive reporting requirements both to all affected patients as well as the U.S. Department of Health and Human Services Office for Civil Rights, and likely causing the breached covered entity to incur hefty penalties and costs to mitigate the damages of the breach.



With new innovations comes new risk

- New developments in healthcare technology are rapidly providing innovative advances in the delivery of care and treatment to patients while enhancing the health care delivery experience for both patients and their treating providers and professionals.
- These developments are likewise reshaping and facilitating health information storage and databasing to an extent previously thought untenable.
- These developments raise corresponding new challenges that must be met, both in terms of sharing data and access to physicians' and providers' data bases by payors and health device/equipment manufacturers, as well as managing care and treatment and being compliant with both HIPAA's privacy and security regulations and Florida medical record confidentiality, privacy and security laws.



Securing Connected Devices in Health Care

- Connected devices (e.g., an infusion pump that receives drip instructions from a server and communicates with the HER, or a continuous glucose monitor that sends data about one's glucose levels to an Android, iPhone, or Apple Watch) are one of the more significant technological advances in health care.
- There are significant legal implications for their use in health care: data privacy, use and security, patient safety, risks, and liability concerns.
- As health care becomes more reliant on connected devices, the risks of patient harm, loss of data privacy, and crippling cyber-attack all grow.
- Failure to identify, allocate, and mitigate the risks can result in patient harm, loss or disclosure of protected health information, serious interruption in the delivery of treatment, significant financial exposure, and loss of patient, employee and community trust in the provider organization.



Securing Connected Devices in Health Care

➤ **CYBERSECURITY BEST PRACTICES FOR CONNECTED DEVICES**

➤ The U.S. Department of Health and Human Services' Office of Inspector General (OIG) has set forth a compliance framework consisting of seven core elements.

1. Developing standards of conduct, policies, and procedures;
2. Designating a compliance officer or compliance committee to oversee the compliance program;
3. Conducting training and education;
4. Maintaining effective lines of communication;
5. Undertaking internal audits and monitoring;
6. Enforcing the compliance program through disciplinary standards; and,
7. Responding to noncompliance and implementing corrective action.



Securing Connected Devices in Health Care

➤ **Potential Patient Harm:**

- A significant risk factor with connected medical devices is the potential for patient harm.
- Risks from intentional cyberattack are in addition to the risks to patients from the increasing complexity of software and firmware associated with medical devices, which are more appropriately classified as potential product defects.
- Attacks on connected medical devices may also be used to infiltrate and compromise other systems on the network, such as the EHR, Access to the EHR could enable a cybercriminal to alter data to cause patient harm.
- Even when the cyberattack leads to patient harm, the cause of the injury may not be obvious to those responding and thus may not be attributed to a cyberattack.



Securing Connected Devices in Health Care

➤ Safeguards

- Safeguards are a necessary component of any cybersecurity framework.
- Technical safeguards refer to technology, policies, and procedures that are used to protect ePHI and control access to it.
- Physical safeguards encompass measures that protect buildings and equipment from unauthorized intrusion, destruction, or disasters.



Securing Connected Devices in Health Care

➤ Training and Education

- Training and education are crucial components of a strong cybersecurity program.
- Training and education should cover relevant cybersecurity policies and procedures, as well as industry trends and specific cybersecurity threats associated with connected medical devices.
- During training, an organization can reinforce best practices to guard against cyberattacks, including password hygiene (such as using different passwords for different accounts and not sharing passwords).
- Training and education should be specific to the cybersecurity risks facing the health care industry in general and the organization in particular, and it should be conducted in a frequent and ongoing manner to ensure effectiveness.



Securing Connected Devices in Health Care

➤ Proactive Monitoring

- Adopt a proactive compliance approach that regularly tests the cybersecurity standards, policies, and procedures that are in place for connected medical devices.
- As testing in an ongoing process, involving evaluating random samples, monitoring high-risk activities, and conducting trend analysis.
- Testing should ideally be conducted at frequent and regular intervals, as well as when major personnel and process changes occur that impact the cybersecurity program.



Securing Connected Devices in Health Care

➤ Risk Assessment

- Develop and implement approaches for identifying and mitigating potential threats and vulnerabilities to connected devices.
- Risk assessments should be conducted on an annual basis and more frequently for high-risk areas.
- Risk assessments serve to identify, measure, and prioritize compliance risks.
- Risk assessments allow organizations to pinpoint high-risk areas, develop responses to mitigate those risks, and conserve resources by targeting areas where patient care may be compromised or business operations may be impaired; all of which could lead to harm to patients, and financial and reputational harm to the organization.



Any
questions?



Science & Management Symposium





LOWE & EVANDER, P.A.

707 Monroe Road
Sanford, FL 32771

Copies and contact information

Request copies of this presentation
and more information from

Michael R. Lowe, Esquire

www.lowehealthlaw.com

407-332-6353



Science & Management Symposium

